



Georgia Hospital Association Document Retention Schedule

**Arnall
Golden
Gregory** LLP

INTRODUCTION

The Georgia Hospital Association (“GHA”) is pleased to provide its membership with this 2022 edition of the Document Retention Schedule (the “Schedule”). This is the fifth edition of the Schedule, having first been published by GHA and the Georgia Academy of Healthcare Attorneys in 2003. Over the past eighteen years, member hospitals have recognized the value of this Schedule as a resource and reference in developing document retention policies and procedures. Thus, in 2013, GHA commissioned Arnall Golden Gregory LLP to revamp the Schedule and update it periodically.

The Schedule includes several user-friendly features, including: 1) internal hyperlinks to the various sections and cross-references within the Schedule and hyperlinks to an Appendix of cited laws; 2) an Appendix that includes a sample legal hold memorandum and notice template to consider for document retention during reasonably foreseeable government investigations and litigation; 3) an Appendix of a sample email policy; 4) an Appendix of a sample electronic record retention guideline; and 5) a comment feature on GHA’s website to allow for feedback on hyperlink functionality as well as recommendations for future versions.

Though the Schedule includes a thorough compilation of record retention laws that apply to documents routinely created by healthcare providers, particularly hospitals, it is impossible to develop a one-size-fits-all retention policy. Your hospital may generate records this Schedule does not contemplate; it may not be governed by certain sections, line items, or cited laws; or it may be subject to additional legal requirements that are not addressed (e.g., retention requirements for publicly traded companies under Sarbanes-Oxley or that apply only to government contractors, including, for instance, hospitals with research grants or those that provide healthcare to active or retired military under contract with the Department of Veterans’ Affairs or the Department of Defense). A hospital may also be subject to varying retention requirements pursuant to third-party payor contracts, malpractice insurers, corporate integrity agreements, bond and financing covenants, or requirements of other entities with which the hospital transacts business. Moreover, developing a retention policy is not purely a legal exercise as there may be, and often are, other reasons to hold documents for a shorter or longer time, including storage capabilities, risk tolerance, historical and administrative value, specific circumstances, or other business reasons. Finally, when retention is no longer required, a hospital must carefully plan appropriately secure document disposition methods compliant with the Health Insurance Portability and Accountability Act (“HIPAA”) and other privacy laws that are beyond the scope of this document. Accordingly, this Schedule is provided as a benefit to GHA’s members, but is *intended for informational purposes only and should not be construed as legal advice or opinion* on particular matters. Hospitals should seek advice from their business, compliance, information technology, legal, and other departments when adopting and updating such policies.

GHA trusts you will find this Schedule a useful resource and welcomes any comments or questions you may have. GHA would like to thank Arnall Golden Gregory LLP for their time and effort updating the Schedule.

Keri Conley
Georgia Hospital Association

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DOCUMENT RETENTION SCHEDULE

BUSINESS, FINANCIAL, AND HOSPITAL ADMINISTRATION RECORDS¹

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Accounts Payable	Date of tax filing plus 6 years.	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

¹ Pursuant to [O.C.G.A. § 31-7-22](#) and [Ga. Comp. R. & Regs. 111-8-41-.04, -.05, and -.06](#), hospitals are required to post a link in a “prominent location” on their main website to the most recent version of “federal related disclosures” and “Georgia supplemental disclosures.” Required federal disclosures include copies of audited financial statements expressing the unqualified opinion of an independent certified public accounting firm for the most recently completed fiscal year. Required Georgia supplemental disclosures include (1) a copy of the hospital’s completed annual questionnaire; (2) listing of all the hospital’s real property holdings; (3) listing of any ownership or interest a nonprofit hospital has in any joint venture, partnership, subsidiary, or captive insurance; (4) the most recent legal chart of corporate structure; (5) listing of salaries and fringe benefits for the ten highest paid administrative positions in the hospital; and (6) evidence of hospital accreditation. These disclosures are required to be updated yearly. Noncurrent documents must remain posted and accessible on the hospital’s website indefinitely. For more information, including the complete list of required documents, please visit the statute and regulations provided in Appendix D by clicking the links in this footnote.

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Accounts Receivable	Date of tax filing plus 6 years.	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Annual Financial Reports	Permanent.	<p>Though legal citations support a retention period of 6 years, organizations may maintain annual financial reports permanently for historical and administrative reasons.</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Bank Accounts Reconciliation	Date of tax filing plus 6 years.	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Bank Deposit Slips	Date of tax filing plus 6 years.	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Bank Statements	Date of tax filing plus 6 years.	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Budgets – Outdated and Not Currently in Use	At least 6 years.	<p>There may be historical value in some records that could lead the hospital to keep them for a longer time period (e.g., budgets for large construction projects).</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p style="text-align: center;">Cash Receipts</p> <p>(records that are not related to payment for health services)</p> <p><i>For payments for health services generally, see p. 11; for payments for DMEPOS, clinical laboratory services, imaging services, or home health service, see p. 12.</i></p>	<p>Date of tax filing plus 6 years.</p>	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Charge Slips to Patients	Date of tax filing plus 6 years.	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Checks – Cancelled	Date of tax filing plus 6 years.	<p>The hospital may wish to maintain certain checks for a longer time period as evidence of purchases for warranty and other reasons.</p> <p>O.C.G.A. § 10-12-12(a) (if a law requires retention of a check, that requirement is satisfied by retention of an electronic record of the information on the front and back of the check).</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

DOCUMENT RETENTION SCHEDULE

BUSINESS, FINANCIAL, AND HOSPITAL ADMINISTRATION RECORDS¹

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Check Registers	Date of tax filing plus 6 years.	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>
<p>Claims and Charges to Patients, Fiscal Intermediaries, Third-Party Payors</p> <p><i>For claims relating to Hospital Medicare Part A or B services, items, or drugs ordered by a physician or other permitted eligible professional, see below, p. 12.</i></p>	6 years.	<p>The Hospital’s primary exposure for these records is under the False Claims Act, which has a 6-year statute of limitation and 10-year statute of repose. 31 U.S.C. § 3731(b).</p> <p>Corporate Integrity Agreements (“CIAs”) with health care providers typically last 5 years. https://oig.hhs.gov/compliance/corporate-integrity-agreements/. CIAs generally require that documents relating to reimbursement from the Federal health care programs be retained for “six years (or longer if otherwise required by law) from the Effective Date” of a 5-year CIA. <i>See, e.g.,</i> Corporate Integrity Agreement between the Office of the Inspector General of the Department of Health and Human Services and Agenda, Inc., pp. 1, 20 (available at https://oig.hhs.gov/fraud/cia/agreements/Agendia_Inc_01132021.pdf, last visited December 14, 2021).</p>

DOCUMENT RETENTION SCHEDULE

BUSINESS, FINANCIAL, AND HOSPITAL ADMINISTRATION RECORDS¹

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Claims or Requests for Payment for Medicare Part A or B services, items, or drugs ordered by a physician or other permitted eligible professional</p> <p><i>For other patient claims, see above, p. 11).</i></p>	<p>7 years.</p>	<p>42 C.F.R. § 424.516(f); Medicare Program Integrity Manual, Ch. 15 § 18 (BOTH physicians (or other eligible professionals) who order, certify, refer, or prescribe Part A or B services, items, or drugs (“Covered Benefits”) AND providers that furnish covered ordered, certified, referred, or prescribed Covered Benefits must maintain written and electronic documents (including the national provider identifier (NPI) of the physician or other eligible professional who ordered/certified/referred/prescribed the Covered Benefits) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Covered Benefits for 7 years from the date of service).</p> <p>42 C.F.R. §424.535(a)(10) (provider who fails to comply with document retention requirements in 424.516(f) is <i>subject to revocation</i> of Medicare enrollment for a period of not more than 1 year).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>In more recent Corporate Integrity Agreements (“CIAs”), the OIG requires that documents relating to reimbursement from the Federal health care programs be retained for 6 years after the CIA’s effective date (<i>i.e.</i>, 1 year after the expiration of the 5-year CIA) or longer if otherwise required by law.</p>

DOCUMENT RETENTION SCHEDULE

<p align="center">Contracts and Supporting Documentation</p>	<p>Full term of contract plus 6 years.</p> <p><i>See comments regarding instruments signed under seal.</i></p>	<p>Some contracts expressly delineate that they are being signed “under seal.” The statute of limitations for these contracts is 20 years. O.C.G.A. § 9-3-23. The hospital should retain any contracts that are signed under seal and their supporting documentation for 20 years.</p> <p>O.C.G.A. § 9-3-24 (6 year statute of limitation for breach of written contracts not involving the sale of goods); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract for the sale of goods).</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>48 C.F.R. § 4.703 (a), (b) (Federal government contractors shall make available records and other supporting evidence to satisfy contract negotiation, administration, and audit requirements of the contracting agencies and the Comptroller General for three years after final payment on the contract, or shorter if allowed by Subparts 4.705-1, -2, and -3, or longer if so required by a specific contract clause, the contractor’s own schedules requiring longer retention, or failure to meet the final indirect cost rate submission deadline referenced in 48 C.F.R. 4.703(b)(3)).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>
<p>Corporate Records and Permits</p> <p><i>(e.g., Articles of Incorporation, Hospital and Medical Staff Bylaws,</i></p>	<p>Permanent.</p>	<p>Ga. Comp. R. & Regs. 111-8-40-.03 (hospitals must have a permit); Ga. Comp. R. & Regs. 111-8-40-.05 (hospitals must submit the original copy of the application); Interpretive Guideline citing Ga. Comp. R. & Regs. 290-9-7-.05, recodified to Ga. Comp. R. & Regs. 111-8-40.05</p>

DOCUMENT RETENTION SCHEDULE

BUSINESS, FINANCIAL, AND HOSPITAL ADMINISTRATION RECORDS¹

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Board Minutes, Licenses, Certifications, Registrations and Permits, Certificate of Need Records, Determinations and Related Requests, Letters of Nonreviewability, State Health Planning Documents)		(hospitals should keep a copy of the application submitted to get a permit and any supporting documents). O.C.G.A. § 14-2-1601 (corporations must keep permanent records of minutes of all meetings of its shareholders and board of directors, executed consents evidencing all actions taken by the shareholders or board of directors without a meeting, a record of all actions taken by a committee of the board of directors in place of the board of directors on behalf of the corporation, and waivers of notice of all meetings of the board of directors and its committees).
Credit Card Payment Information	As determined by individual credit card vendors.	Generally, the credit card issuers restrict what data can be retained. Hospitals should therefore purge unnecessary data when no longer needed, reviewing the data for necessity at least quarterly.
Donor Records and Correspondence	If the contributor attached a condition to the contribution: Permanent. Generally: 6 years from the date of tax filing.	Hospitals may have a foundation that is a separate legal entity that handles monetary donations. This document retention schedule does not address the documents that foundation may maintain. 26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>). 31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years). 18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions, including Anti-Kickback). 15 U.S.C. § 15b (4 years statute of limitation for antitrust claims).

DOCUMENT RETENTION SCHEDULE

BUSINESS, FINANCIAL, AND HOSPITAL ADMINISTRATION RECORDS¹

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Financial Audits	Permanent.	<p>Organizations often maintain annual financial reports permanently for historical and administrative reasons, even though legal citations support a retention period of 6 to 10 years.</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.M.B. Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations (Non-profits that expend more than \$500,000 in federal money per year are required to submit financial audit reports. Records of those reports must be retained for 3 years).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

DOCUMENT RETENTION SCHEDULE

BUSINESS, FINANCIAL, AND HOSPITAL ADMINISTRATION RECORDS¹

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Financial Correspondence	Date of tax filing plus 6 years.	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>15 U.S.C. § 15b (4 years statute of limitation for antitrust claims).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

DOCUMENT RETENTION SCHEDULE

BUSINESS, FINANCIAL, AND HOSPITAL ADMINISTRATION RECORDS¹

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Fire Drill Reports	3 years.	<p>Ga. Comp. R. & Regs. 111-8-40-15 (the hospital shall document participation of all areas of the hospital in quarterly fire drills).</p> <p>Ga. Comp. R. & Regs. 111-8-40-14 (hospitals must develop and implement an effective hospital-wide safety program that includes a fire safety program including compliance with the applicable provisions of the <i>Life Safety Code</i> (NFPA 101), as enforced by the state fire marshal).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p> <p>Joint Commission, Comprehensive Accreditation Manual – Environment of Care (hospitals must have processes to report and investigate incidents and issues, including fire safety management problems).</p>
<p>Joint Commission Records</p> <p>(e.g., original Joint Commission survey results, documents related to Joint Commission surveys, correspondence from Joint Commission)</p>	Permanent.	<p>The hospital may wish to maintain Joint Commission records permanently for historical purposes.</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p>

DOCUMENT RETENTION SCHEDULE

BUSINESS, FINANCIAL, AND HOSPITAL ADMINISTRATION RECORDS¹

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Journals</p> <p>Ledgers, Ledger Cards</p> <p>Registers</p>	<p>Date of tax filing plus 6 years.</p>	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>
<p>Medicare and Medicaid Cost Reports</p>	<p>6 years from date of filing.</p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part II: Policies and Procedures for Hospital Services, § 1002 (Medicaid cost reporting requirements); Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(R) (providers must retain Medicaid records for 6 years after the date of service. Records meeting the secure electronic signature requirements are acceptable).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p>

DOCUMENT RETENTION SCHEDULE

BUSINESS, FINANCIAL, AND HOSPITAL ADMINISTRATION RECORDS¹

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Policies and Procedures – Outdated</p>	<p>Policies relating to use of equipment/products, including Pharmacy policies: 10 years.</p> <p>Policies for Compliance, HIPAA Privacy², Human Resources, Marketing, Nursing, or Quality Assurance: 6 years.</p> <p>Other policies: At least 3 years.</p> <p><i>See also Document Retention Schedule for the department that maintains the policy.</i></p>	<p>The hospital may wish to maintain policies for a longer period of time for historical purposes.</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>45 C.F.R. § 164.530(j) (a covered entity must maintain required HIPAA documentation for 6 years after the date of its creation or the date when it was last in effect).</p> <p>O.C.G.A. § 9-3-24 (6 year statute of limitations for breach of written contract. The Employee Handbooks should be maintained for this period for any claim that the Handbook constituted a contract between the employer and employee).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for medical malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

² The U.S. Department of Health and Human Services has proposed elimination of the requirements for a covered health care provider with a direct treatment relationship to an individual to obtain a written acknowledgment of receipt of its Notice of Privacy Policy, and, if unable to obtain the written acknowledgment, to document their good faith efforts and the reason for not obtaining the acknowledgment. See Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446-01 at 6485 (Jan. 21, 2021). The proposal, if finalized, would also remove the current requirement to retain copies of such documentation for six years. *Id.*

DOCUMENT RETENTION SCHEDULE

BUSINESS, FINANCIAL, AND HOSPITAL ADMINISTRATION RECORDS¹

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Quality Assurance Records	<p>6 years.</p> <p>For quality assurance records that are Medical Staff Records, see <i>Medical Staff Records</i>, p. 75</p>	<p>Hospitals may consider keeping quality assurance records for 10 years to cover the statute of limitations for products liability and the statute of repose for False Claims Act liability.</p> <p>Although arguably not discoverable, quality assurance meeting records may be helpful to hospital and defense counsel in assessing malpractice claims and suits. In addition, the hospital may wish to consider keeping these records longer to access quality assurance records for trending and other administrative purposes.</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).</p> <p>O.C.G.A. § 9-3-72 (statute of limitations for foreign objects left in a patient’s body is 1 year after object is discovered).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years)</p>

DOCUMENT RETENTION SCHEDULE

BUSINESS, FINANCIAL, AND HOSPITAL ADMINISTRATION RECORDS¹

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Rate Schedules	At least 6 years.	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>
Tax Exempt Status Application IRS Certification Letter	7 years (or at least as long as the Hospital's exempt status is retained).	<p>26 C.F.R. § 301.6104(d)-1(a) (tax exempt application must be available on-site as long as the organization retains tax exempt status. In addition, the annual information return (Form 990, Return of Organization Exempt From Income Tax, Form 990-PF, Return of Private Foundation, or any other version of Form 990 and Form 1065) should be available for public inspection for a period of three years beginning on the date the return is required to be filed or is filed, whichever is later. It may be advisable to retain the applicable Form 990 for 7 years or permanently if feasible.).</p>

DOCUMENT RETENTION SCHEDULE

BUSINESS, FINANCIAL, AND HOSPITAL ADMINISTRATION RECORDS¹

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Unclaimed Property	Ten years after unclaimed property becomes reportable	<p>O.C.G.A. § 44-12-228 (any person required to file a report under O.C.G.A. § 44-12-214 shall retain all books, records, and documents necessary to establish the accuracy and compliance of such report for ten years after the property becomes reportable, except to the extent that shorter time is provided in accordance with Article 5 of Chapter 18 of Title 50, the “Georgia Records Act,” or in subsection (b) of this Code section or by rule of the commissioner).</p> <p>O.C.G.A. § 44-12-214 (every person holding funds or other property, tangible or intangible, presumed abandoned under Article 5 of Chapter 12 of Title 44 shall report and remit to the commissioner with respect to the property as provided in this Code section); O.C.G.A. § 44-12-192 through -211.1 (unclaimed property is presumed abandoned as specified in the applicable statute or 5 years if not specified).</p>

DOCUMENT RETENTION SCHEDULE

COMPLIANCE RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Checks (Monthly) of the List of Excluded Individuals/Entities and of the Excluded Parties List System</p> <p><i>See comments regarding monthly check requirement.</i></p>	<p>6 years.</p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>42 C.F.R. § 455.436; HHS-OIG Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (May 8, 2013) (state Medicaid agencies are required to conduct monthly checks to identify excluded providers); 76 Fed. Reg. 5,861, 5,898 (Feb. 2, 2011) (CMS recommends that states consider making this a requirement for all providers).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(W) (providers are required to search the HHS-OIG and EPLS websites monthly to capture exclusions and reinstatements of employees and contracted persons or entities that have occurred since the last search).</p>
<p>Compliance Investigations/Audits</p> <p>(both internal and government)</p> <p>(for example, activity notes, memos, other items generated or collected by Compliance Office)</p> <p><i>See footnote to section.</i></p>	<p>6 years after resolution and discontinuation of monitoring.</p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (general Federal criminal statute of limitation of 5 years).</p> <p>O.C.G.A. § 16-14-8 (Georgia RICO statute of limitation of 5 years).</p> <p>In more recent Corporate Integrity Agreements (“CIAs”), the OIG requires that documents relating to compliance with the CIA or to reimbursement from the Federal health care programs be retained for 6 years after the CIA’s effective date (1 year after expiration of the 5-year CIA) or longer if otherwise required by law.</p> <p>45 C.F.R. § 164.530(j) (a covered entity must maintain required HIPAA documentation for 6 years after the date of its creation or the date when it was last in effect).</p>

* Note that PPACA § 6401 requires that providers establish a compliance program as a condition to enrolling and participating in Medicare. There is no specified timeline for implementation of this section, and in February 2011, CMS indicated it was holding on the rulemaking process. [76 Fed. Reg. 5,861, 5,942-5,943 \(Feb. 2, 2011\)](#). Any upcoming regulations could have an impact on the standard retention periods for compliance records.
17642659v1

DOCUMENT RETENTION SCHEDULE

COMPLIANCE RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Compliance Log of Prior Year (including hotline calls reporting occurrences)</p>	<p>6 years.</p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (general Federal criminal statute of limitation of 5 years).</p> <p>O.C.G.A. § 16-14-8 (Georgia RICO statute of limitation of 5 years).</p> <p>45 C.F.R. § 164.530(j) (a covered entity must maintain required HIPAA documentation for 6 years after the date of its creation or the date when it was last in effect).</p> <p>In more recent Corporate Integrity Agreements (“CIAs”), the OIG requires that documents relating to compliance with the CIA or to reimbursement from the Federal health care programs be retained for 6 years after the CIA’s effective date (1 year after expiration of the 5-year CIA) or longer if otherwise required by law.</p>
<p>Correspondence with OIG</p>	<p>10 years.</p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p>

* Note that PPACA § 6401 requires that providers establish a compliance program as a condition to enrolling and participating in Medicare. There is no specified timeline for implementation of this section, and in February 2011, CMS indicated it was holding on the rulemaking process. [76 Fed. Reg. 5,861, 5,942-5,943 \(Feb. 2, 2011\)](#). Any upcoming regulations could have an impact on the standard retention periods for compliance records.
17642659v1

DOCUMENT RETENTION SCHEDULE

COMPLIANCE RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>HIPAA Compliance Records</p> <p><u>Including:</u></p> <p>HIPAA privacy rule required policies and procedures³</p> <p>Privacy related communications required to be in writing</p> <p>Privacy practices notices</p> <p>Dispositions of complaints</p> <p>Accounting of disclosures</p> <p>Other actions, activities, or designations required to be documented</p>	<p>6 years from the date of creation or the date when it was last in effect, whichever is later.</p>	<p>45 C.F.R. § 164.530(j) (a covered entity must maintain required HIPAA documentation for 6 years after the date of its creation or the date when it was last in effect).</p> <p>45 C.F.R. § 164.528 (patients have a right to receive an accounting of all disclosures of protected health information made by the hospital in the previous 6 years).</p>

³ The U.S. Department of Health and Human Services has proposed elimination of the requirements for a covered health care provider with a direct treatment relationship to an individual to obtain a written acknowledgment of receipt of its Notice of Privacy Policy, and, if unable to obtain the written acknowledgment, to document their good faith efforts and the reason for not obtaining the acknowledgment. See Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446-01 at 6485 (Jan. 21, 2021). The proposal also would remove the current requirement to retain copies of such documentation for six years. *Id.*

* Note that PPACA § 6401 requires that providers establish a compliance program as a condition to enrolling and participating in Medicare. There is no specified timeline for implementation of this section, and in February 2011, CMS indicated it was holding on the rulemaking process. [76 Fed. Reg. 5,861, 5,942-5,943 \(Feb. 2, 2011\)](#). Any upcoming regulations could have an impact on the standard retention periods for compliance records.
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DOCUMENT RETENTION SCHEDULE

COMPLIANCE RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Internal Compliance Records</p> <p>(for example, reports which generally summarize compliance activities to the Board of Directors or from Compliance Liaisons to the Compliance Officer)</p>	<p>6 years.</p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (general Federal criminal statute of limitation of 5 years).</p> <p>O.C.G.A. § 16-14-8 (Georgia RICO statute of limitation of 5 years).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p> <p>In more recent Corporate Integrity Agreements (“CIAs”), the OIG requires that documents relating to compliance with the CIA or to reimbursement from the Federal health care programs be retained for 6 years after the CIA’s effective date (1 year after expiration of the 5-year CIA) or longer if otherwise required by law.</p>

* Note that PPACA § 6401 requires that providers establish a compliance program as a condition to enrolling and participating in Medicare. There is no specified timeline for implementation of this section, and in February 2011, CMS indicated it was holding on the rulemaking process. [76 Fed. Reg. 5,861, 5,942-5,943 \(Feb. 2, 2011\)](#). Any upcoming regulations could have an impact on the standard retention periods for compliance records.

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DOCUMENT RETENTION SCHEDULE

COMPLIANCE RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Manuals and Forms – Outdated</p> <p><u>Including:</u></p> <p>Compliance Manuals (including Code of Conduct and Policies and Procedures)</p> <p>Coding Manuals</p> <p>Training Manuals</p> <p>Examples of all Forms in Use</p>	<p>6 years from date materials replaced or updated.</p>	<p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>45 C.F.R. § 164.530(j) (a covered entity must maintain required HIPAA documentation for 6 years after the date of its creation or the date when it was last in effect).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>45 C.F.R. § 164.530(j) (a covered entity must maintain required HIPAA documentation, including training materials and records of trainings, for 6 years after the date of its creation or the date when it was last in effect).</p> <p>18 U.S.C. § 3282 (general Federal criminal statute of limitation of 5 years).</p> <p>O.C.G.A. § 16-14-8 (Georgia RICO statute of limitation of 5 years).</p> <p>In more recent Corporate Integrity Agreements (“CIAs”), the OIG requires that documents relating to compliance with the CIA or to reimbursement from the Federal health care programs be retained for 6 years after the CIA’s effective date (1 year after expiration of the 5-year CIA) or longer if otherwise required by law</p>

* Note that PPACA § 6401 requires that providers establish a compliance program as a condition to enrolling and participating in Medicare. There is no specified timeline for implementation of this section, and in February 2011, CMS indicated it was holding on the rulemaking process. [76 Fed. Reg. 5,861, 5,942-5,943 \(Feb. 2, 2011\)](#). Any upcoming regulations could have an impact on the standard retention periods for compliance records.
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DOCUMENT RETENTION SCHEDULE

COMPLIANCE RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Minutes of Compliance Committee Meetings	Permanent.	<p>Many organizations’ document retention policies recommend retaining minutes of Compliance Committee Meetings permanently. Some organizations may prefer a less conservative approach, such as 6 years.</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (general Federal criminal statute of limitation of 5 years).</p> <p>O.C.G.A. § 16-14-8 (Georgia RICO statute of limitation of 5 years).</p> <p>In more recent Corporate Integrity Agreements (“CIAs”), the OIG requires that documents relating to compliance with the CIA or to reimbursement from the Federal health care programs be retained for 6 years after the CIA’s effective date (1 year after expiration of the 5-year CIA) or longer if otherwise required by law.</p>

* Note that PPACA § 6401 requires that providers establish a compliance program as a condition to enrolling and participating in Medicare. There is no specified timeline for implementation of this section, and in February 2011, CMS indicated it was holding on the rulemaking process. [76 Fed. Reg. 5,861, 5,942-5,943 \(Feb. 2, 2011\)](#). Any upcoming regulations could have an impact on the standard retention periods for compliance records.
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DOCUMENT RETENTION SCHEDULE

EMERGENCY DEPARTMENT

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Emergency Department Logs (in the original or legally reproduced form in hard copy, microfilm, microfiche, optical disks, computer disks, or computer memory)</p>	<p>5 years.</p>	<p>EMTALA 42 U.S.C. § 1395cc(a)(1)(I)(ii); 42 C.F.R. § 489.20(r)(1); CMS State Operations Manual, Appendix V – Part II – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases, Tag A-2403/C-2403 (transferring and receiving hospitals must maintain medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of the transfer).</p>
<p>Emergency Department Medical Records</p>	<p><u>Adults:</u> 10 years from last discharge or contact that resulted in a record.</p> <p><u>Minors:</u> Until the patient’s 23rd birthday or 10 years from last discharge or contact that resulted in a record, whichever is longer.</p> <p><i>See Medical Records Section, p. 71.</i></p>	<p>EMTALA requires emergency department medical records be kept a minimum of 5 years, but these records will need to be kept longer per the general medical record retention requirements. <i>See Medical Records Section, p. 71.</i></p> <p>EMTALA 42 U.S.C. § 1395cc(a)(1)(I)(ii); 42 C.F.R. § 489.20(r)(1); CMS State Operations Manual, Appendix V – Part II – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases, Tag A-2403/C-2403 (transferring and receiving hospitals must maintain medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of the transfer).</p>
<p>Patient Index, On-Call Schedules, Staffing Schedules</p>	<p>5 years.</p>	<p>EMTALA 42 U.S.C. § 1395cc(a)(1)(I)(ii); 42 C.F.R. § 489.20(r)(1); CMS State Operations Manual, Appendix V – Part II – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases, Tag A-2403/C-2403 (transferring and receiving hospitals must maintain medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of the transfer).</p>
<p>Transfer Records</p>	<p>5 years.</p>	<p>EMTALA 42 U.S.C. § 1395cc(a)(1)(I)(ii); 42 C.F.R. § 489.20(r)(1); CMS State Operations Manual, Appendix V – Part II – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases, Tag A-2403/C-2403 (transferring and receiving hospitals must maintain medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of the transfer).</p>

DOCUMENT RETENTION SCHEDULE

ENVIRONMENTAL RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Asbestos Records</p> <p>(e.g., building components surveys, inspections, and maintenance records; operation and maintenance plans; exposure records; records of removal of asbestos or renovation)</p>	<p>Recommended that documents related to existing asbestos-containing components be retained permanently while they remain in the building.</p> <p>If employees have been exposed, records must be maintained for term of employment plus 30 years, regardless of whether asbestos has been removed.</p> <p><i>See OSHA Records, p. 50.</i></p> <p>Documents related to removal or renovation off asbestos containing materials from a building should be retained for 5 years after removal.</p> <p>Documents related to a release of asbestos fibers should be retained one year.</p>	<p>Surveys, inspections, and maintenance records regarding building components containing asbestos materials should be maintained for the life of the building for administrative reasons and for use with future construction projects, but this is not a legal requirement.</p> <p>29 C.F.R. §§ 1910.1001(m), 1910.1020(d) (OSHA requires employers to keep records of all employee exposure to asbestos for term of employment plus 30 years. Certain required employee medical records, which are delineated in the law, must be maintained for duration of employment plus 30 years). <i>See OSHA Records, p. 50.</i></p> <p>40 C.F.R. §§ 61.145 and 61.150. (Advance notice to EPA of renovation or demolition that will impact asbestos-containing materials and documentation of compliance with certain procedures required. There is no set retention requirement nor statute of limitations in the Clean Air Act for these documents, so the general five-year federal statute of limitations in 28 U.S.C. Section 2462 would apply and should be used for the retention period. Additionally, the Georgia Asbestos Safety Act, O.C.G.A. § 12-12-10, requires notification of any asbestos removal to the Georgia Environmental Protection Division.).</p> <p>40 C.F.R. § 302.8. (Must notify EPA if there has been a release of asbestos fibers of 1 pound or more. Supporting documentation related to the release must be kept on file for one year).</p>
<p>Disposal of Biomedical Waste</p>	<p>3 years.</p>	<p>Ga. Comp. R. & Regs. 391-3-4-.15 (disposal of biomedical waste).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p> <p>Email from Spenser Nelson, Georgia Department of Natural Resources Solid Waste Program Environmental Engineer on 10/21/2021: Georgia EPD does not have a specific record retention requirement for records that an entity generates relating to the disposal of biomedical waste. A generator of biomedical waste should keep the records (<i>i.e.</i>, either the purchase records for the disposal bins or the waste manifest) in accordance with its own policy.</p>

DOCUMENT RETENTION SCHEDULE

ENVIRONMENTAL RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
		<p>the applicable emergency planning agencies. There is no set retention requirement nor statute of limitations in EPCRA so the general five-year federal statute of limitations in 28 U.S.C. § 2462 would apply.</p> <p>HSRA O.C.G.A. § 12-8-97(d), Ga Rules and Regulations 391-3-19-.04. Must report certain releases of regulated substances to groundwater or to soils to the Georgia Environmental Protection Division within 30 days of discovery. Recommended to consult counsel for further specifics.</p> <p>O.C.G.A. § 12-4-3. Must notify the EPD of any spill or release of oil or hazardous substance exceeding the reportable quantity. Recommended to consult counsel for further specifics.</p>
<p>Emergency Generators and other Equipment that Emit Pollutants into the Air</p>	<p>Emergency Generators: 2 or 5-year retention period, depending on type of engine may apply, but 5 years is recommended for relevant documents; data for the 2 most recent years must be stored on-site.</p> <p>Other Equipment: variable but at least 5 year retention period</p>	<p>40 CFR Part 60. There are separate environmental regulations under the Clean Air Act for each type of emergency generator (<i>e.g.</i>, generators fueled by propane, generators fueled by diesel, generators made before 2006, various methods of ignition, etc.). Retention periods in these regulations are generally 5 years. <i>See, e.g.,</i> 40 C.F.R. § 63.10(b)(1); 40 C.F.R. § 63.6660 (5 year retention period for reports and notifications (the most recent 2 years kept on-site); for all records for stationary sources and reciprocating internal combustion engines); <i>but see, e.g.,</i> 40 C.F.R. § 60.7(f) (records for certain compression ignition and spark ignition generator equipment measurement data must be retained for 2 years).</p> <p>If not otherwise specified for particular types of generators, there is no overall statute of limitations under the Clean Air Act so the general five-year federal statute of limitations in 28 U.S.C. § 2462 would apply for actions by the federal government. Many courts have applied the same five-year statute of limitations to actions brought by private citizens. Therefore 5 years should be the default retention period for records for which there are no specific retention periods in the regulations.</p> <p>Reference should be made to Clean Air Act regulations applicable to a specific type of equipment or the pollutants being emitted into the air thereby. If no specific retention requirements, the default 5-year statute of limitations will apply and serve as the retention period.</p>

DOCUMENT RETENTION SCHEDULE

ENVIRONMENTAL RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Environmental Due Diligence for Acquisition or Disposition of Real Property	Due diligence records showing the hospital made “all appropriate inquiry” into the environmental conditions of the real property when acquired: Recommended retention: permanent.	CERCLA, 42 U.S.C. § 9601(35)(B) ; 40 C.F.R. § 312.20 ; O.C.G.A. § 12-8-96.1 (due diligence to establish the innocent landowner defense or the bona fide prospective purchaser defense to federal or state liability for environmental cleanup. Note, the statute of limitations for CERCLA does not begin to run until the contamination is discovered). See also above for statute of limitations on contribution and cost recovery actions under CERCLA and HSRA against property owners.
	Endangered Species Survey or permit, if applicable: Recommended retention: 5 years.	16 U.S.C. § 1538(a) (unlawful taking of endangered species). There is no set retention requirement nor statute of limitations in the Endangered Species Act so the general five-year federal statute of limitations in 28 U.S.C. § 2462 would apply for actions by the federal government. The ESA provides for citizen suits but many courts have applied the same five-year statute of limitations to actions brought by private citizens. Therefore, a five-year retention policy is recommended.
	Jurisdictional Waters Survey, Jurisdictional Determination and/or Jurisdictional Waters Permit (and mitigation evidence) from the Army Corps of Engineers, if applicable: Recommended retention: 5 years from the completion of the development. Survey, Permit and/or State of Georgia Stream Buffer Variance (and mitigation evidence)	See Clean Water Act, 33 U.S.C. § 1311(a) ; 33 U.S.C. § 1344 (e); 33 C.F.R. § 331.2 ; U.S. Army Corps of Engineers, Regulatory Guidance Letter No. 16-01 (October 2016) . (An Approved Jurisdictional Determination remains valid for 5 years, so a 5-year retention period is recommended. There is no set retention requirement nor statute of limitations in the Clean Water Act so the general five-year federal statute of limitations in 28 U.S.C. Section 2462 would apply for actions by the federal government. The CWA provides for citizen suits but many courts have applied the same five-year statute of limitations to actions brought by private citizens. Therefore, a five-year retention policy is recommended.) Georgia Erosion and Sedimentation Control Act O.C.G.A. § 12-7-6 and Ga. Rules and Regulations 391-3-7-.05. There is no retention policy in the statute so consultation with counsel is recommended.
Storage Tanks	10 years or life of equipment plus 5 years, whichever is longer.	Georgia Underground Storage Tank Act: Owners of underground storage tanks must maintain evidence of financial responsibility (O.C.G.A. § 12-13-9), notification and registration (O.C.G.A. § 12-13-13), and proof of payment of fees (O.C.G.A. § 12-13-18). There is no retention policy in the statute so consultation with counsel is recommended. The Georgia Environmental Compliance Assistance Program, (GECAP) a voluntary, non-regulatory environmental compliance program funded by the Georgia Legislature through the University System of Georgia recommends retaining tank repair records for the life of the system. Additional GECAP recommendations may be found in its guidance on Underground Storage Tanks.

DOCUMENT RETENTION SCHEDULE

ENVIRONMENTAL RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Hospital/Medical/Infectious Waste Incinerators	5 years (but see comments).	<p>40 C.F.R. § 60.58c(b) (required 5-year retention period of certain reports).</p> <p>Note, if incinerators burn hazardous waste, they are considered disposal facilities and regulated under RCRA. RCRA, 40 C.F.R. § 262; 40 C.F.R. § 264; and under the Georgia Hazardous Waste Management Act (see above)/.</p>
Mold Contamination and Abatement Records	<p>At least 2 years, but see comments.</p> <p>If employees have been exposed, records must be maintained for term of employment plus 30 years.</p> <p><i>See OSHA Records, p. 50.</i></p>	<p>O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>29 C.F.R. § 1910.1020(d) (if records include records of monitoring or sampling of employee exposure to toxic substances or other hazards, OSHA generally requires retention for employees’ term of employment plus 30 years). <i>See OSHA Records, p. 50.</i></p>
Use of Chemicals	<p>Documents related to use of chemicals to which employees might be exposed should be retained 30 years, but see notes.</p> <p>Documents related to chemical storage and use should be retained 5 years</p>	<p>29 C.F.R. § 1910.1020(d)(1)(ii) Maintain exposure records at least 30 years with following exceptions:</p> <ul style="list-style-type: none"> (1) Background data: 1 year, so long as sampling results, collection methodology (sampling plan), description of methods used, and summary of relevant background data are retained at least 30 years. (2) Material safety data sheets and chemical inventory or other records concerning identity of substance or agent: No specified period so long as some record of substance or agent identity, where, and when it was used is retained at least 30 years. <p>Biological monitoring results designated as exposure records by specific occupational safety and health standards: Must be maintained as required by specific standards</p> <p>Emergency Planning and Community Right-to-Know (EPCRA) 42 U.S.C. §§ 11021-11023. There is no set retention requirement nor statute of limitations in EPCRA so the general five-year federal statute of limitations in 28 U.S.C. § 2462 would apply to the list of the Safety Data Sheets (SDS) for hazardous chemicals, a chemical inventory form, and the toxic chemical release form for applicable toxic chemicals used in quantities exceeding 10,000 pounds, if submittal to emergency planning agencies is required.</p>

DOCUMENT RETENTION SCHEDULE

HOUSEKEEPING RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Cleaning Logs (logs to confirm general areas of the hospital have been cleaned according to schedule)</p>	<p>3 years (or long enough to be able to confirm who did the work or who approved it if there are any questions on surveys or concerns regarding quality of work).</p>	<p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p> <p>O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>42 C.F.R. § 482.42; CMS State Operations Manual, Appendix A – Regulations and Interpretive Guidelines § 482.42, Tag A-0747 (hospitals must have active hospital-wide programs for the surveillance, prevention, and control of hospital acquired infections (HAIs) and other infectious diseases, and for the optimization of antibiotic use through stewardship).</p> <p>CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (Update: May 2019), available at https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf.</p>
<p align="center">Cleaning Records (e.g., duty rosters, assignment sheets)</p>	<p>3 years.</p>	<p>The hospital should keep these records long enough to be able to confirm who did the work if there are any questions on surveys or concerns regarding quality of work.</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10).</p> <p>O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>42 C.F.R. § 482.42; CMS State Operations Manual, Appendix A – Regulations and Interpretive Guidelines § 482.42, Tag A-0747 (hospitals must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship).</p> <p>CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (Update: May 2019), available at https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf.</p>

DOCUMENT RETENTION SCHEDULE

HOUSEKEEPING RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Exterminator Records	3 years.	<p>The hospital should keep these records long enough to be able to confirm who did the work if there are any questions on surveys or concerns regarding quality of work.</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10).</p> <p>O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>42 C.F.R. § 482.42; CMS State Operations Manual, Appendix A – Regulations and Interpretive Guidelines § 482.42, Tag A-0747 (hospitals must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship).</p>

DOCUMENT RETENTION SCHEDULE

HOUSEKEEPING RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Housekeeping and Exterminator Contracts	Full term of contract plus 6 years.	<p>O.C.G.A. § 9-3-24 (6 year statute of limitation for breach of written contract).</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to contracts valued over \$10,000 for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>
Housekeeping Policies and Procedures – Outdated	3 years.	<p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p> <p>O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>42 C.F.R. § 482.42; CMS State Operations Manual, Appendix A – Regulations and Interpretive Guidelines § 482.42, Tag A-0747 (hospitals must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship).</p> <p>CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (Update: May 2019), available at https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf.</p>

DOCUMENT RETENTION SCHEDULE

HUMAN RESOURCES / PERSONNEL RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Advertisements about Job Openings, Promotions, Training Programs, or Opportunities for Overtime Work</p>	<p>Medical staff positions: 6 years. Non-medical staff positions: 1 year. <i>See footnote to section.</i></p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years). 18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions, including Anti-Kickback). 29 C.F.R. § 1627.3(b) (employers must maintain any advertisements or notices to the public or to employees relating to job openings, promotions, training programs, or opportunities for overtime work for 1 year).</p>
<p>Accident Reports Related to Employees</p>	<p>5 years following the end of the calendar year the records cover.</p>	<p>29 C.F.R. § 1904.33 (employers must maintain the OSHA 300 Log, the privacy case list, the annual summary, and the OSHA 301 Incident Report form for 5 years following the end of the calendar year that the records cover). 29 C.F.R. § 1602.14 (all personnel records must be retained for 1 year. If a discrimination case is brought, records must be maintained until final disposition of the case). O.C.G.A. § 34-9-82(a) (the right to workers' compensation shall be barred unless a claim is filed within 1 year after injury. If payment of weekly benefits has been made or remedial treatment has been furnished by the employer on account of the injury, the claim may be filed within 1 year after the date of the last remedial treatment furnished by the employer or within 2 years after the date of the last payment of weekly benefits). O.C.G.A. § 9-3-33 (2 year statute of limitation for personal injuries).</p>

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Hospitals that are covered government contractors (for example, hospitals that have contracts with the federal government to provide health care to members of the military or to do research) are subject to additional document retention requirements, including a 2-year retention requirement for some for personnel records. [41 C.F.R. § 60-1.12](#). Note that a hospital is not considered a covered government contractor merely due to participation in Medicare or Medicaid. [Office of Federal Contract Compliance Programs, Frequently Asked Questions – Jurisdiction](#), available at <http://www.dol.gov/ofccp/regs/compliance/faqs/juristn.htm>.
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DOCUMENT RETENTION SCHEDULE

HUMAN RESOURCES / PERSONNEL RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Applications for Employment</p> <p><i>For applications from physicians, see Medical Staff Records, p. 75.</i></p>	<p>Accepted Applications: Term of employment plus 1 year.</p> <p>Rejected Applications: At least 1 year.</p> <p><i>See footnote to section.</i></p>	<p>For rejected applications, hospitals may consider maintaining these records for a length of time that would cover re-application by such applicants, which may be more than 1 year.</p> <p>29 C.F.R. § 1627.3(b) (job applications, resumes, and any other form of employment inquiry submitted in response to a job posting must be retained for 1 year from the date of the personnel action to which any records relate).</p> <p>29 C.F.R. § 1602.14 (all personnel records must be retained for 1 year; if a discrimination case is brought, records must be maintained until final disposition of the case).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.12 (the hospital must maintain personnel records that contain the employment application or resume).</p>

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DOCUMENT RETENTION SCHEDULE

HUMAN RESOURCES / PERSONNEL RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p style="text-align: center;">Benefit Records</p> <p style="text-align: center;">Pension Plan Records</p> <p>(e.g., including administrative materials, beneficiary materials, IRS forms, plan, plan summary, plan amendments, COBRA documents, long term disability claims granted and denied)</p>	<p>Plan and Plan Amendments: Permanent.</p>	<p>Plan and Plan Amendments should be retained permanently for historic purposes.</p> <p>29 U.S.C. § 1027 (ERISA § 107 requires a retention period of 6 years for benefit reports filed and their supporting documentation); 29 U.S.C. § 1059 (ERISA § 209 imposes an additional obligation to maintain all records necessary to determine benefits that are or may become due to each employee). The U.S. Department of Labor has taken the position that participant benefit records must be retained “as long as a possibility exists that they might be relevant to a determination of the benefit entitlements of a participant or beneficiary.” For more information, please see the AICPA Employee Benefit Plan Audit Quality Center Advisory on the Importance of Retaining and Protecting Employee Benefit Records.</p> <p>29 C.F.R. § 1627.3(b) (employee benefit plans, including pension and insurance records, must be retained for 1 year after the plan’s termination).</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>O.C.G.A. § 48-7-111 (records of remunerations to employees must be maintained for 4 years after the tax is due or the tax is paid, whichever is later).</p> <p>29 C.F.R. § 1620.32; 29 C.F.R. §§ 516.2, 516.11-12 (2 year retention period for wage data, explanations of pay differentials, and other required information to show compliance with the Equal Pay Act).</p> <p>29 C.F.R. § 516.5 (3 year retention requirement for payroll records, collective bargaining agreements, and related documentation).</p>

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DOCUMENT RETENTION SCHEDULE

HUMAN RESOURCES / PERSONNEL RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Checks (Monthly) of the List of Excluded Individuals/Entities and of the Excluded Parties List System</p> <p><i>See comments regarding monthly check requirement.</i></p>	<p>6 years.</p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>42 C.F.R. § 455.436; HHS-OIG Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (May 8, 2013) (state Medicaid agencies are required to conduct monthly checks to identify excluded providers); 76 Fed. Reg. 5,861, 5,898 (Feb. 2, 2011) (CMS recommends that states consider making this a requirement for all providers).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(W) (providers are required to search the HHS-OIG and EPLS websites monthly to capture exclusions and reinstatements of employees and contracted persons or entities that have occurred since the last search).</p>
<p>Collective Bargaining Agreements and Related Documentation</p>	<p>Duration of agreement plus 3 years.</p>	<p>29 C.F.R. § 516.5 (3 year retention requirement for payroll records, collective bargaining agreements, and related documentation).</p>
<p>Complaints of Handicap Discrimination and Relevant Employment Records of the Charging Party and Employees in Similar Positions</p>	<p>3 years.</p>	<p>29 C.F.R. § 32.49 (programs that receive federal financial assistance must maintain records related to complaints of handicap discrimination for 3 years).</p>

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DOCUMENT RETENTION SCHEDULE

HUMAN RESOURCES / PERSONNEL RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p style="text-align: center;">Contracts of Employment</p> <p><i>For contracts with physicians, see Medical Staff Records, p. 75.</i></p>	<p>Contract term plus 6 years.</p>	<p>O.C.G.A. § 9-3-24 (6 year statute of limitations for breach of written contract).</p> <p>29 C.F.R. § 516.5 (3 year retention requirement for payroll records, collective bargaining agreements, and related documentation, including some employment contracts).</p> <p>29 C.F.R. § 1602.14 (all personnel records must be retained for 1 year. If a discrimination case is brought, records must be maintained until final disposition of the case).</p> <p>Ga. Comp. R. & Regs. 111-8-40-12 (the hospital must maintain personnel records that contain the employment application or resume, dates of hire and position changes, job descriptions, all evaluations of performance or competencies since the date of hire or at least the last 5 years, credible evidence of current registration, license, or certification, evidence of completion of in-service training as required by the hospital, and evidence of completion of any requirements of the occupational health program at the hospital).</p>
<p style="text-align: center;">Correspondence with Employment Agencies</p>	<p>1 year from date job order submitted.</p> <p><i>See footnote to section.</i></p>	<p>29 C.F.R. § 1627.3(b) (job orders submitted by the employer to an employment agency for recruitment of personnel must be retained for 1 year).</p>

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Disciplinary Action Records for Non-Physician Staff</p> <p><i>For disciplinary action records for physicians, see Medical Staff Records, p. 75.</i></p>	<p>Term of employment plus 6 years.</p>	<p>Collective Bargaining Agreements may specify a retention period for these records.</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 9-3-24 (6 year statute of limitations for breach of written contract); O.C.G.A. § 9-3-25 (4 year statute of limitation for breach of oral contract).</p> <p>29 C.F.R. § 1627.3(b) (records relating to promotion, demotion, transfer, selection for training, layoff, recall, or discharge of an employee must be retained for 1 year from the date of the personnel action to which any records relate).</p> <p>29 C.F.R. § 1602.14 (all personnel records must be retained for 1 year; if a discrimination case is brought, records must be maintained until final disposition of the case).</p> <p>Ga. Comp. R. & Regs. 111-8-40-12 (the hospital must maintain personnel records that contain the employment application or resume, dates of hire and position changes, job descriptions, all evaluations of performance or competencies since the date of hire or at least the last 5 years, credible evidence of current registration, license, or certification, evidence of completion of in-service training as required by the hospital, and evidence of completion of any requirements of the occupational health program at the hospital).</p>
<p>Employee Background Checks</p>	<p>Term of employment plus 6 years.</p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose).</p> <p>O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>15 U.S.C.A. § 1681p (limitations period for violation of Fair Credit Reporting Act (15 U.S.C. § 1681 <i>et seq.</i>) is the earlier of 5 years after violation or 2 years after violation discovery. Employers using third-party vendors to conduct background checks should be aware of the vendor’s data retention policy if relying on the vendor for access to background check records, as general practice in the background screening industry is to maintain documents for no more than 5 years.).</p>

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DOCUMENT RETENTION SCHEDULE

HUMAN RESOURCES / PERSONNEL RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Employee Certification and Qualifications</p> <p>(certification, licenses, etc.)</p> <p><i>For certification records for physicians, see Medical Staff Records, p. 75.</i></p>	<p>Term of employment plus 6 years.</p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).</p> <p>29 C.F.R. § 1627.3(b) (records relating to promotion, demotion, transfer, selection for training, layoff, recall, or discharge of an employee must be retained for 1 year from the date of the personnel action to which any records relate).</p> <p>29 C.F.R. § 1602.14 (all personnel records must be retained for 1 year. If a discrimination case is brought, records must be maintained until final disposition of the case).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.12 (the hospital must maintain personnel records that contain the employment application or resume, dates of hire and position changes, job descriptions, all evaluations of performance or competencies since the date of hire or at least the last 5 years, credible evidence of current registration, license, or certification, evidence of completion of in-service training as required by the hospital, and evidence of completion of any requirements of the occupational health program at the hospital).</p>

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Hospitals that are covered government contractors (for example, hospitals that have contracts with the federal government to provide health care to members of the military or to do research) are subject to additional document retention requirements, including a 2-year retention requirement for some for personnel records. [41 C.F.R. § 60-1.12](#). Note that a hospital is not considered a covered government contractor merely due to participation in Medicare or Medicaid. [Office of Federal Contract Compliance Programs, Frequently Asked Questions – Jurisdiction](#), available at <http://www.dol.gov/ofccp/regs/compliance/faqs/juristn.htm>.
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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Employee Handbooks and Policy and Procedure Manuals – Outdated	6 years from the date it when it was last in effect.	<p>O.C.G.A. § 9-3-24 (6 year statute of limitations for breach of written contract. The Employee Handbooks should be maintained for this period for any claim that the Handbook constituted a contract between the employer and employee).</p> <p>45 C.F.R. § 164.530(j) (a covered entity must maintain required HIPAA documentation, including training materials and records of trainings, for 6 years after the date of its creation or the date when it was last in effect).</p> <p>29 C.F.R. § 825.500 (3 year retention requirement for records required under the Family and Medical Leave Act, including payroll data, dates FMLA leave is taken, and documents describing employee benefits or employer policies and practices regarding leave).</p> <p>29 C.F.R. § 1627.3(b) (records relating to promotion, demotion, transfer, selection for training, layoff, recall, or discharge of an employee must be retained for 1 year from the date of the personnel action to which any records relate. Employers must also maintain employee benefit plans, copies of any seniority systems and merit systems for at least 1 year after the plans are terminated).</p>
Employment Eligibility Verification Forms (“Form I-9”)	Term of employment; or, upon termination, the retention period is 3 years after the date of hire or 1 year after termination, whichever is longer.	<p>8 C.F.R. § 274a.2(b)(2)(i)(A) (employers must maintain a Form I-9 for current employees. Upon termination, employers must retain the I-9 for employees for 3 years after the date of hire or 1 year after termination, whichever is longer).</p>
Equal Pay Records	3 years from time record is created.	<p>29 C.F.R. § 1620.33 (2 year statute of limitations for action to recover unpaid wages under the Equal Pay Act; 3 year statute of limitations for an action if the violation was willful).</p> <p>29 C.F.R. § 1620.32; 29 C.F.R. §§ 516.2, 516.11-12 (2 year retention period for wage data, explanations of pay differentials, and other required information to show compliance with the Equal Pay Act).</p> <p>29 C.F.R. § 1627.3(b) (records relating to promotion, demotion, transfer, selection for training, layoff, recall, or discharge of an employee must be retained for 1 year from the date of the personnel action to which any records relate).</p> <p>29 C.F.R. § 1602.14 (all personnel records must be retained for 1 year; if a discrimination case is brought, records must be maintained until final disposition of the case).</p>

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Evaluations for Performance or Competencies	5 years.	<p>Ga. Comp. R. & Regs. 111-8-40-.12 (the hospital must maintain all evaluations of performance or competencies since the date of hire or at least the last 5 years).</p> <p>29 C.F.R. § 1627.3(b) (records relating to promotion, demotion, transfer, selection for training, layoff, recall, or discharge of an employee must be retained for 1 year from the date of the personnel action to which any records relate).</p> <p>29 C.F.R. § 1602.14 (all personnel records must be retained for 1 year; if a discrimination case is brought, records must be maintained until final disposition of the case).</p>
Family Medical Leave Act of 1993 Records	3 years.	<p>29 C.F.R. § 825.500 (3 year retention requirement for records required under the Family and Medical Leave Act, including payroll data, dates FMLA leave is taken, and documents describing employee benefits or employer policies and practices regarding leave).</p>
Family and Medical Leave under the Families First Coronavirus Relief Act (FFCRA)	4 years	<p>29 C.F.R. § 826.140(a) (Employers must retain FFCRA documents for four years, regardless whether leave was granted or denied. Employers must also document and retain oral statements given to support an employee’s request for leave for four years.).</p> <p>29 C.F.R. § 826.140(b) (If an employer denies an employee’s leave request under the under 50 employees exemption, the employer’s determination must be documented and maintained for four years.).</p> <p>29 C.F.R. § 826.140(c) (To claim tax credits, employers must retain documentation to show how the employer calculated the amount of leave, including records of work, telework, and Paid Sick Leave and Expanded Family Medical Leave; documentation to show how the employer determined the amount of qualified health plan expenses allocated to wages; copies of IRS Forms 7200 that the employer submitted to the IRS; copies of IRS Forms 941 or records of information provided to third party payers; and other documents necessary to support the employer’s request for tax credits.).</p>

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Grievance Records (general employee grievances or complaints)</p> <p>Dispute Resolution Records</p>	<p>Term of employment plus 3 years.</p>	<p>The grievance records should be retained for the length that the current Collective Bargaining Agreement is in place between the employer and the Union, typically three years. Grievances or complaints of employees should be maintained for the same amount of time as personnel records.</p> <p>29 C.F.R. § 1627.3(b) (records relating to promotion, demotion, transfer, selection for training, layoff, recall, or discharge of an employee must be retained for 1 year from the date of the personnel action to which any records relate).</p> <p>29 C.F.R. § 1602.14 (all personnel records must be retained for 1 year; if a discrimination case is brought, records must be maintained until final disposition of the case).</p>
<p>Immigration Documentation</p>	<p>1 year: H-1B Public Access File</p> <p>3 years: Required payroll records for H-1B employees; H-2B Records for Temporary Non-Agricultural Workers; J-1 Records for Alien Physicians</p> <p>5 years: PERM/Labor Certification for Permanent Residence</p>	<p>20 C.F.R. § 655.760 (c) (H-1B Public Access File (PAF) for Specialty Occupation Workers: The PAF must be retained and available for inspection for 1 year after the end of the period of employment specified in the Labor Condition Application (LCA), or 1 year after the LCA is withdrawn. The PAF must include a copy of the certified LCA. Required payroll records for H-1B employees and other employees in the occupational classification shall be retained at the employer's principal place of business or at the place of employment for a period of 3 years from the date(s) of the creation of the record(s).).</p> <p>20 C.F.R. § 655.56 (H-2B Records for Temporary Non-Agricultural Workers: Employers must retain records and documents for 3 years from the date the H-2B application is certified, or from the date of adjudication if the application is denied, or from the day the U.S. Department of Labor receives the letter of withdrawal if the employer withdraws the application.).</p> <p>22 C.F.R. § 62.10 (g) (J-1 Records for Alien Physicians: Employer sponsors must retain all records related to their exchange visitor program and exchange visitors (to include accompanying spouse and dependents, if any) for 3 years following the completion of each exchange visitor program.).</p> <p>20 C.F.R. § 656.10 (f) (PERM/Labor Certification for Permanent Residence: Copies of applications for permanent employment certification filed with the U.S. Department of Labor and all supporting documentation must be retained by the employer for 5 years from the date of filing the labor certification.).</p>

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DOCUMENT RETENTION SCHEDULE

HUMAN RESOURCES / PERSONNEL RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Job Classifications – Outdated	3 years.	<p>29 C.F.R. § 1620.32; 29 C.F.R. §§ 516.2, 516.11-12 (2 year retention period for wage data, explanations of pay differentials, and other required information to show compliance with the Equal Pay Act; 3 year statute of limitations if violation was willful).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.12 (the hospital must maintain personnel records that contain the employment application or resume, dates of hire and position changes, job descriptions, all evaluations of performance or competencies since the date of hire or at least the last 5 years, credible evidence of current registration, license, or certification, evidence of completion of in-service training as required by the hospital, and evidence of completion of any requirements of the occupational health program at the hospital).</p> <p>29 C.F.R. § 1627.3(b) (advertisements or notices to the public or to employees relating to job openings, promotions, training programs, or opportunities for overtime work must be retained for 1 year from the date of the personnel action to which any records relate).</p> <p>29 C.F.R. § 1602.14 (all personnel records must be retained for 1 year; if a discrimination case is brought, records must be maintained until final disposition of the case).</p>

* Human resources records that are not specifically addressed herein should be retained for the term of employment plus 6 years.

Hospitals that are covered government contractors (for example, hospitals that have contracts with the federal government to provide health care to members of the military or to do research) are subject to additional document retention requirements, including a 2-year retention requirement for some for personnel records. [41 C.F.R. § 60-1.12](#). Note that a hospital is not considered a covered government contractor merely due to participation in Medicare or Medicaid. [Office of Federal Contract Compliance Programs, Frequently Asked Questions – Jurisdiction](#), available at <http://www.dol.gov/ofccp/regs/compliance/faqs/juristn.htm>.
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DOCUMENT RETENTION SCHEDULE

HUMAN RESOURCES / PERSONNEL RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Locum Tenens Arrangements, Documents	Term of contract plus 6 years.	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 9-3-24 (6 year statute of limitations for breach of written contract).</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in an amount in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).</p> <p>O.C.G.A. § 9-3-72 (statute of limitations for foreign objects left in a patient’s body is 1 year after object is discovered).</p> <p>29 C.F.R. § 1627.3(b) (records relating to promotion, demotion, transfer, selection for training, layoff, recall, or discharge of an employee must be retained for 1 year from the date of the personnel action to which any records relate).</p> <p>29 C.F.R. § 1602.14 (all personnel records must be retained for 1 year; if a discrimination case is brought, records must be maintained until final disposition of the case).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to contracts valued over \$10,000 for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p>

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DOCUMENT RETENTION SCHEDULE

HUMAN RESOURCES / PERSONNEL RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p style="text-align: center;">OSHA Records</p> <p style="text-align: center;">(continued on next page)</p>	<p>Employee exposure records: At least 30 years with exceptions.</p> <p>Documents related to chemical storage and use should be retained 5 years</p>	<p>29 C.F.R. § 1910.1020(d)(1)(ii) Maintain exposure records at least 30 years with following exceptions:</p> <ul style="list-style-type: none"> (3) Background data: 1 year, so long as sampling results, collection methodology (sampling plan), description of methods used, and summary of relevant background data are retained at least 30 years. (4) Material safety data sheets and chemical inventory or other records concerning identity of substance or agent: No specified period so long as some record of substance or agent identity, where, and when it was used is retained at least 30 years. (5) Biological monitoring results designated as exposure records by specific occupational safety and health standards: Must be maintained as required by specific standards. <p>29 C.F.R. § 1910.1020 does not mandate the form, manner, or process by which employer preserves a record so long as information is preserved and retrievable, except chest x-rays files shall be preserved in original state.</p> <p>EPCRA 42 U.S.C. §§ 11021-11023. There is no set retention requirement nor statute of limitations in EPCRA so the general five-year federal statute of limitations in 28 U.S.C. § 2462 would apply to the list of the Safety Data Sheets (SDS) for hazardous chemicals, a chemical inventory form, and the toxic chemical release form for applicable toxic chemicals used in quantities exceeding 10,000 pounds, if submittal to emergency planning agencies is required.</p>
	<p>Employee Exposure to COVID-19: Term of COVID-19 Healthcare Emergency Temporary Standard</p>	<p>29 C.F.R. § 1910.502(q) (employers must maintain records, including all versions of the employer’s COVID-19 plan, and a COVID-19 log to record each instance identified by the employer in which an employee is confirmed COVID-19 positive, regardless of whether the employee contracted COVID-19 at work. The COVID-19 log must include: the employee’s name, contact information, occupation, location of work, date of last day at the workplace, date of a COVID-19 positive test or diagnosis, and date of symptom onset.)</p>

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DOCUMENT RETENTION SCHEDULE

HUMAN RESOURCES / PERSONNEL RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">OSHA Records <i>(continued from previous page)</i></p>	<p>Employee Medical Records: Term of employment plus 30 years.</p>	<p>29 C.F.R. § 1910.1020(d)(1)(i) (medical record for each employee must be retained for the duration of employment plus 30 years. Exceptions: (i) health insurance claims records maintained separately from employer’s medical program and its records; (ii) certain first aid records; and (iii) records of employees who worked less than 1 year for employer if provided to employee upon termination).</p> <p>29 C.F.R. § 1910.1030(h) (medical records for each employee with occupational exposure to bloodborne pathogens must be maintained for the duration of employment plus 30 years).</p> <p>29 C.F.R. § 1910.1020 does not mandate the form, manner, or process by which employer preserves a record so long as information is preserved and retrievable, except chest x-rays files shall be preserved in original state.</p>
	<p>OSHA Logs and Summary Forms: 5 years following the end of the calendar year that the records cover.</p>	<p>29 C.F.R. § 1904.33 (employers must maintain the OSHA 300 Log, the privacy case list, the annual summary, and the OSHA 301 Incident Report form for 5 years following the end of the calendar year that the records cover).</p> <p>29 C.F.R. § 1602.14 (all personnel records must be retained for 1 year; if a discrimination case is brought, records must be maintained until final disposition of the case).</p> <p>29 C.F.R. § 1627.3(b) (records relating to promotion, demotion, transfer, selection for training, layoff, recall, or discharge of an employee must be retained for 1 year from the date of the personnel action to which any records relate).</p> <p>29 C.F.R. § 1910.502(q) (employers must continue to record all work-related confirmed cases of COVID-19 on their OSHA Forms 300, 300AA, and 301, or the equivalent forms.).</p>
	<p>Training Records for Employees with Occupational Exposure to Bloodborne Pathogens: 3 years.</p>	<p>29 C.F.R. § 1910.1030 (training records for employees with occupational exposure to bloodborne pathogens must be maintained for 3 years after the date of the training).</p>

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DOCUMENT RETENTION SCHEDULE

<p align="center">Payroll Records</p> <p>(e.g., hours worked, leaves of absence, overtime, vacation, sick leave entries, time cards, wages paid, deduction authorizations, registers and journals, and garnishment records)</p>	<p>7 years.</p>	<p>Hospitals may consider maintaining these records for longer (e.g., for 6 years) to cover any related breach of contract lawsuits.</p> <p>O.C.G.A. § 9-3-24 (6 year statute of limitations for breach of written contract).</p> <p>26 C.F.R. § 31.6001-1(e)(2) (records relating to payments to employees and payroll taxes must be retained for 4 years after the due date of such tax for the return period to which the records relate, or the date such tax is paid, whichever is later).</p> <p>26 C.F.R. § 31.6001-2 (employers subject to FICA must keep records of all payments to employees. Such records should be retained for 7 years); 26 C.F.R. § 31.6001-4 (employers subject to the Federal Unemployment Tax must keep records of all payments to employees and to the state unemployment fund. Such records should be retained for 7 years.).</p> <p>O.C.G.A. § 48-7-111 (records of payments to employees must be maintained for 4 years after the tax is due or the tax is paid, whichever is later).</p> <p>29 C.F.R. § 1627.3(a) (all payroll records must be retained for 3 years).</p> <p>29 C.F.R. § 825.500 (3 year retention requirement for records required under the Family and Medical Leave Act, including payroll data, dates FMLA leave is taken, and documents describing employee benefits or employer policies and practices regarding leave).</p> <p>29 C.F.R. §§ 516.2, 516.11-12 (employers must maintain wage data and other required information to show compliance with the Fair Labor Standards Act).</p> <p>29 C.F.R. § 516.23 (additional recordkeeping requirements for hospitals who compensate employees for overtime based on a work period of 14 consecutive days).</p> <p>29 C.F.R. § 516.5 (3 year retention requirement for payroll records, collective bargaining agreements, and related documentation).</p> <p>29 C.F.R. § 1620.32; 29 C.F.R. §§ 516.2, 516.11-12 (2 year retention period for wage data, explanations of pay differentials, and other required information to show compliance with the Equal Pay Act).</p> <p>29 C.F.R. § 516.6 (2 year retention requirement for time cards, productivity records, and other records used to determine an employee’s earnings, wage rate tables, and any records of additions to or deductions from wages paid).</p> <p>O.C.G.A. § 34-2-11 (1 year retention of employment records, including daily and weekly hours worked and wages paid).</p>
<p align="center">Personnel Records</p>	<p>Term of employment plus 6 years.</p>	<p>O.C.G.A. § 9-3-24 (6 year statute of limitations for breach of written contract).</p>

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DOCUMENT RETENTION SCHEDULE

<p>(to the extent not otherwise described in this section)</p> <p>See also <i>Medical Staff Records</i>, p. 75.</p>	<p><u>But note</u> longer retention requirements for (1) employee medical records and exposure records and (2) records relating to physicians. See <i>OSHA Records</i>, p. 50 and <i>Medical Staff Records</i>, p. 75.</p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in excess of 25 percent of the amount of gross income stated in the return. <i>But note</i>: In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose).</p> <p>26 C.F.R. § 31.6001-1(e)(2) (records relating to payments to employees and payroll taxes must be retained for 4 years after the due date of such tax for the return period to which the records relate, or the date such tax is paid, whichever is later); O.C.G.A. § 48-7-111 (records of payments to employees must be maintained for 4 years after the tax is due or the tax is paid, whichever is later).</p> <p>29 C.F.R. § 1627.3(a) (all payroll records must be retained for 3 years).</p> <p>29 C.F.R. § 825.500 (3 year retention requirement for records required under the Family and Medical Leave Act, including payroll data, dates FMLA leave is taken, and documents describing employee benefits or employer policies and practices regarding leave).</p> <p>29 C.F.R. § 516.5 (3 year retention requirement for payroll records, collective bargaining agreements, and related documentation, including some employment contracts); 29 C.F.R. § 516.23 (additional recordkeeping requirements for hospitals who compensate employees for overtime based on a work period of 14 consecutive days).</p> <p>29 C.F.R. § 1620.32; 29 C.F.R. §§ 516.2, 516.11-12 (2 year retention period for wage data, explanations of pay differentials, and other information required by the Equal Pay Act).</p> <p>29 C.F.R. § 516.6 (2 year retention requirement for time cards, productivity records, and other records used to determine an employee’s earnings).</p> <p>O.C.G.A. § 34-2-11 (1 year retention of employment records).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.12 (hospital must maintain personnel records that contain the employment application or resume, dates of hire and position changes, job descriptions, all evaluations of performance or competencies since the date of hire or at least the last 5 years, credible evidence of current registration, license, or certification, evidence of completion of in-service training as required by the hospital, and evidence of completion of any requirements of the occupational health program at the hospital).</p>
<p>Substance Abuse Testing</p>	<p>Term of employment plus 6 years.</p>	<p>29 C.F.R. § 1627.3(b)(1)(v) (the results of any physical examination where such examination is considered by the employer in connection with any personnel action shall be retained for 1 year from the date of the personnel action).</p>

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DOCUMENT RETENTION SCHEDULE

HUMAN RESOURCES / PERSONNEL RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p><i>For substance abuse testing for physicians, see Medical Staff Records, p. 75.</i></p>		<p>O.C.G.A. § 9-3-24 (6 year statute of limitation for breach of written contract).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-72 (statute of limitations for foreign objects left in a patient’s body is 1 year after object is discovered).</p>
<p>Termination Records</p> <p><i>For termination records for physicians, see Medical Staff Records, p. 75.</i></p>	<p>6 years after termination.</p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 9-3-24 (6 year statute of limitations for breach of written contract); O.C.G.A. § 9-3-25 (4 year statute of limitation for breach of oral contract).</p> <p>29 C.F.R. § 1627.3(b) (records relating to layoff or discharge of an employee must be retained for 1 year from the date of the personnel action to which any records relate).</p> <p>29 C.F.R. § 1602.14 (all personnel records must be retained for 1 year; if a discrimination case is brought, records must be maintained until final disposition of the case).</p>

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DOCUMENT RETENTION SCHEDULE

HUMAN RESOURCES / PERSONNEL RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Training Materials – Outdated</p>	<p>Trainings involving uses of medical devices: 10 years.</p> <p>HIPAA trainings: 6 years.</p> <p>For training of patient care staff: 5 years.</p> <p>For training of non-patient care staff: 3 years.</p>	<p>45 C.F.R. § 164.530(j) (a covered entity must maintain required HIPAA documentation, including training materials and records of trainings, for 6 years after the date of its creation or the date when it was last in effect).</p> <p>29 C.F.R. § 1627.3(b) (records relating to selection for training must be retained for 1 year from the date of the personnel action to which any records relate).</p> <p>Ga. Comp. R. & Regs. 111-8-40-12 (the hospital must maintain personnel records that contain the employment application or resume, dates of hire and position changes, job descriptions, all evaluations of performance or competencies since the date of hire or at least the last 5 years, credible evidence of current registration, license, or certification, evidence of completion of in-service training as required by the hospital, and evidence of completion of any requirements of the occupational health program at the hospital).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).</p> <p>O.C.G.A. § 9-3-72 (statute of limitations for foreign objects left in a patient’s body is 1 year after object is discovered).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p> <p>O.C.G.A. § 9-3-33 (2 year statute of limitation for personal injury).</p>

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DOCUMENT RETENTION SCHEDULE

HUMAN RESOURCES / PERSONNEL RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Unemployment Compensation Payments and Records	7 years.	<p>26 C.F.R. §§ 31.6001-1(e)(2) (records relating to payments to employees and payroll taxes must be retained for 4 years after the due date of such tax filing, for the return period to which the records relate, or the date such tax is paid, whichever is later).</p> <p>26 C.F.R. § 31.6001-2 (employers subject to FICA must keep records of all payments to employees. Such records should be retained for 7 years.).</p> <p>26 C.F.R. § 31.6001-4 (employers subject to the Federal Unemployment Tax must keep records of all payments to employees and to the state unemployment fund. Such records should be retained for 7 years.).</p>
W-2, W-4 Forms	7 years.	<p>26 C.F.R. §§ 31.6001-1(e)(2) (records relating to payments to employees and payroll taxes must be retained for 4 years after the due date of such tax filing, for the return period to which the records relate, or the date such tax is paid, whichever is later).</p> <p>26 C.F.R. § 31.6001-2 (employers subject to FICA must keep records of all payments to employees. Such records should be retained for 7 years.).</p>
Workers' Compensation Records	Accident Reports: 2 years.	<p>O.C.G.A. § 9-3-33 (2 year statute of limitation for personal injuries).</p> <p>O.C.G.A. § 34-9-80 (every injured employee shall give notice of the accident in person to the employer immediately or as soon thereafter as immediately practicable; in the event that within 30 days after the accident the employee has failed to give notice, a written notice must be given).</p> <p>O.C.G.A. § 34-9-82(a) (the right to workers' compensation shall be barred unless a claim is filed within 1 year after injury. If payment of weekly benefits has been made or remedial treatment has been furnished by the employer on account of the injury, the claim may be filed within 1 year after the date of the last remedial treatment furnished by the employer or within 2 years after the date of the last payment of weekly benefits).</p>

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DOCUMENT RETENTION SCHEDULE

HUMAN RESOURCES / PERSONNEL RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
	<p>Benefit Claim Forms: 1 year with the following exceptions:</p> <p>(i) if the case is pending before the Worker’s Compensation Board, retain records for as long as the case is active;</p> <p>(ii) if the hospital has furnished remedial treatment to the employee on account of the injury, retain claim form for 1 year after the date of the last remedial treatment furnished;</p> <p>(iii) if the hospital has paid weekly benefits to the employee, retain form for 2 years after the date of the last payment of weekly benefits.</p>	<p>O.C.G.A. § 34-9-82(a) (the right to compensation shall be barred unless a claim is filed within 1 year after injury. If payment of weekly benefits has been made or remedial treatment has been furnished by the employer on account of the injury, the claim may be filed within 1 year after the date of the last remedial treatment furnished by the employer or within 2 years after the date of the last payment of weekly benefits).</p>

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DOCUMENT RETENTION SCHEDULE

LABORATORY RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Autopsy Reports (Non-Forensic Autopsies)</p>	<p>Retention of copies should be treated as medical records and filed with the patient’s medical record and maintained for 10 years.</p> <p><i>See Medical Records Generally, p. 73.</i></p>	<p>Ga. Comp. R. & Regs. 111-8-40-18(3)(a) (report of autopsy results should be included in medical record).</p> <p>Ga. Comp. R. & Regs. 111-8-40-18(1)(h) (hospital must preserve medical records in the hospital’s format of choice for “at least until the fifth anniversary of the patients’ discharges”); O.C.G.A. § 31-33-2 (the 5 year rule for hospitals is an exception from the general rule, which requires all other providers to maintain records for 10 years).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose).</p>
<p>Blood and Blood-Testing Records, Blood Donor Records, Blood Transfusion Records, Blood Bank Records, and Immunohematology Reports</p>	<p>Records for blood or blood components with no expiration date: Permanent</p> <p>Other records: The later of:</p> <p>(i) 10 years after the records of processing are completed;</p> <p>(ii) 10 years from the date of disposition of the blood or blood component; or</p> <p>(iii) 6 months after the latest expiration date for the individual product.</p>	<p>21 C.F.R. § 606.160 (“Records shall be retained for such interval beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical reactions. You must retain individual product records no less than 10 years after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date. When there is no expiration date, records shall be retained indefinitely”); 42 C.F.R. § 493.1105(a)(3)(ii) (hospital must retain immunohematology, blood bank, blood product, and transfusion records as specified in 21 C.F.R. § 606.160).</p> <p>42 C.F.R. § 482.27 (a hospital must maintain records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval).</p> <p>Ga. Comp. R. & Regs. 111-8-10-26 (Immunohematology records must be retained for 5 years).</p>

* This section addresses retention requirements for the documentation of laboratory tests, assays, and examinations. Retention requirements for specimens (e.g., slides, tissue blocks, etc.) are not addressed in this schedule.
17642659v1

DOCUMENT RETENTION SCHEDULE

LABORATORY RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Cytology Reports	10 years.	<p>42 C.F.R. § 493.1105(a)(6)(ii) (hospital must retain Pathology test records for 10 years); 42 C.F.R. 493.643(c)(3)(vi) (for the purpose of determining the fee for determination of program compliance, the specialty of Pathology includes Cytology and Histopathology).</p> <p>42 C.F.R. § 424.516(f); Medicare Program Integrity Manual, Ch. 15 § 18 (BOTH physicians (or other eligible professionals) who order, certify, refer, or prescribe Part A or B services, items, or drugs (“Covered Benefits”) AND providers that furnish covered ordered, certified, referred, or prescribed Covered Benefits must maintain written and electronic documents (including the NPI of the physician or other eligible professional who ordered/certified/referred/prescribed the Covered Benefits) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Covered Benefits for 7 years from the date of service).</p> <p>Ga. Comp. R. & Regs. 111-8-10-.26 (Cytology records must be retained for 5 years); Ga. Comp. R. & Regs. 111-8-10-.15 (all slides for Exfoliative Cytology should be retained for at least 5 years for comparison to later exams).</p>

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DOCUMENT RETENTION SCHEDULE

LABORATORY RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Equipment Records</p> <p>(e.g., calibration and validation, maintenance and inspection, operating instructions and manuals)</p> <p><i>See Environmental Records, p. 30 and Radiology and Nuclear Medicine Records, p. 113 for additional requirements for equipment that is a source of air emissions or discharges to water or land and equipment that uses radiation.</i></p>	<p align="center">Life of equipment or 2 years, whichever is longer.</p>	<p>Hospitals may consider maintaining these records for 10 years to cover the statute of limitations for products liability and the statute of repose for False Claims Act liability.</p> <p>42 C.F.R. § 493.1105 (quality systems assessment records and system performance specifications must be retained for the period of time the laboratory uses them, but no less than 2 years).</p> <p>Ga. Comp. R. & Regs. 111-8-10-.09(b) (documentation of validation of each quantitative method shall be maintained for a period of at least 2 years).</p> <p>Ga. Comp. R. & Regs. 111-8-10-.09(i) (a copy of each procedure should be maintained for 2 years after the procedure is discontinued).</p> <p>42 C.F.R. § 482.41(d)(2) (facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.14 (hospitals must have a program to inspect, monitor, and maintain biomedical equipment, electrical equipment, and emergency power generators).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p>

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17642659v1

DOCUMENT RETENTION SCHEDULE

LABORATORY RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Errors – Laboratory Errors	In Test Results: 5 years.	<p>42 C.F.R. § 493.903(d) (the proficiency testing program acting as a designated agent of the government will maintain the laboratory’s performance records for 5 years or such time as may be necessary for any legal proceeding).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).</p>
	Records of inadequately prepared slides, unsatisfactory specimens, and associated notifications in Cytology labs: 5 years.	<p>Ga. Comp. R. & Regs. 111-8-10-15 (records of inadequately prepared slides, unsatisfactory specimens, and associated notifications should be retained for 5 years).</p>
Histopathology	10 years.	<p>42 C.F.R. § 493.1105(a)(6)(ii) (Pathology test records must be retained for 10 years); 42 C.F.R. 493.643(c)(3)(vi) (for the purpose of determining the fee for determination of program compliance, the specialty of Pathology includes Cytology and Histopathology).</p> <p>42 C.F.R. § 424.516(f); Medicare Program Integrity Manual, Ch. 15 § 18 (BOTH physicians (or other eligible professionals) who order, certify, refer, or prescribe Part A or B services, items, or drugs (“Covered Benefits”) AND providers that furnish covered ordered, certified, referred, or prescribed Covered Benefits must maintain written and electronic documents (including the NPI of the physician or other eligible professional who ordered/certified/referred/prescribed the Covered Benefits) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Covered Benefits for 7 years from the date of service).</p> <p>Ga. Comp. R. & Regs. 111-8-10-26 (Surgical Pathology records must be retained for 10 years).</p> <p>Ga. Comp. R. & Regs. 111-8-10-15 (stained Histopathology slides must be retained for at least 10 years. Tissue blocks must be retained for at least 2 years).</p>

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DOCUMENT RETENTION SCHEDULE

LABORATORY RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Orders for Clinical Laboratory Services and Related Documentation	<p>Same retention period as other medical records:</p> <p><u>Adults:</u> 10 years from last discharge or contact that resulted in a record.</p> <p><u>Minors:</u> If the patient is a minor, until the patient’s 23rd birthday or 10 years from last discharge or contact that resulted in a record, whichever is longer.</p> <p><i>See Medical Records Generally, p. 73.</i></p>	<p>42 C.F.R. § 424.516(f); Medicare Program Integrity Manual, Ch. 15 § 18 (BOTH physicians (or other eligible professionals) who order, certify, refer, or prescribe Part A or B services, items, or drugs (“Covered Benefits”) AND providers that furnish covered ordered, certified, referred, or prescribed Covered Benefits must maintain written and electronic documents (including the NPI of the physician or other eligible professional who ordered/certified/referred/prescribed the Covered Benefits) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Covered Benefits for 7 years from the date of service).</p> <p>42 C.F.R. §424.535(a)(10) (provider who fails to comply with document retention requirements in 424.516(f) is <u>subject to revocation</u> of Medicare enrollment for a period of not more than 1 year).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.18(1)(h) (hospital must preserve medical records in the hospital’s format of choice for “at least until the fifth anniversary of the patients’ discharges.” If the patient is a minor, the records must be retained for at least 5 years past the age of majority); O.C.G.A. § 31-33-2 (the 5 year rule for hospitals is an exception from the general rule, which requires all other providers to maintain records for 10 years); Interpretive Guideline citing Ga. Comp. R. & Regs. 290-9-7-.18, which has been recodified to Ga. Comp. R. & Regs. 111-8-40-.18 (the age of majority is 18 years old).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.24(2)(c) (hospital must retain films, scans, and other images for at least 5 years after the date of the last procedure unless the release of the original image is required for the patient. For minors, they must be retained for 5 years after the minor reaches the age of majority).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p>
Pathology	10 years.	42 C.F.R. § 493.1105(a)(6)(ii) (Pathology test records must be retained for 10 years).

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DOCUMENT RETENTION SCHEDULE

LABORATORY RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Patient Test Records and Instrument Printouts (copies maintained in addition to the patient's medical record)	Pathology Records: 10 years.	<p>42 C.F.R. § 493.1105(a)(6)(ii) (Pathology test records must be retained for 10 years); 42 C.F.R. 493.643(c)(3)(vi) (for the purpose of determining the fee for determination of program compliance, the specialty of Pathology includes Cytology and Histopathology).</p> <p>Ga. Comp. R. & Regs. 111-8-10-26 (surgical pathology records must be retained for 10 years. Cytology records must be retained for 5 years).</p> <p>42 C.F.R. § 424.516(f); Medicare Program Integrity Manual, Ch. 15 § 18 (BOTH physicians (or other eligible professionals) who order, certify, refer, or prescribe Part A or B services, items, or drugs ("Covered Benefits") AND providers that furnish covered ordered, certified, referred, or prescribed Covered Benefits must maintain written and electronic documents (including the NPI of the physician or other eligible professional who ordered/certified/referred/prescribed the Covered Benefits) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Covered Benefits for 7 years from the date of service).</p>
	Other Patient Testing Records: 7 years.	<p>42 C.F.R. § 424.516(f); Medicare Program Integrity Manual, Ch. 15 § 18 (BOTH physicians (or other eligible professionals) who order, certify, refer, or prescribe Part A or B services, items, or drugs ("Covered Benefits") AND providers that furnish covered ordered, certified, referred, or prescribed Covered Benefits must maintain written and electronic documents (including the NPI of the physician or other eligible professional who ordered/certified/referred/prescribed the Covered Benefits) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Covered Benefits for 7 years from the date of service).</p> <p>Ga. Comp. R. & Regs. 111-8-10-26 (Immunohematology records must be maintained for 5 years. General laboratory records must be retained for 2 years).</p> <p>42 C.F.R. § 493.1105(a)(3) (patient test records, including instrument printouts, must be retained for 2 years).</p>

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DOCUMENT RETENTION SCHEDULE

LABORATORY RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Personnel Records as to Qualification</p> <p align="center"><i>For certification records for physicians, see Medical Staff Records, p. 75.</i></p>	<p align="center">Term of employment plus 6 years.</p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>Ga. Comp. R. & Regs. 111-8-10-06(1)(h) (laboratories must keep current written documentation that demonstrates that each employee meets personnel qualifications).</p> <p>Ga. Comp. R. & Regs. 111-8-40-12 (the hospital must maintain personnel records that contain the employment application or resume, credible evidence of current registration, license, or certification, evidence of completion of in-service training as required by the hospital, and evidence of completion of any requirements of the occupational health program at the hospital).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose).</p> <p>29 C.F.R. § 1602.14 (all personnel records must be retained for 1 year; if a discrimination case is brought, records must be maintained until final disposition of the case).</p>
<p align="center">Procedure Manuals – Outdated</p>	<p align="center">2 years after the procedure has been discontinued.</p>	<p>42 C.F.R. § 493.1251 (a laboratory must have written procedure manual for all tests, assays, and examinations it performs); 42 C.F.R. § 493.1105(a)(2) (2 year retention period for test procedures).</p> <p>Ga. Comp. R. & Regs. 111-8-10-09(i) (a copy of each procedure should be maintained for 2 years after the procedure is discontinued).</p> <p>These outdated materials should also be maintained for purposes of DCH, Medicare, and Joint Commission surveys.</p>
<p align="center">Proficiency Testing Records and Records of Remedial Actions for an Unacceptable Score</p>	<p align="center">At least 2 years after satisfactory completion of the proficiency testing.</p>	<p>42 C.F.R. § 493.801(b)(5); 42 C.F.R. § 493.1105(a)(4) (laboratories must maintain all records relating to proficiency testing for 2 years).</p> <p>42 C.F.R. §§ 493.823–865 (for each of the laboratory subspecialties, if a laboratory receives an unsatisfactory testing event score, remedial action must be documented. Documentation must be maintained for 2 years after the date of participation in the proficiency testing).</p> <p>Ga. Comp. R. & Regs. 111-8-10-23(d) (all records of proficiency testing must be maintained and available for inspection for at least 2 years).</p>

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DOCUMENT RETENTION SCHEDULE

LABORATORY RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Quality Control Records	Surgical Pathology records: 10 years.	<p>Ga. Comp. R. & Regs. 111-8-10-26(c) (Surgical Pathology records must be retained for 10 years).</p> <p>42 C.F.R. § 493.1105(a)(3) (hospital must retain quality control records for 2 years).</p>
	Immunohematology and Cytology records: 5 years.	<p>Ga. Comp. R. & Regs. 111-8-10-26 (records of Surgical Pathology must be retained for 10 years. Records of Immunohematology and Cytology must be retained for 5 years. General laboratory records and quality control records must be retained for 2 years).</p> <p>42 C.F.R. § 493.1105(a)(3) (hospital must retain quality control records for 2 years).</p>
	General laboratory quality control records: 2 years.	<p>42 C.F.R. § 493.1105(a)(3) (hospital must retain quality control records as required by 42 C.F.R. §§ 493.1252–1289 for 2 years).</p> <p>Ga. Comp. R. & Regs. 111-8-10-26(a) (general laboratory records and quality control records must be retained for 2 years).</p>

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DOCUMENT RETENTION SCHEDULE

LABORATORY RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Request for Tests (copies maintained in addition to the patient’s medical record) <i>See Medical Records, p. 71.</i></p>	<p>Requests for Surgical Pathology tests: 10 years.</p>	<p>Ga. Comp. R. & Regs. 111-8-10-26 (records of Surgical Pathology must be retained for 10 years. Records of Immunohematology and Cytology must be retained for 5 years. General laboratory records and quality control records must be retained for 2 years).</p> <p>42 C.F.R. § 424.516(f); Medicare Program Integrity Manual, Ch. 15 § 18 (BOTH physicians (or other eligible professionals) who order, certify, refer, or prescribe Part A or B services, items, or drugs (“Covered Benefits”) AND providers that furnish covered ordered, certified, referred, or prescribed Covered Benefits must maintain written and electronic documents (including the NPI of the physician or other eligible professional who ordered/certified/referred/prescribed the Covered Benefits) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Covered Benefits for 7 years from the date of service).</p> <p>42 C.F.R. § 493.1105(a)(1) (2 year retention requirement for requests for tests and documents supporting the requests for tests).</p>
	<p>Requests for other tests: 7 years.</p>	<p>42 C.F.R. § 424.516(f); Medicare Program Integrity Manual, Ch. 15 § 18(BOTH physicians (or other eligible professionals) who order, certify, refer, or prescribe Part A or B services, items, or drugs (“Covered Benefits”) AND providers that furnish covered ordered, certified, referred, or prescribed Covered Benefits must maintain written and electronic documents (including the NPI of the physician or other eligible professional who ordered/certified/referred/prescribed the Covered Benefits) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Covered Benefits for 7 years from the date of service).</p> <p>Ga. Comp. R. & Regs. 111-8-10-26(a) and (b) (records of Immunohematology and Cytology must be retained for 5 years. General laboratory records and quality control records must be retained for 2 years).</p> <p>42 C.F.R. § 493.1105(a)(1) (2 year retention requirement for requests for tests and documents supporting the requests for tests).</p>
<p>Sperm Bank, Embryology, and Assisted Reproductive Technology (ART) Records</p>	<p>10 years beyond the date of final disposition or disposal of all specimens obtained during each patient’s ART cycle. Records must be retained on site for 2 years.</p>	<p>Ga. Comp. R. & Regs. 111-8-10-17(2)(g) (ART laboratories must retain records for 10 years beyond the date of final disposition or disposal of all specimens obtained during each patient’s ART cycle. Records must be retained on site for 2 years).</p>

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DOCUMENT RETENTION SCHEDULE

LABORATORY RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Tissue Bank Records	7 years.	Ga. Comp. R. & Regs. 111-8-10-16 (tissue bank records, including procedures followed, donor information, and other required information, must be retained for 7 years. Storage temperature records need only be retained for 5 years).
Validation of Quantitative Methods	Period of time the method is used or 2 years, whichever is longer.	Ga. Comp. R. & Regs. 111-8-10-09(b) (quantitative methods should be validated before they are used. Documentation of validation shall be maintained for the period of time that the method is used or for 2 years, whichever is longer).
<p>Waived/Exempt Screening and Monitoring Test Records</p> <p>(copies maintained in addition to the patient's medical record)</p> <p><i>See also Orders for Clinical Laboratory Services and Related Documentation, p. 62.</i></p>	2 years.	Ga. Comp. R. & Regs. 111-8-10-20(3) (records for exempt screening and monitoring tests must be retained outside of the medical record for at least 2 years).

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DOCUMENT RETENTION SCHEDULE

MARKETING AND PUBLIC RELATIONS RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Advertisements and Marketing Materials that are No Longer in Use</p> <p>(e.g., radio or television advertisements, newspaper clippings, press releases, printed materials for the general public or for limited release, media advertisements, in-house publications, sales materials, internet/email advertisements, etc.)</p>	<p>At least 6 years.</p>	<p>The hospital may wish to permanently retain materials with historical value.</p> <p>O.C.G.A. § 9-3-24 (6 year statute of limitations for breach of written contract).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions, including Anti-Kickback).</p> <p>O.C.G.A. § 9-3-31 (4 year statute of limitation for injuries to personalty, including actions brought under the Georgia Uniform Deceptive Trade Practices Act or the federal Lanham Act).</p> <p>O.C.G.A. § 10-1-401 (2 year statute of limitation under Fair Business Practices Act).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10).</p> <p>O.C.G.A. § 9-3-33 (2 year statute of limitation for invasion of privacy action. 1 year statute of limitation for defamation action).</p> <p>29 C.F.R. § 1627.3(b) (employers must maintain any advertisements or notices to the public or to employees relating to job openings, promotions, training programs, or opportunities for overtime work for 1 year).</p>

DOCUMENT RETENTION SCHEDULE

MARKETING AND PUBLIC RELATIONS RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Contracts for Advertising or Public Relations Services</p>	<p>Full contract term plus 6 years.</p>	<p>O.C.G.A. § 9-3-24 (6 year statute of limitation for breach of written contracts).</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions, including Anti-Kickback).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p>
<p>Permission to Release Information and Use Photographs for Marketing Purposes</p>	<p>Full contract term plus 6 years.</p>	<p>O.C.G.A. § 9-3-24 (6 year statute of limitations for breach of written contract).</p> <p>45 C.F.R. § 164.530(j) (a covered entity must maintain required HIPAA documentation for 6 years after the date of its creation or the date when it was last in effect).</p> <p>O.C.G.A. § 9-3-33 (2 year statute of limitation for invasion of privacy action. 1 year statute of limitation for defamation action).</p>

DOCUMENT RETENTION SCHEDULE

MARKETING AND PUBLIC RELATIONS RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Photographs (taken for marketing purposes but which are not ultimately published)</p>	<p align="center">No required retention period.</p>	<p>The hospital may wish to permanently retain photographs with historical value.</p>
<p align="center">Policies and Procedures – Outdated</p>	<p align="center">At least 6 years.</p>	<p>The hospital may wish to keep these records longer for administrative purposes.</p> <p>45 C.F.R. § 164.530(j) (a covered entity must maintain required HIPAA documentation, including training materials and records of trainings, for 6 years after the date of its creation or the date when it was last in effect).</p> <p>O.C.G.A. § 9-3-24 (6 year statute of limitations for breach of written contract).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions, including Anti-Kickback).</p> <p>O.C.G.A. § 9-3-31 (4 year statute of limitation for injuries to personalty, including actions brought under the Georgia Uniform Deceptive Trade Practices Act or the federal Lanham Act).</p> <p>O.C.G.A. § 10-1-401 (2 year statute of limitation under Fair Business Practices Act).</p>

DOCUMENT RETENTION SCHEDULE

MEDICAL RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Birth Certificates</p>	<p>An original filing is mandated with the local registrar of the county in which the birth occurred. Retention of copies should be treated as medical records of a minor and kept until the patient's 23rd birthday.</p> <p><i>See Medical Records Generally, p. 73.</i></p>	<p>O.C.G.A. § 31-10-9 (certificate of birth for each live birth shall be filed with the State Office of Vital Records within five days of the birth).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.18(1)(h) (hospital must preserve medical records in the hospital's format of choice for "at least until the fifth anniversary of the patients' discharges"); O.C.G.A. § 31-33-2 (the 5 year rule for hospitals is an exception from the general rule, which requires all other providers to maintain records for 10 years).</p>
<p>Cancer Registry Files (copies of cancer registry information submitted, annual reports)</p>	<p>10 years.</p>	<p>Georgia Comprehensive Cancer Registry – Policy and Procedure Manual for Reporting Facilities (large facilities (those with an average annual case load of greater than or equal to 50 cases per year) must report new cancer diagnoses monthly; small facilities must report annually); O.C.G.A. § 31-12-2 (DPH can require reporting of certain diseases).</p> <p>Telephone call to Judy Andrews, Georgia Center for Cancer Statistics at Emory University, Rollins School of Public Health, phone number 404-727-8700, 12/03/2013 (Ms. Andrews confirmed that the state cancer registry does not require a hospital to maintain the filings it makes to the registry for any specific period of time. She thought 10 years would be more than adequate. She noted that a hospital that has a specific agreement to maintain data on cancer diagnoses may keep these records longer. A hospital may also wish to maintain its own cancer registry internally, which may be kept longer than 10 years for historical purposes).</p>
<p>Death Certificates</p>	<p>An original filing is mandated with the local registrar of the county in which the death occurred.</p> <p>Retention of copies should be treated as medical records and filed with the patient's medical record and maintained for 10 years.</p> <p><i>See Medical Records Generally, p. 73.</i></p>	<p>O.C.G.A. § 31-10-15 (certificate of death must be filed with the local registrar of the county in which the death occurred or the body was found within 10 days of the death).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.18(1)(h) (hospital must preserve medical records in the hospital's format of choice for "at least until the fifth anniversary of the patients' discharges"); O.C.G.A. § 31-33-2 (the 5 year rule for hospitals is an exception from the general rule, which requires all other providers to maintain records for 10 years).</p>

DOCUMENT RETENTION SCHEDULE

MEDICAL RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Films, scans, images and reports</p>	<p>Same retention period as other medical records:</p> <p><u>Adults:</u> 10 years from last discharge or contact that resulted in a record.</p> <p><u>Minors:</u> If the patient is a minor, until the patient’s 23rd birthday or 10 years from last discharge or contact that resulted in a record, whichever is longer.</p> <p><i>See Medical Records Generally, p. 73.</i></p>	<p>42 C.F.R. § 424.516(f); Medicare Program Integrity Manual, Ch. 15 § 18 (BOTH physicians (or other eligible professionals) who order, certify, refer, or prescribe Part A or B services, items, or drugs (“Covered Benefits”) AND providers that furnish covered ordered, certified, referred, or prescribed Covered Benefits must maintain written and electronic documents (including the NPI of the physician or other eligible professional who ordered/certified/referred/prescribed the Covered Benefits) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Covered Benefits for 7 years from the date of service)..</p> <p>42 C.F.R. §424.535(a)(10) (provider who fails to comply with document retention requirements in 424.516(f) is <i>subject to revocation</i> of Medicare enrollment for a period of not more than 1 year).</p> <p>Ga. Comp. R. & Regs. 111-8-40-24(2)(c) (hospital must retain films, scans, and other images for at least 5 years after the date of the last procedure unless the release of the original image is required for the patient. For minors, they must be retained for 5 years after the minor reaches the age of majority).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p>
<p>Index to Medical Records/Card Files</p>	<p>Permanent.</p>	<p>The index to medical records and card files may be helpful for administrative and historical purposes.</p>

DOCUMENT RETENTION SCHEDULE

<p>Medical Records Generally</p>	<p><u>Adults:</u> 10 years from last discharge or contact that resulted in a record.</p> <p><u>Minors:</u> Until the patient’s 23rd birthday or 10 years from last discharge or contact that resulted in a record, whichever is longer.</p> <p><i>While the Georgia hospital regulations arguably allow for a shorter retention period, most hospitals retain and other sources recommend retaining medical records as proposed above.</i></p>	<p>Ga. Comp. R. & Regs. 111-8-40-.18(1)(h) (a hospital must preserve medical records in the hospital’s format of choice “at least until the fifth anniversary of the patients’ discharges.” If the patient is a minor, the records must be retained until the minor is 23 (5 years after majority)); O.C.G.A. § 31-33-2 (5 year rule for hospitals is an exception to the general rule that requires all other providers to maintain records for 10 years); Interpretive Guideline citing Ga. Comp. R. & Regs. 290-9-7-.18, recodified to Ga. Comp. R. & Regs. 111-8-40-.18 (age of majority is 18).</p> <p>Ga. Comp. R. & Regs. 360-3-.02(16)(a) (unprofessional conduct for which a physician can be subject to discipline includes failure to maintain patient records for a period of at least 10 years after the patient’s last office visit).</p> <p>42 C.F.R. § 424.516(f); Medicare Program Integrity Manual, Ch. 15 § 18 (BOTH physicians (or other eligible professionals) who order, certify, refer, or prescribe Part A or B services, items, or drugs (“Covered Benefits”) AND providers that furnish covered ordered, certified, referred, or prescribed Covered Benefits must maintain written and electronic documents (including the NPI of the physician or other eligible professional who ordered/certified/referred/prescribed the Covered Benefits) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Covered Benefits for 7 years from the date of service).</p> <p>42 C.F.R. § 482.24(b)(1); Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (medical records must be retained in their original or legally reproduced form for at least 5 years). NOTE: Effective March 1, 2020 through the end of the COVID-19 public health emergency, CMS has issued a blanket waiver of the requirements of 42 C.F.R. § 482.24(a) – (c), including the records retention requirement under (b)(1), so long as such waiver is not inconsistent with a state’s emergency preparedness or pandemic plan. See COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers (updated 10/7/21) p. 4.</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(R) (providers must retain Medicaid records for 6 years after the date of service. Records meeting the secure electronic signature requirements are acceptable).</p> <p>42 C.F.R. 485.638(c) (critical access hospitals must maintain medical records for at least 6 years from the date of last entry or if the records may be needed in any pending proceeding).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases); O.C.G.A. § 9-3-72 (statute of limitations for foreign objects left in a patient’s body is 1 year after object is discovered).</p>
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DOCUMENT RETENTION SCHEDULE

MEDICAL RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
		<p>Contracts with payors may have specific retention requirements for medical records. For example, Medicare HMO contracts often require a document retention period of 10 years, and some Tricare agreements that require specific retention periods.</p> <p>11 U.S.C. § 351 Disposal of patient records (a health care business in bankruptcy may dispose of patient records if it lacks sufficient funds to pay to store the records in accord with applicable state or federal law if notice procedures required by this section are followed)</p>
<p>Orders of DMEPOS, clinical laboratory, imaging services, or covered ordered/certified home health services which the hospital provided or a physician in the hospital ordered</p>	<p>Same retention period as other medical records:</p> <p><u>Adults:</u> 10 years from last discharge or contact that resulted in a record.</p> <p><u>Minors:</u> If the patient is a minor, until the patient’s 23rd birthday or 10 years from last discharge or contact that resulted in a record, whichever is longer.</p> <p><i>See Medical Records Generally, p. 73.</i></p>	<p>42 C.F.R. § 424.516(f); Medicare Program Integrity Manual, Ch. 15 § 18 (BOTH physicians (or other eligible professionals) who order, certify, refer, or prescribe Part A or B services, items, or drugs (“Covered Benefits”) AND providers that furnish covered ordered, certified, referred, or prescribed Covered Benefits must maintain written and electronic documents (including the NPI of the physician or other eligible professional who ordered/certified/referred/prescribed the Covered Benefits) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Covered Benefits for 7 years from the date of service).</p> <p>42 C.F.R. §424.535(a)(10) (provider who fails to comply with document retention requirements in 424.516(f) is <u>subject to revocation</u> of Medicare enrollment for a period of not more than 1 year).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.18(1)(h) (hospital must preserve medical records in the hospital’s format of choice for “at least until the fifth anniversary of the patients’ discharges.” If the patient is a minor, the records must be retained for at least 5 years past the age of majority); O.C.G.A. § 31-33-2 (the 5 year rule for hospitals is an exception from the general rule, which requires all other providers to maintain records for 10 years); Interpretive Guideline citing Ga. Comp. R. & Regs. 290-9-7-.18, which has been recodified to Ga. Comp. R. & Regs. 111-8-40-.18 (the age of majority is 18 years old).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.24(2)(c) (hospital must retain films, scans, and other images for at least 5 years after the date of the last procedure unless the release of the original image is required for the patient. For minors, they must be retained for 5 years after the minor reaches the age of majority).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p>

DOCUMENT RETENTION SCHEDULE

MEDICAL STAFF RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Medical Staff Records</p> <p><u>Including:</u></p> <p>Medical Staff Personnel Files</p> <p>Resident, Intern, and Fellow Personnel Files</p> <p>Credentialing and Certification Files</p> <p>Medical Staff Applications (accepted and rejected)</p> <p>Medical Staff Committee Records (including minutes, reports, etc.)</p> <p>Impaired Physician Files</p> <p>Peer Review Files</p> <p><i>For peer review or other quality assurance records not related to an individual physician, see Quality Assurance Records, p. 20.</i></p>	<p>At least 30 years.</p>	<p>Hospitals should retain medical staff records for a sufficient period to cover the length of time for a practitioner's career so that the records are accessible if the practitioner reapplies to the medical staff. For example, maintaining peer review files for 30 to 50 years would likely cover this time period. There is a documented case in which a practitioner reapplied for medical staff privileges 18 years after being removed from the same medical staff.</p> <p>No specific federal or state record retention requirements for these records beyond those for all personnel records have been identified. Some sources reviewed include Medicare Conditions of Participation (42 C.F.R. § 482.22), National Practitioner Data Bank Regulations (45 C.F.R. Part 60), and Georgia Composite Medical Board Licensing Laws.</p> <p>O.C.G.A. § 43-34-174(b) (hospital must maintain a current copy of the licensing certificate for each physician who practices in the hospital).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 9-3-24 (6 year statute of limitations for breach of written contract).</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases); O.C.G.A. § 9-3-72 (statute of limitations for foreign objects left in a patient’s body is 1 year after object is discovered).</p> <p>29 C.F.R. § 1627.3(b) (records relating to promotion, demotion, transfer, selection for training, layoff, recall, or discharge of an employee must be retained for 1 year from the date of the personnel action to which any records relate).</p> <p>29 C.F.R. § 1602.14 (all personnel records must be retained for 1 year. If a discrimination case is brought, records must be maintained until final disposition of the case).</p>

DOCUMENT RETENTION SCHEDULE

NURSING RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Meeting Minutes	Quality assurance meeting minutes: 6 years. <i>See Quality Assurance Records, p. 20.</i> Administrative meeting minutes: 3 years.	Hospitals may consider keeping quality assurance records for 10 years to cover the statute of limitations for products liability and the statute of repose for False Claims Act liability. Although arguably not discoverable, quality assurance meeting records may be helpful to hospital and defense counsel in assessing malpractice claims and suits. In addition, the hospital may wish to consider keeping these records longer to access quality assurance records for trending and other administrative purposes. 31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years). O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i> , 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases). O.C.G.A. § 9-3-72 (statute of limitations for foreign objects left in a patient’s body is 1 year after object is discovered). O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years)
Operating Room Records and Charge Sheets	10 years. <i>See Medical Records Generally, p. 73.</i>	31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years). O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product). O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i> , 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases). O.C.G.A. § 9-3-72 (statute of limitations for foreign objects left in a patient’s body is 1 year after object is discovered).

DOCUMENT RETENTION SCHEDULE

NURSING RECORDS

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Organ Donation Logs	10 years after date of transplant, distribution, disposition or expiration of donor's tissue.	<p>21 C.F.R. § 1270.33(h) (records concerning suitability of donor shall be retained for 10 years beyond date of transplantation, distribution, disposition, or expiration, whichever is latest).</p> <p>Ga. Comp. R. & Regs. 111-8-28-.07(3) (6 year retention period for eye bank records).</p>
<p align="center">Patient Logs</p> <p>(logs of patient names, admission and discharge dates, and physician names which are not part of the medical record)</p>	<p>Emergency Department Logs: 5 years.</p> <p><i>See Emergency Department Logs, p. 29.</i></p> <p>Logs for other departments: 3 years.</p>	<p>EMTALA 42 U.S.C. 1395cc(a)(1)(I)(ii); 42 C.F.R. 489.20(r)(1); CMS State Operations Manual, Appendix V – Part II – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases, Tag A-2403/C-2403 (transferring and receiving hospitals must maintain medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of the transfer).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>
Policies and Procedures – Outdated	<p>Policies involving uses of medical devices: 10 years.</p> <p>Other policies: 6 years.</p>	<p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>45 C.F.R. § 164.530(j) (a covered entity must maintain required HIPAA documentation for 6 years after the date of its creation or the date when it was last in effect).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).</p> <p>O.C.G.A. § 9-3-72 (statute of limitations for foreign objects left in a patient’s body is 1 year after object is discovered).</p>

DOCUMENT RETENTION SCHEDULE

NURSING RECORDS

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p style="text-align: center;">Pump Records</p> <p>(e.g., calibration, maintenance and inspection, operating instructions and manuals)</p> <p><i>See Environmental Records, p. 30 for additional requirements for equipment that is a source of air emissions or discharges to water or land.</i></p>	<p>10 years or life of equipment plus 5 years, whichever is longer.</p>	<p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).</p> <p>42 C.F.R. § 482.41(d)(2) (facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.14 (hospitals must have a program to inspect, monitor, and maintain biomedical equipment, electrical equipment, and emergency power generators).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p>

DOCUMENT RETENTION SCHEDULE

NURSING RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Quality Assurance Records</p>	<p>6 years.</p> <p>For quality assurance records that are Medical Staff Records, see <i>Medical Staff Records</i>, p. 75.</p>	<p>Hospitals may consider keeping these records for 10 years to cover the statute of limitations for products liability and the statute of repose for False Claims Act liability.</p> <p>Although arguably not discoverable, quality assurance meeting records may be helpful to hospital and defense counsel in assessing malpractice claims and suits. In addition, the hospital may wish to consider keeping these records longer to access quality assurance records for trending and other administrative purposes.</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).</p> <p>O.C.G.A. § 9-3-72 (statute of limitations for foreign objects left in a patient’s body is 1 year after object is discovered).</p>

DOCUMENT RETENTION SCHEDULE

NURSING RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Refrigerator Temperature Records (for refrigerators where blood, drugs, organs, etc. are stored)	5 years.	Hospitals may consider keeping these records for 10 years to cover the statute of limitations for products liability. Ga. Comp. R. & Regs. 111-8-10-16 (storage temperature records for tissue banks must be retained for 5 years). O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury). O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i> , 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).
Staffing Patterns and Schedules	5 years.	Plaintiffs often seek staffing records during discovery. O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i> , 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases). O.C.G.A. § 9-3-72 (statute of limitations for foreign objects left in a patient’s body is 1 year after object is discovered).

DOCUMENT RETENTION SCHEDULE

NURSING RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Sterilization Records and Graphs, Including Autoclaves</p> <p><i>See Environmental Records, p. 30, for additional requirements for equipment that is a source of air emissions or discharges to water or land.</i></p>	<p>10 years.</p>	<p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).</p> <p>O.C.G.A. § 9-3-72 (statute of limitations for foreign objects left in a patient’s body is 1 year after object is discovered).</p> <p>42 C.F.R. § 482.42; CMS State Operations Manual, Appendix A – Regulations and Interpretive Guidelines § 482.42, Tag A-0747 (hospitals must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship).</p> <p>CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (Update: May 2019), available at https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf.</p>
<p>Training Materials for Nursing Staff – Outdated</p>	<p>Trainings involving uses of medical devices: 10 years.</p> <p>HIPAA trainings: 6 years.</p> <p>Other trainings: 5 years.</p>	<p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>45 C.F.R. § 164.530(i) (a covered entity must maintain required HIPAA documentation, including training materials and records of trainings, for 6 years after the date of its creation or the date when it was last in effect).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).</p> <p>O.C.G.A. § 9-3-72 (statute of limitations for foreign objects left in a patient’s body is 1 year after object is discovered).</p>

DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Adverse Drug Reaction Reports	5 years.	<p>Ga. Comp. R. & Regs. 480-13-.06(9) (adverse drug reaction reports must be readily available for inspection).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>
Alcohol Inventory – Records Pertaining to Ethyl Alcohol and Tax Free Alcohol	3 years.	<p>Ga. Comp. R. & Regs. 480-13-.06(9) (alcohol and flammables reports must be readily available for inspection).</p> <p>27 C.F.R. § 22.164(a) (records relating to tax free alcohol must be retained for 3 years and must be kept on-site); 27 C.F.R. § 22.165(a) (records may be kept in any form that accurately reproduces the original record and that forms a durable medium for reproducing and preserving the original record).</p> <p>27 C.F.R. § 22.161 (records that must be retained include records reflecting receipt, shipment, usage, destruction and claims relating to tax-free alcohol); 27 C.F.R. § 22.162 (semi-annual inventory of tax-free alcohol must be retained).</p> <p>The federal regulation requiring that tax free alcohol records be retained for 3 years permits the appropriate Alcohol and Tobacco Tax and Trade (“TTB”) officer to add an additional 3 years period to the retention period. 27 C.F.R. § 22.164. Marilyn Brinker, a TTB Agent for the Atlanta region (202-453-3147), confirmed in a telephone call on January 14, 2014 that records relating to tax free alcohol must be retained for only 3 years.</p>
Automated or Robotic Pharmacy Systems Records	2 years.	<p>Ga. Comp. R. & Regs. 480-10-.19(d) (an electronic or hard copy record of medications produced by an automated or robotic pharmacy system must be maintained for 2 years. The records should include identification of the person stocking/filling the system and, if a pharmacy intern or registered pharmacy technician, the name of the pharmacist providing the supervision).</p> <p>Ga. Comp. R. & Regs. 480-27-.03 (records of dispensing original and refill prescriptions must be retained for 2 years).</p>

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DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Committee Minutes</p> <p>(e.g., Pharmacy and Therapeutics Committee, Pharmacy Nursing Liaison Committee, Nutrition Support Committee)</p>	<p>Quality assurance meeting minutes: 6 years.</p> <p><i>See Quality Assurance Records, p. 20.</i></p> <p>Administrative meeting minutes: 3 years.</p>	<p>Hospitals may consider keeping quality assurance records for 10 years to cover the statute of limitations for products liability and the statute of repose for False Claims Act liability.</p> <p>Although arguably not discoverable, quality assurance meeting records may be helpful to hospital and defense counsel in assessing malpractice claims and suits. In addition, the hospital may wish to consider keeping these records longer to access quality assurance records for trending and other administrative purposes.</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

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DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

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Controlled Substances: Records of Distributions and Purchases	2 years.	<p>A hospital may wish to retain such records for 5 years, the statute of repose for malpractice actions, to allow their use in defense of a malpractice suit.</p> <p>21 C.F.R. § 1304.04(a) (controlled substances records must be retained for at least 2 years); 21 C.F.R. § 1304.04(b) (records must be retained on-site); 21 C.F.R. § 1304.04(c) (registrants may maintain records on an in-house computer system); 21 C.F.R. § 1304.04(h)(5) (prescription records may be maintained on off-site computers if the records are readily retrievable in-house and comply with 21 C.F.R. § 1311).</p> <ul style="list-style-type: none"> - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(1) (inventories and records of all controlled substances listed in Schedules I and II must be maintained separately from all other records of the pharmacy). - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(2)-(3) (inventories, records, and prescriptions for controlled substances listed in Schedules III, IV and V must be maintained either separately from all other records of the pharmacy or in such form that the information required is “readily retrievable” from other pharmacy records). <p>O.C.G.A. § 16-13-39; 21 C.F.R. § 1304.22(c); 42 C.F.R. § 482.25(a)(3) (complete and accurate records must be kept reflecting all controlled substances on hand, received, sold, dispensed or otherwise disposed of).</p> <p>DEA Pharmacist’s Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).</p> <p>Ga. Comp. R. & Regs. 480-27-.03 (records of dispensing original and refill prescriptions must be retained for 2 years).</p> <p>Ga. Comp. R. & Regs. 480-27-.05 (a pharmacy may use an automated data processing system for purposes of the drugs dispensed if certain requirements set forth in Ga. Comp. R. & Regs. 480-27-.05 and Ga. Comp. R. & Regs. 480-27-.06 are met).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor’s prescription).</p>

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DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Controlled Substances: Inventory	2 years.	<p>Ga. Comp. R & Regs. 480-13-.06(6)(e) (hospital pharmacies must maintain a “perpetual” inventory of Schedule II substances and accountability of such drugs must be by a Proof of Use form).</p> <p>21 U.S.C. § 827(a)(1); 21 C.F.R. § 1304.11(c); Ga. Comp. R. & Regs. 480-13-.06(9) (registrants must do a biennial inventory of controlled substances and maintain the records readily accessible and on-site for 2 years).</p> <p>21 C.F.R. § 1304.04(a) (controlled substances records must be retained for at least 2 years); 21 C.F.R. § 1304.04(b) (records must be retained on-site); 21 C.F.R. § 1304.04(c) (registrants may maintain records on an in-house computer system).</p> <ul style="list-style-type: none"> - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(1) (inventories, records, and prescriptions of all controlled substances listed in Schedules I and II must be maintained separately from all other records of the pharmacy). - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(2)–(3) (inventories, records, and prescriptions for controlled substances listed in Schedules III, IV and V must be maintained either separately from all other records of the pharmacy or in such form that the information required is “readily retrievable” from other pharmacy records). <p>DEA Pharmacist’s Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).</p>

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As a general matter, each hospital pharmacy must maintain records of all transactions of the hospital pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials. [Ga. Comp. R. & Regs. 480-13-.06\(2\)\(k\)](#). Hospital pharmacies must maintain access to such records and reports as are required “to insure patient health, safety and welfare.” [Ga. Comp. R. & Regs. 480-13-.06\(9\)](#). Pharmacy records should be readily available for inspection by the Board of Pharmacy or the Georgia Drugs and Narcotics Agency. [Ga. Comp. R. & Regs. 480-13-.06\(9\)](#).

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PHARMACY RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Controlled Substances: Proof of Use Forms	2 years.	<p>A hospital may wish to retain such records for 5 years, the statute of repose for malpractice actions, to allow their use in defense of a malpractice suit.</p> <p>Ga. Comp. R. & Regs. 480-13-.06(6)(a) (proof of use of controlled substances and such other drugs as may be specified by an appropriate committee of the hospital must be submitted to the pharmacy on forms provided by the pharmacy).</p> <p>21 C.F.R. § 1304.04(a) (controlled substances records must be retained for at least 2 years); 21 C.F.R. § 1304.04(b) (records must be retained on-site); 21 C.F.R. § 1304.04(c) (registrants may maintain records on an in-house computer system); 21 C.F.R. § 1304.04(h)(5) (prescription records may be maintained on off-site computers if the records are readily retrievable in-house and comply with 21 C.F.R. § 1311).</p> <ul style="list-style-type: none"> - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(1) (inventories, records, and prescriptions of all controlled substances listed in Schedules I and II must be maintained separately from all other records of the pharmacy). - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(2)–(3) (inventories, records, and prescriptions for controlled substances listed in Schedules III, IV and V must be maintained either separately from all other records of the pharmacy or in such form that the information required is “readily retrievable” from other pharmacy records). <p>Ga. Comp. R & Regs. 480-13-.06(6)(e) (hospital pharmacies must maintain a “perpetual” inventory of Schedule II substances and accountability of such drugs must be by a Proof of Use form).</p> <p>DEA Pharmacist’s Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>

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DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Controlled Substances: Schedule I or II – Order Form (DEA Form 222) for Schedule I or II Controlled Substances</p>	<p>2 years.</p>	<p>A hospital may wish to retain such records for 5 years, the statute of repose for malpractice actions, to allow their use in defense of a malpractice suit.</p> <p>21 C.F.R. § 1305.13(a) (a purchaser of Schedule I or Schedule II controlled must make a copy of the original DEA Form 222 for its records and then submit the original to the supplier. The copy retained by the purchaser may be in paper or electronic form.).</p> <p>21 C.F.R. § 1305.15(d) (a purchaser must also retain all copies of each unaccepted or defective order form and each statement attached thereto).</p> <p>21 C.F.R. § 1305.17(c) (DEA Form 222 must be maintained separately from all other records and must be retained for 2 years).</p> <p>DEA Pharmacist’s Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>

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DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Controlled Substances: Schedule II – Partially-Filled Prescription for Schedule II Controlled Substances for Patients in Long Term Care Facilities or Who are Terminally Ill</p>	<p>2 years.</p>	<p>A hospital may wish to retain such records for 5 years, the statute of repose for malpractice actions, to allow their use in defense of a malpractice suit.</p> <p>21 C.F.R. § 1306.13(b) (for each partial filling, the dispensing pharmacist: (1) shall record on the prescription whether the patient is “terminally ill” or a Long Term Care Facility (“LTCF) patient”; and (2) shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist); 21 C.F.R. § 1306.13(c) (these records may be computerized if certain requirements are met).</p> <p>21 C.F.R. § 1304.04(a) (controlled substances records must be retained for at least 2 years); 21 C.F.R. § 1304.04(b) (records must be retained on-site); 21 C.F.R. § 1304.04(c) (registrants may maintain records on an in-house computer system); 21 C.F.R. § 1304.04(h)(5) (prescription records may be maintained on off-site computers if the records are readily retrievable in-house and comply with 21 C.F.R. § 1311).</p> <ul style="list-style-type: none"> - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(1) (inventories, records, and prescriptions of all controlled substances listed in Schedules I and II must be maintained separately from all other records of the pharmacy). <p>DEA Pharmacist’s Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>

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<p>Controlled Substances: Schedule II, III, IV or V – Record Book of Schedule II-V Substances that do NOT Require a Prescription that are Dispensed by the Pharmacy</p>	<p>2 years.</p>	<p>A hospital may wish to retain such records for 5 years, the statute of repose for malpractice actions, to allow their use in defense of a malpractice suit.</p> <p>21 C.F.R. § 1306.26 (records must be kept for all non-prescription Schedule II, III, IV or V controlled substances that are dispensed).</p> <p>21 C.F.R. § 1304.04(a) (controlled substances records must be retained for at least 2 years); 21 C.F.R. § 1304.04(b) (records must be retained on-site); 21 C.F.R. § 1304.04(c) (registrants may maintain records on an in-house computer system).</p> <ul style="list-style-type: none"> - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(1) (inventories, records, and prescriptions of all controlled substances listed in Schedules I and II must be maintained separately from all other records of the pharmacy). - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(2)–(3) (inventories, records, and prescriptions for controlled substances listed in Schedules III, IV and V must be maintained either separately from all other records of the pharmacy or in such form that the information required is “readily retrievable” from other pharmacy records). <p>DEA Pharmacist’s Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>

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<p>Controlled Substances: Schedule III & IV – Medication Records that List Refills of Schedule III & IV Substances</p>	<p>2 years.</p>	<p>A hospital may wish to retain such records for 5 years, the statute of repose for malpractice actions, to allow their use in defense of a malpractice suit.</p> <p>21 C.F.R. § 1306.22 (for each refill, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of filled or refilled, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The pharmacy may use an automated data processing system for refill information if the requirements of 21 C.F.R § 1306.22(b) are met).</p> <p>21 C.F.R. § 1304.04(a) (controlled substances records must be retained for at least 2 years); 21 C.F.R. § 1304.04(b) (records must be retained on-site); 21 C.F.R. § 1304.04(c) (registrants may maintain records on an in-house computer system); 21 C.F.R. § 1304.04(h)(5) (prescription records may be maintained on off-site computers if the records are readily retrievable in-house and comply with 21 C.F.R. § 1311).</p> <ul style="list-style-type: none"> - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(2)–(3) (inventories, records, and prescriptions for controlled substances listed in Schedules III, IV and V must be maintained either separately from all other records of the pharmacy or in such form that the information required is “readily retrievable” from other pharmacy records). <p>DEA Pharmacist’s Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Controlled Substances: Schedule V – Sales of Schedule V Substances without a Prescription</p>	<p>2 years.</p>	<p>A hospital may wish to retain such records for 5 years, the statute of repose for malpractice actions, to allow their use in defense of a malpractice suit.</p> <p>Ga. Comp. R. & Regs. 480-19-.03 (logbooks of sales of pseudoephedrine Schedule V Controlled Substances must be retained for 2 years).</p> <p>Ga. Comp. R. & Regs. 480-19-.01(b)(2) (to sell, dispense, or otherwise dispose of a non-pseudoephedrine Schedule V Controlled Substance, pharmacists must create records of the date of the transaction, the name, kind, quantity and intended use of the drug).</p> <p>21 C.F.R. § 1304.04(a) (controlled substances records must be retained for at least 2 years); 21 C.F.R. § 1304.04(b) (records must be retained on-site); 21 C.F.R. § 1304.04(c) (registrants may maintain records on an in-house computer system).</p> <ul style="list-style-type: none"> - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(2)–(3) (inventories, records, and prescriptions for controlled substances listed in Schedules III, IV and V must be maintained either separately from all other records of the pharmacy or in such form that the information required is “readily retrievable” from other pharmacy records). <p>DEA Pharmacist’s Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>
<p>Credit Memo for Returns Made to Manufacturer/Distributor</p>	<p>3 years.</p>	<p>21 C.F.R. § 203.23(b); 21 C.F.R. § 203.20 (a hospital’s return of a prescription drug is exempt from the prohibition of re-sale if the hospital forwards a copy of each credit memo to the manufacturer and retains a copy of each credit memo for its records).</p> <p>Ga. Comp. R. & Regs. 480-7-.07 (pharmacies can return expired drugs to the wholesale distributor for full credit or replacement for up to 6 months after the labeled expiration date).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

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As a general matter, each hospital pharmacy must maintain records of all transactions of the hospital pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials. [Ga. Comp. R. & Regs. 480-13-.06\(2\)\(k\)](#). Hospital pharmacies must maintain access to such records and reports as are required “to insure patient health, safety and welfare.” [Ga. Comp. R. & Regs. 480-13-.06\(9\)](#). Pharmacy records should be readily available for inspection by the Board of Pharmacy or the Georgia Drugs and Narcotics Agency. [Ga. Comp. R. & Regs. 480-13-.06\(9\)](#).
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DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Dangerous Drug Records (received, purchased, sold, or dispensed)</p>	<p align="center">2 years.</p>	<p>A hospital may wish to retain such records for 5 years, the statute of repose for malpractice actions, to allow their use in defense of a malpractice suit.</p> <p>O.C.G.A. § 16-13-72(6) (records of all dangerous drugs received, purchased, sold, dispensed or otherwise disposed of must be retained for 2 years).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p> <p>DEA Pharmacist's Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).</p>
<p align="center">Drug Therapy Modification – Patient Records</p>	<p align="center">10 years after the drug therapy modification protocol with the physician expires.</p>	<p>Ga. Comp. R. & Regs. 480-35-.05(2) (if a pharmacist has entered into a drug therapy modification protocol with a physician, patient records for those patients covered by the protocol must be retained for 10 years after the protocol expires).</p>

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DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Emergency Kits/Night Cabinets Inventory & Related Records	2 years.	<p>Ga. Comp. R. & Regs. 480-13-.06(9) (inventories of emergency kits and night cabinets must be readily available for inspection).</p> <p>21 C.F.R. § 1304.04(a) (controlled substances records must be retained for at least 2 years); 21 C.F.R. § 1304.04(b) (records must be retained on-site); 21 C.F.R. § 1304.04(c) (registrants may maintain records on an in-house computer system); 21 C.F.R. § 1304.04(h)(5) (prescription records may be maintained on off-site computers if the records are readily retrievable in-house and comply with 21 C.F.R. § 1311).</p> <ul style="list-style-type: none"> - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(1) (inventories, records, and prescriptions of all controlled substances listed in Schedules I and II must be maintained separately from all other records of the pharmacy). - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(2)–(3) (inventories, records, and prescriptions for controlled substances listed in Schedules III, IV and V must be maintained either separately from all other records of the pharmacy or in such form that the information required is “readily retrievable” from other pharmacy records). <p>DEA Pharmacist’s Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).</p>
Inspection Reports – Monthly Internal Inspections	5 years. If a deficiency is noted: 5 years after the deficiency has been resolved.	<p>Ga. Comp. R. & Regs. 480-13-.10(1) (the Director of Pharmacy or a qualified designee must inspect all matters within his/her jurisdiction and responsibility at least monthly and make written records of such).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>

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As a general matter, each hospital pharmacy must maintain records of all transactions of the hospital pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials. [Ga. Comp. R. & Regs. 480-13-.06\(2\)\(k\)](#). Hospital pharmacies must maintain access to such records and reports as are required “to insure patient health, safety and welfare.” [Ga. Comp. R. & Regs. 480-13-.06\(9\)](#). Pharmacy records should be readily available for inspection by the Board of Pharmacy or the Georgia Drugs and Narcotics Agency. [Ga. Comp. R. & Regs. 480-13-.06\(9\)](#).
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DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Inspection Reports – State and Federal Inspections</p>	<p>5 years.</p> <p>If a deficiency is noted: 5 years after the deficiency has been resolved.</p>	<p>Ga. Comp. R. & Regs. 480-13-.10(2) (the Board of Pharmacy conducts inspections at least once every 2 years).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>

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DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Inventory</p> <p><i>See also Alcohol Inventory, p. 82, and Controlled Substances: Inventory, p. 85.</i></p>	<p>Alcohol Inventory: 3 years.</p> <p>Other Inventory: 2 years.</p>	<p>27 C.F.R. § 22.164 (records relating to tax free alcohol must be retained for 3 years and must be kept on-site); 27 C.F.R. § 22.165 (records may be kept in any form that accurately reproduces the original record and that forms a durable medium for reproducing and preserving the original record).</p> <p>Ga. Comp. R. & Regs. 480-13-.06(9) (inventories of the pharmacy must be readily available for inspection).</p> <p>O.C.G.A. § 16-13-39; 21 C.F.R. § 1304.22(c); 42 C.F.R. § 482.25(a)(3) (complete and accurate records must be kept reflecting all controlled substances on hand, received, sold, dispensed or otherwise disposed of).</p> <p>21 C.F.R. § 1304.04(a) (controlled substances records must be retained for at least 2 years); 21 C.F.R. § 1304.04(b) (records must be retained on-site); 21 C.F.R. § 1304.04(c) (registrants may maintain records on an in-house computer system); 21 C.F.R. § 1304.04(h)(5) (prescription records may be maintained on off-site computers if the records are readily retrievable in-house and comply with 21 C.F.R. § 1311).</p> <ul style="list-style-type: none"> - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(1) (inventories, records, and prescriptions of all controlled substances listed in Schedules I and II must be maintained separately from all other records of the pharmacy). - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(2)–(3) (inventories, records, and prescriptions for controlled substances listed in Schedules III, IV and V must be maintained either separately from all other records of the pharmacy or in such form that the information required is “readily retrievable” from other pharmacy records). <p>Ga. Comp. R & Regs. 480-13-.06(6)(e) (hospital pharmacies must maintain a “perpetual” inventory of Schedule II substances is required and accountability of such drugs must be by a proof of use form).</p> <p>DEA Pharmacist’s Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).</p>

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DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Invoices	Date of tax filing plus 6 years.	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract for the sale of goods).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product).</p> <p>21 C.F.R. § 1304.04(a) (invoices for controlled substances (but not order forms) may be kept at a central location if the pharmacy has notified the DEA of its intentions to keep central records).</p>

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DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Medication Error Reports	5 years.	<p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>
Patient Profiles – Maintained in the Pharmacy	2 years from the date of the last entry in the profile record.	<p>A hospital may wish to retain such records for 5 years, the statute of repose for malpractice actions, to allow their use in defense of a malpractice suit.</p> <p>O.C.G.A. § 26-4-83; Ga. Comp. R. & Regs. 480-13-.06(2)(d) (the patient profile or the ability to generate such profile electronically shall be under the control of the Director of Pharmacy for 2 years).</p> <p>Ga. Comp. R. & Regs. 480-31-.01(a)(3) (a patient record must be maintained for not less than 2 years from the date of the last entry in the profile record).</p> <p>Ga. Comp. R. & Regs. 480-13-.06(9) (patient profiles must be readily available for inspection).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>
Poison – Log of Sales of Poison	5 years.	<p>O.C.G.A. § 26-4-161 (the book that lists the log of sales of the poisons enumerated in O.C.G.A. § 26-4-160 must be preserved for 5 years).</p>

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DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Policies and Procedures – Outdated	10 years.	<p>The hospital may wish to maintain policies for a longer period of time for historical purposes.</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (general Federal criminal statute of limitation of 5 years).</p> <p>O.C.G.A. § 16-14-8 (Georgia RICO statute of limitation of 5 years).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p> <p>45 C.F.R. § 164.530(j) (a covered entity must maintain required HIPAA documentation for 6 years after the date of its creation or the date when it was last in effect).</p> <p>DEA Pharmacist's Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).</p>

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Prescriptions (original, refill, or transferred prescriptions)</p>	<p align="center">2 years.</p>	<p>A hospital may wish to retain such records for 5 years, the statute of repose for malpractice actions, to allow their use in defense of a malpractice suit.</p> <p>Ga. Comp. R. & Regs. 480-27-.03 (records of dispensing original and refill prescriptions must be retained for 2 years).</p> <p>21 C.F.R. § 1304.04(a) (controlled substances records must be retained for at least 2 years); 21 C.F.R. § 1304.04(b) (records must be retained on-site); 21 C.F.R. § 1304.04(c) (registrants may maintain records on an in-house computer system); 21 C.F.R. § 1304.04(h)(5) (prescription records may be maintained on off-site computers if the records are readily retrievable in-house and comply with 21 C.F.R. § 1311).</p> <ul style="list-style-type: none"> - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(1) (prescriptions of all controlled substances listed in Schedules I and II must be maintained separately from all other records of the pharmacy). - 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(h)(2)–(3) (prescriptions for controlled substances listed in Schedules III, IV and V must be maintained either separately from all other records of the pharmacy or in such form that the information required is “readily retrievable” from other pharmacy records). <p>Ga. Comp. R. & Regs. 480-27-.05 (a pharmacy may use an automated data processing system for purposes of the drugs dispensed if certain requirements set forth in Ga. Comp. R. & Regs. 480-27-.05 and Ga. Comp. R. & Regs. 480-27-.06 are met).</p> <p>DEA Pharmacist’s Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>

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DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

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Quality Assurance Records	6 years. For quality assurance records that are Medical Staff Records, <i>see Medical Staff Records, p. 75.</i>	Hospitals may consider keeping these records for 10 years to cover the statute of limitations for products liability and the statute of repose for False Claims Act liability. Although arguably not discoverable, quality assurance meeting records may be helpful to hospital and defense counsel in assessing malpractice claims and suits. In addition, the hospital may wish to consider keeping these records longer to access quality assurance records for trending and other administrative purposes. 31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years). O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury). O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i> , 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription). DEA Pharmacist's Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Recall Records (records of a manufacturer’s recall)</p>	<p align="center">10 years.</p>	<p>Ga. Comp. R. & Regs. 480-13-.06(9) (the Director of Pharmacy shall develop and implement a policy and procedure to assure that all drugs within the hospital included on a recall are returned to the pharmacy for proper destruction).</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>
<p align="center">Remote Entry Records</p>	<p align="center">2 years.</p>	<p>Ga. Comp. R. & Regs. 480-13-.04(5) (the remote entry pharmacist must maintain records of any and all records entered for the hospital for a minimum of 2 years).</p>
<p align="center">Standard Ward Inventory (Floor Stock) Records and Surveys of Usage Trends</p>	<p align="center">2 years.</p>	<p>Ga. Comp. R. & Regs. 480-13-.01(i) (the Director of Pharmacy or his/her pharmacist designee must maintain a copy of the list of items on the standard ward inventory).</p> <p>Ga. Comp. R. & Regs. 480-13-.06(10) (records relating to the standard ward inventory, including the monthly surveys of usage trends, must be retained for 2 years).</p> <p>Ga. Comp. R. & Regs. 480-13-.06(9) (standard ward inventories must be readily available for inspection).</p>

* Any drug information maintained in medical records should be retained for the longer period required for those records. This section only addresses records created and maintained by the pharmacy.

As a general matter, each hospital pharmacy must maintain records of all transactions of the hospital pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials. [Ga. Comp. R. & Regs. 480-13-.06\(2\)\(k\)](#). Hospital pharmacies must maintain access to such records and reports as are required “to insure patient health, safety and welfare.” [Ga. Comp. R. & Regs. 480-13-.06\(9\)](#). Pharmacy records should be readily available for inspection by the Board of Pharmacy or the Georgia Drugs and Narcotics Agency. [Ga. Comp. R. & Regs. 480-13-.06\(9\)](#).
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DOCUMENT RETENTION SCHEDULE

PHARMACY RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Signature Logs	2 years.	<p>A hospital may wish to retain such records for 5 years, the statute of repose for malpractice actions, to allow their use in defense of a malpractice suit.</p> <p>Ga. Comp. R. & Regs. 480-27-.03 (records of dispensing original and refill prescriptions must be retained for 2 years).</p> <p>Ga. Comp. R. & Regs. 480-19-.03 (logbooks of sales of pseudoephedrine Schedule V Controlled Substances must be retained for 2 years).</p> <p>Ga. Comp. R. & Regs. 480-19-.01(b)(2) (to sale, dispense, or otherwise dispose of a non-pseudoephedrine Schedule V Controlled Substance, pharmacists must create records of the date of the transaction, the name, kind, quantity and intended use of the drug).</p> <p>21 C.F.R. § 1304.04(a) (controlled substances records must be retained for at least 2 years); 21 C.F.R. § 1304.04(b) (records must be retained on-site); 21 C.F.R. § 1304.04(c) (registrants may maintain records on an in-house computer system); 21 C.F.R. § 1304.04(h)(5) (prescription records may be maintained on off-site computers if the records are readily retrievable in-house and comply with 21 C.F.R. § 1311).</p> <p>DEA Pharmacist’s Manual, Section VI (all records concerning controlled substances must be maintained for at least 2 years for inspection and copying by duly authorized DEA officials).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>

* Any drug information maintained in medical records should be retained for the longer period required for those records. This section only addresses records created and maintained by the pharmacy.

As a general matter, each hospital pharmacy must maintain records of all transactions of the hospital pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials. [Ga. Comp. R. & Regs. 480-13-.06\(2\)\(k\)](#). Hospital pharmacies must maintain access to such records and reports as are required “to insure patient health, safety and welfare.” [Ga. Comp. R. & Regs. 480-13-.06\(9\)](#). Pharmacy records should be readily available for inspection by the Board of Pharmacy or the Georgia Drugs and Narcotics Agency. [Ga. Comp. R. & Regs. 480-13-.06\(9\)](#).

DOCUMENT RETENTION SCHEDULE

PHYSICIAN AGREEMENT RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Agreements and Contracts with Physicians</p> <p>(e.g., Physician Recruitment Agreement, Consulting Agreements, Space Lease Agreements, Personnel Lease, Clinic Service Agreements, etc.)</p>	<p>Term of contract plus 6 years.</p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 9-3-24 (6 year statute of limitation for breach of written contract).</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>42 C.F.R. § 411.357(e) (Stark law provides that records of the actual costs and the passed-through amounts are to be maintained for a period of at least 6 years to satisfy the exception to the referral prohibition related to compensation arrangements).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to contracts valued over \$10,000 for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p>

DOCUMENT RETENTION SCHEDULE

PROPERTY AND EQUIPMENT RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Building Blueprints	Permanent. Updated by architect as projects are completed.	Hospitals may consider these records invaluable. In addition, records concerning historic development could be helpful in any environmental or land use litigation.
Building Plans and Specifications	Permanent. Updated by architect as projects are completed.	Hospitals may consider these records invaluable. In addition, records concerning historic development could be helpful in any environmental or land use litigation.
<p align="center">Equipment Records</p> <p><i>(e.g., calibration, maintenance and inspection, operating instructions and manuals)</i></p> <p><i>See Environmental Records, p. 30 and Radiology and Nuclear Medicine Records, p. 113 for additional requirements for equipment that is a source of air emissions or discharges to water or land and equipment that uses radiation.</i></p>	Life of equipment or 10 years, whichever is longer.	<p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>42 C.F.R. § 482.41(d)(2) (facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.14 (hospitals must have a program to inspect, monitor, and maintain biomedical equipment, electrical equipment, and emergency power generators).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p>

DOCUMENT RETENTION SCHEDULE

PROPERTY AND EQUIPMENT RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p style="text-align: center;">Pump Records</p> <p>(e.g., calibration, maintenance and inspection, operating instructions and manuals)</p> <p><i>See Environmental Records, p. 30 for additional requirements for equipment that is a source of air emissions or discharges to water or land.</i></p>	<p>10 years or life of equipment plus 5 years, whichever is longer.</p>	<p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).</p> <p>42 C.F.R. § 482.41(d)(2) (facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.14 (hospitals must have a program to inspect, monitor, and maintain biomedical equipment, electrical equipment, and emergency power generators).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p>

DOCUMENT RETENTION SCHEDULE

PROPERTY AND EQUIPMENT RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Purchase Orders for Equipment	Life of the equipment or 10 years, whichever is longer.	<p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product).</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>O.C.G.A. § 11-2-725 (4 year statute of limitations for breach of contract for the sale of goods).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

DOCUMENT RETENTION SCHEDULE

PROPERTY AND EQUIPMENT RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Recall Records (records of a manufacturer’s recall)</p>	<p align="center">10 years.</p>	<p>Ga. Comp. R. & Regs. 480-13-06(9) (the Director of Pharmacy shall develop and implement a policy and procedure to assure that all drugs within the hospital included on a recall are returned to the pharmacy for proper destruction).</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>
<p align="center">Work Orders – Internal Orders</p>	<p>Work orders for repair, maintenance, or calibration of equipment: Life of the equipment or 10 years, whichever is longer.</p> <p>Other work orders: At least 3 years.</p>	<p>42 C.F.R. § 482.41(d)(2) (facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety).</p> <p>Ga. Comp. R. & Regs. 111-8-40-14 (hospitals must have a program to inspect, monitor, and maintain biomedical equipment, electrical equipment, and emergency power generators).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p>

DOCUMENT RETENTION SCHEDULE

PROPERTY AND EQUIPMENT RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Work Orders – External Orders	<p>Work orders for repair, maintenance, or calibration of equipment: Life of the equipment or 10 years, whichever is longer.</p> <p>Other work orders: Date of tax filing plus 6 years.</p>	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>O.C.G.A. § 11-2-725 (4 year statute of limitations for breach of contract for the sale of goods).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p>

DOCUMENT RETENTION SCHEDULE

PURCHASING RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Packing Slips</p> <p>Receiving Reports</p>	<p>Date of tax filing plus 6 years.</p>	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract for the sale of goods).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>
<p>Price List Files</p>	<p>At least 4 years.</p>	<p>O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract for the sale of goods).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

DOCUMENT RETENTION SCHEDULE

PURCHASING RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Purchase Invoices, Purchase Orders, and Purchase Requests</p> <p><i>See also Purchase Orders for Equipment, p. 106.</i></p> <p><i>See also Checks (Monthly) of the List of Excluded Individuals/Entities and of the Excluded Parties List System, p. 23.</i></p>	<p>Date of tax filing plus 6 years.</p>	<p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract for the sale of goods).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product).</p>

DOCUMENT RETENTION SCHEDULE

PURCHASING RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Purchase Orders for Equipment</p> <p><i>See also Checks (Monthly) of the List of Excluded Individuals/Entities and of the Excluded Parties List System, p. 23.</i></p>	<p>Life of the equipment or 10 years, whichever is longer.</p>	<p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product).</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>Medicare Claims Processing Manual, Ch. 1, §§ 110.1, 110.3 (5 year retention for supporting documentation for Medicare cost reports).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>O.C.G.A. § 11-2-725 (4 year statute of limitations for breach of contract for the sale of goods).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>
<p>Returned Goods Credit</p>	<p>4 years.</p>	<p>O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract for the sale of goods).</p>

DOCUMENT RETENTION SCHEDULE

PURCHASING RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Supplier and Vendor Files</p> <p>(Internal files containing information on suppliers/vendors but not evidencing specific hospital purchases)</p> <p><i>See also Checks (Monthly) of the List of Excluded Individuals/Entities and of the Excluded Parties List System, p. 23.</i></p>	<p>6 years or term of contract plus 4 years, whichever is longer.</p>	<p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z) (providers must maintain complete information about the ownership of any subcontractor with whom it had business transactions totaling more than \$25,000 during the previous 12 months and information regarding any significant business transactions between the provider and a wholly-owned supplier or between the provider and any subcontractor, during the previous 6 years).</p> <p>42 C.F.R. § 420.302 (HHS must be granted access to many contracts for goods and services and to books, documents, and records necessary to verify their costs. Retention period for this purpose is 4 years after expiration of said contracts).</p> <p>O.C.G.A. § 11-2-725 (4-year statute of limitation for breach of contract, warranty for the sale of goods).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

DOCUMENT RETENTION SCHEDULE

RADIOLOGY AND NUCLEAR MEDICINE RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units</p> <p>(Records of installation, maintenance, adjustment, and repair, full calibrations, periodic spot-checks, and other required inspections)</p> <p><i>See also Surveys of all Therapeutic Units, p. 121.</i></p>	<p>Records of Five-Year Inspection for Teletherapy and Gamma Stereotactic Surgery Units: Duration of the use of the unit.</p> <hr/> <p>All other records: 3 years.</p>	<p>Ga. Comp. R. & Regs. 391-3-17-.05(114) (records of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units must be retained for the duration of the use of the unit).</p> <hr/> <p>Ga. Comp. R. & Regs. 391-3-17-.05(106) (3 year retention period for records of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.05(108) (3 year retention period for records of full calibrations of the teletherapy, remote afterloader, and stereotactic radiosurgery units).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.05(109) (3 year retention period for records of each periodic spot-check of teletherapy units).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.05(110) (3 year retention period for records of each spot-check of remote afterloader units).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.05(111) (3 year retention period for records of each spot-check of Gamma Stereotactic Radiosurgery units).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.05(112) (3 year retention period for records of each check for mobile remote afterloader units).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p>
<p>Air Sampling, Surveys, and Bioassays Results</p> <p>Ambient Radiation Exposure Records</p>	<p>Permanent.</p>	<p>Ga. Comp. R. & Regs. 391-3-17-.03(14)(g), (c) (must retain all required forms and records regarding air sampling and release of radioactive effluents into the environment until the Department terminates each pertinent license).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.05(95) (3 year retention period for records of surveys of ambient radiation exposure).</p>

* This section focuses on the retention requirements for the use of radionuclides in the healing arts as listed in [Ga. Comp. R. & Regs. 391-3-17-.05](#). Though it touches on regulations from other sections of Ga. Comp. R. & Regs. 391-3-17, it is not comprehensive for all potential situations involving radioactive materials, as hospitals do not often face such situations. Please note that in the event of any accident involving radioactive materials (e.g., overexposure, employee exposure, spills, etc.), a general rule is to maintain related documentation permanently.

DOCUMENT RETENTION SCHEDULE

RADIOLOGY AND NUCLEAR MEDICINE RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Brachytherapy and Sealed Sources</p> <p>(Records of accountability, inventory, calibration measurements, and leakage tests)</p> <p><i>See also Surveys of all Therapeutic Units, p. 121.</i></p>	<p>3 years after the last use of the source or after the record is made, whichever is longer.</p>	<p>Ga. Comp. R. & Regs. 391-3-17-.05(103) (3 year retention period for accountability of all brachytherapy sources in storage or in use).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.05(94) (3 year retention period for semi-annual physical inventory of sealed sources and brachytherapy sources).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.05(104) (records of calibrations on brachytherapy sources must be retained for 3 years after the last use of the source).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.03(14)(d) (3 year retention period after the record is made for tests for leakage or contamination of sealed sources).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p>
<p>Directives</p> <p>(Records of written directives required for some nuclear medicine patients)</p>	<p>3 years.</p>	<p>Ga. Comp. R. & Regs. 391-3-17-.05(88) (3 year retention period for records of each written directive).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.05(19) (written directives required for some nuclear medicine patients).</p>
<p>Disposal of Radioactive Materials</p> <p><i>See footnote to section.</i></p>	<p>Generally: Permanent.</p>	<p>Ga. Comp. Rules & Regs. 391-3-17-.03(14)(c)(2) (The licensee shall retain the records required by the Rule “until the Department terminates each pertinent license requiring the record”);</p>
	<p>Licensed decay-in-storage material with a half-life of less than 120 days: 3 years.</p>	<p>Ga. Comp. R. & Regs. 391-3-17-.05(98) (3 year retention period for records of the disposal of licensed decay-in-storage material with a half-life of less than 120 days).</p>
<p>Dosimetry equipment</p>	<p>Permanent.</p>	<p>Ga. Comp. R. & Regs. 391-3-17-.05(107) (records of the calibration, inter-comparison, and comparisons of dosimetry equipment must be maintained for the duration of the license).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p>

* This section focuses on the retention requirements for the use of radionuclides in the healing arts as listed in [Ga. Comp. R. & Regs. 391-3-17-.05](#). Though it touches on regulations from other sections of Ga. Comp. R. & Regs. 391-3-17, it is not comprehensive for all potential situations involving radioactive materials, as hospitals do not often face such situations. Please note that in the event of any accident involving radioactive materials (e.g., overexposure, employee exposure, spills, etc.), a general rule is to maintain related documentation permanently.

DOCUMENT RETENTION SCHEDULE

RADIOLOGY AND NUCLEAR MEDICINE RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Equipment Records for "Radiation Machines"	Receipt, transfer or disposal of equipment: Life of equipment plus 3 years	<p>Ga. Comp. R. & Regs. 11-8-90-.07(1)(f) (required to keep records showing the receipt, transfer, or disposal of radiation machines).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>
	Maintenance records: Life of equipment.	<p>Ga. Comp. R. & Regs. 11-8-90-.07(1)(g) (required to keep records of all major maintenance and/or modifications performed on each radiation machine and transfer said records to any subsequent owner of the equipment).</p>
Mammography Records	<p>10 years from last discharge or contact that resulted as a record.</p> <p><i>See Medical Records Generally, p. 73.</i></p>	<p>21 C.F.R. § 900.12(c)(4)(i) (a facility that performs mammograms must maintain films and reports in a permanent medical record of the patient for at least 5 years, or at least 10 years if no additional mammograms of the patient are performed at the facility).</p> <p>42 C.F.R. § 424.516(f); Medicare Program Integrity Manual, Ch. 15 § 18 (BOTH physicians (or other eligible professionals) who order, certify, refer, or prescribe Part A or B services, items, or drugs ("Covered Benefits") AND providers that furnish covered ordered, certified, referred, or prescribed Covered Benefits must maintain written and electronic documents (including the NPI of the physician or other eligible professional who ordered/certified/referred/prescribed the Covered Benefits) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Covered Benefits for 7 years from the date of service).</p>

* This section focuses on the retention requirements for the use of radionuclides in the healing arts as listed in [Ga. Comp. R. & Regs. 391-3-17-.05](#). Though it touches on regulations from other sections of Ga. Comp. R. & Regs. 391-3-17, it is not comprehensive for all potential situations involving radioactive materials, as hospitals do not often face such situations. Please note that in the event of any accident involving radioactive materials (e.g., overexposure, employee exposure, spills, etc.), a general rule is to maintain related documentation permanently.

DOCUMENT RETENTION SCHEDULE

RADIOLOGY AND NUCLEAR MEDICINE RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Medical Records, not Including Mammography Records</p> <p>(e.g., films, scans, images and reports)</p>	<p><u>Adults:</u> 10 years from last discharge or contact that resulted as a record.</p> <p><u>Minors:</u> Until the patient’s 23rd birthday or 10 years from last discharge or contact that resulted in a record, whichever is longer.</p> <p><i>See Medical Records Generally, p. 73.</i></p>	<p>EPD regulation of radioactive materials requires that some portions of the medical record be kept for a minimum of 3 years (e.g., radiation dose records, records of patients released containing radioactive drugs or implants, records of exposure to pregnant or nursing mothers, etc.), but these records will need to be kept for the longer period of time required for medical records generally.</p> <p>42 C.F.R. § 424.516(f); Medicare Program Integrity Manual, Ch. 15 § 18 (BOTH physicians (or other eligible professionals) who order, certify, refer, or prescribe Part A or B services, items, or drugs (“Covered Benefits”) AND providers that furnish covered ordered, certified, referred, or prescribed Covered Benefits must maintain written and electronic documents (including the NPI of the physician or other eligible professional who ordered/certified/referred/prescribed the Covered Benefits) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Covered Benefits for 7 years from the date of service).</p> <p>42 C.F.R. §424.535(a)(10) (provider who fails to comply with document retention requirements in 424.516(f) is <i>subject to revocation</i> of Medicare enrollment for a period of not more than 1 year).</p> <p>42 C.F.R. § 482.26(d) (hospitals must retain records of radiological services, including copies of reports and printouts, films, scans, and other image records, for 5 years).</p> <p>42 C.F.R. § 482.53(d) (hospitals must retain copies of nuclear medicine records, including interpretations, consultations, and procedures, for 5 years).</p> <p>Ga. Comp. R. & Regs. 111-8-40-.24(2)(c) (hospital must retain films, scans, and other images for at least 5 years after the date of the last procedure unless the release of the original image is required for the patient. For minors, they must be retained for 5 years after the minor reaches the age of majority).</p>

* This section focuses on the retention requirements for the use of radionuclides in the healing arts as listed in [Ga. Comp. R. & Regs. 391-3-17-.05](#). Though it touches on regulations from other sections of Ga. Comp. R. & Regs. 391-3-17, it is not comprehensive for all potential situations involving radioactive materials, as hospitals do not often face such situations. Please note that in the event of any accident involving radioactive materials (e.g., overexposure, employee exposure, spills, etc.), a general rule is to maintain related documentation permanently.

The U.S. Nuclear Regulatory Commission (“NRC”) regulates nuclear materials, including medical equipment that uses radiation. However, Georgia has entered into an agreement with the NRC to assume NRC regulatory authority within the state. Atomic Energy Act of 1954, [42 U.S.C. § 2021](#).
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DOCUMENT RETENTION SCHEDULE

RADIOLOGY AND NUCLEAR MEDICINE RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p style="text-align: center;">Misadministrations</p> <p><i>See footnote to section.</i></p>	<p>At least 3 years.</p>	<p>Hospitals may consider maintaining these records for 5 years to cover the statute of repose for medical malpractice or for longer in the event of exposure to members of the public.</p> <p>Ga. Comp. R. & Regs. 391-3-17-.05(89) (3 year retention period for records of misadministrations).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10).</p> <p><i>But note:</i> Ga. Comp. R. & Regs. 391-3-17-.03(14)(h) (must retain all required forms and records regarding doses to individual members of the public until the Department terminates each pertinent license. Upon termination, retention obligations continue for some documents).</p>
<p style="text-align: center;">Mobile Services</p> <p><i>See also Surveys of all Therapeutic Units, p. 121.</i></p>	<p>3 years.</p>	<p>Ga. Comp. R. & Regs. 391-3-17-.05(97) (3 year retention period for documentation of administrative and technical requirements that apply to the mobile use of radioactive materials).</p>
<p style="text-align: center;">Occupational Radiation Exposure History</p>	<p>Permanent.</p>	<p>Ga. Comp. R. & Regs. 391-3-17-.03(14)(g), (e) (must retain all required forms and records regarding employee exposure to radiation until the Department terminates each pertinent license. Upon termination, retention obligations continue for some documents).</p> <p>29 C.F.R. § 1910.1020(d) (if records include records of monitoring or sampling of employee exposure to toxic substances or other hazards, OSHA generally requires retention for at least 30 years). <i>See OSHA Records, p. 50.</i></p>
<p style="text-align: center;">Records of Packages Received Containing Radioactive Materials</p>	<p>3 years.</p>	<p>Ga. Comp. R. & Regs. 391-3-17-.03(14)(c), (12)(f)(2) (3 year retention period after record is made).</p>

* This section focuses on the retention requirements for the use of radionuclides in the healing arts as listed in [Ga. Comp. R. & Regs. 391-3-17-.05](#). Though it touches on regulations from other sections of Ga. Comp. R. & Regs. 391-3-17, it is not comprehensive for all potential situations involving radioactive materials, as hospitals do not often face such situations. Please note that in the event of any accident involving radioactive materials (e.g., overexposure, employee exposure, spills, etc.), a general rule is to maintain related documentation permanently.

DOCUMENT RETENTION SCHEDULE

RADIOLOGY AND NUCLEAR MEDICINE RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Records Regarding Pregnant and Nursing Mothers (Certain records of a dose given to an embryo, nursing child, or nursing mother)	Records of a dose given to a fetus or nursing child: 3 years.	Ga. Comp. R. & Regs. 391-3-17-.05(90) (3 year retention period for records of a dose given to an embryo/fetus or nursing child).
	Records of instructions given to breast-feeding mothers who received radioactive drugs or implants: 3 years after date of release.	Ga. Comp. R. & Regs. 391-3-17-.05(96) (3 year retention period after the date of release for instructions given upon release to breast-feeding mothers who received radioactive drugs or implants).
Radiation Exposure Records <i>See footnote to section.</i>	5 years after termination of the individual's employment or association with the registrant.	Ga. Comp. R. & Regs. 11-8-90-.07(1)(c) (5 year retention period after termination of the individual's employment or association with the registrant for records of individual radiation exposure). Ga. Comp. R. & Regs. 391-3-17-.05(93) (3 year retention period for records of dosages of unsealed radioactive material for medical use). <i>But note:</i> Ga. Comp. R. & Regs. 391-3-17-.03(14)(c)(2)(i)-(ii) (must retain all required forms, records and results regarding surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents, and of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose, until the Department terminates each pertinent license. Upon termination, retention obligations continue for some documents).
Radiation Protection Program Records <i>See also Records of Safety Instruction and Training Records, p. 120</i>	Provisions of the program: Permanent.	Ga. Comp. R. & Regs. 391-3-17-.03(14)(b) (must retain documentation of provisions of the program "until the Department terminates each pertinent license requiring the record").
	Records of authority, responsibilities, actions taken, and safety program changes: 5 years	Ga. Comp. R. & Regs. 391-3-17-.05(86)-(87) (5 year retention period).
	Audits and other reviews of program content and implementation: 3 years after record is made.	Ga. Comp. R. & Regs. 391-3-17-.03(14)(b) (3 year retention period after record is made).

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DOCUMENT RETENTION SCHEDULE

RADIOLOGY AND NUCLEAR MEDICINE RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Radionuclide Purity Records	3 years.	Ga. Comp. R. & Regs. 391-3-17-.05(99) (3 year retention period for records of radionuclide contaminant concentration tests).
Requests for Imaging Services	7 years from the date of service.	<p>42 C.F.R. § 424.516(f); Medicare Program Integrity Manual, Ch. 15 § 18 (BOTH physicians (or other eligible professionals) who order, certify, refer, or prescribe Part A or B services, items, or drugs (“Covered Benefits”) AND providers that furnish covered ordered, certified, referred, or prescribed Covered Benefits must maintain written and electronic documents (including the NPI of the physician or other eligible professional who ordered/certified/referred/prescribed the Covered Benefits) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Covered Benefits for 7 years from the date of service).</p> <p>42 C.F.R. §424.535(a)(10) (provider who fails to comply with document retention requirements in 424.516(f) is <i>subject to revocation</i> of Medicare enrollment for a period of not more than 1 year).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>42 C.F.R. § 482.26(d) (hospitals must retain records of radiological services, including copies of reports and printouts, films, scans, and other image records, for 5 years).</p> <p>42 C.F.R. § 482.53(d) (hospitals must retain copies of nuclear medicine records, including interpretations, consultations, and procedures, for 5 years).</p>
Records of Release of Individuals Containing Radioactive Drugs or Implants	3 years after the date of release.	Ga. Comp. R. & Regs. 391-3-17-.05(96) (3 year retention period after the date of release).

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DOCUMENT RETENTION SCHEDULE

RADIOLOGY AND NUCLEAR MEDICINE RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Reports of Overexposure	Permanent.	<p>Ga. Comp. R. & Regs. 391-3-17-.03(14)(g), (e) (must retain all required forms and records regarding employee exposure to radiation until the Department terminates each pertinent license. Upon termination, retention obligations continue for some documents).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.03(14)(h) (must retain all required forms and records regarding doses to individual members of the public until the Department terminates each pertinent license. Upon termination, retention obligations continue for some documents).</p>
<p style="text-align: center;">Safety Instruction and Training Records</p> <p>(Training of Nuclear Medicine Technologists, Radiation Therapists, all personnel caring for patients or human research subjects who have received therapy with a radioactive drug or implant and cannot be released, and all individuals who operate remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units)</p>	3 years after the last date the individual was authorized to act in such role at the licensee’s facility.	<p>Ga. Comp. R. & Regs. 391-3-17-.05(100) (records of training for Nuclear Medicine Technologists and Radiation Therapists must be retained for 3 years after the last date the individual was authorized to act in such role at the licensee’s facility).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.05(101) (must maintain required employee training records for 3 years after the last date the individual was authorized to act in such role at the licensee’s facility).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.05(49) (sets forth general recordkeeping requirements for training for all personnel caring for patients or human research subjects who have received therapy with a radioactive drug and cannot be released).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.05(58) (sets forth general recordkeeping requirements for training for all personnel caring for patients or human research subjects who have received therapy with a radioactive implants and cannot be released).</p> <p>Ga. Comp. R. & Regs. 391-3-17-.05(70) (sets forth general recordkeeping requirements for training for all individuals who operate remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units).</p>

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DOCUMENT RETENTION SCHEDULE

RADIOLOGY AND NUCLEAR MEDICINE RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Survey Instruments (Records of calibrations and leak tests) <i>See also Dosimetry Equipment, p. 114.</i>	Records that assure that required tests were performed: Until EPD 3 years.	Ga. Comp. R. & Regs. 391-3-17-.02(6)(c)(3)(iv) (records that “assure that the tests required by” regulation are performed must be “maintained for three years.”)
	Survey Instrument Calibration: 3 years.	Ga. Comp. R. & Regs. 391-3-17-.05(92) (3 year retention period for records of calibrations of survey instrument – specific rule for healing arts uses). Ga. Comp. R. & Regs. 391-3-17-.03(14)(c), (8)(a) (3 year retention period for records of calibrations of survey instruments – general rule). Ga. Comp. R. & Regs. 391-3-17-.05(91) (3 year retention period for records of calibrations of instruments used to measure the activity of unsealed radioactive material).
	Leak Tests and tests of the on/off mechanism and indicator: 3 year after performance of the next required leak test.	Ga. Comp. R. & Regs. 391-3-17-.02(6)(c)(3)(iv) (3 year retention period).
Surveys of Exposure to Patients and Human Research Subjects	3 years.	Ga. Comp. R. & Regs. 391-3-17-.05(102) (3 year retention period of surveys after source implant and removal and surveys of patients and research subject treated with a remote afterloader unit).
Strontium-90: Records of the Decay of Sr-90 Sources	Life of the source.	Ga. Comp. R. & Regs. 391-3-17-.05(105) (records of the activity of a strontium 90 source must be retained for the life of the source).
Surveys of Therapeutic Treatment Units	Duration of the use of the unit.	Ga. Comp. R. & Regs. 391-3-17-.05(113) (records of radiation surveys of treatment units must be maintained for the duration of the use of the unit).

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DOCUMENT RETENTION SCHEDULE

RESEARCH RECORDS*

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RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Contracts with Study Sponsor or Principal Investigator and Supporting Documentation</p> <p><i>See footnote to section.</i></p>	<p>At least 10 years.</p>	<p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>O.C.G.A. § 9-3-24 (6 year statute of limitations for breach of written contract).</p> <p>26 U.S.C. § 6501 (Generally 3-year statute of limitations from date of filing tax return, but 6-year statute of limitations from date of filing for omissions of gross income in excess of 25 percent of the amount of gross income stated in the return. <i>But note:</i> In the event of a false return, fraud, or failure to file a return, the tax may be assessed at <i>any time</i>).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (5 year statute of limitation for criminal fraud actions).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).</p>
<p>Institutional Review Board Reviews and Records</p> <p>(copies of all research proposals reviewed, protocols, progress reports, meeting minutes, reports of injuries to patients, sample informed consent, etc.)</p> <p><i>See footnote to section.</i></p>	<p>3 years after completion of the research.</p>	<p>21 C.F.R. § 56.115 (documentation of institutional review board (“IRB”) activity for research regulated by the FDA must be retained for 3 years after completion of research).</p> <p>45 C.F.R. § 46.115; 7 C.F.R. § 1c.115 (documentation of IRB activity for all research involving human subjects that is supported by federal agencies or otherwise subject to federal regulations must be retained for 3 years after completion of research).</p>

* The retention period for records of clinical trials and other research should be made on a case-by-case basis. The retention periods required by federal regulations are short, but records are typically maintained for much longer for various reasons, including: (1) protection of any intellectual property rights that result from the research; (2) document retention requirements imposed by the research sponsor; (3) medical malpractice exposure; (4) products liability exposure in all states where the drug or device is eventually marketed; (5) terms of the contracts with the study sponsor or principal investigator, including indemnification provisions; and (6) the scientific and historical value of the data. All data that is part of a patient’s medical record should be retained for the entire period required for medical records generally. *See Medical Records Generally, p. 73.*
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DOCUMENT RETENTION SCHEDULE

RESEARCH RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Records Relating to Clinical Research on Drugs</p> <p><i>See footnote to section.</i></p>	<p>Medical Records:</p> <p><u>Adults</u>: 10 years from last discharge or contact that resulted in a record.</p> <p><u>Minors</u>: Until the patient’s 23rd birthday or 10 years from last discharge or contact that resulted in a record, whichever is longer.</p> <p><i>See Medical Records Section, p. 71.</i></p>	<p>FDA regulation of retention of research data does not exempt hospitals from maintaining the entire medical record, including records of research participation, for the entire period of time required for medical records generally.</p>
	<p>Case Histories: At least 2 years (<i>but see comments</i>).</p> <p><i>See also Institutional Review Board Reviews and Records, p. 122.</i></p>	<p>Though FDA regulations only require case histories be kept for two years, data is typically retained significantly longer. Data should be maintained long enough to protect any intellectual property related to the work (<i>i.e.</i>, patents) and to satisfy any requirements of the research sponsor. There may also be historical and scientific value to the data. Additionally, all records that are part of a patient’s medical record should be maintained for the longer period of time required for medical records generally.</p> <p>21 C.F.R. § 312.62 (2 year retention period for case histories, including the case report forms and supporting data. Retention period starts when drug is approved or, if it is not approved, when the investigation is terminated and FDA is notified).</p> <p>There may be records of certain types of studies the hospital may wish to maintain longer, including the following:</p> <ul style="list-style-type: none"> (1) studies involving children; (2) OB/reproductive research; (3) genetic research; (4) radiation research; and (5) research on people of child-bearing years.
	<p>Disposition of an Investigational Drug: 2 years after the drug is approved or investigation is discontinued and FDA is notified.</p> <p>(Including: Dates, quantity, use by subjects, and other records FDA requires be maintained)</p>	<p>21 C.F.R. § 312.62 (2 year retention period for records of the disposition of an investigational drug. Retention period starts when drug is approved or, if it is not approved, when the investigation is terminated and FDA is notified).</p>

* The retention period for records of clinical trials and other research should be made on a case-by-case basis. The retention periods required by federal regulations are short, but records are typically maintained for much longer for various reasons, including: (1) protection of any intellectual property rights that result from the research; (2) document retention requirements imposed by the research sponsor; (3) medical malpractice exposure; (4) products liability exposure in all states where the drug or device is eventually marketed; (5) terms of the contracts with the study sponsor or principal investigator, including indemnification provisions; and (6) the scientific and historical value of the data. All data that is part of a patient’s medical record should be retained for the entire period required for medical records generally. *See Medical Records Generally, p. 73.*
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DOCUMENT RETENTION SCHEDULE

RESEARCH RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Records Relating to Clinical Research on Medical Devices</p> <p><i>See footnote to section.</i></p>	<p>Medical Records:</p> <p><u>Adults:</u> 10 years from last discharge or contact that resulted in a record.</p> <p><u>Minors:</u> Until the patient’s 23rd birthday or 10 years from last discharge or contact that resulted in a record, whichever is longer.</p> <p><i>See Medical Records Section, p. 71.</i></p>	<p>FDA regulation of retention of research data does not exempt hospitals from maintaining the entire medical record, including records of research participation, for the entire period of time required for medical records generally.</p>
	<p>Case Histories: at least 2 years (<i>but see comments</i>).</p> <p><i>See also Institutional Review Board Reviews and Records, p. 122.</i></p>	<p>Though FDA regulations only require case histories be kept for two years, data is typically retained significantly longer. Data should be maintained long enough to protect any intellectual property related to the work (<i>i.e.</i>, patents) and to satisfy any requirements of the research sponsor. There may also be historical and scientific value to the data. Additionally, all records that are part of a patient’s medical record should be maintained for the longer period of time required for medical records generally.</p> <p><u>21 C.F.R. § 812.140</u> (2 year retention period for case histories, including the case report forms and supporting data. The retention period starts on the date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application, a notice of completion of a product development protocol, a humanitarian device exemption application, a premarket notification submission, or a request for De Novo classification.)</p> <p>There may be records of certain types of studies the hospital may wish to maintain longer, including the following:</p> <ul style="list-style-type: none"> (1) studies involving children; (2) OB/reproductive research; (3) genetic research; (4) radiation research; and (5) research on people of child-bearing years.

* The retention period for records of clinical trials and other research should be made on a case-by-case basis. The retention periods required by federal regulations are short, but records are typically maintained for much longer for various reasons, including: (1) protection of any intellectual property rights that result from the research; (2) document retention requirements imposed by the research sponsor; (3) medical malpractice exposure; (4) products liability exposure in all states where the drug or device is eventually marketed; (5) terms of the contracts with the study sponsor or principal investigator, including indemnification provisions; and (6) the scientific and historical value of the data. All data that is part of a patient’s medical record should be retained for the entire period required for medical records generally. *See Medical Records Generally, p. 73.*

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DOCUMENT RETENTION SCHEDULE

RESEARCH RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
	<p>Other Records: 2 years (<i>but see comments</i> regarding start of retention period).</p> <p>(Including: Disposition, receipt, or use of an investigational device; protocols; observations; adverse event reports; and all other records FDA requires be maintained)</p>	<p>21 C.F.R. § 812.140 (2 year retention period for records of the disposition, receipt, or use of an investigational device. The retention period starts on the date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application, a notice of completion of a product development protocol, a humanitarian device exemption application, a premarket notification submission, or a request for De Novo classification.).</p>

* The retention period for records of clinical trials and other research should be made on a case-by-case basis. The retention periods required by federal regulations are short, but records are typically maintained for much longer for various reasons, including: (1) protection of any intellectual property rights that result from the research; (2) document retention requirements imposed by the research sponsor; (3) medical malpractice exposure; (4) products liability exposure in all states where the drug or device is eventually marketed; (5) terms of the contracts with the study sponsor or principal investigator, including indemnification provisions; and (6) the scientific and historical value of the data. All data that is part of a patient’s medical record should be retained for the entire period required for medical records generally. *See Medical Records Generally, p. 73.*
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DOCUMENT RETENTION SCHEDULE

RESEARCH RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Records Relating to Other Clinical Research</p> <p align="center"><i>See footnote to section.</i></p>	<p>Medical Records:</p> <p><u>Adults:</u> 10 years from last discharge or contact that resulted in a record.</p> <p><u>Minors:</u> Until the patient’s 23rd birthday or 10 years from last discharge or contact that resulted in a record, whichever is longer.</p> <p><i>See Medical Records Section, p. 71.</i></p>	<p>Regulation of retention of research data does not exempt hospitals from maintaining the entire medical record, including records of research participation, for the entire period of time required for medical records generally.</p>
	<p>Other Clinical Research Records: At least 2 years (<i>but see comments</i>).</p> <p><i>See also Institutional Review Board Reviews and Records, p. 122.</i></p>	<p>This retention period is extrapolated from the requirements for research on drugs and devices. Most data is typically retained significantly longer than 2 years. Data should be maintained long enough to protect any intellectual property related to the work and to satisfy any requirements of the research sponsor. There may also be historical and scientific value to the data. Additionally, all records that are part of a patient’s medical record should be maintained for the longer period of time required for medical records generally.</p> <p>There may be records of certain types of studies the hospital may wish to maintain for longer, including the following:</p> <ul style="list-style-type: none"> (1) studies involving children; (2) OB/reproductive research; (3) genetic research; (4) radiation research; and (5) research on people of child-bearing years.

* The retention period for records of clinical trials and other research should be made on a case-by-case basis. The retention periods required by federal regulations are short, but records are typically maintained for much longer for various reasons, including: (1) protection of any intellectual property rights that result from the research; (2) document retention requirements imposed by the research sponsor; (3) medical malpractice exposure; (4) products liability exposure in all states where the drug or device is eventually marketed; (5) terms of the contracts with the study sponsor or principal investigator, including indemnification provisions; and (6) the scientific and historical value of the data. All data that is part of a patient’s medical record should be retained for the entire period required for medical records generally. *See Medical Records Generally, p. 73.*
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DOCUMENT RETENTION SCHEDULE

RESEARCH RECORDS*

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Records Relating to Non-Clinical Research</p> <p><i>(e.g., documentation records, raw data, master schedule sheet, summaries of training, experience, and job descriptions, records of maintenance and calibration of equipment, etc.)</i></p> <p align="center"><i>See footnote to section.</i></p>	<p>If the non-clinical research supports an Investigational New Drug (“IND”) application or an investigational device exemption (“IDE”): 5 years after the data is submitted to the FDA in support of an application.</p> <p>If the non-clinical research does NOT support an IND or an IDE: The lesser of:</p> <ul style="list-style-type: none"> - 5 years after the data is submitted to the FDA in support of an application; or - 2 years after the application for a research or marketing permit is approved or 2 years after research terminates if no permit is approved. 	<p>21 C.F.R. § 58.195 (5 or 2 year retention period for records relating to non-clinical research, including data and administrative records).</p>

* The retention period for records of clinical trials and other research should be made on a case-by-case basis. The retention periods required by federal regulations are short, but records are typically maintained for much longer for various reasons, including: (1) protection of any intellectual property rights that result from the research; (2) document retention requirements imposed by the research sponsor; (3) medical malpractice exposure; (4) products liability exposure in all states where the drug or device is eventually marketed; (5) terms of the contracts with the study sponsor or principal investigator, including indemnification provisions; and (6) the scientific and historical value of the data. All data that is part of a patient’s medical record should be retained for the entire period required for medical records generally. *See Medical Records Generally, p. 73.*

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DOCUMENT RETENTION SCHEDULE

RISK MANAGEMENT RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Accident / Incident Reports and Unusual Occurrence Reports</p>	<p>10 years.</p>	<p>Applicable Statutes of Limitations:</p> <ul style="list-style-type: none"> - O.C.G.A. § 9-3-24 (written contracts - 6 years); - O.C.G.A. § 9-3-25 (oral contracts - 4 years); - O.C.G.A. § 9-3-27 (against fiduciaries - 10 years); - O.C.G.A. § 9-3-30 (trespass or damage to realty - 4 years); - O.C.G.A. § 9-3-31 (personalty - 4 years); - O.C.G.A. § 9-3-32 (personal property - 4 years); - O.C.G.A. § 9-3-33 (personal injury - 2 years); - O.C.G.A. § 9-3-33 (loss of consortium - 4 years); - O.C.G.A. § 9-3-71 (medical malpractice - 2 years with 5 years statute of repose); - O.C.G.A. § 9-3-72 (foreign bodies - 1 year from discovery); - O.C.G.A. § 9-3-73 (medical malpractice statute of limitations tolled if minor was under age 5 at occurrence). - O.C.G.A. § 51-1-11 (products liability against manufacturer – 10 years after first sale); <p>29 C.F.R. § 1904.33 (employers must maintain the OSHA 300 Log, the privacy case list, the annual summary, and the OSHA 301 Incident Report form for 5 years following the end of the calendar year that the records cover).</p> <p>Joint Commission, Comprehensive Accreditation Manual – Environment of Care (hospitals must have processes to report and investigate incidents and issues, including injuries to patients or others in the hospital’s facilities, occupational illnesses and staff injuries, incidents of damage to its property or the property of others, security incidents, hazardous materials and waste spills and exposures, fire safety management problems, medical/laboratory equipment problems, and utility systems management problems).</p>
<p>Appraisal Reports (property, building, equipment or grounds appraisals)</p>	<p>Permanent.</p>	<p>These records are often kept permanently for certificate of need purposes and for business reasons.</p>
<p>Complaints of Handicap Discrimination and Relevant Employment Records of the Charging Party and Employees in Similar Positions</p>	<p>3 years.</p>	<p>29 C.F.R. § 32.49 (programs that receive federal financial assistance must maintain records related to complaints of handicap discrimination for 3 years).</p>

DOCUMENT RETENTION SCHEDULE

RISK MANAGEMENT RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Insurance Documents</p> <p align="center">(including current and expired policies, correspondence and pre-certifications, claims, releases and settlements, surety bonds, fidelity bonds)</p>	<p align="center">Permanent.</p>	<p>“Old” exposures occur fairly often necessitating review of policies and the documents supporting the insurance policy transaction. Unknown continuing torts do trigger coverage, especially as to environmental liability, professional liability, and premise liability.</p>
<p>Medical Device Reports (MDR) and Records of MDR Reportable Events</p>	<p align="center">2 years.</p>	<p>Hospitals may wish to retain these records for 10 years, the statute of limitation for products liability actions.</p> <p>21 C.F.R. § 803.18 (user facilities, including hospitals, must retain a medical device reporting file relating to an adverse event for 2 years after the date of the event).</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p>
<p>Medical Device Tracking Records</p>	<p align="center">Useful life of the device.</p>	<p>21 C.F.R. § 821.60 (medical device tracking reports must be retained for the useful life of the device).</p>

DOCUMENT RETENTION SCHEDULE

RISK MANAGEMENT RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Patient Complaints	Relating to drugs or devices: 10 years. Other complaints: 6 years.	<p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>18 U.S.C. § 3282 (general Federal criminal statute of limitation of 5 years).</p> <p>O.C.G.A. § 16-14-8 (Georgia RICO statute of limitation of 5 years).</p> <p>45 C.F.R. § 164.530(j) (a covered entity must maintain required HIPAA documentation for 6 years after the date of its creation or the date when it was last in effect).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases); O.C.G.A. § 9-3-72 (statute of limitations for foreign objects left in a patient’s body is 1 year after object is discovered).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

DOCUMENT RETENTION SCHEDULE

RISK MANAGEMENT RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p>Policies and Procedures – Outdated</p>	<p>Policies relating to use of equipment/products, including Pharmacy policies: 10 years.</p> <p>Other policies (e.g., Billing, Compliance, HIPAA Privacy⁴, Human Resources, Marketing, Nursing, Patient Care, Quality Assurance, etc.): 6 years.</p> <p>Security policies: At least 3 years.</p> <p><i>See also Document Retention Schedule for the department that maintains the policy.</i></p>	<p>The hospital may wish to maintain policies for a longer period of time for historical purposes.</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>31 U.S.C. § 3731(b) (False Claims Act civil fraud actions statute of limitation of 6 years; statute of repose of 10 years).</p> <p>45 C.F.R. § 164.530(j) (a covered entity must maintain required HIPAA documentation for 6 years after the date of its creation or the date when it was last in effect).</p> <p>O.C.G.A. § 9-3-24 (6 year statute of limitations for breach of written contract. The Employee Handbooks should be maintained for this period for any claim that the Handbook constituted a contract between the employer and employee).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>McCord v. Lee</i>, 286 Ga. 179 (2009) (recognizing a “new injury” exception to the statute of limitations in misdiagnosis cases).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>

⁴ The U.S. Department of Health and Human Services has proposed elimination of the requirements for a covered health care provider with a direct treatment relationship to an individual to obtain a written acknowledgment of receipt of its Notice of Privacy Policy, and, if unable to obtain the written acknowledgment, to document their good faith efforts and the reason for not obtaining the acknowledgment. See Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446-01 at 6485 (Jan. 21, 2021). The proposal also would remove the current requirement to retain copies of such documentation for six years. *Id.*

DOCUMENT RETENTION SCHEDULE

RISK MANAGEMENT RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
<p align="center">Recall Records (records of a manufacturer’s recall)</p>	<p align="center">10 years.</p>	<p>Ga. Comp. R. & Regs. 480-13-.06(9) (the Director of Pharmacy shall develop and implement a policy and procedure to assure that all drugs within the hospital included on a recall are returned to the pharmacy for proper destruction).</p> <p>O.C.G.A. § 51-1-11 (statute of limitation for products liability for the manufacturer is 10 years from the date of the first sale of the product); O.C.G.A. § 11-2-725 (4 year statute of limitation for breach of contract or breach of warranty for the sale of goods); O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>O.C.G.A. § 9-3-71 (2 year statute of limitation for malpractice actions, 5 year statute of repose); O.C.G.A. § 9-3-73 (for minors who are under age 5 when malpractice occurred, the statute of limitations ends at age 7 and the statute of repose ends at age 10); <i>Robinson v. Williamson</i>, 245 Ga. App. 17 (Ga. Ct. App. 2000) (statute of limitation in O.C.G.A. § 9-3-71 applies to an action based upon the conduct of a pharmacist in dispensing medication upon a doctor's prescription).</p>

DOCUMENT RETENTION SCHEDULE

SECURITY AND TRANSPORTATION RECORDS

Upon issuance of a formal legal hold, all purging should be suspended as specified in the legal hold. A sample legal hold memorandum is provided at Appendix C.

RECORD DESCRIPTION	RETENTION PERIODS	COMMENTS
Security Departmental Policies and Procedures – Outdated	3 years.	<p>Ga. Comp. R. & Regs. 111-8-40-.15 (hospitals must develop and implement an effective hospital-wide safety program that includes security procedures for controlling access to sensitive areas, an incident monitoring system, and other safety policies).</p> <p>O.C.G.A. § 10-11-2 (unless there is a specific retention requirement, business records required to be kept may be destroyed after 3 years).</p>
Security Incident Reports	4 years.	<p>O.C.G.A. § 9-3-30 (4 year statute of limitation for trespass and damage to realty).</p> <p>O.C.G.A. § 9-3-31 (4 year statute of limitation for damage to personal property).</p> <p>O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p> <p>Joint Commission, Comprehensive Accreditation Manual – Environment of Care (hospitals must have processes to report and investigate incidents and issues, including security incidents).</p>
Shuttle Logs and Daily Dispatch Logs	4 years.	<p>O.C.G.A. § 9-3-30 (4 year statute of limitation for trespass and damage to realty).</p> <p>O.C.G.A. § 9-3-31 (4 year statute of limitation for damage to personal property).</p> <p>O.C.G.A. § 9-3-33 (2 year statute of limitations for personal injury).</p>

Appendix A:

**Sample Electronic Record Retention
Guidelines for Georgia Law**

Electronic Patient Health Records

- Under Georgia law, any healthcare provider may, in its sole discretion, create, maintain, transmit, receive, and store a patient's health record in an electronic format.
- A healthcare provider may temporarily or permanently convert patient health records into an electronic format.
- A healthcare provider is not required to maintain separate tangible copies of electronically stored patient health records.
- A tangible copy of a patient's health record reproduced from an electronically stored record is considered an original for purposes of providing copies to patients or other authorized parties and for introduction of the patient's health records into evidence in administrative or court proceedings.
- Electronic patient health records must comply with federal laws governing the security and confidentiality of a patient's personal health information.
- Hospital health records that are converted to or stored as electronic records must be readable and capable of being reproduced in paper format upon request.
- These guidelines also apply to psychiatric, psychological, or other mental health records of a patient.

Electronic Records Generally

- Any record required to be retained under Georgia law can be maintained electronically so long as the electronic record:
 - (1) Accurately reflects the information in the original record after it was first generated in its final (paper or electronic) form; and
 - (2) Remains accessible for the retention period required by law.
- If Georgia law requires a record to be presented or retained in its original form, or provides consequences if it is not presented or retained in its original form, the law will still be considered fulfilled so long as an electronic record of the document is maintained in accordance with the requirements above.

- It is permissible to satisfy the requirements above by using the services of another person so long as that person also complies.
- There may be instances where a Georgia governmental agency specifies additional retention obligations for records subject to its jurisdiction. Such obligations are not precluded by the requirements above.
- A record retained as an electronic record in accordance with the requirements above satisfies any law that requires retention of a record for evidentiary, audit, or like purposes unless a law enacted after July 1, 2009 specifically prohibits the use of an electronic record for the specified purpose.
- There may be instances in which an original paper record should not be destroyed due to administrative or historical reasons, even though an electronic version of the document exists.

Relevant Sources

- O.C.G.A. § 31-33-8 (Electronic Records; Application to Psychiatric, Psychological, or Other Mental Health Records)
- O.C.G.A. § 31-33-1 (Definition of Patient, Provider, Record)
- O.C.G.A. § 10-12-12 (Retention of Electronic Records)
- O.C.G.A. § 10-12-2 (Definitions Relevant to Electronic Records)
- Ga. Comp. R. & Regs. 111-8-40-.18 (Rules and Regulations for Hospitals, Medical Records)
- 28 U.S.C. § 1732 (Record Made in Regular Course of Business; Photographic Copies) (photographic copies of business records or reproductions of electronic records are acceptable as evidence in federal court)
- Centers for Medicare & Medicaid Services, “Medical Record Retention and Media Formats for Medical Records,” MLN Matters, No. SE 1022 (2010), available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/se1022.pdf>(Medicare program does not have requirements for the media formats for medical records)

Appendix B:

Sample E-Mail Retention and Acceptable Use Policy

Intent

This policy establishes acceptable uses for e-mails, as well as retention practices for e-mail retained on active servers.

Scope

This retention policy applies to:

1. All e-mail systems and services provided or funded (in whole or in part) by the Health System;
2. All e-mail account users/holders at the Health System (both temporary and permanent); and
3. All e-mail messages sent or received using the Health System's e-mail systems.

Procedural Guidelines

A. General Provisions Regarding E-mails

1. **E-mail Privileges:** E-mail is a critical mechanism for business communications at the Health System. However, use of the Health System's e-mail systems and services are a privilege, not a right, and therefore must be used with respect and in accordance with the goals of the Health System. This policy outlines appropriate and inappropriate use of the Health System's e-mail systems and services in order to minimize disruptions to services and activities. This policy also defines the e-mail retention strategy at the Health System. All associates who use electronic forms of communication should familiarize themselves with this policy.
2. **Account Activation:** E-mail access at the Health System is controlled through individual accounts and passwords. Each user of the Health System's e-mail system is required to read a copy of this E-mail Retention and Acceptable Use Policy prior to receiving an e-mail access account and password. It is the responsibility of the associate to protect the confidentiality of their account and password information. Only a subset of associates of the Health System will receive an e-mail account. E-mail accounts may be granted to third-party non-employees (for example, temporary contract workers) on a case-by-case basis.
3. **General Expectations of Users:** The Health System often delivers important communications via e-mail. As a result, associates of the Health System with e-mail accounts are expected to check their e-mail in a consistent and timely manner so that they are aware of important Health System announcements and updates, as well as for fulfilling business and role-oriented tasks. E-mail users are responsible for mailbox management, including organization and cleaning. If a user subscribes to a mailing list, he or she must be aware of how to unsubscribe from the list and is responsible for doing so in the event that his or her current e-mail address changes.

4. **Access Termination:** The Health System may terminate e-mail access at any time for any reason, including but not limited to disciplinary reasons as outlined in this policy. E-mail access will be terminated when the associate or third party terminates his or her association with the Health System, unless other arrangements are made. The Health System is under no obligation to store or forward the contents of an individual's e-mail inbox/outbox after access is terminated or after the term of his or her employment has ceased.

B. Appropriate Use Standards

1. **E-mail as Business Tool:** Associates at the Health System are encouraged to use e-mail to further the goals and objectives of the Health System. The types of activities that are encouraged include:
 - a. Communicating with fellow associates, business associates of the Health System, and clients within the context of an individual's assigned responsibilities.
 - b. Acquiring or sharing information necessary or related to the performance of an individual's assigned responsibilities.
 - c. Participating in educational or professional development activities.
2. **Professionalism and Courtesy:** E-mail users are expected to remember that e-mail sent from the Health System's e-mail accounts reflects on the Health System. E-mail users must maintain a high degree of professional and personal courtesy and conduct. The Health System's policies against discrimination, sexual harassment and any other kind of unlawful harassment apply fully to the e-mail system.
3. **Discretion in Communications and HIPAA:** Keep in mind that all e-mail messages sent outside of the Health System may continue to exist for decades. Therefore, a good rule is not to communicate anything that you would not feel comfortable being made public. Demonstrate particular care when using the "Reply All" command during e-mail correspondence to ensure the resulting message is not delivered to unintended recipients. Use caution when communicating confidential or sensitive information via e-mail, and ensure that all communications comply with the Health System's policies on protected health information under HIPAA.
4. **System Conservation:** The Health System's e-mail systems and services are not to be used for purposes that could be reasonably expected to strain storage or bandwidth (for example e-mailing large attachments instead of pointing to a location on a shared drive). Individual e-mail use will not interfere with others' use and enjoyment of the Health System's e-mail system and services.
5. **Inappropriate Use:** The following activities are deemed inappropriate uses of the Health System's e-mail systems and services, and are strictly prohibited:
 - a. Use of e-mail for illegal or unlawful purposes, including copyright infringement, obscenity, libel, slander, fraud, defamation, plagiarism, harassment, intimidation, forgery, impersonation, soliciting for illegal pyramid schemes, and computer tampering (for example, spreading of computer viruses).

- b. Use of e-mail in any way that violates the Health System's policies, rules, or administrative orders.
 - c. Viewing, copying, altering, or deletion of e-mail accounts or files belonging to the Health System or another individual without authorized permission.
 - d. Sending of unreasonably large e-mail attachments. The total size of an individual e-mail message sent (including attachment) should be 10 MB or less.
 - e. Opening e-mail attachments from unknown or unsigned sources. Attachments are the primary source of computer viruses and should be treated with utmost caution.
 - f. Sharing e-mail account passwords with another person, or attempting to obtain another person's e-mail account password. E-mail accounts are only to be used by the registered user.
 - g. Excessive personal use of the Health System e-mail resources. The Health System allows limited personal use for communication with family and friends, independent learning, and public service so long as it does not interfere with staff productivity, pre-empt any business activity, or consume more than a trivial amount of resources.
 - h. The Health System prohibits personal use of its e-mail systems and services for unsolicited mass mailings, non-Health System commercial activity, political campaigning, and dissemination of chain letters.
 - i. Transmittal of offensive, threatening or discriminatory statements or language that disparages others including, but not limited to, messages based on race, national origin, gender, sexual orientation, age, disability, religion, or any other characteristic protected by law.
 - j. Sending or soliciting sexually oriented, obscene, or pornographic messages or images.
 - k. Expression of personal opinions in blogs, e-mails, or on the internet using Health System credentials unless the user has obtained prior consent from the Health System.
6. **Personal E-mail Accounts:** Associates may not utilize personal e-mail accounts (e.g., gmail, yahoo, etc.) to conduct Health System business or to transmit Health System or patient information. If Health System related matters are transmitted on a personal e-mail accounts, the Associate will provide the Health System, upon discovery and demand, access to all personal e-mail accounts for the purpose of retrieving Health System-related e-mails.

C. Retention

1. **Retention by Exception:** E-mail is not a document storage system. E-mail should only be retained if: (i) it has lasting value criteria due to the nature of the content; (ii) there is a formal legal hold initiated by the Health System in accordance with this Policy; (iii) a legal requirement necessitates retention; or (iv) the e-mail is subject to the retention periods set forth in the Health System's document retention schedule. Data files on the Health System's network should be managed by the owner/creator of the files according to the Health System's retention policies.

2. **Alternative Storage Prohibited:** Saving e-mails to locations other than the Health System's network is not authorized. Likewise, saving e-mails as a message file (.msg) is not authorized and is against the spirit of this guideline.
3. **Default Retention Periods:** E-mails and attachments that are retained on active e-mail services for longer than ____ days will be automatically deleted. This auto-delete policy applies to messages within all e-mail folders (inbox, sent items, outbox, drafts, personal, etc.) stored on active e-mail servers. Except for e-mails that are saved on the Health System's network, the Health System will not retain e-mail past ____ days in any form: no local copies, no backups, and no archive.
4. **Deleted E-mail Folder:** E-mails and attachments that are retained by users in the "deleted items" folder on active e-mail services for longer than ____ days will be automatically deleted.
5. **Storage Limits:** In addition to the automatic deletion schedules, the Health System may in its discretion establish individual user account storage limitations for excessive e-mails on active e-mail services that are less than ____ days old. Upon reaching the storage limitation, the user will be required to manually delete e-mails from the active e-mail services in order to free space for new e-mails.
6. **Litigation Hold:** When certain types of litigation are pending or threatened against the Health System or its associates, the Health System may be required to preserve documents and records that pertain to the issues. The issuance of a litigation hold is dependent upon many factors and will generally involve input and consultation from outside counsel. A litigation hold directive must be issued to the legal custodians of those documents by the Health System's Compliance Officer or General Counsel. A litigation hold directive overrides this policy, as well as any records destruction schedules or policies that may have otherwise called for the transfer, disposal or destruction of relevant documents, until the hold has been cleared by the Health System's Compliance Officer or General Counsel. E-mails and accounts of terminated associates that have been placed on litigation hold status will be maintained by the Information Services Department until the hold is released. No associate who has received a litigation hold directive may alter or delete an electronic record that falls within the scope of that hold. Those associates are required to provide access to or copies of electronic records that they have downloaded, saved, or moved to some other storage account or device.

D. Monitoring and Confidentiality

1. **No Expectation of Privacy:** The e-mail systems and services used at the Health System are owned by the Health System and are therefore the Health System's property. This gives the Health System the right to monitor any and all e-mail traffic passing through its e-mail system. The Health System, in its discretion as owner of the e-mail system, reserves and may exercise the right to monitor, access, retrieve, and delete any matter stored in, created, received, or sent over the e-mail system, for any reason and without the permission of any employee. This monitoring may include, but is not limited to, inadvertent reading by

information services staff during the normal course of managing the e-mail system, review by the legal team during the e-mail discovery phase of litigation, observation by management in cases of suspected abuse or to monitor associate efficiency. Associates have no reasonable expectation of privacy when it comes to business and personal use of the Health System's e-mail system.

2. **Access Limited:** Even though the Health System has the right to retrieve and read any e-mail messages, those messages should still be treated as confidential by other employees and accessed only by the intended recipient. Employees are not authorized to retrieve or read any e-mail messages that are not sent to them. Any exception to this policy must receive prior approval.
3. **Confidential, Proprietary, and Protected Health Information:** Unless authorized to do so, associates are prohibited from using e-mail to transmit confidential information to outside parties. Associates may not access, send, receive, solicit, print, copy or reply to confidential or proprietary information about the Health System, its employees, clients, suppliers, and other business associates. Confidential information includes, but is not limited to, client lists, credit card numbers, Social Security numbers, associate performance reviews, salary details, trade secrets, passwords, and information that could embarrass the Health System and its associates if the information were disclosed to the public. All communications involving protected health information of patients must adhere to the Health System's policies and procedures on HIPAA.

E. Failure to Comply

Violations of this policy will be treated like other infractions at the Health System. Allegations of misconduct will be adjudicated according to established procedures. Sanctions for inappropriate use on the Health System's e-mail systems and services may include, but are not limited to, one or more of the following:

1. Temporary or permanent revocation of e-mail access;
2. Disciplinary action according to applicable Health System policies;
3. Termination of employment; or
4. Legal action according to applicable laws and contractual agreements.

F. Acknowledgement

I acknowledge that I have read and understand the Health System's E-mail Retention and Acceptable Use Policy. If I have any questions about this Policy, I will seek clarification from the Human Resources Department.

I understand that my use of the Health System's e-mail and internet systems constitutes my consent to, and full understanding of, all the terms and conditions of this Policy. In particular, I understand that (1) the e-mail system and internet system and all information transmitted by, received from, or stored in these systems is the property of the Health System, and (2) I have no expectation of privacy in connection with the use of these

DOCUMENT RETENTION SCHEDULE

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systems or with the transmission, receipt, or storage of information in these systems. I acknowledge and consent to the Health System's monitoring of my use of the e-mail system and the internet at any time at its discretion, including printing and reading all e-mails entering, leaving, or stored in the system.

Signature: _____

Date: _____

Print Name: _____

Appendix C:

**Sample Legal Hold Memorandum
(Attached)**

Confidential, Attorney-Health System Privileged,
and Work Product Protected

SAMPLE LEGAL HOLD MEMORANDUM

[HEALTH SYSTEM LETTERHEAD]

TO: Distribution List (Attached)
FROM: [Health System Representative]
CC: [Legal Hold Attorney]
DATE: [Date]
RE: **URGENT:** Legal Hold in connection with [Matter]

We need your assistance to meet our legal obligation to preserve all potentially relevant information—in any form, be it electronic or paper—in connection with the above-referenced [Matter]. This memorandum institutes what is called a “legal hold.” Please review the following carefully and, until further notice, adhere to the outlined legal hold policy. **If you do not abide by the legal hold, [Health System] could be exposed to severe penalties for failing to preserve potentially relevant information to the [Matter].**

At the end of this memorandum, there is an acknowledgment form that we need for you to complete, sign, and return via fax or e-mail by no later than **[Date + One Week]** certifying that you have read and understand your obligations as outlined in this memorandum.

1. What Must be Preserved

Here are the categories of “documents” that we need you to preserve—*i.e.*, protect from deletion:

- a. Any and all documents about... [Define categories broadly]
- b. ...

These categories are broad. That is by design. In applying this policy, if you are unsure about whether something falls within the above categories, please preserve it. **It is better to be over-inclusive than under-inclusive when it comes to preserving potentially relevant data.**

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We are using the term “documents” very broadly. “Documents” means not only hard copy documents, but also electronic data, including e-mail, instant messages, text messages, voice-mail, word processing documents, spreadsheets, databases, calendars, contact messenger information, audio recordings, video recordings, and all other kinds of electronic information. In short, it includes anything that contains or conveys information.

In that regard, we need you to preserve the above-referenced categories of documents, no matter where or how they are stored. They could be located within hard copy files, computer hard drives, removable media (e.g., CDs, DVDs, and USB or “thumb” drives), laptop or desktop computers, networked servers and drives, back-up tapes or drives, PDAs, Smart Phones (e.g., iPhones or Android Phones), Tablets (e.g., iPads or Microsoft Surfaces), and any other locations where hard copy and electronic data is stored. The information may also be stored on the Internet—either in cloud storage (e.g., Google Docs, Box, or DropBox), social media (e.g., Facebook, LinkedIn, Twitter, Salesforce, etc.) or company or private e-mail accounts (e.g., Yahoo! Mail, gMail, Hotmail).

2. How to Preserve

As of now, any documents or data that falls within the categories listed above must be preserved. This means not only being careful not to affirmatively delete any documents or data that fall within the categories listed above, but taking steps to make sure that nothing is deleted automatically. [Identify any known “custodial” operations that could impact documents that need to be preserved.] And be careful not to alter the data by saving it to a new location—the idea is to “preserve it in place.”

Please note that our preservation obligation applies to all versions of a document, regardless of the format. For example, if a particular document exists in both hard copy and in e-mail, both versions must be saved. Similarly, if the same document resides in the files of more than one person, each person’s copy must be preserved.

Regarding instant messages and text messages, as noted above, you should save any instant messages or text messages containing information that falls within the categories of information that must be preserved, identified above. Going forward, however, please do not engage in any text or instant messaging conversations about this matter or that would fall within one of the categories listed above. If you happen to receive a text or instant message that would fall within this legal hold, please copy the text of that message into an e-mail and

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respond to it via e-mail. That way, we are able to properly preserve those conversations.

Regarding information on personal e-mail accounts, if you use or have ever used personal internet e-mail accounts, such as gMail, Hotmail, or Yahoo!, for [Health System's] business purposes, please indicate that in the space provided on the acknowledgment form so that we can take the requisite steps to preserve any potentially relevant material stored on those accounts.

3. Distribution of this Legal Hold memorandum

This Legal Hold Memorandum is being sent to you because you have been identified as someone who may have documents relevant to [Matter]. If, after a diligent search, you do not have any relevant documents in your possession, custody, or control, please notify me via e-mail.

Also, please take a moment to review the attached Distribution List. If there are other employees whom you believe may also possess documents or evidence related to [the Matter] but who are not identified on the Distribution List, please advise me immediately.

4. Other Instructions

Please do NOT discuss (either in person, by telephone, by e-mail, or by text message) the [Matter] amongst yourselves or with any third party without prior approval from the legal team. **Unless a member of the legal team is involved in such discussions, those conversations may not be protected by any privilege, and so the people involved may be required to testify about what they remember having been said.** Since memories may differ, if our personnel are later called upon to testify as witnesses, this can lead to needless doubts about their credibility. Be aware that anything you say about this dispute other than with the legal team may be introduced into evidence, so please conduct yourself accordingly.

5. Reminders

Please note that, until the hold gets lifted, you will get a "reissue notice" on a quarterly basis simply to remind you of the ongoing preservation obligation. When you receive this reissue notice, no further action is required other than continuing to comply with the legal hold.

[Matter] Legal Hold Memo
[Date]

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and Work Product Protected

Thank you for your cooperation regarding this important matter. As always, if you have any questions, please do not hesitate to contact me or our outside legal counsel:

- [Attorney Name—Phone Number—E-mail Address]

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Acknowledgment Form

****Please return by fax or e-mail by [Date + One Week]****

To: [Health System]

Fax No.: [Health System Fax?]

E-Mail: [\[Health System E-mail\]](#)

From: _____

(Please print your full name here)

This acknowledges that I have read the Legal Hold Memorandum dated [Date], and that I understand and will comply with the obligations outlined therein with respect to [Matter].

Signature: _____

(Please sign here)

1. I believe that the following employees, not listed on the Distribution List, may possess documents or evidence relevant to this lawsuit:
2. I _____ (have or have never) used a personal e-mail account for [Health System's] business purposes.
3. I _____ (do or do not) have voice-mails, instant messages, or text messages containing information that falls within the categories of information that must be preserved, identified above.
4. I _____ (do or do not) have information that falls within the categories of information that must be preserved, identified above, that is stored on the Internet (a/k/a "The Cloud")—*e.g.*, Google Docs, Dropbox, Evernote, Salesforce.com.

Appendix D:**Legal Citations****UNITED STATES CODE****11 U.S.C. § 351. Disposal of patient records**

If a health care business commences a case under chapter 7, 9, or 11, and the trustee does not have a sufficient amount of funds to pay for the storage of patient records in the manner required under applicable Federal or State law, the following requirements shall apply:

(1) The trustee shall--

(A) promptly publish notice, in 1 or more appropriate newspapers, that if patient records are not claimed by the patient or an insurance provider (if applicable law permits the insurance provider to make that claim) by the date that is 365 days after the date of that notification, the trustee will destroy the patient records; and

(B) during the first 180 days of the 365-day period described in subparagraph (A), promptly attempt to notify directly each patient that is the subject of the patient records and appropriate insurance carrier concerning the patient records by mailing to the most recent known address of that patient, or a family member or contact person for that patient, and to the appropriate insurance carrier an appropriate notice regarding the claiming or disposing of patient records.

(2) If, after providing the notification under paragraph (1), patient records are not claimed during the 365-day period described under that paragraph, the trustee shall mail, by certified mail, at the end of such 365-day period a written request to each appropriate Federal agency to request permission from that agency to deposit the patient records with that agency, except that no Federal agency is required to accept patient records under this paragraph.

(3) If, following the 365-day period described in paragraph (2) and after providing the notification under paragraph (1), patient records are not claimed by a patient or insurance provider, or request is not granted by a Federal agency to deposit such records with that agency, the trustee shall destroy those records by--

(A) if the records are written, shredding or burning the records; or

(B) if the records are magnetic, optical, or other electronic records, by otherwise destroying those records so that those records cannot be retrieved.

15 U.S.C. § 15b. Limitation of actions.

Any action to enforce any cause of action under section 4, 4A, or 4C [15 USCS § 15, 15a, or 15c] shall be forever barred unless commenced within four years after the cause of action accrued. No cause of action barred under existing law on the effective date of this Act shall be revived by this Act.

15 U.S.C.A. § 1681b. Permissible purposes of consumer reports.

(b) *Conditions for furnishing and using consumer reports for employment purposes*

(1) *Certification from user*

A consumer reporting agency may furnish a consumer report for employment purposes only if--

(A) the person who obtains such report from the agency certifies to the agency that--

(i) the person has complied with paragraph (2) with respect to the consumer report, and the person will comply with paragraph (3) with respect to the consumer report if paragraph (3) becomes applicable; and

(ii) information from the consumer report will not be used in violation of any applicable Federal or State equal employment opportunity law or regulation; and

(B) the consumer reporting agency provides with the report, or has previously provided, a summary of the consumer's rights under this subchapter, as prescribed by the Bureau under section 1681g(c)(3) of this title.

(2) *Disclosure to consumer*

(A) *In general*

Except as provided in subparagraph (B), a person may not procure a consumer report, or cause a consumer report to be procured, for employment purposes with respect to any consumer, unless--

(i) a clear and conspicuous disclosure has been made in writing to the consumer at any time before the report is procured or caused to be procured, in a document that consists solely of the disclosure, that a consumer report may be obtained for employment purposes; and

(ii) the consumer has authorized in writing (which authorization may be made on the document referred to in clause (i)) the procurement of the report by that person.

(B) *Application by mail, telephone, computer, or other similar means*

If a consumer described in subparagraph (C) applies for employment by mail, telephone, computer, or other similar means, at any time before a consumer report is procured or caused to be procured in connection with that application--

(i) the person who procures the consumer report on the consumer for employment purposes shall provide to the consumer, by oral, written, or electronic means, notice that a consumer report may be obtained for employment purposes, and a summary of the consumer's rights under section 1681m(a)(3) of this title; and

(ii) the consumer shall have consented, orally, in writing, or electronically to the procurement of the report by that person.

15 U.S.C.A. § 1681p. Jurisdiction of courts; limitation of actions.

An action to enforce any liability created under this subchapter may be brought in any appropriate United States district court, without regard to the amount in controversy, or in any other court of competent jurisdiction, not later than the earlier of--

(1) 2 years after the date of discovery by the plaintiff of the violation that is the basis for such liability; or

(2) 5 years after the date on which the violation that is the basis for such liability occurs.

16 U.S.C. § 1538. Prohibited acts.

(a) *Generally.*

(1) Except as provided in sections 6(g)(2) and 10 of this Act [16 USCS §§ 1535(g)(2), 1539], with respect to any endangered species of fish or wildlife listed pursuant to section 4 of this Act [16 USCS § 1533] it is unlawful for any person subject to the jurisdiction of the United States to--

- (A) import any such species into, or export any such species from the United States;
- (B) take any such species within the United States or the territorial sea of the United States;
- (C) take any such species upon the high seas;
- (D) possess, sell, deliver, carry, transport, or ship, by any means whatsoever, any such species taken in violation of subparagraphs (B) and (C);
- (E) deliver, receive, carry, transport, or ship in interstate or foreign commerce, by any means whatsoever and in the course of a commercial activity, any such species;
- (F) sell or offer for sale in interstate or foreign commerce any such species; or
- (G) violate any regulation pertaining to such species or to any threatened species of fish or wildlife listed pursuant to section 4 of this Act [16 USCS § 1533] and promulgated by the Secretary pursuant to authority provided by this Act.

(2) Except as provided in sections 6(g)(2) and 10 of this Act [16 USCS §§ 1535(g)(2), 1539], with respect to any endangered species of plants listed pursuant to section 4 of this Act [16 USCS § 1533], it is unlawful for any person subject to the jurisdiction of the United States to--

- (A) import any such species into, or export any such species from, the United States;
- (B) remove and reduce to possession any such species from areas under Federal jurisdiction; maliciously damage or destroy any such species on any such area; or remove, cut, dig up, or damage or destroy any such species on any other area in knowing violation of any law or regulation of any State or in the course of any violation of a State criminal trespass law;
- (C) deliver, receive, carry, transport, or ship in interstate or foreign commerce, by any means whatsoever and in the course of a commercial activity, any such species;
- (D) sell or offer for sale in interstate or foreign commerce any such species; or
- (E) violate any regulation pertaining to such species or to any threatened species of plants listed pursuant to section 4 of this Act [16 USCS § 1533] and promulgated by the Secretary pursuant to authority provided by this Act.

18 U.S.C. § 3282. Offenses not capital.

(a) *In general.* Except as otherwise expressly provided by law, no person shall be prosecuted, tried, or punished for any offense, not capital, unless the indictment is found or the information is instituted within five years next after such offense shall have been committed.

(b) DNA profile indictment.

(1) In general. In any indictment for an offense under chapter 109A [18 USCS §§ 2241 et seq.] for which the identity of the accused is unknown, it shall be sufficient to describe the accused as an individual whose name is unknown, but who has a particular DNA profile.

(2) Exception. Any indictment described under paragraph (1), which is found not later than 5 years after the offense under chapter 109A [18 USCS §§ 2241 et seq.] is committed, shall not be subject to--

(A) the limitations period described under subsection (a); and

(B) the provisions of chapter 208 [18 USCS §§ 3161 et seq.] until the individual is arrested or served with a summons in connection with the charges contained in the indictment.

(3) Defined term. For purposes of this subsection, the term "DNA profile" means a set of DNA identification characteristics.

21 U.S.C. § 827. Records and reports of registrants.

(a) *Inventory.* Except as provided in subsection (c)—

(1) every registrant under this subchapter shall, on May 1, 1971, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this subchapter manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after May 1, 1971, every registrant under this subchapter manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) *Availability of records.* Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General

26 U.S.C. § 6501. Limitations on assessment and collection.

(a) *General rule.* Except as otherwise provided in this section, the amount of any tax imposed by this title shall be assessed within 3 years after the return was filed (whether or not

such return was filed on or after the date prescribed) or, if the tax is payable by stamp, at any time after such tax became due and before the expiration of 3 years after the date on which any part of such tax was paid, and no proceeding in court without assessment for the collection of such tax shall be begun after the expiration of such period. For purposes of this chapter, the term “return” means the return required to be filed by the taxpayer (and does not include a return of any person from whom the taxpayer has received an item of income, gain, loss, deduction, or credit).

(b) *Time return deemed filed.*

(1) *Early return.* For purposes of this section, a return of tax imposed by this title, except tax imposed by chapter 3, 4, 21, or 24, filed before the last day prescribed by law or by regulations promulgated pursuant to law for the filing thereof, shall be considered as filed on such last day.

(2) *Return of certain employment and withholding taxes.* For purposes of this section, if a return of tax imposed by chapter 3, 4, 21, or 24 for any period ending with or within a calendar year is filed before April 15 of the succeeding calendar year, such return shall be considered filed on April 15 of such calendar year.

(3) *Return executed by Secretary.* Notwithstanding the provisions of paragraph (2) of section 6020(b), the execution of a return by the Secretary pursuant to the authority conferred by such section shall not start the running of the period of limitations on assessment and collection.

(4) *Return of excise taxes.* For purposes of this section, the filing of a return for a specified period on which an entry has been made with respect to a tax imposed under a provision of subtitle D (including a return on which an entry has been made showing no liability for such tax for such period) shall constitute the filing of a return of all amounts of such tax which, if properly paid, would be required to be reported on such return for such period.

(c) *Exceptions.*

(1) *False return.* In the case of a false or fraudulent return with the intent to evade tax, the tax may be assessed, or a proceeding in court for collection of such tax may be begun without assessment, at any time.

(2) *Willful attempt to evade tax.* In case of a willful attempt in any manner to defeat or evade tax imposed by this title (other than tax imposed by subtitle A or B), the tax may be assessed, or a proceeding in court for the collection of such tax may be begun without assessment, at any time.

(3) *No return.* In the case of failure to file a return, the tax may be assessed, or a proceeding in court for the collection of such tax may be begun without assessment, at any time.

(4) *Extension by agreement.*

(A) *In general.* Where, before the expiration of the time prescribed for the assessment of any tax imposed by this title, except the estate tax provided in chapter 11, both the Secretary and the taxpayer have consented in writing to its assessment after such time, the tax may be assessed at any time prior to the expiration of the period agreed upon. The period so agreed upon may be extended by subsequent agreements in writing made before the expiration of the period previously agreed upon.

(B) *Notice to taxpayer of right to refuse or limit extension.* The Secretary shall notify the taxpayer of the taxpayer's right to refuse to extend the period of limitations, or to limit such extension to particular issues or to a particular period of time, on each occasion when the taxpayer is requested to provide such consent.

(5) *Tax resulting from changes in certain income tax or estate tax credits.* For special rules applicable in cases where the adjustment of certain taxes allowed as a credit against income taxes or estate taxes results in additional tax, see section 905(c) (relating to the foreign tax credit for income tax purposes) and section 2016 (relating to taxes of foreign countries, States, etc., claimed as credit against estate taxes).

(6) *Termination of private foundation status.* In the case of a tax on termination of private foundation status under section 507, such tax may be assessed, or a proceeding in court for the collection of such tax may be begun without assessment, at any time.

(7) *Special rule for certain amended returns.* Where, within the 60-day period ending on the day on which the time prescribed in this section for the assessment of any tax imposed by subtitle A for any taxable year would otherwise expire, the Secretary receives a written document signed by the taxpayer showing that the taxpayer owes an additional amount of such tax for such taxable year, the period for the assessment of such additional amount shall not expire before the day 60 days after the day on which the Secretary receives such document.

(8) *Failure to notify Secretary of certain foreign transfers.*

(A) *In general.* In the case of any information which is required to be reported to the Secretary pursuant to an election under section 1295(b) or under section 1298(f), 6038, 6038A, 6038B, 6038D, 6046, 6046A, or 6048, the time for assessment of any tax imposed by this title with respect to any tax return, event, or period to which such information relates shall not expire before the date which is 3 years after the date on which the Secretary is furnished the information required to be reported under such section.

(B) *Application to failures due to reasonable cause.* If the failure to furnish the information referred to in subparagraph (A) is due to reasonable cause and not willful neglect, subparagraph (A) shall apply only to the item or items related to such failure.

(9) *Gift tax on certain gifts not shown on return.* If any gift of property the value of which (or any increase in taxable gifts required under section 2701(d) which) is required to be shown on a return of tax imposed by chapter 12 (without regard to section 2503(b)), and is not shown on such return, any tax imposed by chapter 12 on such gift may be assessed, or a proceeding in court for the collection of such tax may be begun without assessment, at any time. The preceding sentence shall not apply to any item which is disclosed in such return, or in a statement attached to the return, in a manner adequate to apprise the Secretary of the nature of such item.

(10) *Listed transactions.* If a taxpayer fails to include on any return or statement for any taxable year any information with respect to a listed transaction (as defined in section 6707A(c)(2)) which is required under section 6011 to be included with such return or statement, the time for assessment of any tax imposed by this title with

respect to such transaction shall not expire before the date which is 1 year after the earlier of--

(A) the date on which the Secretary is furnished the information so required, or

(B) the date that a material advisor meets the requirements of section 6112 with respect to a request by the Secretary under section 6112(b) relating to such transaction with respect to such taxpayer.

(11) *Certain orders of criminal restitution.* In the case of any amount described in section 6201(a)(4), such amount may be assessed, or a proceeding in court for the collection of such amount may be begun without assessment, at any time.

(12) *Certain taxes attributable to partnership adjustments.* In the case of any partnership adjustment determined under subchapter C of chapter 63, the period for assessment of any tax imposed under chapter 2 or 2A which is attributable to such adjustment shall not expire before the date that is 1 year after--

(A) in the case of an adjustment pursuant to the decision of a court in a proceeding brought under section 6234, such decision becomes final, or

(B) in any other case, 90 days after the date on which the notice of the final partnership adjustment is mailed under section 6231.

(d) *Request for prompt assessment.* Except as otherwise provided in subsection (c), (e), or (f), in the case of any tax (other than the tax imposed by chapter 11 of subtitle B, relating to estate taxes) for which return is required in the case of a decedent, or by his estate during the period of administration, or by a corporation, the tax shall be assessed, and any proceeding in court without assessment for the collection of such tax shall be begun, within 18 months after written request therefor (filed after the return is made and filed in such manner and such form as may be prescribed by regulations of the Secretary) by the executor, administrator, or other fiduciary representing the estate of such decedent, or by the corporation, but not after the expiration of 3 years after the return was filed. This subsection shall not apply in the case of a corporation unless--

(1) (A) such written request notifies the Secretary that the corporation contemplates dissolution at or before the expiration of such 18-month period, (B) the dissolution is in good faith begun before the expiration of such 18-month period, and (C) the dissolution is completed;

(2) (A) such written request notifies the Secretary that a dissolution has in good faith been begun, and (B) the dissolution is completed; or

(3) a dissolution has been completed at the time such written request is made.

(e) *Substantial omission of items.* Except as otherwise provided in subsection (c)--

(1) *Income taxes.* In the case of any tax imposed by subtitle A--

(A) *General rule.* If the taxpayer omits from gross income an amount properly includible therein and--

(i) such amount is in excess of 25 percent of the amount of gross income stated in the return, or

(ii) such amount--

(I) is attributable to one or more assets with respect to which information is required to be reported under section 6038D (or would be so required if such section were applied without regard to the dollar threshold specified in subsection (a) thereof

and without regard to any exceptions provided pursuant to subsection (h)(1) thereof), and

(II) is in excess of \$ 5,000,

the tax may be assessed, or a proceeding in court for collection of such tax may be begun without assessment, at any time within 6 years after the return was filed.

(B) Determination of gross income. For purposes of subparagraph (A)-

(i) In the case of a trade or business, the term “gross income” means the total of the amounts received or accrued from the sale of goods or services (if such amounts are required to be shown on the return) prior to diminution by the cost of such sales or services;

(ii) An understatement of gross income by reason of an overstatement of unrecovered cost or other basis is an omission from gross income; and

(iii) In determining the amount omitted from gross income (other than in the case of an overstatement of unrecovered cost or other basis), there shall not be taken into account any amount which is omitted from gross income stated in the return if such amount is disclosed in the return, or in a statement attached to the return, in a manner adequate to apprise the Secretary of the nature and amount of such item

(C) *Constructive dividends*. If the taxpayer omits from gross income an amount properly includible therein under section 951(a), the tax may be assessed, or a proceeding in court for the collection of such tax may be done without assessing, at any time within 6 years after the return was filed.

(2) *Estate and gift taxes*. In the case of a return of estate tax under chapter 11 or a return of gift tax under chapter 12, if the taxpayer omits from the gross estate or from the total amount of the gifts made during the period for which the return was filed items includible in such gross estate or such total gifts, as the case may be, as exceed in amount 25 percent of the gross estate stated in the return or the total amount of gifts stated in the return, the tax may be assessed, or a proceeding in court for the collection of such tax may be begun without assessment, at any time within 6 years after the return was filed. In determining the items omitted from the gross estate or the total gifts, there shall not be taken into account any item which is omitted from the gross estate or from the total gifts stated in the return if such item is disclosed in the return, or in a statement attached to the return, in a manner adequate to apprise the Secretary of the nature and amount of such item.

(3) *Excise taxes*. In the case of a return of a tax imposed under a provision of subtitle D, if the return omits an amount of such tax properly includible thereon which exceeds 25 percent of the amount of such tax reported thereon, the tax may be assessed, or a proceeding in court for the collection of such tax may be begun without assessment, at any time within 6 years after the return is filed. In determining the amount of tax omitted on a return, there shall not be taken into account any amount of tax imposed by chapter 41, 42, 43, or 44 which is omitted from the return if the transaction giving rise to such tax is disclosed in the return, or in a statement attached to the return, in a manner adequate to apprise the Secretary of the existence and nature of such item.

(f) *Personal holding company tax.* If a corporation which is a personal holding company for any taxable year fails to file with its return under chapter 1 for such year a schedule setting forth--

(1) the items of gross income and adjusted ordinary gross income, described in section 543, received by the corporation during such year, and

(2) the names and addresses of the individuals who owned, within the meaning of section 544 (relating to rules for determining stock ownership), at any time during the last half of such year more than 50 percent in value of the outstanding capital stock of the corporation,

the personal holding company tax for such year may be assessed, or a proceeding in court for the collection of such tax may be begun without assessment, at any time within 6 years after the return for such year was filed.

(g) *Certain income tax returns of corporations.*

(1) *Trusts or partnerships.* If a taxpayer determines in good faith that it is a trust or partnership and files a return as such under subtitle A, and if such taxpayer is thereafter held to be a corporation for the taxable year for which the return is filed, such return shall be deemed the return of the corporation for purposes of this section.

(2) *Exempt organizations.* If a taxpayer determines in good faith that it is an exempt organization and files a return as such under section 6033, and if such taxpayer is thereafter held to be a taxable organization for the taxable year for which the return is filed, such return shall be deemed the return of the organization for purposes of this section.

(3) *DISC.* If a corporation determines in good faith that it is a DISC (as defined in section 992(a)) and files a return as such under section 6011(c)(2) and if such corporation is thereafter held to be a corporation which is not a DISC for the taxable year for which the return is filed, such return shall be deemed the return of a corporation which is not a DISC for purposes of this section.

(h) *Net operating loss carryback or capital loss carrybacks.* In the case of a deficiency attributable to the application to the taxpayer of a net operating loss carryback or a capital loss carryback (including deficiencies which may be assessed pursuant to the provisions of section 6213(b)(3)), such deficiency may be assessed at any time before the expiration of the period within which a deficiency for the taxable year of the net operating loss or net capital loss which results in such carryback may be assessed.

(i) *Foreign tax carrybacks.* In the case of a deficiency attributable to the application to the taxpayer of a carryback under section 904(c) (relating to carryback and carryover of excess foreign taxes) or under section 907(f) (relating to carryback and carryover of disallowed foreign oil and gas taxes), such deficiency may be assessed at any time before the expiration of one year after the expiration of the period within which a deficiency may be assessed for the taxable year of the excess taxes described in section 904(c) or 907(f) which result in such carryback.

(j) *Certain credit carrybacks.*

(1) *In general.* In the case of a deficiency attributable to the application to the taxpayer of a credit carryback (including deficiencies which may be assessed pursuant to the provisions of section 6213(b)(3)), such deficiency may be assessed at any time before the expiration of the period within which a deficiency for the taxable year of the unused credit which results in such carryback may be assessed, or with respect to any portion of a credit carryback from a taxable year attributable to a net operating loss carryback,

capital loss carryback, or other credit carryback from a subsequent taxable year, at any time before the expiration of the period within which a deficiency for such subsequent taxable year may be assessed.

(2) *Credit carryback defined.* For purposes of this subsection, the term "credit carryback" has the meaning given such term by section 6511(d)(4)(C).

(k) *Tentative carryback adjustment assessment period.* In a case where an amount has been applied, credited, or refunded under section 6411 (relating to tentative carryback and refund adjustments) by reason of a net operating loss carryback, a capital loss carryback, or a credit carryback (as defined in Section 6511(d)(4)(C)) to a prior taxable year, the period described in subsection (a) of this section for assessing a deficiency for such prior taxable year shall be extended to include the period described in subsection (h) or (j), whichever is applicable; except that the amount which may be assessed solely by reason of this subsection shall not exceed the amount so applied, credited, or refunded under section 6411, reduced by any amount which may be assessed solely by reason of subsection (h) or (j), as the case may be.

(1) *Special rule for chapter 42 and similar taxes.*

(1) *In general.* For purposes of any tax imposed by section 4912, by chapter 42 (other than section 4940), or by section 4975, the return referred to in this section shall be the return filed by the private foundation, plan, trust, or other organization (as the case may be) for the year in which the act (or failure to act) giving rise to liability for such tax occurred. For purposes of section 4940, such return is the return filed by the private foundation for the taxable year for which the tax is imposed.

(2) *Certain contributions to section 501(c)(3) organizations.* In the case of a deficiency of tax of a private foundation making a contribution in the manner provided in section 4942(g)(3) (relating to certain contributions to section 501(c)(3) organizations) attributable to the failure of a section 501(c)(3) organization to make the distribution prescribed by section 4942(g)(3), such deficiency may be assessed at any time before the expiration of one year after the expiration of the period within which a deficiency may be assessed for the taxable year with respect to which the contribution was made.

(3) *Certain set-asides described in section 4942(g)(2).* In the case of a deficiency attributable to the failure of an amount set aside by a private foundation for a specific project to be treated as a qualifying distribution under the provisions of section 4942(g)(2)(B)(ii), such deficiency may be assessed at any time before the expiration of 2 years after the expiration of the period within which a deficiency may be assessed for the taxable year to which the amount set aside relates.

(m) *Deficiencies attributable to election of certain credits.* The period for assessing a deficiency attributable to any election under section 30B(h)(9), 30C(e)(4), 30D(e)(4), 35(g)(11), 40(f), 43, 45B, 45C(d)(4), 45H(g), or 51(j) (or any revocation thereof) shall not expire before the date 1 year after the date on which the Secretary is notified of such election (or revocation).

(n) *Cross references.* For period of limitations for assessment and collection in the case of a joint income return filed after separate returns have been filed, see section 6013(b)(3) and (4).

28 U.S.C. § 2462. Time for commencing proceedings.

Except as otherwise provided by Act of Congress, an action, suit or proceeding for the enforcement of any civil fine, penalty, or forfeiture, pecuniary or otherwise, shall not be entertained unless commenced within five years from the date when the claim first accrued if,

within the same period, the offender or the property is found within the United States in order that proper service may be made thereon.

29 U.S.C. § 1027. Retention of records.

Every person subject to a requirement to file any report (including the documents described in subparagraphs (E) through (I) of section 1021(k) of this title) or to certify any information therefor under this title or who would be subject to such a requirement but for an exemption or simplified reporting requirement under section 1024(a)(2) or (3) of this title [29 USCS § 1024(a)(2) or (3)] shall maintain records on the matters of which disclosure is required which will provide in sufficient detail the necessary basic information and data from which the documents thus required may be verified, explained, or clarified, and checked for accuracy and completeness, and shall include vouchers, worksheets, receipts, and applicable resolutions, and shall keep such records available for examination for a period of not less than six years after the filing date of the documents based on the information which they contain, or six years after the date on which such documents would have been filed but for an exemption or simplified reporting requirement under section 1024(a)(2) or (3) of this title [29 USCS § 1024(a)(2) or (3)].

29 U.S.C.A. § 1059. Recordkeeping and reporting requirements.

(a)

(1) Except as provided by paragraph (2) every employer shall, in accordance with such regulations as the Secretary may prescribe, maintain records with respect to each of his employees sufficient to determine the benefits due or which may become due to such employees. The plan administrator shall make a report, in such manner and at such time as may be provided in regulations prescribed by the Secretary, to each employee who is a participant under the plan and who--

(A) requests such report, in such manner and at such time as may be provided in such regulations,

(B) terminates his service with the employer, or

(C) has a 1-year break in service (as defined in section 1053(b)(3)(A) of this title).

The employer shall furnish to the plan administrator the information necessary for the administrator to make the reports required by the preceding sentence. Not more than one report shall be required under subparagraph (A) in any 12-month period. Not more than one report shall be required under subparagraph (C) with respect to consecutive 1-year breaks in service. The report required under this paragraph shall be in the same form, and contain the same information, as periodic benefit statements under section 1025(a) of this title.

(2) If more than one employer adopts a plan, each such employer shall furnish to the plan administrator the information necessary for the administrator to maintain the records, and make the reports, required by paragraph (1). Such administrator shall maintain the records, and make the reports, required by paragraph (1).

(b) If any person who is required, under subsection (a), to furnish information or maintain records for any plan year fails to comply with such requirement, he shall pay to the Secretary a civil penalty of \$10 for each employee with respect to whom such failure occurs, unless it is shown that such failure is due to reasonable cause.

31 U.S.C. § 3731. False claims procedure.

- (b) A civil action under section 3730 may not be brought—
- (1) more than 6 years after the date on which the violation of section 3729 is committed, or
 - (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last.

33 U.S.C. § 1311. Effluent limitations.

(a) *Illegality of pollutant discharges except in compliance with law.* Except as in compliance with this section and sections 302, 306, 307, 318, 402, and 404 of this Act [33 USCS §§ 1312, 1316, 1317, 1328, 1342, 1344], the discharge of any pollutant by any person shall be unlawful.

33 U.S.C.A. § 1344. Permits for dredged or fill material

- (e) General permits on State, regional, or nationwide basis
- (1) In carrying out his functions relating to the discharge of dredged or fill material under this section, the Secretary may, after notice and opportunity for public hearing, issue general permits on a State, regional, or nationwide basis for any category of activities involving discharges of dredged or fill material if the Secretary determines that the activities in such category are similar in nature, will cause only minimal adverse environmental effects when performed separately, and will have only minimal cumulative adverse effect on the environment. Any general permit issued under this subsection shall (A) be based on the guidelines described in subsection (b)(1) of this section, and (B) set forth the requirements and standards which shall apply to any activity authorized by such general permit.
 - (2) No general permit issued under this subsection shall be for a period of more than five years after the date of its issuance and such general permit may be revoked or modified by the Secretary if, after opportunity for public hearing, the Secretary determines that the activities authorized by such general permit have an adverse impact on the environment or such activities are more appropriately authorized by individual permits.

42 U.S.C. § 1395cc. Agreements with providers of services; enrollment processes.

- (a) *Filing of agreements; eligibility for payment; charges with respect to items and services.*
- (1) Any provider of services (except a fund designated for purposes of section 1395f(g) and section 1395n(e) of this title) shall be qualified to participate under this subchapter and shall be eligible for payments under this subchapter if it files with the Secretary an agreement--
 - (I) in the case of a hospital or critical access hospital--
 - (i) to adopt and enforce a policy to ensure compliance with the requirements of section 1395dd of this title and to meet the requirements of such section,

(ii) to maintain medical and other records related to individuals transferred to or from the hospital for a period of five years from the date of the transfer, and

(iii) to maintain a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition,

42 U.S.C. § 2021. Cooperation with States.

(a) *Purpose.* It is the purpose of this section--

(1) to recognize the interests of the States in the peaceful uses of atomic energy, and to clarify the respective responsibilities under this Act [42 USCS §§ 2011 et seq.] of the States and the Commission with respect to the regulation of byproduct, source, and special nuclear materials;

(2) to recognize the need, and establish programs for, cooperation between the States and the Commission with respect to control of radiation hazards associated with use of such materials;

(3) to promote an orderly regulatory pattern between the Commission and State governments with respect to nuclear development and use and regulation of byproduct, source, and special nuclear materials;

(4) to establish procedures and criteria for discontinuance of certain of the Commission's regulatory responsibilities with respect to byproduct, source, and special nuclear materials, and the assumption thereof by the States;

(5) to provide for coordination of the development of radiation standards for the guidance of Federal agencies and cooperation with the States; and

(6) to recognize that, as the States improve their capabilities to regulate effectively such materials, additional legislation may be desirable.

(b) *Agreements with States.* Except as provided in subsection (c), the Commission is authorized to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission under chapters 6, 7, and 8, and section 161 of this Act [42 USCS §§ 2071 et seq., 2091 et seq., and 2111 et seq., and § 2201], with respect to any one or more of the following materials within the State:

(1) Byproduct materials (as defined in section 11(e) [42 USCS § 2014(e)]).

(2) Source materials.

(3) Special nuclear materials in quantities not sufficient to form a critical mass.

During the duration of such an agreement it is recognized that the State shall have authority to regulate the materials covered by the agreement for the protection of the public health and safety from radiation hazards.

(c) *Commission regulation of certain activities.* No agreement entered into pursuant to subsection (b) shall provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of--

(1) the construction and operation of any production or utilization facility or any uranium enrichment facility;

(2) the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;

(3) the disposal into the ocean or sea of byproduct, source, or special nuclear waste materials as defined in regulations or orders of the Commission;

(4) the disposal of such other byproduct, source, or special nuclear material as the Commission determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed of without a license from the Commission.

The Commission shall also retain authority under any such agreement to make a determination that all applicable standards and requirements have been met prior to termination of a license for byproduct material, as defined in section 11(e) (2) [42 USCS § 2014(e)(2)]. Notwithstanding any agreement between the Commission and any State pursuant to subsection (b), the Commission is authorized by rule, regulation, or order to require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license issued by the Commission.

(d) *Conditions.* The Commission shall enter into an agreement under subsection (b) of this section with any State if--

(1) The Governor of that State certifies that the State has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by the proposed agreement, and that the State desires to assume regulatory responsibility for such materials; and

(2) the Commission finds that the State program is in accordance with the requirements of subsection (c) and in all other respects compatible with the Commission's program for the regulation of such materials, and that the State program is adequate to protect the public health and safety with respect to the materials covered by the proposed agreement.

(e) *Publication in Federal Register; comment of interested persons.*

(1) Before any agreement under subsection (b) is signed by the Commission, the terms of the proposed agreement and of proposed exemptions pursuant to subsection (f) shall be published once each week for four consecutive weeks in the Federal Register; and such opportunity for comment by interested persons on the proposed agreement and exemptions shall be allowed as the Commission determines by regulation or order to be appropriate.

(2) Each proposed agreement shall include the proposed effective date of such proposed agreement or exemptions. The agreement and exemptions shall be published in the Federal Register within thirty days after signature by the Commission and the Governor.

(f) *Exemptions.* The Commission is authorized and directed, by regulation or order, to grant such exemptions from the licensing requirements contained in chapters 6, 7, and 8 [42 USCS §§ 2071 et seq. 2091 et seq., and 2111 et seq.], and from its regulations applicable to licensees as the Commission finds necessary or appropriate to carry out any agreement entered into pursuant to subsection (b) of this section.

(g) *Compatible radiation standards.* The Commission is authorized and directed to cooperate with the States in the formulation of standards for protection against hazards of radiation to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible.

(h) *Consultative, advisory, and miscellaneous functions of Administrator of Environmental Protection Agency.* [There is hereby established a Federal Radiation Council,

consisting of the Secretary of Health, Education, and Welfare, the Chairman of the Atomic Energy Commission, the Secretary of Defense, the Secretary of Commerce, the Secretary of Labor, or their designees, and such other members as shall be appointed by the President.] The Council [Administrator of the Environmental Protection Agency] shall consult qualified scientists and experts in radiation matters, including the President of the National Academy of Sciences, the Chairman of the National Committee on Radiation Protection and Measurement, and qualified experts in the field of biology and medicine and in the field of health physics. The Special Assistant to the President for Science and Technology, or his designee, is authorized to attend meetings, participate in the deliberations of, and to advise the Council [Administrator]. The Chairman of the Council [Administrator] shall be designated by the President, from time to time, from among the members of the Council [Administrator]. The Council [Administrator] shall advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States. The Council [Administrator] shall also perform such other functions as the President may assign to it by Executive order.

(i) *Inspections and other functions; training and other assistance.* The Commission in carrying out its licensing and regulatory responsibilities under this Act [42 USCS §§ 2011 et seq.] is authorized to enter into agreements with any State, or group of States, to perform inspections or other functions on a cooperative basis as the Commission deems appropriate. The Commission is also authorized to provide training, with or without charge, to employees of, and such other assistance to, any State or political subdivision thereof or group of States as the Commission deems appropriate. Any such provision or assistance by the Commission shall take into account the additional expenses that may be incurred by a State as a consequence of the State's entering into an agreement with the Commission pursuant to subsection (b).

(j) *Reserve power to terminate or suspend agreements; emergency situations; State nonaction on causes of danger; authority exercisable only during emergency and commensurate with danger.*

(1) The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State with which an agreement under subsection (b) has become effective, or upon request of the Governor of such State, may terminate or suspend all or part of its agreement with the State and reassert the licensing and regulatory authority vested in it under this Act [42 USCS §§ 2011 et seq.], if the Commission finds that (1) such termination or suspension is required to protect the public health and safety, or (2) the State has not complied with one or more of the requirements of this section. The Commission shall periodically review such agreements and actions taken by the States under the agreements to ensure compliance with the provisions of this section.

(2) The Commission, upon its own motion or upon request of the Governor of any State, may, after notifying the Governor, temporarily suspend all or part of its agreement with the State without notice or hearing if, in the judgment of the Commission:

(A) an emergency situation exists with respect to any material covered by such an agreement creating danger which requires immediate action to protect the health or safety of persons either within or outside the State, and

(B) the State has failed to take steps necessary to contain or eliminate the cause of the danger within a reasonable time after the situation arose.

A temporary suspension under this paragraph shall remain in effect only for such time as the emergency situation exists and shall authorize the Commission to exercise its authority only to the extent necessary to contain or eliminate the danger.

(k) *State regulation of activities for certain purposes.* Nothing in this section shall be construed to affect the authority of any State or local agency to regulate activities for purposes other than protection against radiation hazards.

(l) *Commission regulated activities; notice of filing; hearing.* With respect to each application for Commission license authorizing an activity as to which the Commission's authority is continued pursuant to subsection (c), the Commission shall give prompt notice to the State or States in which the activity will be conducted of the filing of the license application; and shall afford reasonable opportunity for State representatives to offer evidence, interrogate witnesses, and advise the Commission as to the application without requiring such representatives to take a position for or against the granting of the application.

(m) *Limitation of agreements and exemptions.* No agreement entered into under subsection (b), and no exemption granted pursuant to subsection (f), shall affect the authority of the Commission under subsection 161(b) or (i) [42 USCS § 2201(b) or (i)] to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data or to guard against the loss or diversion of special nuclear material. For purposes of subsection 161(i) [42 USCS § 2201(i)], activities covered by exemptions granted pursuant to subsection (f) shall be deemed to constitute activities authorized pursuant to this Act [42 USCS §§ 2011 et seq.]; and special nuclear material acquired by any person pursuant to such an exemption shall be deemed to have been acquired pursuant to section 53 [42 USCS § 2073].

(n) *"State" and "agreement" defined.* As used in this section, the term "State" means any State, Territory, or possession of the United States, the Canal Zone, Puerto Rico, and the District of Columbia. As used in this section, the term "agreement" includes any amendment to any agreement.

(o) *State compliance requirements: compliance with section 2113(b) of this title and health and environmental protection standards; procedures for licenses, rulemaking, and license impact analysis; amendment of agreements for transfer of State collected funds; proceedings duplication restriction; alternative requirements.* In the licensing and regulation of byproduct material, as defined in section 11(e)(2) of this Act [42 USCS § 2014(e)(2)], or of any activity which results in the production of byproduct material as so defined under an agreement entered into pursuant to subsection b., a State shall require--

(1) compliance with the requirements of subsection (b) of section 83 [42 USCS § 2113] (respecting ownership of byproduct material and land), and

(2) compliance with standards which shall be adopted by the State for the protection of the public health, safety, and the environment from hazards associated with such material which are equivalent, to the extent practicable, or more stringent than, standards adopted and enforced by the Commission for the same purpose, including requirements and standards promulgated by the Commission and the Administrator of the Environmental Protection Agency pursuant to sections 83, 84, and 275, [42 USCS §§ 2022, 2113, 2114] and

(3) procedures which--

- (A) in the case of licenses, provide procedures under State law which include--
- (i) an opportunity, after public notice, for written comments and a public hearing, with a transcript,
 - (ii) an opportunity for cross examination, and
 - (iii) a written determination which is based upon findings included in such determination and upon the evidence presented during the public comment period and which is subject to judicial review;
- (B) in the case of rulemaking, provide an opportunity for public participation through written comments or a public hearing and provide for judicial review of the rule;
- (C) require for each license which has a significant impact on the human environment a written analysis (which shall be available to the public before the commencement of any such proceedings) of the impact of such license, including any activities conducted pursuant thereto, on the environment, which analysis shall include--
- (i) an assessment of the radiological and nonradiological impacts to the public health of the activities to be conducted pursuant to such license;
 - (ii) an assessment of any impact on any waterway and groundwater resulting from such activities;
 - (iii) consideration of alternatives, including alternative sites and engineering methods, to the activities to be conducted pursuant to such license; and
 - (iv) consideration of the long-term impacts, including decommissioning, decontamination, and reclamation impacts, associated with activities to be conducted pursuant to such license, including the management of any byproduct material, as defined by section 11(e)(2) [42 USCS § 2014(e)(2)]; and
- (D) prohibit any major construction activity with respect to such material prior to complying with the provisions of subparagraph (C).

If any State under such agreement imposes upon any licensee any requirement for the payment of funds to such State for the reclamation or long-term maintenance and monitoring of such material, and if transfer to the United States of such material is required in accordance with section 83(b) of this Act [42 USCS § 2113(b)], such agreement shall be amended by the Commission to provide that such State shall transfer to the United States upon termination of the license issued to such licensee the total amount collected by such State from such licensee for such purpose. If such payments are required, they must be sufficient to ensure compliance with the standards established by the Commission pursuant to section 161(x) of this Act [42 USCS § 2201(x)]. No State shall be required under paragraph (3) to conduct proceedings concerning any license or regulation which would duplicate proceedings conducted by the Commission. In adopting requirements pursuant to paragraph (2) of this subsection with respect to sites at which ores are processed primarily for their source material content or which are used for the disposal of byproduct material as defined in section 11(e)(2) [42 USCS § 2014(e)(2)], the State may adopt alternatives (including, where appropriate, site-specific alternatives) to the requirements adopted and enforced by the Commission for the same purpose if, after notice and opportunity for public

hearing, the Commission determines that such alternatives will achieve a level of stabilization and containment of the sites concerned, and a level of protection for public health, safety, and the environment from radiological and nonradiological hazards associated with such sites, which is equivalent to, to the extent practicable, or more stringent than the level which would be achieved by standards and requirements adopted and enforced by the Commission for the same purpose and any final standards promulgated by the Administrator of the Environmental Protection Agency in accordance with section 275 [42 USCS § 2022]. Such alternative State requirements may take into account local or regional conditions, including geology, topography, hydrology and meteorology.

42 U.S.C. § 9601(35)(B). Reason to know.

- (i) *All appropriate inquiries.* To establish that the defendant had no reason to know of the matter described in subparagraph (A)(i), the defendant must demonstrate to a court that—
- (I) on or before the date on which the defendant acquired the facility, the defendant carried out all appropriate inquiries, as provided in clauses (ii) and (iv), into the previous ownership and uses of the facility in accordance with generally accepted good commercial and customary standards and practices; and
 - (II) the defendant took reasonable steps to—
 - (aa) stop any continuing release;
 - (bb) prevent any threatened future release; and
 - (cc) prevent or limit any human, environmental, or natural resource exposure to any previously released hazardous substance.
- (ii) *Standards and practices.* Not later than 2 years after January 11, 2002, the Administrator shall by regulation establish standards and practices for the purpose of satisfying the requirement to carry out all appropriate inquiries under clause (i).
- (iii) *Criteria.* In promulgating regulations that establish the standards and practices referred to in clause (ii), the Administrator shall include each of the following:
- (I) The results of an inquiry by an environmental professional.
 - (II) Interviews with past and present owners, operators, and occupants of the facility for the purpose of gathering information regarding the potential for contamination at the facility.
 - (III) Reviews of historical sources, such as chain of title documents, aerial photographs, building department records, and land use records, to determine previous uses and occupancies of the real property since the property was first developed.
 - (IV) Searches for recorded environmental cleanup liens against the facility that are filed under Federal, State, or local law.
 - (V) Reviews of Federal, State, and local government records, waste disposal records, underground storage tank records, and hazardous waste handling, generation, treatment, disposal, and spill records, concerning contamination at or near the facility.
 - (VI) Visual inspections of the facility and of adjoining properties.
 - (VII) Specialized knowledge or experience on the part of the defendant.
 - (VIII) The relationship of the purchase price to the value of the property, if the property was not contaminated.
 - (IX) Commonly known or reasonably ascertainable information about the property.

(X) The degree of obviousness of the presence or likely presence of contamination at the property, and the ability to detect the contamination by appropriate investigation.

(iv) *Interim standards and practices.*

(I) Property purchased before May 31, 1997. With respect to property purchased before May 31, 1997, in making a determination with respect to a defendant described in clause (i), a court shall take into account--

(aa) any specialized knowledge or experience on the part of the defendant;

(bb) the relationship of the purchase price to the value of the property, if the property was not contaminated;

(cc) commonly known or reasonably ascertainable information about the property;

(dd) the obviousness of the presence or likely presence of contamination at the property; and

(ee) the ability of the defendant to detect the contamination by appropriate inspection.

(II) Property purchased on or after May 31, 1997. With respect to property purchased on or after May 31, 1997, and until the Administrator promulgates the regulations described in clause (ii), the procedures of the American Society for Testing and Materials, including the document known as "Standard E1527-97", entitled "Standard Practice for Environmental Site Assessment: Phase 1 Environmental Site Assessment Process", shall satisfy the requirements in clause (i).

(v) *Site inspection and title search.* In the case of property for residential use or other similar use purchased by a nongovernmental or noncommercial entity, a facility inspection and title search that reveal no basis for further investigation shall be considered to satisfy the requirements of this subparagraph.

42 U.S.C. § 9607. Liability.

(a) *Covered persons; scope; recoverable costs and damages; interest rate; "comparable maturity" date.* Notwithstanding any other provision or rule of law, and subject only to the defenses set forth in subsection (b) of this section—

(3) any person who by contract, agreement, or otherwise arranged for disposal or treatment, or arranged with a transporter for transport for disposal or treatment, of hazardous substances owned or possessed by such person, by any other party or entity, at any facility or incineration vessel owned or operated by another party or entity and containing such hazardous substances, and

(4) [. . .] shall be liable for—

(A) all costs of removal or remedial action incurred by the United States Government or a State or an Indian tribe not inconsistent with the national contingency plan;

(B) any other necessary costs of response incurred by any other person consistent with the national contingency plan;

(C) damages for injury to, destruction of, or loss of natural resources, including the reasonable costs of assessing such injury, destruction, or loss resulting from such a release; and

(D) the costs of any health assessment or health effects study carried out under section 9604(i) of this title.

The amounts recoverable in an action under this section shall include interest on the amounts recoverable under subparagraphs (A) through (D). Such interest shall accrue from the later of (i) the date payment of a specified amount is demanded in writing, or (ii) the date of the expenditure concerned. The rate of interest on the outstanding unpaid balance of the amounts recoverable under this section shall be the same rate as is specified for interest on investments of the Hazardous Substance Superfund established under subchapter A of chapter 98 of Title 26. For purposes of applying such amendments to interest under this subsection, the term “comparable maturity” shall be determined with reference to the date on which interest accruing under this subsection commences.

CODE OF FEDERAL REGULATIONS

7 C.F.R. § 1c.115

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in § 1c.109(f)(1).

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in § 1c.108(a)(2).

(6) Written procedures for the IRB in the same detail as described in §§ 1c.108(a)(3) and (4).

(7) Statements of significant new findings provided to subjects, as required by § 1c.116(cb)(5).

(8) The rationale for an expedited reviewer's determination under § 1c.110(b)(1)(i) that research appearing on the expedited review list described in § 1c.110(a) is more than minimal risk.

(9) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in § 1c.103(e).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

8 C.F.R. § 274a.2. Verification of identity and employment authorization.

(a) *General.* This section establishes requirements and procedures for compliance by persons or entities when hiring, or when recruiting or referring for a fee, or when continuing to employ individuals in the United States.

(b) (2) *Retention and Inspection of Form I-9.* (i) A paper (with original handwritten signatures), electronic (with acceptable electronic signatures that meet the requirements of paragraphs (h) and (i) of this section or original paper scanned into an electronic format, or a combination of paper and electronic formats that meet the requirements of paragraphs (e), (f), and (g) of this section), or microfilm or microfiche copy of the original signed version of Form I-9 must be retained by an employer or a recruiter or referrer for a fee for the following time periods:

(A) In the case of an employer, three years after the date of the hire or one year after the date the individual's employment is terminated, whichever is later;

20 C.F.R. § 656.10. General instructions.

(f) Retention of documents. Copies of applications for permanent employment certification filed with the Department of Labor and all supporting documentation must be retained by the employer for 5 years from the date of filing the Application for Permanent Employment Certification.

20 C.F.R. § 655.56. Document retention requirements of H-2B employers.

(a) Entities required to retain documents. All employers filing an Application for Temporary Employment Certification requesting H-2B workers are required to retain the documents and records proving compliance with 29 CFR part 503 and this subpart, including but not limited to those specified in paragraph (c) of this section.

(b) Period of required retention. The employer must retain records and documents for 3 years from the date of certification of the Application for Temporary Employment Certification, or from the date of adjudication if the Application for Temporary Employment Certification is denied, or 3 years from the day the Department of Labor receives the letter of withdrawal provided in accordance with § 655.62. For the purposes of this section, records and documents required to be retained in connection with an H-2B Registration must be retained in connection with all of the Applications for Temporary Employment Certification that are supported by it.

(c) Documents and records to be retained by all employer applicants. All employers filing an H-2B Registration and an Application for Temporary Employment Certification must retain the following documents and records and must provide the documents and records to the Department of Labor and other Federal agencies in the event of an audit or investigation:

- (1) Documents and records not previously submitted during the registration process that substantiate temporary need;
- (2) Proof of recruitment efforts, as applicable, including:

- (i) Job order placement as specified in § 655.16;
- (ii) Contact with former U.S. workers as specified in § 655.43;
- (iii) Contact with bargaining representative(s), or a copy of the posting of the job opportunity, if applicable, as specified in § 655.45(a) or (b); and
- (iv) Additional employer-conducted recruitment efforts as specified in § 655.46;

(3) Substantiation of the information submitted in the recruitment report prepared in accordance with § 655.48, such as evidence of nonapplicability of contact with former workers as specified in § 655.43;

(4) The final recruitment report and any supporting resumes and contact information as specified in § 655.48;

(5) Records of each worker's earnings, hours offered and worked, location(s) of work performed, and other information as specified in § 655.20(i);

(6) If appropriate, records of reimbursement of transportation and subsistence costs incurred by the workers, as specified in § 655.20(j).

(7) Evidence of contact with U.S. workers who applied for the job opportunity in the Application for Temporary Employment Certification, including documents demonstrating that any rejections of U.S. workers were for lawful, job-related reasons, as specified in § 655.20(r);

(8) Evidence of contact with any former U.S. worker in the occupation at the place of employment in the Application for Temporary Employment Certification, including documents demonstrating that the U.S. worker had been offered the job opportunity in the Application for Temporary Employment Certification, as specified in § 655.20(w), and that the U.S. worker either refused the job opportunity or was rejected only for lawful, job-related reasons, as specified in § 655.20(r);

(9) The written contracts with agents or recruiters as specified in §§ 655.8 and 655.9, and the list of the identities and locations of persons hired by or working for the agent or recruiter and these entities' agents or employees, as specified in § 655.9;

(10) Written notice provided to and informing OFLC that an H-2B worker or worker in corresponding employment has separated from employment before the end date of employment specified in the Application for Temporary Employment Certification, as specified in § 655.20(y);

(11) The H-2B Registration, job order and a copy of the Application for Temporary Employment Certification and the original signed Appendix B of the Application. If the Application for Temporary Employment Certification and H-2B Registration is electronically filed, a printed copy of each adjudicated Application for Temporary Employment Certification, including any modifications, amendments or extensions must be signed by the employer as directed by the CO and retained;

(12) The H-2B Petition, including all accompanying documents; and

(13) Any collective bargaining agreement(s), individual employment contract(s), or payroll records from the previous year necessary to substantiate any claim that certain incumbent workers are not included in corresponding employment, as specified in § 655.5.

(d) Availability of documents for enforcement purposes. An employer must make available to the Administrator, WHD within 72 hours following a request by the WHD the

documents and records required under 29 CFR part 503 and this section so that the Administrator, WHD may copy, transcribe, or inspect them.

20 C.F.R. § 655.760. What records are to be made available to the public, and what records are to be retained?

Paragraphs (a)(1) thru (a)(6) and paragraphs (b) and (c) of this section also apply to the H-1B1 and E-3 visa categories.

(a) Public examination. The employer shall make a filed labor condition application and necessary supporting documentation available for public examination at the employer's principal place of business in the U.S. or at the place of employment within one working day after the date on which the labor condition application is filed with DOL. The following documentation shall be necessary:

(1) A copy of the certified labor condition application (Form ETA 9035E or Form ETA 9035) and cover pages (Form ETA 9035CP). If the Form ETA 9035E is submitted electronically, a printout of the certified application shall be signed by the employer and maintained in its files and included in the public examination file.

(2) Documentation which provides the wage rate to be paid the H-1B nonimmigrant;

(3) A full, clear explanation of the system that the employer used to set the “actual wage” the employer has paid or will pay workers in the occupation for which the H-1B nonimmigrant is sought, including any periodic increases which the system may provide—e.g., memorandum summarizing the system or a copy of the employer's pay system or scale (payroll records are not required, although they shall be made available to the Department in an enforcement action).

(4) A copy of the documentation the employer used to establish the “prevailing wage” for the occupation for which the H-1B nonimmigrant is sought (a general description of the source and methodology is all that is required to be made available for public examination; the underlying individual wage data relied upon to determine the prevailing wage is not a public record, although it shall be made available to the Department in an enforcement action); and

(5) A copy of the document(s) with which the employer has satisfied the union/employee notification requirements of § 655.734 of this part.

(6) A summary of the benefits offered to U.S. workers in the same occupational classifications as H-1B nonimmigrants, a statement as to how any differentiation in benefits is made where not all employees are offered or receive the same benefits (such summary need not include proprietary information such as the costs of the benefits to the employer, or the details of stock options or incentive distributions), and/or, where applicable, a statement that some/all H-1B nonimmigrants are receiving “home country” benefits (see § 655.731(c)(3));

(7) Where the employer undergoes a change in corporate structure, a sworn statement by a responsible official of the new employing entity that it accepts all obligations, liabilities and undertakings under the LCAs filed by the predecessor employing entity, together with a list of each affected LCA and its date of certification, and a description of the actual wage system and FEIN of the new employing entity (see § 655.730(e)(1)).

(8) Where the employer utilizes the definition of “single employer” in the IRC, a list of any entities included as part of the single employer in making the determination as to its H-1B-dependency status (see § 655.736(d)(7));

(9) Where the employer is H-1B-dependent and/or a willful violator, and indicates on the LCA(s) that only “exempt” H-1B nonimmigrants will be employed, a list of such “exempt” H-1B nonimmigrants (see § 655.737(e)(1));

(10) Where the employer is H-1B-dependent or a willful violator, a summary of the recruitment methods used and the time frames of recruitment of U.S. workers (or copies of pertinent documents showing this information) (see § 655.739(i)(4)).

[. . .]

(c) Retention of records. Either at the employer's principal place of business in the U.S. or at the place of employment, the employer shall retain copies of the records required by this subpart for a period of one year beyond the last date on which any H-1B nonimmigrant is employed under the labor condition application or, if no nonimmigrants were employed under the labor condition application, one year from the date the labor condition application expired or was withdrawn. Required payroll records for the H-1B employees and other employees in the occupational classification shall be retained at the employer's principal place of business in the U.S. or at the place of employment for a period of three years from the date(s) of the creation of the record(s), except that if an enforcement action is commenced, all payroll records shall be retained until the enforcement proceeding is completed through the procedures set forth in subpart I of this part.

21 C.F.R. § 56.115. IRB Records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

(6) Written procedures for the IRB as required by §56.108 (a) and (b).

(7) Statements of significant new findings provided to subjects, as required by §50.25.

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by

authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.

(c) The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the IRB that reviewed the investigation refuses to allow an inspection under this section.

21 C.F.R. § 58.195. Retention of records.

(a) Record retention requirements set forth in this section do not supersede the record retention requirements of any other regulations in this chapter.

(b) Except as provided in paragraph (c) of this section, documentation records, raw data and specimens pertaining to a nonclinical laboratory study and required to be made by this part shall be retained in the archive(s) for whichever of the following periods is shortest:

(1) A period of at least 2 years following the date on which an application for a research or marketing permit, in support of which the results of the nonclinical laboratory study were submitted, is approved by the Food and Drug Administration. This requirement does not apply to studies supporting investigational new drug applications (IND's) or applications for investigational device exemptions (IDE's), records of which shall be governed by the provisions of paragraph (b)(2) of this section.

(2) A period of at least 5 years following the date on which the results of the nonclinical laboratory study are submitted to the Food and Drug Administration in support of an application for a research or marketing permit.

(3) In other situations (e.g., where the nonclinical laboratory study does not result in the submission of the study in support of an application for a research or marketing permit), a period of at least 2 years following the date on which the study is completed, terminated, or discontinued.

(c) Wet specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids), samples of test or control articles, and specially prepared material, which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. In no case shall retention be required for longer periods than those set forth in paragraphs (a) and (b) of this section.

(d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by §58.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified in paragraphs (a) and (b) of this section.

(e) Summaries of training and experience and job descriptions required to be maintained by §58.29(b) may be retained along with all other testing facility employment records for the length of time specified in paragraphs (a) and (b) of this section.

(f) Records and reports of the maintenance and calibration and inspection of equipment, as required by §58.63(b) and (c), shall be retained for the length of time specified in paragraph (b) of this section.

(g) Records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

(h) If a facility conducting nonclinical testing goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of

the sponsor of the study. The Food and Drug Administration shall be notified in writing of such a transfer.

21 C.F.R. § 203.20. Sales restrictions.

Except as provided in §203.22 or §203.23, no person may sell, purchase, or trade, or offer to sell, purchase, or trade any prescription drug that was:

- (a) Purchased by a public or private hospital or other health care entity; or
- (b) Donated or supplied at a reduced price to a charitable organization.

21 C.F.R. § 203.23. Returns.

The return of a prescription drug purchased by a hospital or health care entity or acquired at a reduced price by or donated to a charitable institution is exempt from the prohibitions in §203.20, provided that:

- (a) The hospital, health care entity, or charitable institution documents the return by filling out a credit memo specifying:
 - (1) The name and address of the hospital, health care entity, or charitable institution;
 - (2) The name and address of the manufacturer or wholesale distributor from which it was acquired;
 - (3) The product name and lot or control number;
 - (4) The quantity returned; and
 - (5) The date of the return.
- (b) The hospital, health care entity, or charitable institution forwards a copy of each credit memo to the manufacturer and retains a copy of each credit memo for its records;
- (c) Any drugs returned to a manufacturer or wholesale distributor are kept under proper conditions for storage, handling, and shipping, and written documentation showing that proper conditions were maintained is provided to the manufacturer or wholesale distributor to which the drugs are returned.

21 C.F.R. § 312.62. Investigator recordkeeping and record retention.

(a) *Disposition of drug.* An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under §312.59.

(b) *Case histories.* An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.

(c) *Record retention.* An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or

if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

21 C.F.R. § 606.160. Records.

(a) (1) Records shall be maintained concurrently with the performance of each significant step in the collection, processing, compatibility testing, storage and distribution of each unit of blood and blood components so that all steps can be clearly traced. All records shall be legible and indelible, and shall identify the person performing the work, include dates of the various entries, show test results as well as the interpretation of the results, show the expiration date assigned to specific products, and be as detailed as necessary to provide a complete history of the work performed.

(2) Appropriate records shall be available from which to determine lot numbers of supplies and reagents used for specific lots or units of the final product.

(b) Records shall be maintained that include, but are not limited to, the following when applicable:

(1) Donor records:

(i) Donor selection, including medical interview and examination and where applicable, informed consent.

(ii) Permanent and temporary deferrals for health reasons including reason(s) for deferral.

(iii) Donor adverse reaction complaints and reports, including results of all investigations and follow up.

(iv) Therapeutic bleedings, including signed requests from attending physicians, the donor's disease and disposition of units.

(v) Immunization, including informed consent, identification of the antigen, dosage and route of administration.

(vi) Blood collection, including identification of the phlebotomist.

(vii) Records to relate the donor with the unit number of each previous donation from that donor.

(viii) Records concerning the following activities performed under §§ 610.46, 610.47, and 610.48 of this chapter: Quarantine; consignee notification; testing; notification of a transfusion recipient, the recipient's physician of record, or the recipient's legal representative; and disposition.

(ix) Records of notification of donors deferred or determined not to be suitable for donation, including appropriate followup if the initial attempt at notification fails, performed under § 630.6 of this chapter.

(x) The donor's address provided at the time of donation where the donor may be contacted within 8 weeks after donation.

(xi) Records of notification of the referring physician of a deferred autologous donor, including appropriate followup if the initial notification attempt fails, performed under § 630.6 of this chapter.

(2) Processing records:

(i) Blood processing, including results and interpretation of all tests and retests.

- (ii) Component preparation, including all relevant dates and times.
 - (iii) Separation and pooling of recovered plasma.
 - (iv) Centrifugation and pooling of source plasma.
 - (v) Labeling, including initials of the person(s) performing the procedure.
- (3) Storage and distribution records:
 - (i) Distribution and disposition, as appropriate, of blood and blood products.
 - (ii) Visual inspection of whole blood and red blood cells during storage and immediately before distribution.
 - (iii) Storage temperature, including initialed temperature recorder charts.
 - (iv) Reissue, including records of proper temperature maintenance.
 - (v) Emergency release of blood, including signature of requesting physician obtained before or after release.
- (4) Compatibility test records:
 - (i) Results of all compatibility tests, including cross-matching, testing of patient samples, antibody screening and identification.
 - (ii) Results of confirmatory testing.
- (5) Quality control records:
 - (i) Calibration and standardization of equipment.
 - (ii) Performance checks of equipment and reagents.
 - (iii) Periodic check on sterile technique.
 - (iv) Periodic tests of capacity of shipping containers to maintain proper temperature in transit.
 - (v) Proficiency test results.
- (6) Transfusion reaction reports and complaints, including records of investigations and follow-up.
- (7) General records:
 - (i) Sterilization of supplies and reagents prepared within the facility, including date, time interval, temperature and mode.
 - (ii) Responsible personnel.
 - (iii) Biological product deviations.
 - (iv) Maintenance records for equipment and general physical plant.
 - (v) Supplies and reagents, including name of manufacturer or supplier, lot numbers, expiration date and date of receipt.
 - (vi) Disposition of rejected supplies and reagents used in the collection, processing and compatibility testing of blood and blood components.
 - (vii) A donor number shall be assigned to each accepted donor, which relates the unit of blood collected to that donor, to his medical record, to any component or blood product from that donor's unit of blood,

and to all records describing the history and ultimate disposition of these products.

(c) Records shall be retained for such interval beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical reactions. You must retain individual product records no less than 10 years after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date. When there is no expiration date, records shall be retained indefinitely.

(d) A record shall be available from which unsuitable donors may be identified so that products from such individuals will not be distributed.

21 C.F.R. § 803.18. What are the requirements for establishing and maintaining MDR files or records that apply to me?

(a) If you are a user facility, importer, or manufacturer, you must establish and maintain MDR event files. You must clearly identify all MDR event files and maintain them to facilitate timely access.

(b) (1) For purposes of this part, “MDR event files” are written or electronic files maintained by user facilities, importers, and manufacturers. MDR event files may incorporate references to other information (e.g., medical records, patient files, engineering reports), in lieu of copying and maintaining duplicates in this file. Your MDR event files must contain:

(i) Information in your possession or references to information related to the adverse event, including all documentation of your deliberations and decision making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable under this part;

(ii) Copies of all reports submitted under this part (whether paper or electronic), and of all other information related to the event that you submitted to us or other entities such as an importer, distributor, or manufacturer; and

(iii) Copies of all electronic acknowledgments FDA sends you in response to electronic MDR submission.

(2) If you are a user facility, importer, or manufacturer, you must permit any authorized FDA employee, at all reasonable times, to access, to copy, and to verify the records required by this part.

(c) If you are a user facility, you must retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event. If you are a manufacturer or importer, you must retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. If the device is no longer distributed, you still must maintain MDR event files for the time periods described in this paragraph (c).

(d) (1) If you are a device distributor, you must establish and maintain device complaint records (files). Your records must contain any incident information, including any written, electronic, or oral communication, either received or generated by you, that alleges deficiencies related to the identity (e.g., labeling), quality, durability, reliability, safety, effectiveness, or performance of a device. You must also maintain information about your evaluation of the allegations, if any, in the incident record. You must clearly identify the records

as device incident records and file these records by device name. You may maintain these records in written or electronic format. You must back up any file maintained in electronic format.

(2) You must retain copies of the required device incident records for a period of 2 years from the date of inclusion of the record in the file or for a period of time equivalent to the expected life of the device, whichever is greater. You must maintain copies of these records for this period even if you no longer distribute the device.

(3) You must maintain the device complaint files established under this section at your principal business establishment. If you are also a manufacturer, you may maintain the file at the same location as you maintain your complaint file under part 820 of this chapter. You must permit any authorized FDA employee, at all reasonable times, to access, to copy, and to verify the records required by this part.

(e) If you are a manufacturer, you may maintain MDR event files as part of your complaint file, under part 820 of this chapter, if you prominently identify these records as MDR reportable events. We will not consider your submitted MDR report to comply with this part unless you evaluate an event in accordance with the quality system requirements described in part 820 of this chapter. You must document and maintain in your MDR event files an explanation of why you did not submit or could not obtain any information required by this part, as well as the results of your evaluation of each event.

21 C.F.R. § 812.140. Records.

(a) *Investigator records.* A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:

(1) All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.

(2) Records of receipt, use or disposition of a device that relate to:

(i) The type and quantity of the device, the dates of its receipt, and the batch number or code mark.

(ii) The names of all persons who received, used, or disposed of each device.

(iii) Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.

(3) Records of each subject's case history and exposure to the device. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. Such records shall include:

(i) Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. The case history for each individual shall document that informed consent was obtained prior to participation in the study.

(ii) All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information

and data on the condition of each subject upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests.

(iii) A record of the exposure of each subject to the investigational device, including the date and time of each use, and any other therapy.

(4) The protocol, with documents showing the dates of and reasons for each deviation from the protocol.

(5) Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.

(b) *Sponsor records.* A sponsor shall maintain the following accurate, complete, and current records relating to an investigation:

(1) All correspondence with another sponsor, a monitor, an investigator, an IRB, or FDA, including required reports.

(2) Records of shipment and disposition. Records of shipment shall include the name and address of the consignee, type and quantity of device, date of shipment, and batch number or code mark. Records of disposition shall describe the batch number or code marks of any devices returned to the sponsor, repaired, or disposed of in other ways by the investigator or another person, and the reasons for and method of disposal.

(3) Signed investigator agreements including the financial disclosure information required to be collected under §812.43(c)(5) in accordance with part 54 of this chapter.

(4) For each investigation subject to §812.2(b)(1) of a device other than a significant risk device, the records described in paragraph (b)(5) of this section and the following records, consolidated in one location and available for FDA inspection and copying:

(i) The name and intended use of the device and the objectives of the investigation;

(ii) A brief explanation of why the device is not a significant risk device:

(iii) The name and address of each investigator:

(iv) The name and address of each IRB that has reviewed the investigation:

(v) A statement of the extent to which the good manufacturing practice regulation in part 820 will be followed in manufacturing the device; and

(vi) Any other information required by FDA.

(5) Records concerning adverse device effects (whether anticipated or unanticipated) and complaints and

(6) Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigation or a particular investigation.

(c) *IRB records.* An IRB shall maintain records in accordance with part 56 of this chapter.

(d) *Retention period.* An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the

records are no longer required for purposes of supporting a premarket approval application, a notice of completion of a product development protocol, a humanitarian device exemption application, a premarket notification submission, or a request for De Novo classification.

(e) *Records custody.* An investigator or sponsor may withdraw from the responsibility to maintain records for the period required in paragraph (d) of this section and transfer custody of the records to any other person who will accept responsibility for them under this part, including the requirements of §812.145. Notice of a transfer shall be given to FDA not later than 10 working days after transfer occurs.

21 C.F.R. § 821.60. Retention of records.

Persons required to maintain records under this part shall maintain such records for the useful life of each tracked device they manufacture or distribute. The useful life of a device is the time a device is in use or in distribution for use. For example, a record may be retired if the person maintaining the record becomes aware of the fact that the device is no longer in use, has been explanted, returned to the manufacturer, or the patient has died.

21 C.F.R. § 900.12. Quality standards.

(c) Medical records and mammography reports—

(4) *Recordkeeping.* Each facility that performs mammograms:

(i) Shall (except as provided in paragraph (c)(4)(ii) of this section) maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility, or a longer period if mandated by State or local law

21 C.F.R. § 1270.33. Records, general requirements.

(a) Records shall be maintained concurrently with the performance of each significant step required in this part in the performance of infectious disease screening and testing of donors of human tissue. All records shall be accurate, indelible, and legible. The records shall identify the person performing the work, the dates of the various entries, and shall be as detailed as necessary to provide a complete history of the work performed and to relate the records to the particular tissue involved.

(b) All human tissue shall be quarantined until the following criteria for donor suitability are satisfied:

(1) All infectious disease testing under §1270.21 has been completed, reviewed by the responsible person, and found to be negative; and

(2) Donor screening has been completed, reviewed by the responsible person, and determined to assure freedom from risk factors for and clinical evidence of HIV infection, hepatitis B, and hepatitis C.

(c) All human tissue processed or shipped prior to determination of donor suitability must be under quarantine, accompanied by records assuring identification of the donor and indicating that the tissue has not been determined to be suitable for transplantation.

(d) All human tissue determined to be suitable for transplantation must be accompanied by a summary of records, or copies of such original records, documenting that all infectious disease testing and screening under §1270.21 has been completed, reviewed by the

responsible person, and found to be negative, and that the tissue has been determined to be suitable for transplantation.

(e) Human tissue shall be quarantined until the tissue is either determined to be suitable for transplantation or appropriate disposition is accomplished.

(f) All persons or establishments that generate records used in determining the suitability of the donor shall retain such records and make them available for authorized inspection or upon request by FDA. The person(s) or establishment(s) making the determination regarding the suitability of the donor shall retain all records, or true copies of such records required under §1270.21, including all testing and screening records, and shall make them available for authorized inspection or upon request from FDA. Records that can be retrieved from another location by electronic means meet the requirements of this paragraph.

(g) Records required under this part may be retained electronically, or as original paper records, or as true copies such as photocopies, microfiche, or microfilm, in which case suitable reader and photocopying equipment shall be readily available.

(h) Records shall be retained at least 10 years beyond the date of transplantation if known, distribution, disposition, or expiration, of the tissue, whichever is latest.

21 C.F.R. § 1304.04. Maintenance of records and inventories.

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

(1) Financial and shipping records (such as invoices and packing slips but not executed order forms subject to §§1305.17 and 1305.27 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge. All notifications must include the following:

- (i) The nature of the records to be kept centrally.
- (ii) The exact location where the records will be kept.
- (iii) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.
- (iv) Whether central records will be maintained in a manual, or computer readable, form.

(2) A registered retail pharmacy that possesses additional registrations for automated dispensing systems at long term care facilities may keep all records required by this part for those additional registered sites at the retail pharmacy or other approved central location.

(b) All registrants that are authorized to maintain a central recordkeeping system under paragraph (a) of this section shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms and inventories, which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the Administration for such records, and if the Administration chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Administration to inspect such records at the central location upon request by such employees without a warrant of any kind.

...

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy.

(2) Paper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file.

(3) Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.

...

(5) Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of part 1311 of this chapter. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the Administration or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

21 C.F.R. § 1304.11. Inventory requirements.

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

21 C.F.R. § 1304.22. Records for manufacturers, distributors, dispensers, researchers, importers and exporters.

Each person registered or authorized (by §1301.13(e) or §§1307.11-1307.13 of this chapter) to manufacture, distribute, dispense, import, export or conduct research with controlled substances shall maintain records with the information listed in paragraphs (a) through (f) of this section.

(c) *Records for dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. In addition to the requirements of this paragraph, practitioners dispensing gamma-hydroxybutyric acid under a prescription must also comply with §1304.26.

21 C.F.R. § 1305.13. Procedure for filling DEA Forms 222.

(a) A purchaser must make a copy of the original DEA Form 222 for its records and then submit the original to the supplier. The copy retained by the purchaser may be in paper or electronic form.

21 C.F.R. § 1305.15. Unaccepted and defective DEA Forms 222.

(a) A DEA Form 222 must not be filled if either of the following apply:

(1) The order is not complete, legible, or properly prepared, executed, or endorsed.

(2) The order shows any alteration, erasure, or change of any description.

(b) If a DEA Form 222 cannot be filled for any reason under this section, the supplier must return Copies 1 and 2 to the purchaser with a statement as to the reason (e.g., illegible or altered).

(c) A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph.

(d) When a purchaser receives an unaccepted order, the original DEA Form 222 and the statement must be retained in the files of the purchaser in accordance with §1305.17. A defective DEA Form 222 may not be corrected; it must be replaced by a new DEA Form 222 for the order to be filled.

21 C.F.R. § 1305.17. Preservation of DEA Forms 222.

(a) The purchaser must retain a copy of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.

(b) The supplier must retain the original of each DEA Form 222 that it has filled.

(c) DEA Forms 222 must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, the purchaser must retain a copy of the executed DEA Form 222 and any attached statements or other related documents (not including unexecuted DEA Forms 222, which may be kept elsewhere under §1305.12(e)), at the registered location printed on the DEA Form 222.

(d) The supplier of thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine must maintain DEA Forms 222 for these substances separately from all other DEA Forms 222 and records required to be maintained by the registrant.

(e) Electronic copies of DEA Forms 222 will be deemed to be maintained separately from all other records of the registrant, for the purposes of this section, if such copies are readily retrievable separately from all other records. Electronic copies of DEA Forms 222 may be stored on a system at a location different from the registered location, provided such copies are readily retrievable at the registered location.

21 C.F.R. § 1306.13. Partial filling of prescriptions.

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is “terminally ill” or an “LTCF patient.” A prescription that is partially filled and does not contain the notation “terminally ill” or “LTCF patient” shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

(c) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:

(1) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage, form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription and the information required in §1306.13(b).

(2) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.

(3) Retrieval of partially filled Schedule II prescription information is the same as required by §1306.22(b) (4) and (5) for Schedule III and IV prescription refill information.

21 C.F.R. § 1306.22. Refilling of prescriptions.

(a) No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued. No

prescription for a controlled substance listed in Schedule III or IV authorized to be refilled may be refilled more than five times.

(b) Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document or electronic prescription record. If entered on another document, such as a medication record, or electronic prescription record, the document or record must be uniformly maintained and readily retrievable.

(c) The following information must be retrievable by the prescription number:

- (1) The name and dosage form of the controlled substance.
- (2) The date filled or refilled.
- (3) The quantity dispensed.
- (4) The initials of the dispensing pharmacist for each refill.
- (5) The total number of refills for that prescription.

(d) If the pharmacist merely initials and dates the back of the prescription or annotates the electronic prescription record, it shall be deemed that the full face amount of the prescription has been dispensed.

(e) The prescribing practitioner may authorize additional refills of Schedule III or IV controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

(1) The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.

(2) The pharmacist obtaining the oral authorization records on the reverse of the original paper prescription or annotates the electronic prescription record with the date, quantity of refill, number of additional refills authorized, and initials the paper prescription or annotates the electronic prescription record showing who received the authorization from the prescribing practitioner who issued the original prescription.

(3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

(4) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five-refill, six-month limitation.

(f) As an alternative to the procedures provided by paragraphs (a) through (e) of this section, a computer application may be used for the storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

(1) Any such proposed computerized application must provide online retrieval (via computer monitor or hard-copy printout) of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number; date of issuance of the original prescription order by the practitioner; full name and address of the patient; name, address, and DEA registration number of the practitioner; and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(2) Any such proposed computerized application must also provide online retrieval (via computer monitor or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill

during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original paper, fax, or oral prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such an application. If such an application provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated are correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized application within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such an application for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized application shall have the capability of producing a printout of any refill data that the user pharmacy is responsible for maintaining under the Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized application employed by a user pharmacy the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Diversion Investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its application by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized application experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III and IV controlled substance prescription orders. This auxiliary procedure must ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data are retained for online data entry as soon as the computer system is available for use again.

(g) When filing refill information for original paper, fax, or oral prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two applications described in paragraphs (a) through (e) or (f) of this section.

(h) When filing refill information for electronic prescriptions, a pharmacy must use an application that meets the requirements of part 1311 of this chapter.

21 C.F.R. § 1306.26. Dispensing without prescription.

A controlled substance listed in Schedules II, III, IV, or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) Such dispensing is made only by a pharmacist (as defined in part 1300 of this chapter), and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);

(b) Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;

(c) The purchaser is at least 18 years of age;

(d) The pharmacist requires every purchaser of a controlled substance under this section not known to him to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of §1304.04 of this chapter); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law.

(g) Central fill pharmacies may not dispense controlled substances to a purchaser at retail pursuant to this section.

22 C.F.R. § 62.10. Program administration.

Sponsors are responsible for the effective administration of their exchange visitor program(s). These responsibilities include:

(g) Retention of records. Sponsors must retain all records related to their exchange visitor program and exchange visitors (to include accompanying spouse and dependents, if any) for a minimum of three years following the completion of each exchange visitor program.

26 C.F.R. § 31.6001-1. Records in general.

(e) Place and period for keeping records.

(1) All records required by the regulations in this part shall be kept, by the person required to keep them, at one or more convenient and safe locations accessible to

internal revenue officers, and shall at all times be available for inspection by such officers.

(2) Except as otherwise provided in the following sentence, every person required by the regulations in this part to keep records in respect of a tax (whether or not such person incurs liability for such tax) shall maintain such records for at least four years after the due date of such tax for the return period to which the records relate, or the date such tax is paid, whichever is the later. The records of claimants required by paragraph (c) of this section shall be maintained for a period of at least four years after the date the claim is filed.

26 C.F.R. § 31.6001-2. Additional records under Federal Insurance Contributions Act.

(a) *In general.* (1) Every employer liable for tax under the Federal Insurance Contributions Act shall keep records of all remuneration, whether in cash or in a medium other than cash, paid to his employees after 1954 for services (other than agricultural labor which constitutes or is deemed to constitute employment, domestic service in a private home of the employer, or service not in the course of the employer's trade or business) performed for him after 1936. Such records shall show with respect to each employee receiving such remuneration--

(i) The name, address, and account number of the employee and such additional information with respect to the employee as is required by paragraph (c) of § 31.6011(b)-2 when the employee does not advise the employer what his account number and name are as shown on an account number card issued to the employee by the Social Security Administration.

(ii) The total amount and date of each payment of remuneration (including any sum withheld therefrom as tax or for any other reason) and the period of services covered by such payment.

(iii) The amount of each such remuneration payment which constitutes wages subject to tax. See §§ 31.3121(a)-1 to 31.3121(a)(12)-1, inclusive.

(iv) The amount of employee tax, or any amount equivalent to employee tax, collected with respect to such payment, and, if collected at a time other than the time such payment was made, the date collected. See paragraph (b) of § 31.3102-1 for provisions relating to collection of amounts equivalent to employee tax.

(v) If the total remuneration payment (paragraph (a)(1)(ii) of this section) and the amount thereof which is taxable (paragraph (a)(1)(iii) of this section) are not equal, the reason therefor.

(2) Every employer shall keep records of the details of each adjustment or settlement of taxes under the Federal Insurance Contributions Act made pursuant to the regulations in this part. The employer shall keep as a part of his records a copy of each statement furnished pursuant to paragraph (c) of § 31.6011(a)-1.

(3) Every employer shall keep records of all remuneration in the form of tips received by his employees after 1965 in the course of their employment and reported to him pursuant to section 6053(a) [26 USCS § 6053(a)]. The employer shall keep as part of his records employee statements of tips furnished him pursuant to section 6053(a) [26 USCS § 6053(a)] (unless the information disclosed by such statements is recorded on

another document retained by the employer pursuant to paragraph (a)(1) of this section) and copies of employer statements furnished employees pursuant to section 6053(b) [26 USCS § 6053(b)].

(b) *Agricultural labor, domestic service, and service not in the course of employer's trade or business.* (1) Every employer who pays cash remuneration after 1954 for the performance for him after 1950 of agricultural labor which constitutes or is deemed to constitute employment, of domestic service in a private home of the employer not on a farm operated for profit, or of service not in the course of his trade or business shall keep records of all such cash remuneration with respect to which he incurs, or expects to incur, liability for the taxes imposed by the Federal Insurance Contributions Act, or with respect to which amounts equivalent to employee tax are deducted pursuant to section 3102(a) [26 USCS § 3102(a)]. See §§ 31.3101-3, 31.3111-3, and 31.3121(a)-2 for provisions relating, respectively, to the liability for employee tax which is incurred when wages are received, the liability for employer tax which is incurred when wages are paid, and the time when wages are paid and received. Such records shall show with respect to each employee receiving such cash remuneration--

(i) The name of the employee.

(ii) The account number of each employee to whom wages for such services are paid within the meaning of § 31.3121(a)-2, and such additional information as is required by paragraph (c) of § 31.6011(b)-2 when the employee does not advise the employer what his account number and name are as shown on an account number card issued to the employee by the Social Security Administration.

(iii) The amount of such cash remuneration paid to the employee (including any sum withheld therefrom as tax or for any other reason) for agricultural labor which constitutes or is deemed to constitute employment, for domestic service in a private home of the employer not on a farm operated for profit, or for service not in the course of the employer's trade or business; the calendar month in which such cash remuneration was paid; and the character of the services for which such cash remuneration was paid. When the employer incurs liability for the taxes imposed by the Federal Insurance Contributions Act with respect to any such cash remuneration which he did not previously expect would be subject to the taxes, the amount of any such cash remuneration not previously made a matter of record shall be determined by the employer to the best of his knowledge and belief.

(iv) The amount of employee tax, or any amount equivalent to employee tax, collected with respect to such cash remuneration and the calendar month in which collected. See paragraph (b) of § 31.3102-1 for provisions relating to collection of amounts equivalent to employee tax.

(v) To the extent material to a determination of tax liability, the number of days during each calendar year after 1956 on which agricultural labor which constitutes or is deemed to constitute employment is performed by the employee for cash remuneration computed on a time basis.

(2) Every person to whom a "crew leader", as that term is defined in section 3121(i) [26 USCS § 3121(i)], furnishes individuals for the performance of agricultural

labor after December 31, 1958, shall keep records of the name; permanent mailing address, or if none, present address; and identification number, if any, of such "crew leader".

26 C.F.R. § 31.6001-4. Additional records under Federal Unemployment Tax Act.

(a) *Records of employers.* Every employer liable for tax under the Federal Unemployment Tax Act for any calendar year shall, with respect to each such year, keep such records as are necessary to establish—

(1) The total amount of remuneration (including any sum withheld therefrom as tax or for any other reason) paid to his employees during the calendar year for services performed after 1938.

(2) The amount of such remuneration which constitutes wages subject to the tax. See §31.3306(b)-1 through §31.3306(b)(8)-1.

(3) The amount of contributions paid by him into each State unemployment fund, with respect to services subject to the law of such State, showing separately (i) payments made and neither deducted nor to be deducted from the remuneration of his employees, and (ii) payments made and deducted or to be deducted from the remuneration of his employees.

(4) The information required to be shown on the prescribed return and the extent to which the employer is liable for the tax.

(5) If the total remuneration paid (paragraph (a)(1) of this section) and the amount thereof which is subject to the tax (paragraph (a)(2) of this section) are not equal, the reason therefor.

(6) To the extent material to a determination of tax liability, the dates, in each calendar quarter, on which each employee performed services not in the course of the employer's trade or business, and the amount of cash remuneration paid at any time for such services performed within such quarter See §31.3306(c)(3)-1.

The term "remuneration," as used in this paragraph, includes all payments whether in cash or in a medium other than cash, except that the term does not include payments in a medium other than cash for services not in the course of the employer's trade or business. See §31.3306(b)(7)-1.

(b) *Records of persons who are not employers.* Any person who employs individuals in employment (see §§31.3306(c)-1 to 31.3306(c)-3, inclusive) during any calendar year but who considers that he is not an employer subject to the tax (see §31.3306(a)-1) shall, with respect to each such year, be prepared to establish by proper records (including, where necessary, records of the number of employees employed each day) that he is not an employer subject to the tax.

26 C.F.R. § 301.6104(d)-1. Public inspection and distribution of applications for tax exemption and annual information returns of tax-exempt organizations.

(a) *In general.* Except as otherwise provided in this section, if a tax-exempt organization (as defined in paragraph (b)(1) of this section) filed an application for recognition of exemption under section 501, it shall make its application for tax exemption (as defined in paragraph (b)(3) of this section) available for public inspection without charge at its principal, regional and district offices during regular business hours. Except as otherwise provided in this section, a tax-exempt organization shall make its annual information returns (as defined in paragraph (b)(4) of this section) available for public inspection without charge in the same offices during regular business hours. Each annual information return shall be made available for

a period of three years beginning on the date the return is required to be filed (determined with regard to any extension of time for filing) or is actually filed, whichever is later. In addition, except as provided in §§301.6104(d)-2 and 301.6104(d)-3, an organization shall provide a copy without charge, other than a reasonable fee for reproduction and actual postage costs, of all or any part of any application or return required to be made available for public inspection under this paragraph to any individual who makes a request for such copy in person or in writing. See paragraph (d)(3) of this section for rules relating to fees for copies.

27 C.F.R. § 22.161. Records.

(a) *General.* All persons qualified under this part shall keep accurate records of all receipts, shipments, usage, destructions and claims pertaining to the withdrawal and use of tax-free alcohol. These records shall be in sufficient detail to enable the permittee to reconcile any losses or gains for the semi-annual inventory, and to enable appropriate TTB officers to verify all transactions and to ascertain whether there has been compliance with law and regulations. All records required by this section shall identify tax-free alcohol by proof, date of transaction, and quantity involved, and shall include alcohol received from the General Services Administration and the recovery of alcohol and its disposition. Records shall be kept current at all times.

(b) *Records of receipt and shipment.* Records of receipt and shipment shall consist of the consignor's or consignee's (as the case may be) invoice, bill or bill of lading, or another document used for the intended purpose. Records of receipt shall record only the quantity of tax-free alcohol actually received. Losses in transit shall not be considered as received, but may be the subject of a claim for allowances of losses, as prescribed in subpart I of this part.

(c) *Records of usage.* For the purpose of this subpart, tax-free or recovered alcohol shall be considered as "used" when permanently removed from a permittee's supply storeroom, compartment, or tank for any authorized use. Records of usage shall identify the tax-free alcohol by quantity, proof, and purpose of removal (office, department or location to which dispensed). This record shall list separately, the usage of tax-free alcohol from recovered alcohol or alcohol received from the General Services Administration.

(d) *Records of destruction.* Records of destruction shall consist of a copy of the notice of intention to destroy, prescribed in §22.141, signed by an appropriate TTB officer or employee witnessing the destruction.

(e) *Claims.* Claims for allowance of losses of tax-free alcohol, required to be filed under subpart I of this part, shall consist of Forms 2635 (5620.8) and supporting data.

27 C.F.R. § 22.162. Inventories.

Each permittee shall take a physical inventory of the tax-free and recovered alcohol in its possession semi-annually for the periods ending June 30 and December 31 of each year; or other inventory periods which are approximately 6 months apart, upon filing written notice with the appropriate TTB officer establishing other inventory periods. These inventories may be recorded separately or as an entry in the record of usage with any necessary adjustments (losses or gains). If an inventory results in a loss in excess of the quantities prescribed by subpart I of this part, the permittee shall file a claim for allowance of loss.

27 C.F.R. § 22.164. Filing and retention of records.

Each person required to maintain records of operations and transactions under this part shall:

(a) Keep on file all records and copies of claims for a period of not less than 3 years following the date of transaction or, at the discretion of the appropriate TTB officer, an additional 3-year period; and

(b) Maintain all records at the permit premises, except that the records may be kept at a central location by a State or political subdivision of a State, or the District of Columbia which distributes tax-free alcohol to multiple dependent agencies, institutions, or departments.

27 C.F.R. § 22.165. Photographic copies of records.

(a) *General.* Permittees may record, copy, or reproduce required records. Any process may be used which accurately reproduces the original record, and which forms a durable medium for reproducing and preserving the original record.

(b) *Copies of records treated as original records.* Whenever records are reproduced under this section, the reproduced records shall be preserved in conveniently accessible files, and provisions shall be made for examining, viewing, and using the reproduced records the same as if they were the original record, and they shall be treated and considered for all purposes as though they were the original record. All provisions of law and regulations applicable to the original are applicable to the reproduced record. As used in this section, “original record” means the record required by this part to be maintained or preserved by the permittee, even though it may be an executed duplicate or other copy of the document.

29 C.F.R. § 32.49. Recordkeeping.

(a) Each recipient shall maintain for a period of not less than three years records regarding complaints and actions taken thereunder, and such employment or other records as required by the Assistant Secretary or by this part and shall furnish such information in the form required by the Assistant Secretary or as the Assistant Secretary deems necessary for the administration of the Act and regulations in this part.

(b) Failure to maintain and furnish complete and accurate records as required under this section is a ground for the imposition of appropriate sanctions

29 C.F.R. § 516.2. Employees subject to minimum wage or minimum wage and overtime provisions pursuant to section 6 or sections 6 and 7(a) of the Act.

(a) Items required. Every employer shall maintain and preserve payroll or other records containing the following information and data with respect to each employee to whom section 6 or both sections 6 and 7(a) of the Act apply:

(1) Name in full, as used for Social Security recordkeeping purposes, and on the same record, the employee's identifying symbol or number if such is used in place of name on any time, work, or payroll records,

(2) Home address, including zip code,

(3) Date of birth, if under 19,

(4) Sex and occupation in which employed (sex may be indicated by use of the prefixes Mr., Mrs., Miss., or Ms.) (Employee's sex identification is related to the equal pay provisions of the Act which are administered by the Equal Employment Opportunity Commission. Other equal pay recordkeeping requirements are contained in 29 CFR part 1620.)

(5) Time of day and day of week on which the employee's workweek begins (or for employees employed under section 7(k) of the Act, the starting time and length of

each employee's work period). If the employee is part of a workforce or employed in or by an establishment all of whose workers have a workweek beginning at the same time on the same day, a single notation of the time of the day and beginning day of the workweek for the whole workforce or establishment will suffice,

(6) (i) Regular hourly rate of pay for any workweek in which overtime compensation is due under section 7(a) of the Act, (ii) explain basis of pay by indicating the monetary amount paid on a per hour, per day, per week, per piece, commission on sales, or other basis, and (iii) the amount and nature of each payment which, pursuant to section 7(e) of the Act, is excluded from the "regular rate" (these records may be in the form of vouchers or other payment data),

(7) Hours worked each workday and total hours worked each workweek (for purposes of this section, a "workday" is any fixed period of 24 consecutive hours and a "workweek" is any fixed and regularly recurring period of 7 consecutive workdays),

(8) Total daily or weekly straight-time earnings or wages due for hours worked during the workday or workweek, exclusive of premium overtime compensation,

(9) Total premium pay for overtime hours. This amount excludes the straight-time earnings for overtime hours recorded under paragraph (a)(8) of this section,

(10) Total additions to or deductions from wages paid each pay period including employee purchase orders or wage assignments. Also, in individual employee records, the dates, amounts, and nature of the items which make up the total additions and deductions,

(11) Total wages paid each pay period,

(12) Date of payment and the pay period covered by payment.

(b) Records of retroactive payment of wages. Every employer who makes retroactive payment of wages or compensation under the supervision of the Administrator of the Wage and Hour Division pursuant to section 16(c) and/or section 17 of the Act, shall:

(1) Record and preserve, as an entry on the pay records, the amount of such payment to each employee, the period covered by such payment, and the date of payment.

(2) Prepare a report of each such payment on a receipt form provided by or authorized by the Wage and Hour Division, and (i) preserve a copy as part of the records, (ii) deliver a copy to the employee, and (iii) file the original, as evidence of payment by the employer and receipt by the employee, with the Administrator or an authorized representative within 10 days after payment is made.

(c) Employees working on fixed schedules. With respect to employees working on fixed schedules, an employer may maintain records showing instead of the hours worked each day and each workweek as required by paragraph (a)(7) of this section, the schedule of daily and weekly hours the employee normally works. Also,

(1) In weeks in which an employee adheres to this schedule, indicates by check mark, statement or other method that such hours were in fact actually worked by him, and

(2) In weeks in which more or less than the scheduled hours are worked, shows that exact number of hours worked each day and each week

29 C.F.R. § 516.5. Records to be preserved 3 years.

Each employer shall preserve for at least 3 years:

(a) *Payroll records.* From the last date of entry, all payroll or other records containing the employee information and data required under any of the applicable sections of this part, and

(b) *Certificates, agreements, plans, notices, etc.* From their last effective date, all written:

(1) Collective bargaining agreements relied upon for the exclusion of certain costs under section 3(m) of the Act,

(2) Collective bargaining agreements, under section 7(b)(1) or 7(b)(2) of the Act, and any amendments or additions thereto,

(3) Plans, trusts, employment contracts, and collective bargaining agreements under section 7(e) of the Act,

(4) Individual contracts or collective bargaining agreements under section 7(f) of the Act. Where such contracts or agreements are not in writing, a written memorandum summarizing the terms of each such contract or agreement,

(5) Written agreements or memoranda summarizing the terms of oral agreements or understandings under section 7(g) or 7(j) of the Act, and

(6) Certificates and notices listed or named in any applicable section of this part.

(c) *Sales and purchase records.* A record of (1) total dollar volume of sales or business, and (2) total volume of goods purchased or received during such periods (weekly, monthly, quarterly, etc.), in such form as the employer maintains records in the ordinary course of business.

29 C.F.R. § 516.6. Records to be preserved 2 years.

(a) Supplementary basic records: Each employer required to maintain records under this part shall preserve for a period of at least 2 years.

(1) Basic employment and earnings records. From the date of last entry, all basic time and earning cards or sheets on which are entered the daily starting and stopping time of individual employees, or of separate work forces, or the amounts of work accomplished by individual employees on a daily, weekly, or pay period basis (for example, units produced) when those amounts determine in whole or in part the pay period earnings or wages of those employees.

(2) Wage rate tables. From their last effective date, all tables or schedules of the employer which provide the piece rates or other rates used in computing straight-time earnings, wages, or salary, or overtime pay computation.

(3) Order, shipping, and billing records: From the last date of entry, the originals or true copies of all customer orders or invoices received, incoming or outgoing shipping or delivery records, as well as all bills of lading and all billings to customers (not including individual sales slips, cash register tapes or the like) which the employer retains or makes in the usual course of business operations.

(b) Records of additions to or deductions from wages paid:

(1) Those records relating to individual employees referred to in § 516.2(a)(10) and

(2) All records used by the employer in determining the original cost, operating and maintenance cost, and depreciation and interest charges, if such costs and charges are involved in the additions to or deductions from wages paid.

29 C.F.R. § 516.11. Employees exempt from both minimum wage and overtime pay requirements under section 13(a) (2), (3), (4), (5), (8), (10), (12), or 13(d) of the Act.

With respect to each and every employee exempt from both the minimum wage and overtime pay requirements of the Act pursuant to the provisions of section 13(a) (2), (3), (4), (5), (8), (10), (12), or 13(d) of the Act, employers shall maintain and preserve records containing the information and data required by § 516.2(a) (1) through (4).

29 C.F.R. § 516.12. Employees exempt from overtime pay requirements pursuant to section 13(b) (1), (2), (3), (5), (9), (10), (15), (16), (17), (20), (21), (24), (27), or (28) of the Act.

With respect to each employee exempt from the overtime pay requirements of the Act pursuant to the provisions of section 13(b) (1), (2), (3), (5), (9), (10), (15), (16), (17), (20), (21), (24), (27), or (28) of the Act, shall maintain and preserve payroll or other records, containing all the information and data required by § 516.2(a) except paragraphs (a) (6) and (9) and, in addition, information and data regarding the basis on which wages are paid (such as the monetary amount paid, expressed as earnings per hour, per day, per week, etc.).

29 C.F.R. § 516.23. Employees of hospitals and residential care facilities compensated for overtime work on the basis of a 14-day work period pursuant to section 7(j) of the Act.

With respect to each employee of hospitals and institutions primarily engaged in the care of the sick, the aged, or mentally ill or defective who reside on the premises compensated for overtime work on the basis of a work period of 14 consecutive days pursuant to an agreement or understanding under section 7(j) of the Act, employers shall maintain and preserve.

(a) The records required by § 516.2 except paragraphs (a) (5) and (7) through (9), and in addition:

- (1) Time of day and day of week on which the employee's 14-day work period begins,
- (2) Hours worked each workday and total hours worked each 14-day work period,
- (3) Total straight-time wages paid for hours worked during the 14-day period,
- (4) Total overtime excess compensation paid for hours worked in excess of 8 in a workday and 80 in the work period.

(b) A copy of the agreement or understanding with respect to using the 14-day period for overtime pay computations or, if such agreement or understanding is not in writing, a memorandum summarizing its terms and showing the date it was entered into and how long it remains in effect.

29 C.F.R. § 825.500. Recordkeeping requirements.

(a) FMLA provides that covered employers shall make, keep, and preserve records pertaining to their obligations under the Act in accordance with the recordkeeping requirements of section 11(c) of the Fair Labor Standards Act (FLSA) and in accordance with these regulations. FMLA also restricts the authority of the Department of Labor to require any employer or plan, fund, or program to submit books or records more than once during any 12-month period unless the Department has reasonable cause to believe a violation of FMLA exists or the Department is investigating a complaint. These regulations establish no requirement for the submission of any records unless specifically requested by a Departmental official.

(b) No particular order or form of records is required. These regulations establish no requirement that any employer revise its computerized payroll or personnel records systems to comply. However, employers must keep the records specified by these regulations for no less than three years and make them available for inspection, copying, and transcription by representatives of the Department of Labor upon request. The records may be maintained and preserved on microfilm or other basic source document of an automated data processing memory provided that adequate projection or viewing equipment is available, that the reproductions are clear and identifiable by date or pay period, and that extensions or transcriptions of the information required herein can be and are made available upon request. Records kept in computer form must be made available for transcription or copying.

(c) Covered employers who have eligible employees must maintain records that must disclose the following:

(1) Basic payroll and identifying employee data, including name, address, and occupation; rate or basis of pay and terms of compensation; daily and weekly hours worked per pay period; additions to or deductions from wages; and total compensation paid.

(2) Dates FMLA leave is taken by FMLA eligible employees (e.g., available from time records, requests for leave, etc., if so designated). Leave must be designated in records as FMLA leave; leave so designated may not include leave required under State law or an employer plan which is not also covered by FMLA.

(3) If FMLA leave is taken by eligible employees in increments of less than one full day, the hours of the leave.

(4) Copies of employee notices of leave furnished to the employer under FMLA, if in writing, and copies of all written notices given to employees as required under FMLA and these regulations See § 825.300(b)-(c). Copies may be maintained in employee personnel files.

(5) Any documents (including written and electronic records) describing employee benefits or employer policies and practices regarding the taking of paid and unpaid leaves.

(6) Premium payments of employee benefits.

(7) Records of any dispute between the employer and an eligible employee regarding designation of leave as FMLA leave, including any written statement from the employer or employee of the reasons for the designation and for the disagreement.

(d) Covered employers with no eligible employees must maintain the records set forth in paragraph (c)(1) of this section.

(e) Covered employers in a joint employment situation (See § 825.106) must keep all the records required by paragraph (c) of this section with respect to any primary employees, and must keep the records required by paragraph (c)(1) with respect to any secondary employees.

(f) If FMLA-eligible employees are not subject to FLSA's recordkeeping regulations for purposes of minimum wage or overtime compliance (i.e., not covered by or exempt from FLSA), an employer need not keep a record of actual hours worked (as otherwise required under FLSA, 29 CFR 516.2(a)(7)), provided that:

(1) Eligibility for FMLA leave is presumed for any employee who has been employed for at least 12 months; and

(2) With respect to employees who take FMLA leave intermittently or on a reduced leave schedule, the employer and employee agree on the employee's normal

schedule or average hours worked each week and reduce their agreement to a written record maintained in accordance with paragraph (b) of this section.

(g) Records and documents relating to certifications, recertifications or medical histories of employees or employees' family members, created for purposes of FMLA, shall be maintained as confidential medical records in separate files/records from the usual personnel files. If the Genetic Information Nondiscrimination Act of 2008 (GINA) is applicable, records and documents created for purposes of FMLA containing family medical history or genetic information as defined in GINA shall be maintained in accordance with the confidentiality requirements of Title II of GINA (See 29 CFR 1635.9), which permit such information to be disclosed consistent with the requirements of FMLA. If the ADA, as amended, is also applicable, such records shall be maintained in conformance with ADA confidentiality requirements (See 29 CFR 1630.14(c)(1)), except that:

- (1) Supervisors and managers may be informed regarding necessary restrictions on the work or duties of an employee and necessary accommodations;
- (2) First aid and safety personnel may be informed (when appropriate) if the employee's physical or medical condition might require emergency treatment; and
- (3) Government officials investigating compliance with FMLA (or other pertinent law) shall be provided relevant information upon request.

(h) Special rules regarding recordkeeping apply to employers of airline flight crew employees. See § 825.803.

29 C.F.R. § 826.140. Recordkeeping

(a) An Employer is required to retain all documentation provided pursuant to § 826.100 for four years, regardless whether leave was granted or denied. If an Employee provided oral statements to support his or her request for Paid Sick Leave or Expanded Family and Medical Leave, the Employer is required to document and maintain such information in its records for four years.

(b) An Employer that denies an Employee's request for Paid Sick Leave or Expanded Family and Medical Leave pursuant to § 826.40(b) shall document the determination by its authorized officer that it is eligible for such exemption and retain such documentation for four years.

(c) In order to claim tax credits from the Internal Revenue Service (IRS), an Employer is advised to maintain the following records for four years:

- (1) Documentation to show how the Employer determined the amount of paid sick leave and expanded family and medical leave paid to Employees that are eligible for the credit, including records of work, Telework and Paid Sick Leave and Expanded Family and Medical Leave;
- (2) Documentation to show how the Employer determined the amount of qualified health plan expenses that the Employer allocated to wages;
- (3) Copies of any completed IRS Forms 7200 that the Employer submitted to the IRS;
- (4) Copies of the completed IRS Forms 941 that the Employer submitted to the IRS or, for Employers that use third party payers to meet their employment tax obligations, records of information provided to the third party payer regarding the Employer's entitlement to the credit claimed on IRS Form 941, and

(5) Other documents needed to support its request for tax credits pursuant to IRS applicable forms, instructions, and information for the procedures that must be followed to claim a tax credit.

29 C.F.R. § 1602.14. Preservation of records made or kept.

Any personnel or employment record made or kept by an employer (including but not necessarily limited to requests for reasonable accommodation, application forms submitted by applicants and other records having to do with hiring, promotion, demotion, transfer, lay-off or termination, rates of pay or other terms of compensation, and selection for training or apprenticeship) shall be preserved by the employer for a period of one year from the date of the making of the record or the personnel action involved, whichever occurs later. In the case of involuntary termination of an employee, the personnel records of the individual terminated shall be kept for a period of one year from the date of termination. Where a charge of discrimination has been filed, or an action brought by the Commission or the Attorney General, against an employer under title VII, the ADA, or GINA, the respondent employer shall preserve all personnel records relevant to the charge or action until final disposition of the charge or the action. The term "personnel records relevant to the charge," for example, would include personnel or employment records relating to the aggrieved person and to all other employees holding positions similar to that held or sought by the aggrieved person and application forms or test papers completed by an unsuccessful applicant and by all other candidates for the same position as that for which the aggrieved person applied and was rejected. The date of final disposition of the charge or the action means the date of expiration of the statutory period within which the aggrieved person may bring an action in a U.S. District Court or, where an action is brought against an employer either by the aggrieved person, the Commission, or by the Attorney General, the date on which such litigation is terminated.

29 C.F.R. § 1620.32. Recordkeeping requirements.

(a) Employers having employees subject to the Act are required to keep records in accordance with U.S. Department of Labor regulations found at 29 CFR part 516 (Records To Be Kept by Employers Under the FLSA). The regulations of that part are adopted herein by reference.

(b) Every employer subject to the equal pay provisions of the Act shall maintain and preserve all records required by the applicable sections of 29 CFR part 516 and in addition, shall preserve any records which he makes in the regular course of his business operation which relate to the payment of wages, wage rates, job evaluations, job descriptions, merit systems, seniority systems, collective bargaining agreements, description of practices or other matters which describe or explain the basis for payment of any wage differential to employees of the opposite sex in the same establishment, and which may be pertinent to a determination whether such differential is based on a factor other than sex.

(c) Each employer shall preserve for at least two years the records he makes of the kind described in § 1620.32(b) which explain the basis for payment of any wage differential to employees of the opposite sex in the same establishment.

29 C.F.R. § 1620.33. Recovery of wages due; injunctions; penalties for willful violations.

(a) Wages withheld in violation of the Act have the status of unpaid minimum wages or unpaid overtime compensation under the FLSA. This is true both of the additional wages required by the Act to be paid to an employee to meet the equal pay standard, and of any wages that the employer should have paid an employee whose wages he reduced in violation of the Act in an attempt to equalize his or her pay with that of an employee of the opposite sex performing equal work, on jobs subject to the Act.

(b) The following methods are provided under sections 16 and 17 of the FLSA for recovery of unpaid wages: The Commission may supervise payment of the back wages and may bring suit for back pay and an equal amount as liquidated damages. The employee may sue for back pay and an additional sum, up to the amount of back pay, as liquidated damages, plus attorney's fees and court costs. The employee may not bring suit if he or she has been paid back wages in full under supervision of the Commission, or if the Commission has filed suit under the Act to collect the wages due the employee. The Commission may also obtain a court injunction to restrain any person from violating the law, including the unlawful withholding by an employer of proper compensation. A 2-year statute of limitations applies to the recovery of unpaid wages, except that an action on a cause of action arising out of a willful violation may be commenced within 3 years after the cause of action accrued.

(c) Willful violations of the Act may be prosecuted criminally and the violator fined up to \$ 10,000. A second conviction for such a violation may result in imprisonment.

(d) Violation of any provision of the Act by any person, including any labor organization or agent thereof, is unlawful, as provided in section 15(a) of the FLSA. Accordingly, any labor organization, or agent thereof, who violates any provision of the Act is subject to injunction proceedings in accordance with the applicable provisions of section 17 of the FLSA. Any such labor organization, or agent thereof, who willfully violates the provisions of section 15 is liable to the penalties set forth in section 16(a) of the FLSA.

29 C.F.R. § 1627.3. Records to be kept by employers.

(a) Every employer shall make and keep for 3 years payroll or other records for each of his employees which contain:

- (1) Name;
- (2) Address;
- (3) Date of birth;
- (4) Occupation;
- (5) Rate of pay, and
- (6) Compensation earned each week.

(b) (1) Every employer who, in the regular course of his business, makes, obtains, or uses, any personnel or employment records related to the following, shall, except as provided in paragraphs (b) (3) and (4) of this section, keep them for a period of 1 year from the date of the personnel action to which any records relate:

(i) Job applications, resumes, or any other form of employment inquiry whenever submitted to the employer in response to his advertisement or other notice of existing or anticipated job openings, including records pertaining to the failure or refusal to hire any individual,

(ii) Promotion, demotion, transfer, selection for training, layoff, recall, or discharge of any employee,

(iii) Job orders submitted by the employer to an employment agency or labor organization for recruitment of personnel for job openings,

(iv) Test papers completed by applicants or candidates for any position which disclose the results of any employer-administered aptitude or other employment test considered by the employer in connection with any personnel action,

(v) The results of any physical examination where such examination is considered by the employer in connection with any personnel action,

(vi) Any advertisements or notices to the public or to employees relating to job openings, promotions, training programs, or opportunities for overtime work.

(2) Every employer shall keep on file any employee benefit plans such as pension and insurance plans, as well as copies of any seniority systems and merit systems which are in writing, for the full period the plan or system is in effect, and for at least 1 year after its termination. If the plan or system is not in writing, a memorandum fully outlining the terms of such plan or system and the manner in which it has been communicated to the affected employees, together with notations relating to any changes or revisions thereto, shall be kept on file for a like period.

(3) When an enforcement action is commenced under section 7 of the Act regarding a particular applicant or employee, the Commission or its authorized representative shall require the employer to retain any record required to be kept under paragraph (b) (1) or (2) of this section which is relative to such action until the final disposition thereof.

29 C.F.R. § 1904.33. Retention and updating.

(a) *Basic requirement.* You must save the OSHA 300 Log, the privacy case list (if one exists), the annual summary, and the OSHA 301 Incident Report forms for five (5) years following the end of the calendar year that these records cover.

(b) *Implementation.*

(1) Do I have to update the OSHA 300 Log during the five-year storage period? Yes, during the storage period, you must update your stored OSHA 300 Logs to include newly discovered recordable injuries or illnesses and to show any changes that have occurred in the classification of previously recorded injuries and illnesses. If the description or outcome of a case changes, you must remove or line out the original entry and enter the new information.

(2) Do I have to update the annual summary? No, you are not required to update the annual summary, but you may do so if you wish.

(3) Do I have to update the OSHA 301 Incident Reports? No, you are not required to update the OSHA 301 Incident Reports, but you may do so if you wish.

29 C.F.R. § 1910.502(q). COVID-19 Emergency Temporary Standard.

(q) Recordkeeping.

(1) Small employer exclusion. Employers with 10 or fewer employees on the effective date of this section are not required to comply with paragraph (q)(2) or (q)(3) of this section.

(2) Required records. Employers with more than 10 employees on the effective date of this section must:

(i) Retain all versions of the COVID-19 plan implemented to comply with this section while this section remains in effect.

(ii) Establish and maintain a COVID-19 log to record each instance identified by the employer in which an employee is COVID-19 positive, regardless of whether the instance is connected to exposure to COVID-19 at work.

(ii) (A) The COVID-19 log must contain, for each instance, the employee's name, one form of contact information, occupation, location where the employee worked, the date of the employee's last day at the workplace, the date of the positive test for, or diagnosis of, COVID-19, and the date the employee first had one or more COVID-19 symptoms, if any were experienced.

(B) The information in the COVID-19 log must be recorded within 24 hours of the employer learning that the employee is COVID-19 positive and must be maintained as though it is a confidential medical record and must not be disclosed except as required by this ETS or other federal law.

(C) The COVID-19 log must be maintained and preserved while this section remains in effect.

NOTE: The COVID-19 log is intended to assist employers with tracking and evaluating instances of employees who are COVID-19 positive without regard to whether those employees were infected at work. The tracking will help evaluate potential workplace exposure to other employees.

(3) Availability of records. By the end of the next business day after a request, the employer must provide, for examination and copying:

(i) All versions of the written COVID-19 plan to all of the following: Any employees, their personal representatives, and their authorized representatives.

(ii) The individual COVID-19 log entry for a particular employee to that employee and to anyone having written authorized consent of that employee.

(iii) A version of the COVID-19 log that removes the names of employees, contact information, and occupation, and only includes, for each employee in the COVID-19 log, the location where the employee worked, the last day that the employee was at the workplace before removal, the date of that employee's positive test for, or diagnosis of, COVID-19, and the date the employee first had one or more COVID-19 symptoms, if any were experienced, to all of the following: Any employees, their personal representatives, and their authorized representatives.

(iv) All records required to be maintained by this section to the Assistant Secretary.

NOTE: Employers must continue to record all work-related confirmed cases of COVID-19 on their OSHA Forms 300, 300A, and 301, or the equivalent forms, if required to do so under 29 CFR part 1904.

29 C.F.R. § 1910.1001. Asbestos.(m) *Recordkeeping –*

(1) *Exposure measurements.* NOTE: The employer may utilize the services of competent organizations such as industry trade associations and employee associations to maintain the records required by this section.

(i) The employer shall keep an accurate record of all measurements taken to monitor employee exposure to asbestos as prescribed in paragraph (d) of this section.

(ii) This record shall include at least the following information:

(A) The date of measurement;

(B) The operation involving exposure to asbestos which is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and results of samples taken;

(E) Type of respiratory protective devices worn, if any; and

(F) Name, social security number and exposure of the employees whose exposure are represented.

(iii) The employer shall maintain this record for at least thirty (30) years, in accordance with 29 CFR 1910.20.

(2) *Objective data for exempted operations.* (i) Where the processing, use, or handling of products made from or containing asbestos is exempted from other requirements of this section under paragraph (d)(2)(iii) of this section, the employer shall establish and maintain an accurate record of objective data reasonably relied upon in support of the exemption.

(ii) The record shall include at least the following:

(A) The product qualifying for exemption;

(B) The source of the objective data;

(C) The testing protocol, results of testing, and/or analysis of the material for the release of asbestos;

(D) A description of the operation exempted and how the data support the exemption; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(3) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance by paragraph (1)(1)(i) of this section, in accordance with 29 CFR 1910.1020.

(ii) The record shall include at least the following information:

(A) The name and social security number of the employee;

(B) Physician's written opinions;

(C) Any employee medical complaints related to exposure to asbestos; and

(D) A copy of the information provided to the physician as required by paragraph (l)(6) of this section.

(iii) The employer shall ensure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with 29 CFR 1910.1020.

(4) *Training.* The employer shall maintain all employee training records for one (1) year beyond the last date of employment of that employee.

(5) *Availability.* (i) The employer, upon written request, shall make all records required to be maintained by this section available to the Assistant Secretary and the Director for examination and copying.

(ii) The employer, upon request shall make any exposure records required by paragraph (m)(1) of this section available for examination and copying to affected employees, former employees, designated representatives and the Assistant Secretary, in accordance with 29 CFR 1910.1020 (a) through (e) and (g) through (i).

(iii) The employer, upon request, shall make employee medical records required by paragraph (m)(3) of this section available for examination and copying to the subject employee, to anyone having the specific written consent of the subject employee, and the Assistant Secretary, in accordance with 29 CFR 1910.1020.

(6) *Transfer of records.* The employer shall comply with the requirements concerning transfer of records set forth in 29 CFR 1910.1020(h).

(n) *Observation of monitoring* -- (1) Employee observation. The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to asbestos conducted in accordance with paragraph (d) of this section.

(2) *Observation procedures.* When observation of the monitoring of employee exposure to asbestos requires entry into an area where the use of protective clothing or equipment is required, the observer shall be provided with and be required to use such clothing and equipment and shall comply with all other applicable safety and health procedures.

(o) *Appendices.* (1) Appendices A, C, D, E, and F to this section are incorporated as part of this section and the contents of these Appendices are mandatory.

(2) Appendices B, G, H, I, and J to this section are informational and are not intended to create any additional obligations not otherwise imposed or to detract from any existing obligations.

29 C.F.R. § 1910.1020. Access to employee exposure and medical records.

(d) *Preservation of records.* (1) Unless a specific occupational safety and health standard provides a different period of time, each employer shall assure the preservation and retention of records as follows:

(i) *Employee medical records.* The medical record for each employee shall be preserved and maintained for at least the duration of employment plus

thirty (30) years, except that the following types of records need not be retained for any specified period:

(A) Health insurance claims records maintained separately from the employer's medical program and its records,

(B) First aid records (not including medical histories) of one-time treatment and subsequent observation of minor scratches, cuts, burns, splinters, and the like which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job, if made on-site by a non-physician and if maintained separately from the employer's medical program and its records, and

(C) The medical records of employees who have worked for less than (1) year for the employer need not be retained beyond the term of employment if they are provided to the employee upon the termination of employment.

(ii) *Employee exposure records.* Each employee exposure record shall be preserved and maintained for at least thirty (30) years, except that:

(A) Background data to environmental (workplace) monitoring or measuring, such as laboratory reports and worksheets, need only be retained for one (1) year as long as the sampling results, the collection methodology (sampling plan), a description of the analytical and mathematical methods used, and a summary of other background data relevant to interpretation of the results obtained, are retained for at least thirty (30) years; and

(B) Material safety data sheets and paragraph (c)(5)(iv) records concerning the identity of a substance or agent need not be retained for any specified period as long as some record of the identity (chemical name if known) of the substance or agent, where it was used, and when it was used is retained for at least thirty (30) years; ^{fn1} and

^{fn1} Material safety data sheets must be kept for those chemicals currently in use that are effected by the Hazard Communication Standard in accordance with 29 CFR 1910.1200(g).

(C) Biological monitoring results designated as exposure records by specific occupational safety and health standards shall be preserved and maintained as required by the specific standard.

(iii) *Analyses using exposure or medical records.* Each analysis using exposure or medical records shall be preserved and maintained for at least thirty (30) years.

(2) Nothing in this section is intended to mandate the form, manner, or process by which an employer preserves a record as long as the information contained in the record is preserved and retrievable, except that chest X-ray films shall be preserved in their original state.

29 C.F.R. § 1910.1030. Bloodborne pathogens.

(h) *Recordkeeping* -- (1) *Medical Records*. (i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

(ii) This record shall include:

(A) The name of the employee;

(B) A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

(C) A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

(D) The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

(E) A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

(iii) *Confidentiality*. The employer shall ensure that employee medical records required by paragraph (h)(1) are:

(A) Kept confidential; and

(B) Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

(iv) The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

(2) *Training Records*. (i) Training records shall include the following information:

(A) The dates of the training sessions;

(B) The contents or a summary of the training sessions;

(C) The names and qualifications of persons conducting the training; and

(D) The names and job titles of all persons attending the training sessions.

(ii) Training records shall be maintained for 3 years from the date on which the training occurred.

(3) *Availability*. (i) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.

(iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

(4) *Transfer of Records.* The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

(5) *Sharps injury log.* (i) The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

- (A) The type and brand of device involved in the incident,
- (B) The department or work area where the exposure incident occurred, and
- (C) An explanation of how the incident occurred.

(ii) The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR part 1904.

(iii) The sharps injury log shall be maintained for the period required by 29 CFR 1904.33.

(i) Dates --(1) Effective Date. The standard shall become effective on March 6, 1992.

(2) The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.

(3) Paragraphs (g)(2) Information and Training and (h) Recordkeeping of this section shall take effect on or before June 4, 1992.

(4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs of this section, shall take effect July 6, 1992.

33 C.F.R. § 331.2. Definitions.

...Jurisdictional determination (JD) means a written Corps determination that a wetland and/or waterbody is subject to regulatory jurisdiction under Section 404 of the Clean Water Act (33 U.S.C. 1344) or a written determination that a waterbody is subject to regulatory jurisdiction under Section 9 or 10 of the Rivers and Harbors Act of 1899 (33 U.S.C. 401 et seq.). Additionally, the term includes a written reverification of expired JDs and a written reverification of JDs where new information has become available that may affect the previously written determination. For example, such geographic JDs may include, but are not limited to, one or more of the following determinations: the presence or absence of wetlands; the location(s) of the wetland boundary, ordinary high water mark, mean high water mark, and/or high tide line; interstate commerce nexus for isolated waters; and adjacency of wetlands to other waters of the United States. All JDs will be in writing and will be identified as either preliminary or approved. JDs do not include determinations that a particular activity requires a DA permit. ...

40 C.F.R. § 60.58c. Reporting and recordkeeping requirements.

(b) The owner or operator of an affected facility shall maintain the following information (as applicable) for a period of at least 5 years:

- (1) Calendar date of each record;
- (2) Records of the following data:

- (i) Concentrations of any pollutant listed in § 60.52c or measurements of opacity as determined by the continuous emission monitoring system (if applicable);
 - (ii) Results of fugitive emissions (by EPA Reference Method 22) tests, if applicable;
 - (iii) HMIWI charge dates, times, and weights and hourly charge rates;
 - (iv) Fabric filter inlet temperatures during each minute of operation, as applicable;
 - (v) Amount and type of dioxin/furan sorbent used during each hour of operation, as applicable;
 - (vi) Amount and type of Hg sorbent used during each hour of operation, as applicable;
 - (vii) Amount and type of HCl sorbent used during each hour of operation, as applicable;
 - (viii) For affected facilities as defined in § 60.50c(a)(3) and (4), amount and type of NO[x] reagent used during each hour of operation, as applicable;
 - (ix) Secondary chamber temperatures recorded during each minute of operation;
 - (x) Liquor flow rate to the wet scrubber inlet during each minute of operation, as applicable;
 - (xi) Horsepower or amperage to the wet scrubber during each minute of operation, as applicable;
 - (xii) Pressure drop across the wet scrubber system during each minute of operation, as applicable,
 - (xiii) Temperature at the outlet from the wet scrubber during each minute of operation, as applicable;
 - (xiv) pH at the inlet to the wet scrubber during each minute of operation, as applicable,
 - (xv) Records indicating use of the bypass stack, including dates, times, and durations, and
 - (xvi) For affected facilities complying with § 60.56c(j) and § 60.57c(d), the owner or operator shall maintain all operating parameter data collected;
 - (xvii) For affected facilities as defined in § 60.50c(a)(3) and (4), records of the annual air pollution control device inspections, any required maintenance, and any repairs not completed within 10 days of an inspection or the timeframe established by the Administrator.
 - (xviii) For affected facilities as defined in § 60.50c(a)(3) and (4), records of each bag leak detection system alarm, the time of the alarm, the time corrective action was initiated and completed, and a brief description of the cause of the alarm and the corrective action taken, as applicable.
 - (xix) For affected facilities as defined in § 60.50c(a)(3) and (4), concentrations of CO as determined by the continuous emissions monitoring system.
- (3) Identification of calendar days for which data on emission rates or operating parameters specified under paragraph (b)(2) of this section have not been obtained, with an identification of the emission rates or operating parameters not

measured, reasons for not obtaining the data, and a description of corrective actions taken.

(4) Identification of calendar days, times and durations of malfunctions, a description of the malfunction and the corrective action taken.

(5) Identification of calendar days for which data on emission rates or operating parameters specified under paragraph (b)(2) of this section exceeded the applicable limits, with a description of the exceedances, reasons for such exceedances, and a description of corrective actions taken.

(6) The results of the initial, annual, and any subsequent performance tests conducted to determine compliance with the emissions limits and/or to establish or re-establish operating parameters, as applicable, and a description, including sample calculations, of how the operating parameters were established or re-established, if applicable.

(7) All documentation produced as a result of the siting requirements of § 60.54c;

(8) Records showing the names of HMIWI operators who have completed review of the information in § 60.53c(h) as required by § 60.53c(i), including the date of the initial review and all subsequent annual reviews;

(9) Records showing the names of the HMIWI operators who have completed the operator training requirements, including documentation of training and the dates of the training;

(10) Records showing the names of the HMIWI operators who have met the criteria for qualification under § 60.53c and the dates of their qualification; and

(11) Records of calibration of any monitoring devices as required under § 60.57c(a) through (d).

40 C.F.R. § 60.7. Notification and record keeping.

(f) Any owner or operator subject to the provisions of this part shall maintain a file of all measurements, including continuous monitoring system, monitoring device, and performance testing measurements; all continuous monitoring system performance evaluations; all continuous monitoring system or monitoring device calibration checks; adjustments and maintenance performed on these systems or devices; and all other information required by this part recorded in a permanent form suitable for inspection. The file shall be retained for at least two years following the date of such measurements, maintenance, reports, and records, except as follows:

(1) This paragraph applies to owners or operators required to install a continuous emissions monitoring system (CEMS) where the CEMS installed is automated, and where the calculated data averages do not exclude periods of CEMS breakdown or malfunction. An automated CEMS records and reduces the measured data to the form of the pollutant emission standard through the use of a computerized data acquisition system. In lieu of maintaining a file of all CEMS subhourly measurements as required under paragraph (f) of this section, the owner or operator shall retain the most recent consecutive three averaging periods of subhourly measurements and a file that contains a hard copy of the data acquisition system algorithm used to reduce the measured data into the reportable form of the standard.

(2) This paragraph applies to owners or operators required to install a CEMS where the measured data is manually reduced to obtain the reportable form of the

standard, and where the calculated data averages do not exclude periods of CEMS breakdown or malfunction. In lieu of maintaining a file of all CEMS subhourly measurements as required under paragraph (f) of this section, the owner or operator shall retain all subhourly measurements for the most recent reporting period. The subhourly measurements shall be retained for 120 days from the date of the most recent summary or excess emission report submitted to the Administrator.

(3) The Administrator or delegated authority, upon notification to the source, may require the owner or operator to maintain all measurements as required by paragraph (f) of this section, if the Administrator or the delegated authority determines these records are required to more accurately assess the compliance status of the affected source.

40 C.F.R. § 61.145. Standard for demolition and renovation.

(a) *Applicability.* To determine which requirements of paragraphs (a), (b), and (c) of this section apply to the owner or operator of a demolition or renovation activity and prior to the commencement of the demolition or renovation, thoroughly inspect the affected facility or part of the facility where the demolition or renovation operation will occur for the presence of asbestos, including Category I and Category II nonfriable ACM. The requirements of paragraphs (b) and (c) of this section apply to each owner or operator of a demolition or renovation activity, including the removal of RACM as follows:

(1) In a facility being demolished, all the requirements of paragraphs (b) and (c) of this section apply, except as provided in paragraph (a)(3) of this section, if the combined amount of RACM is

- (i) At least 80 linear meters (260 linear feet) on pipes or at least 15 square meters (160 square feet) on other facility components, or
- (ii) At least 1 cubic meter (35 cubic feet) off facility components where the length or area could not be measured previously.

(2) In a facility being demolished, only the notification requirements of paragraphs (b)(1), (2), (3)(i) and (iv), and (4)(i) through (vii) and (4)(ix) and (xvi) of this section apply, if the combined amount of RACM is

- (i) Less than 80 linear meters (260 linear feet) on pipes and less than 15 square meters (160 square feet) on other facility components, and
- (ii) Less than one cubic meter (35 cubic feet) off facility components where the length or area could not be measured previously or there is no asbestos.

(3) If the facility is being demolished under an order of a State or local government agency, issued because the facility is structurally unsound and in danger of imminent collapse, only the requirements of paragraphs (b)(1), (b)(2), (b)(3)(iii), (b)(4) (except (b)(4)(viii)), (b)(5), and (c)(4) through (c)(9) of this section apply.

(4) In a facility being renovated, including any individual nonscheduled renovation operation, all the requirements of paragraphs (b) and (c) of this section apply if the combined amount of RACM to be stripped, removed, dislodged, cut, drilled, or similarly disturbed is

- (i) At least 80 linear meters (260 linear feet) on pipes or at least 15 square meters (160 square feet) on other facility components, or
- (ii) At least 1 cubic meter (35 cubic feet) off facility components where the length or area could not be measured previously.

(iii) To determine whether paragraph (a)(4) of this section applies to planned renovation operations involving individual nonscheduled operations, predict the combined additive amount of RACM to be removed or stripped during a calendar year of January 1 through December 31.

(iv) To determine whether paragraph (a)(4) of this section applies to emergency renovation operations, estimate the combined amount of RACM to be removed or stripped as a result of the sudden, unexpected event that necessitated the renovation.

(5) Owners or operators of demolition and renovation operations are exempt from the requirements of §§ 61.05(a), 61.07, and 61.09.

(b) *Notification requirements.* Each owner or operator of a demolition or renovation activity to which this section applies shall:

(1) Provide the Administrator with written notice of intention to demolish or renovate. Delivery of the notice by U.S. Postal Service, commercial delivery service, or hand delivery is acceptable.

(2) Update notice, as necessary, including when the amount of asbestos affected changes by at least 20 percent.

(3) Postmark or deliver the notice as follows:

(i) At least 10 working days before asbestos stripping or removal work or any other activity begins (such as site preparation that would break up, dislodge or similarly disturb asbestos material), if the operation is described in paragraphs (a) (1) and (4) (except (a)(4)(iii) and (a)(4)(iv)) of this section. If the operation is as described in paragraph (a)(2) of this section, notification is required 10 working days before demolition begins.

(ii) At least 10 working days before the end of the calendar year preceding the year for which notice is being given for renovations described in paragraph (a)(4)(iii) of this section.

(iii) As early as possible before, but not later than, the following working day if the operation is a demolition ordered according to paragraph (a)(3) of this section or, if the operation is a renovation described in paragraph (a)(4)(iv) of this section.

(iv) For asbestos stripping or removal work in a demolition or renovation operation, described in paragraphs (a) (1) and (4) (except (a)(4)(iii) and (a)(4)(iv)) of this section, and for a demolition described in paragraph (a)(2) of this section, that will begin on a date other than the one contained in the original notice, notice of the new start date must be provided to the Administrator as follows:

(A) When the asbestos stripping or removal operation or demolition operation covered by this paragraph will begin after the date contained in the notice,

(1) Notify the Administrator of the new start date by telephone as soon as possible before the original start date, and

(2) Provide the Administrator with a written notice of the new start date as soon as possible before, and no later than, the original start date. Delivery of the updated notice by the U.S. Postal Service, commercial delivery service, or hand delivery is acceptable.

(B) When the asbestos stripping or removal operation or demolition operation covered by this paragraph will begin on a date earlier than the original start date,

(1) Provide the Administrator with a written notice of the new start date at least 10 working days before asbestos stripping or removal work begins.

(2) For demolitions covered by paragraph (a)(2) of this section, provide the Administrator written notice of a new start date at least 10 working days before commencement of demolition. Delivery of updated notice by U.S. Postal Service, commercial delivery service, or hand delivery is acceptable.

(C) In no event shall an operation covered by this paragraph begin on a date other than the date contained in the written notice of the new start date.

(4) Include the following in the notice:

(i) An indication of whether the notice is the original or a revised notification.

(ii) Name, address, and telephone number of both the facility owner and operator and the asbestos removal contractor owner or operator.

(iii) Type of operation: demolition or renovation.

(iv) Description of the facility or affected part of the facility including the size (square meters [square feet] and number of floors), age, and present and prior use of the facility.

(v) Procedure, including analytical methods, employed to detect the presence of RACM and Category I and Category II nonfriable ACM.

(vi) Estimate of the approximate amount of RACM to be removed from the facility in terms of length of pipe in linear meters (linear feet), surface area in square meters (square feet) on other facility components, or volume in cubic meters (cubic feet) if off the facility components. Also, estimate the approximate amount of Category I and Category II nonfriable ACM in the affected part of the facility that will not be removed before demolition.

(vii) Location and street address (including building number or name and floor or room number, if appropriate), city, county, and state, of the facility being demolished or renovated.

(viii) Scheduled starting and completion dates of asbestos removal work (or any other activity, such as site preparation that would break up, dislodge, or similarly disturb asbestos material) in a demolition or renovation; planned renovation operations involving individual nonscheduled operations shall only include the beginning and ending dates of the report period as described in paragraph (a)(4)(iii) of this section.

(ix) Scheduled starting and completion dates of demolition or renovation.

(x) Description of planned demolition or renovation work to be performed and method(s) to be employed, including demolition or renovation techniques to be used and description of affected facility components.

(xi) Description of work practices and engineering controls to be used to comply with the requirements of this subpart, including asbestos removal and waste-handling emission control procedures.

(xii) Name and location of the waste disposal site where the asbestos-containing waste material will be deposited.

(xiii) A certification that at least one person trained as required by paragraph (c)(8) of this section will supervise the stripping and removal described by this notification. This requirement shall become effective 1 year after promulgation of this regulation.

(xiv) For facilities described in paragraph (a)(3) of this section, the name, title, and authority of the State or local government representative who has ordered the demolition, the date that the order was issued, and the date on which the demolition was ordered to begin. A copy of the order shall be attached to the notification.

(xv) For emergency renovations described in paragraph (a)(4)(iv) of this section, the date and hour that the emergency occurred, a description of the sudden, unexpected event, and an explanation of how the event caused an unsafe condition, or would cause equipment damage or an unreasonable financial burden.

(xvi) Description of procedures to be followed in the event that unexpected RACM is found or Category II nonfriable ACM becomes crumbled, pulverized, or reduced to powder.

(xvii) Name, address, and telephone number of the waste transporter.

(5) The information required in paragraph (b)(4) of this section must be reported using a form similar to that shown in Figure 3.

(c) *Procedures for asbestos emission control.* Each owner or operator of a demolition or renovation activity to whom this paragraph applies, according to paragraph (a) of this section, shall comply with the following procedures:

(1) Remove all RACM from a facility being demolished or renovated before any activity begins that would break up, dislodge, or similarly disturb the material or preclude access to the material for subsequent removal. RACM need not be removed before demolition if:

(i) It is Category I nonfriable ACM that is not in poor condition and is not friable.

(ii) It is on a facility component that is encased in concrete or other similarly hard material and is adequately wet whenever exposed during demolition; or

(iii) It was not accessible for testing and was, therefore, not discovered until after demolition began and, as a result of the demolition, the material cannot be safely removed. If not removed for safety reasons, the exposed RACM and any asbestos-contaminated debris must be treated as asbestos-containing waste material and adequately wet at all times until disposed of.

(iv) They are Category II nonfriable ACM and the probability is low that the materials will become crumbled, pulverized, or reduced to powder during demolition.

(2) When a facility component that contains, is covered with, or is coated with RACM is being taken out of the facility as a unit or in sections:

- (i) Adequately wet all RACM exposed during cutting or disjoining operations; and
- (ii) Carefully lower each unit or section to the floor and to ground level, not dropping, throwing, sliding, or otherwise damaging or disturbing the RACM.
- (3) When RACM is stripped from a facility component while it remains in place in the facility, adequately wet the RACM during the stripping operation.
 - (i) In renovation operations, wetting is not required if:
 - (A) The owner or operator has obtained prior written approval from the Administrator based on a written application that wetting to comply with this paragraph would unavoidably damage equipment or present a safety hazard; and
 - (B) The owner or operator uses one of the following emission control methods:
 - (1) A local exhaust ventilation and collection system designed and operated to capture the particulate asbestos material produced by the stripping and removal of the asbestos materials. The system must exhibit no visible emissions to the outside air or be designed and operated in accordance with the requirements in [§ 61.152](#).
 - (2) A glove-bag system designed and operated to contain the particulate asbestos material produced by the stripping of the asbestos materials.
 - (3) Leak-tight wrapping to contain all RACM prior to dismantlement.
 - (ii) In renovation operations where wetting would result in equipment damage or a safety hazard, and the methods allowed in paragraph (c)(3)(i) of this section cannot be used, another method may be used after obtaining written approval from the Administrator based upon a determination that it is equivalent to wetting in controlling emissions or to the methods allowed in paragraph (c)(3)(i) of this section.
 - (iii) A copy of the Administrator's written approval shall be kept at the worksite and made available for inspection.
- (4) After a facility component covered with, coated with, or containing RACM has been taken out of the facility as a unit or in sections pursuant to paragraph (c)(2) of this section, it shall be stripped or contained in leak-tight wrapping, except as described in paragraph (c)(5) of this section. If stripped, either:
 - (i) Adequately wet the RACM during stripping; or
 - (ii) Use a local exhaust ventilation and collection system designed and operated to capture the particulate asbestos material produced by the stripping. The system must exhibit no visible emissions to the outside air or be designed and operated in accordance with the requirements in [§ 61.152](#).
- (5) For large facility components such as reactor vessels, large tanks, and steam generators, but not beams (which must be handled in accordance with paragraphs (c)(2), (3), and (4) of this section), the RACM is not required to be stripped if the following requirements are met:

(i) The component is removed, transported, stored, disposed of, or reused without disturbing or damaging the RACM.

(ii) The component is encased in a leak-tight wrapping.

(iii) The leak-tight wrapping is labeled according to [§ 61.149\(d\)\(1\)\(i\), \(ii\), and \(iii\)](#) during all loading and unloading operations and during storage.

(6) For all RACM, including material that has been removed or stripped:

(i) Adequately wet the material and ensure that it remains wet until collected and contained or treated in preparation for disposal in accordance with [§ 61.150](#); and

(ii) Carefully lower the material to the ground and floor, not dropping, throwing, sliding, or otherwise damaging or disturbing the material.

(iii) Transport the material to the ground via leak-tight chutes or containers if it has been removed or stripped more than 50 feet above ground level and was not removed as units or in sections.

(iv) RACM contained in leak-tight wrapping that has been removed in accordance with paragraphs (c)(4) and (c)(3)(i)(B)(3) of this section need not be wetted.

(7) When the temperature at the point of wetting is below 0 °C (32 °F):

(i) The owner or operator need not comply with paragraph (c)(2)(i) and the wetting provisions of paragraph (c)(3) of this section.

(ii) The owner or operator shall remove facility components containing, coated with, or covered with RACM as units or in sections to the maximum extent possible.

(iii) During periods when wetting operations are suspended due to freezing temperatures, the owner or operator must record the temperature in the area containing the facility components at the beginning, middle, and end of each workday and keep daily temperature records available for inspection by the Administrator during normal business hours at the demolition or renovation site. The owner or operator shall retain the temperature records for at least 2 years.

(8) Effective 1 year after promulgation of this regulation, no RACM shall be stripped, removed, or otherwise handled or disturbed at a facility regulated by this section unless at least one on-site representative, such as a foreman or management-level person or other authorized representative, trained in the provisions of this regulation and the means of complying with them, is present. Every 2 years, the trained on-site individual shall receive refresher training in the provisions of this regulation. The required training shall include as a minimum: applicability; notifications; material identification; control procedures for removals including, at least, wetting, local exhaust ventilation, negative pressure enclosures, glove-bag procedures, and High Efficiency Particulate Air (HEPA) filters; waste disposal work practices; reporting and recordkeeping; and asbestos hazards and worker protection. Evidence that the required training has been completed shall be posted and made available for inspection by the Administrator at the demolition or renovation site.

(9) For facilities described in paragraph (a)(3) of this section, adequately wet the portion of the facility that contains RACM during the wrecking operation.

(10) If a facility is demolished by intentional burning, all RACM including Category I and Category II nonfriable ACM must be removed in accordance with the NESHAP before burning.

40 C.F.R. § 61.150. Standard for waste disposal for manufacturing, fabricating, demolition, renovation, and spraying operations.

Each owner or operator of any source covered under the provisions of §§ 61.144, 61.145, 61.146, and 61.147 shall comply with the following provisions:

(a) Discharge no visible emissions to the outside air during the collection, processing (including incineration), packaging, or transporting of any asbestos-containing waste material generated by the source, or use one of the emission control and waste treatment methods specified in paragraphs (a) (1) through (4) of this section.

(1) Adequately wet asbestos-containing waste material as follows:

(i) Mix control device asbestos waste to form a slurry; adequately wet other asbestos-containing waste material; and

(ii) Discharge no visible emissions to the outside air from collection, mixing, wetting, and handling operations, or use the methods specified by § 61.152 to clean emissions containing particulate asbestos material before they escape to, or are vented to, the outside air; and

(iii) After wetting, seal all asbestos-containing waste material in leak-tight containers while wet; or, for materials that will not fit into containers without additional breaking, put materials into leak-tight wrapping; and

(iv) Label the containers or wrapped materials specified in paragraph (a)(1)(iii) of this section using warning labels specified by Occupational Safety and Health Standards of the Department of Labor, Occupational Safety and Health Administration (OSHA) under 29 CFR 1910.1001(j)(4) or 1926.1101(k)(8). The labels shall be printed in letters of sufficient size and contrast so as to be readily visible and legible.

(v) For asbestos-containing waste material to be transported off the facility site, label containers or wrapped materials with the name of the waste generator and the location at which the waste was generated.

(2) Process asbestos-containing waste material into nonfriable forms as follows:

(i) Form all asbestos-containing waste material into nonfriable pellets or other shapes;

(ii) Discharge no visible emissions to the outside air from collection and processing operations, including incineration, or use the method specified by § 61.152 to clean emissions containing particulate asbestos material before they escape to, or are vented to, the outside air.

(3) For facilities demolished where the RACM is not removed prior to demolition according to §§ 61.145(c)(1) (i), (ii), (iii), and (iv) or for facilities demolished according to § 61.145(c)(9), adequately wet asbestos-containing waste material at all times after demolition and keep wet during handling and loading for transport to a disposal site. Asbestos-containing waste materials covered by this paragraph do not have to be sealed in leak-tight containers or wrapping but may be transported and disposed of in bulk.

(4) Use an alternative emission control and waste treatment method that has received prior approval by the Administrator according to the procedure described in § 61.149(c)(2).

(5) As applied to demolition and renovation, the requirements of paragraph (a) of this section do not apply to Category I nonfriable ACM waste and Category II nonfriable ACM waste that did not become crumbled, pulverized, or reduced to powder.

(b) All asbestos-containing waste material shall be deposited as soon as is practical by the waste generator at:

(1) A waste disposal site operated in accordance with the provisions of § 61.154, or

(2) An EPA-approved site that converts RACM and asbestos-containing waste material into nonasbestos (asbestos-free) material according to the provisions of § 61.155.

(3) The requirements of paragraph (b) of this section do not apply to Category I nonfriable ACM that is not RACM.

(c) Mark vehicles used to transport asbestos-containing waste material during the loading and unloading of waste so that the signs are visible. The markings must conform to the requirements of §§ 61.149(d)(1) (i), (ii), and (iii).

(d) For all asbestos-containing waste material transported off the facility site:

(1) Maintain waste shipment records, using a form similar to that shown in Figure 4, and include the following information:

(i) The name, address, and telephone number of the waste generator.

(ii) The name and address of the local, State, or EPA Regional office responsible for administering the asbestos NESHAP program.

(iii) The approximate quantity in cubic meters (cubic yards).

(iv) The name and telephone number of the disposal site operator.

(v) The name and physical site location of the disposal site.

(vi) The date transported.

(vii) The name, address, and telephone number of the transporter(s).

(viii) A certification that the contents of this consignment are fully and accurately described by proper shipping name and are classified, packed, marked, and labeled, and are in all respects in proper condition for transport by highway according to applicable international and government regulations.

(2) Provide a copy of the waste shipment record, described in paragraph (d)(1) of this section, to the disposal site owners or operators at the same time as the asbestos-containing waste material is delivered to the disposal site.

(3) For waste shipments where a copy of the waste shipment record, signed by the owner or operator of the designated disposal site, is not received by the waste generator within 35 days of the date the waste was accepted by the initial transporter, contact the transporter and/or the owner or operator of the designated disposal site to determine the status of the waste shipment.

(4) Report in writing to the local, State, or EPA Regional office responsible for administering the asbestos NESHAP program for the waste generator if a copy of the waste shipment record, signed by the owner or operator of the designated waste disposal site, is not received by the waste generator within 45 days of the date the waste was accepted by the initial transporter. Include in the report the following information:

(i) A copy of the waste shipment record for which a confirmation of delivery was not received, and

(ii) A cover letter signed by the waste generator explaining the efforts taken to locate the asbestos waste shipment and the results of those efforts.

(5) Retain a copy of all waste shipment records, including a copy of the waste shipment record signed by the owner or operator of the designated waste disposal site, for at least 2 years.

(e) Furnish upon request, and make available for inspection by the Administrator, all records required under this section.

40 C.F.R. § 63.10. Recordkeeping and reporting requirements.

(b) *General recordkeeping requirements.* (1) The owner or operator of an affected source subject to the provisions of this part shall maintain files of all information (including all reports and notifications) required by this part recorded in a form suitable and readily available for expeditious inspection and review. The files shall be retained for at least 5 years following the date of each occurrence, measurement, maintenance, corrective action, report, or record. At a minimum, the most recent 2 years of data shall be retained on site. The remaining 3 years of data may be retained off site. Such files may be maintained on microfilm, on a computer, on computer floppy disks, on magnetic tape disks, or on microfiche.

40 C.F.R. § 63.6660. In what form and how long must I keep my records?

(a) Your records must be in a form suitable and readily available for expeditious review according to § 63.10(b)(1).

(b) As specified in § 63.10(b)(1), you must keep each record for 5 years following the date of each occurrence, measurement, maintenance, corrective action, report, or record.

(c) You must keep each record readily accessible in hard copy or electronic form for at least 5 years after the date of each occurrence, measurement, maintenance, corrective action, report, or record, according to § 63.10(b)(1).

40 C.F.R. § 262.10. Purpose, scope, and applicability.

(a) The regulations in this part establish standards for generators of hazardous waste as defined by 40 CFR 260.10...

(2) A generator that accumulates hazardous waste on site is a person that stores hazardous waste; such generator is subject to the applicable requirements of parts 124, 264 through 267, and 270 of this chapter and section 3010 of RCRA, unless it is one of the following:

(i) A very small quantity generator that meets the conditions for exemption in § 262.14;

(ii) A small quantity generator that meets the conditions for exemption in §§ 262.15 and 262.16; or

(iii) A large quantity generator that meets the conditions for exemption in §§ 262.15 and 262.17.

40 C.F.R. § 262.11(f). Recordkeeping for small and large quantity generators.

A small or large quantity generator must maintain records supporting its hazardous waste determinations, including records that identify whether a solid waste is a hazardous waste, as defined by 40 CFR 261.3. Records must be maintained for at least three years from the date that the waste was last sent to on-site or off-site treatment, storage, or disposal. These records must comprise the generator's knowledge of the waste and support the generator's determination, as described at paragraphs (c) and (d) of this section. The records must include, but are not limited to, the following types of information: The results of any tests, sampling, waste analyses, or other determinations made in accordance with this section; records documenting the tests, sampling, and analytical methods used to demonstrate the validity and relevance of such tests; records consulted in order to determine the process by which the waste was generated, the composition of the waste, and the properties of the waste; and records which explain the knowledge basis for the generator's determination, as described at paragraph (d)(1) of this section. The periods of record retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the Administrator.

40 C.F.R. § 262.14. Conditions for exemption for a very small quantity generator.

(a) Provided that the very small quantity generator meets all the conditions for exemption listed in this section, hazardous waste generated by the very small quantity generator is not subject to the requirements of parts 124, 262 (except §§ 262.10–262.14) through 268, and 270 of this chapter, and the notification requirements of section 3010 of RCRA and the very small quantity generator may accumulate hazardous waste on site without complying with such requirements. The conditions for exemption are as follows:

(1) In a calendar month the very small quantity generator generates less than or equal to the amounts specified in the definition of “very small quantity generator” in § 260.10 of this chapter;

(2) The very small quantity generator complies with § 262.11(a) through (d);

(3) If the very small quantity generator accumulates at any time greater than 1 kilogram (2.2 lbs) of acute hazardous waste or 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in §§ 261.31 or 261.33(e) of this chapter, all quantities of that acute hazardous waste are subject to the following additional conditions for exemption:

(i) Such waste is held on site for no more than 90 days beginning on the date when the accumulated wastes exceed the amounts provided above; and

(ii) The conditions for exemption in § 262.17(a) through (g).

(4) If the very small quantity generator accumulates at any time 1,000 kilograms (2,200 lbs) or greater of non-acute hazardous waste, all quantities of that hazardous waste are subject to the following additional conditions for exemption:

(i) Such waste is held on site for no more than 180 days, or 270 days, if applicable, beginning on the date when the accumulated waste exceed the amounts provided above;

(ii) The quantity of waste accumulated on site never exceeds 6,000 kilograms (13,200 lbs); and

(iii) The conditions for exemption in § 262.16(b)(2) through (f).

- (5) A very small quantity generator that accumulates hazardous waste in amounts less than or equal to the limits in paragraphs (a)(3) and (4) of this section must either treat or dispose of its hazardous waste in an on-site facility or ensure delivery to an off-site treatment, storage, or disposal facility, either of which, if located in the U.S., is:
- (i) Permitted under part 270 of this chapter;
 - (ii) In interim status under parts 265 and 270 of this chapter;
 - (iii) Authorized to manage hazardous waste by a state with a hazardous waste management program approved under part 271 of this chapter;
 - (iv) Permitted, licensed, or registered by a state to manage municipal solid waste and, if managed in a municipal solid waste landfill is subject to part 258 of this chapter;
 - (v) Permitted, licensed, or registered by a state to manage non-municipal non-hazardous waste and, if managed in a non-municipal non-hazardous waste disposal unit, is subject to the requirements in §§ 257.5 through 257.30 of this chapter;
 - (vi) A facility which:
 - (A) Beneficially uses or reuses, or legitimately recycles or reclaims its waste; or
 - (B) Treats its waste prior to beneficial use or reuse, or legitimate recycling or reclamation;
 - (vii) For universal waste managed under part 273 of this chapter, a universal waste handler or destination facility subject to the requirements of part 273 of this chapter;
 - (viii) A large quantity generator under the control of the same person as the very small quantity generator, provided the following conditions are met:
 - (A) The very small quantity generator and the large quantity generator are under the control of the same person as defined in § 260.10 of this chapter. “Control,” for the purposes of this section, means the power to direct the policies of the generator, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate generator facilities on behalf of a different person as defined in § 260.10 of this chapter shall not be deemed to “control” such generators.
 - (B) The very small quantity generator marks its container(s) of hazardous waste with:
 - (1) The words “Hazardous Waste” and
 - (2) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704).

(b) The placement of bulk or non-containerized liquid hazardous waste or hazardous waste containing free liquids (whether or not sorbents have been added) in any landfill is prohibited

(c) A very small quantity generator experiencing an episodic event may generate and accumulate hazardous waste in accordance with subpart L of this part in lieu of §§ 262.15, 262.16, and 262.17.

40 C.F.R. § 262.16. Conditions for exemption for a small quantity generator that accumulates hazardous waste.

A small quantity generator may accumulate hazardous waste on site without a permit or interim status, and without complying with the requirements of parts 124, 264 through 267, and 270 of this chapter, or the notification requirements of section 3010 of RCRA, provided that all the conditions for exemption listed in this section are met:

(a) *Generation.* The generator generates in a calendar month no more than the amounts specified in the definition of “small quantity generator” in § 260.10 of this chapter.

(b) *Accumulation.* The generator accumulates hazardous waste on site for no more than 180 days, unless in compliance with the conditions for exemption for longer accumulation in paragraphs (d) and (e) of this section. The following accumulation conditions also apply:

(1) *Accumulation limit.* The quantity of hazardous waste accumulated on site never exceeds 6,000 kilograms (13,200 pounds);

(2) *Accumulation of hazardous waste in containers—*

(i) *Condition of containers.* If a container holding hazardous waste is not in good condition, or if it begins to leak, the small quantity generator must immediately transfer the hazardous waste from this container to a container that is in good condition, or immediately manage the waste in some other way that complies with the conditions for exemption of this section.

(ii) *Compatibility of waste with container.* The small quantity generator must use a container made of or lined with materials that will not react with, and are otherwise compatible with, the hazardous waste to be accumulated, so that the ability of the container to contain the waste is not impaired.

(iii) *Management of containers.*

(A) A container holding hazardous waste must always be closed during accumulation, except when it is necessary to add or remove waste.

(B) A container holding hazardous waste must not be opened, handled, or accumulated in a manner that may rupture the container or cause it to leak.

(iv) *Inspections.* At least weekly, the small quantity generator must inspect central accumulation areas. The small quantity generator must look for leaking containers and for deterioration of containers caused by corrosion or other factors. See paragraph (b)(2)(i) of this section for remedial action required if deterioration or leaks are detected.

(v) *Special conditions for accumulation of incompatible wastes.*

(A) Incompatible wastes, or incompatible wastes and materials, (see appendix V of part 265 for examples) must not be placed in the same container, unless § 265.17(b) of this chapter is complied with.

(B) Hazardous waste must not be placed in an unwashed container that previously held an incompatible waste or material (see appendix V of part 265 for examples), unless § 265.17(b) of this chapter is complied with.

(C) A container accumulating hazardous waste that is incompatible with any waste or other materials accumulated or stored nearby in other containers, piles, open tanks, or surface impoundments must be separated from the other materials or protected from them by means of a dike, berm, wall, or other device.

(3) *Accumulation of hazardous waste in tanks.*

(i) [Reserved]

(ii) A small quantity generator of hazardous waste must comply with the following general operating conditions:

(A) Treatment or accumulation of hazardous waste in tanks must comply with § 265.17(b) of this chapter.

(B) Hazardous wastes or treatment reagents must not be placed in a tank if they could cause the tank or its inner liner to rupture, leak, corrode, or otherwise fail before the end of its intended life.

(C) Uncovered tanks must be operated to ensure at least 60 centimeters (2 feet) of freeboard, unless the tank is equipped with a containment structure (e.g., dike or trench), a drainage control system, or a diversion structure (e.g., standby tank) with a capacity that equals or exceeds the volume of the top 60 centimeters (2 feet) of the tank.

(D) Where hazardous waste is continuously fed into a tank, the tank must be equipped with a means to stop this inflow (e.g., waste feed cutoff system or by-pass system to a stand-by tank).

(iii) Except as noted in paragraph (b)(3)(iv) of this section, a small quantity generator that accumulates hazardous waste in tanks must inspect, where present:

(A) Discharge control equipment (e.g., waste feed cutoff systems, by-pass systems, and drainage systems) at least once each operating day, to ensure that it is in good working order;

(B) Data gathered from monitoring equipment (e.g., pressure and temperature gauges) at least once each operating day to ensure that the tank is being operated according to its design;

(C) The level of waste in the tank at least once each operating day to ensure compliance with paragraph (b)(3)(ii)(C) of this section;

(D) The construction materials of the tank at least weekly to detect corrosion or leaking of fixtures or seams; and

(E) The construction materials of, and the area immediately surrounding, discharge confinement structures (e.g., dikes) at least weekly to detect erosion or obvious signs of leakage (e.g., wet spots or dead vegetation). The generator must remedy any deterioration or malfunction

of equipment or structures which the inspection reveals on a schedule which ensures that the problem does not lead to an environmental or human health hazard. Where a hazard is imminent or has already occurred, remedial action must be taken immediately.

(iv) A small quantity generator accumulating hazardous waste in tanks or tank systems that have full secondary containment and that either use leak detection equipment to alert personnel to leaks, or implement established workplace practices to ensure leaks are promptly identified, must inspect at least weekly, where applicable, the areas identified in paragraphs (b)(3)(iii)(A) through (E) of this section. Use of the alternate inspection schedule must be documented in the generator's operating record. This documentation must include a description of the established workplace practices at the generator.

(v) [Reserved]

(vi) A small quantity generator accumulating hazardous waste in tanks must, upon closure of the facility, remove all hazardous waste from tanks, discharge control equipment, and discharge confinement structures. At closure, as throughout the operating period, unless the small quantity generator can demonstrate, in accordance with § 261.3(c) or (d) of this chapter, that any solid waste removed from its tank is not a hazardous waste, then it must manage such waste in accordance with all applicable provisions of parts 262, 263, 265 and 268 of this chapter.

(vii) A small quantity generator must comply with the following special conditions for accumulation of ignitable or reactive waste:

(A) Ignitable or reactive waste must not be placed in a tank, unless:

(1) The waste is treated, rendered, or mixed before or immediately after placement in a tank so that the resulting waste, mixture, or dissolution of material no longer meets the definition of ignitable or reactive waste under § 261.21 or § 261.23 of this chapter and § 265.17(b) of this chapter is complied with; or

(2) The waste is accumulated or treated in such a way that it is protected from any material or conditions that may cause the waste to ignite or react; or

(3) The tank is used solely for emergencies.

(B) A small quantity generator which treats or accumulates ignitable or reactive waste in covered tanks must comply with the buffer zone requirements for tanks contained in Tables 2-1 through 2-6 of the National Fire Protection Association's "Flammable and Combustible Liquids Code" (1977 or 1981) (incorporated by reference, see § 260.11).

(C) A small quantity generator must comply with the following special conditions for incompatible wastes:

(1) Incompatible wastes, or incompatible wastes and materials, (see part 265 appendix V for examples) must not be placed in the same tank, unless § 265.17(b) of this chapter is complied with.

- (2) Hazardous waste must not be placed in an unwashed tank that previously held an incompatible waste or material, unless § 265.17(b) of this chapter is complied with.
- (4) *Accumulation of hazardous waste on drip pads.* If the waste is placed on drip pads, the small quantity generator must comply with the following:
- (i) Subpart W of 40 CFR part 265 (except § 265.445 (c));
 - (ii) The small quantity generator must remove all wastes from the drip pad at least once every 90 days. Any hazardous wastes that are removed from the drip pad at least once every 90 days are then subject to the 180-day accumulation limit in paragraph (b) of this section and § 262.15 if hazardous wastes are being managed in satellite accumulation areas prior to being moved to the central accumulation area; and
 - (iii) The small quantity generator must maintain on site at the facility the following records readily available for inspection:
 - (A) A written description of procedures that are followed to ensure that all wastes are removed from the drip pad and associated collection system at least once every 90 days; and
 - (B) Documentation of each waste removal, including the quantity of waste removed from the drip pad and the sump or collection system and the date and time of removal.
- (5) *Accumulation of hazardous waste in containment buildings.* If the waste is placed in containment buildings, the small quantity generator must comply with of 40 CFR part 265 subpart DD. The generator must label its containment buildings with the words “Hazardous Waste” in a conspicuous place easily visible to employees, visitors, emergency responders, waste handlers, or other persons on site and also in a conspicuous place provide an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704). The generator must also maintain:
- (i) The professional engineer certification that the building complies with the design standards specified in 40 CFR 265.1101. This certification must be in the generator's files prior to operation of the unit; and
 - (ii) The following records by use of inventory logs, monitoring equipment, or any other effective means:
 - (A) A written description of procedures to ensure that each waste volume remains in the unit for no more than 90 days, a written description of the waste generation and management practices for the facility showing that the generator is consistent with maintaining the 90 day limit, and documentation that the procedures are complied with; or
 - (B) Documentation that the unit is emptied at least once every 90 days.

- (C) Inventory logs or records with the above information must be maintained on site and readily available for inspection.
- (6) Labeling and marking of containers and tanks—
- (i) Containers. A small quantity generator must mark or label its containers with the following:
- (A) The words “Hazardous Waste”;
- (B) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704); and
- (C) The date upon which each period of accumulation begins clearly visible for inspection on each container.
- (ii) Tanks. A small quantity generator accumulating hazardous waste in tanks must do the following:
- (A) Mark or label its tanks with the words “Hazardous Waste”;
- (B) Mark or label its tanks with an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704);
- (C) Use inventory logs, monitoring equipment, or other records to demonstrate that hazardous waste has been emptied within 180 days of first entering the tank if using a batch process, or in the case of a tank with a continuous flow process, demonstrate that estimated volumes of hazardous waste entering the tank daily exit the tank within 180 days of first entering; and
- (D) Keep inventory logs or records with the above information on site and readily available for inspection.
- (7) *Land disposal restrictions.* A small quantity generator must comply with all the applicable requirements under 40 CFR part 268.
- (8) *Preparedness and prevention—*
- (i) *Maintenance and operation of facility.* A small quantity generator must maintain and operate its facility to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water which could threaten human health or the environment.

(ii) *Required equipment.* All areas where hazardous waste is either generated or accumulated must be equipped with the items in paragraphs (b)(8)(ii)(A) through (D) of this section (unless none of the hazards posed by waste handled at the facility could require a particular kind of equipment specified below or the actual waste generation or accumulation area does not lend itself for safety reasons to have a particular kind of equipment specified below). A small quantity generator may determine the most appropriate locations to locate equipment necessary to prepare for and respond to emergencies.

(A) An internal communications or alarm system capable of providing immediate emergency instruction (voice or signal) to facility personnel;

(B) A device, such as a telephone (immediately available at the scene of operations) or a hand-held two-way radio, capable of summoning emergency assistance from local police departments, fire departments, or State or local emergency response teams;

(C) Portable fire extinguishers, fire control equipment (including special extinguishing equipment, such as that using foam, inert gas, or dry chemicals), spill control equipment, and decontamination equipment; and

(D) Water at adequate volume and pressure to supply water hose streams, or foam producing equipment, or automatic sprinklers, or water spray systems.

(iii) *Testing and maintenance of equipment.* All communications or alarm systems, fire protection equipment, spill control equipment, and decontamination equipment, where required, must be tested and maintained as necessary to assure its proper operation in time of emergency.

(iv) *Access to communications or alarm system.*

(A) Whenever hazardous waste is being poured, mixed, spread, or otherwise handled, all personnel involved in the operation must have immediate access (e.g., direct or unimpeded access) to an internal alarm or emergency communication device, either directly or through visual or voice contact with another employee, unless such a device is not required under paragraph (a)(8)(ii) of this section.

(B) In the event there is just one employee on the premises while the facility is operating, the employee must have immediate access (e.g., direct or unimpeded access) to a device, such as a telephone (immediately available at the scene of operation) or a hand-held two-way radio, capable of summoning external emergency assistance, unless such a device is not required under paragraph (a)(8)(ii) of this section.

(v) *Required aisle space.* The small quantity generator must maintain aisle space to allow the unobstructed movement of personnel, fire protection equipment, spill control equipment, and decontamination equipment to any area of facility operation in an emergency, unless aisle space is not needed for any of these purposes.

(vi) *Arrangements with local authorities.*

(A) The small quantity generator must attempt to make arrangements with the local police department, fire department, other emergency response

teams, emergency response contractors, equipment suppliers and local hospitals, taking into account the types and quantities of hazardous wastes handled at the facility. Arrangements may be made with the Local Emergency Planning Committee, if it is determined to be the appropriate organization with which to make arrangements.

(1) A small quantity generator attempting to make arrangements with its local fire department must determine the potential need for the services of the local police department, other emergency response teams, emergency response contractors, equipment suppliers and local hospitals.

(2) As part of this coordination, the small quantity generator shall attempt to make arrangements, as necessary, to familiarize the above organizations with the layout of the facility, the properties of hazardous waste handled at the facility and associated hazards, places where facility personnel would normally be working, entrances to roads inside the facility, and possible evacuation routes as well as the types of injuries or illnesses that could result from fires, explosions, or releases at the facility.

(3) Where more than one police or fire department might respond to an emergency, the small quantity generator shall attempt to make arrangements designating primary emergency authority to a specific fire or police department, and arrangements with any others to provide support to the primary emergency authority.

(B) A small quantity generator shall maintain records documenting the arrangements with the local fire department as well as any other organization necessary to respond to an emergency. This documentation must include documentation in the operating record that either confirms such arrangements actively exist or, in cases where no arrangements exist, confirms that attempts to make such arrangements were made.

(C) A facility possessing 24-hour response capabilities may seek a waiver from the authority having jurisdiction (AHJ) over the fire code within the facility's state or locality as far as needing to make arrangements with the local fire department as well as any other organization necessary to respond to an emergency, provided that the waiver is documented in the operating record.

(9) *Emergency procedures.* The small quantity generator complies with the following conditions for those areas of the generator facility where hazardous waste is generated and accumulated:

(i) At all times there must be at least one employee either on the premises or on call (i.e., available to respond to an emergency by reaching the facility within a short period of time) with the responsibility for coordinating all emergency response measures specified in paragraph (b)(9)(iv) of this section. This employee is the emergency coordinator.

(ii) The small quantity generator must post the following information next to telephones or in areas directly involved in the generation and accumulation of hazardous waste:

(A) The name and emergency telephone number of the emergency coordinator;

(B) Location of fire extinguishers and spill control material, and, if present, fire alarm; and

(C) The telephone number of the fire department, unless the facility has a direct alarm.

(iii) The small quantity generator must ensure that all employees are thoroughly familiar with proper waste handling and emergency procedures, relevant to their responsibilities during normal facility operations and emergencies;

(iv) The emergency coordinator or his designee must respond to any emergencies that arise. The applicable responses are as follows:

(A) In the event of a fire, call the fire department or attempt to extinguish it using a fire extinguisher;

(B) In the event of a spill, the small quantity generator is responsible for containing the flow of hazardous waste to the extent possible, and as soon as is practicable, cleaning up the hazardous waste and any contaminated materials or soil. Such containment and cleanup can be conducted either by the small quantity generator or by a contractor on behalf of the small quantity generator;

(C) In the event of a fire, explosion, or other release that could threaten human health outside the facility or when the small quantity generator has knowledge that a spill has reached surface water, the small quantity generator must immediately notify the National Response Center (using their 24-hour toll free number 800/424-8802). The report must include the following information:

(1) The name, address, and U.S. EPA identification number of the small quantity generator;

(2) Date, time, and type of incident (e.g., spill or fire);

(3) Quantity and type of hazardous waste involved in the incident;

(4) Extent of injuries, if any; and

(5) Estimated quantity and disposition of recovered materials, if any.

(c) *Transporting over 200 miles.* A small quantity generator who must transport its waste, or offer its waste for transportation, over a distance of 200 miles or more for off-site treatment, storage or disposal may accumulate hazardous waste on site for 270 days or less without a permit or without having interim status provided that the generator complies with the conditions of paragraph (b) of this section.

(d) *Accumulation time limit extension.* A small quantity generator who accumulates hazardous waste for more than 180 days (or for more than 270 days if it must transport its waste, or offer its waste for transportation, over a distance of 200 miles or more) is subject to the requirements of 40 CFR parts 264, 265, 267, 268, and 270 of this chapter unless it has been granted an extension to the 180-day (or 270-day if applicable) period. Such extension may be granted by EPA if hazardous wastes must remain on site for longer than 180 days (or 270 days if applicable) due to unforeseen, temporary, and uncontrollable circumstances. An extension of up

to 30 days may be granted at the discretion of the Regional Administrator on a case-by-case basis.

(e) *Rejected load.* A small quantity generator who sends a shipment of hazardous waste to a designated facility with the understanding that the designated facility can accept and manage the waste and later receives that shipment back as a rejected load or residue in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter may accumulate the returned waste on site in accordance with paragraphs (a)-(d) of this section. Upon receipt of the returned shipment, the generator must:

(1) Sign Item 18c of the manifest, if the transporter returned the shipment using the original manifest; or

(2) Sign Item 20 of the manifest, if the transporter returned the shipment using a new manifest.

(f) A small quantity generator experiencing an episodic event may accumulate hazardous waste in accordance with subpart L of this part in lieu of § 262.17.40

40 C.F.R. § 262.17. for exemption for a large quantity generator that accumulates hazardous waste.

A large quantity generator may accumulate hazardous waste on site without a permit or interim status, and without complying with the requirements of parts 124, 264 through 267, and 270 of this chapter, or the notification requirements of section 3010 of RCRA, provided that all of the following conditions for exemption are met:

(a) *Accumulation.* A large quantity generator accumulates hazardous waste on site for no more than 90 days, unless in compliance with the accumulation time limit extension or F006 accumulation conditions for exemption in paragraphs (b) through (e) of this section. The following accumulation conditions also apply:

(1) *Accumulation of hazardous waste in containers.* If the hazardous waste is placed in containers, the large quantity generator must comply with the following:

(i) *Air emission standards.* The applicable requirements of subparts AA, BB, and CC of 40 CFR part 265;

(ii) *Condition of containers.* If a container holding hazardous waste is not in good condition, or if it begins to leak, the large quantity generator must immediately transfer the hazardous waste from this container to a container that is in good condition, or immediately manage the waste in some other way that complies with the conditions for exemption of this section;

(iii) *Compatibility of waste with container.* The large quantity generator must use a container made of or lined with materials that will not react with, and are otherwise compatible with, the hazardous waste to be stored, so that the ability of the container to contain the waste is not impaired;

(iv) *Management of containers.*

(A) A container holding hazardous waste must always be closed during accumulation, except when it is necessary to add or remove waste.

(B) A container holding hazardous waste must not be opened, handled, or stored in a manner that may rupture the container or cause it to leak.

(v) *Inspections.* At least weekly, the large quantity generator must inspect central accumulation areas. The large quantity generator must look for leaking containers and for deterioration of containers caused by corrosion or other factors. See paragraph (a)(1)(ii) of this section for remedial action required if deterioration or leaks are detected.

(vi) *Special conditions for accumulation of ignitable and reactive wastes.*

(A) Containers holding ignitable or reactive waste must be located at least 15 meters (50 feet) from the facility's property line unless a written approval is obtained from the authority having jurisdiction over the local fire code allowing hazardous waste accumulation to occur within this restricted area. A record of the written approval must be maintained as long as ignitable or reactive hazardous waste is accumulated in this area.

(B) The large quantity generator must take precautions to prevent accidental ignition or reaction of ignitable or reactive waste. This waste must be separated and protected from sources of ignition or reaction including but not limited to the following: Open flames, smoking, cutting and welding, hot surfaces, frictional heat, sparks (static, electrical, or mechanical), spontaneous ignition (e.g., from heat-producing chemical reactions), and radiant heat. While ignitable or reactive waste is being handled, the large quantity generator must confine smoking and open flame to specially designated locations. "No Smoking" signs must be conspicuously placed wherever there is a hazard from ignitable or reactive waste.

(vii) *Special conditions for accumulation of incompatible wastes.*

(A) Incompatible wastes, or incompatible wastes and materials, (see appendix V of part 265 for examples) must not be placed in the same container, unless § 265.17(b) of this chapter is complied with.

(B) Hazardous waste must not be placed in an unwashed container that previously held an incompatible waste or material (see appendix V of part 265 for examples), unless § 265.17(b) of this chapter is complied with.

(C) A container holding a hazardous waste that is incompatible with any waste or other materials accumulated or stored nearby in other containers, piles, open tanks, or surface impoundments must be separated from the other materials or protected from them by means of a dike, berm, wall, or other device.

(2) *Accumulation of hazardous waste in tanks.* If the waste is placed in tanks, the large quantity generator must comply with the applicable requirements of subparts J, except § 265.197(c) of Closure and post-closure care and § 265.200—Waste analysis and trial tests, as well as the applicable requirements of AA, BB, and CC of 40 CFR part 265.

(3) *Accumulation of hazardous waste on drip pads.* If the hazardous waste is placed on drip pads, the large quantity generator must comply with the following:

(i) Subpart W of 40 CFR part 265;

(ii) The large quantity generator must remove all wastes from the drip pad at least once every 90 days. Any hazardous wastes that are removed from the

drip pad are then subject to the 90-day accumulation limit in paragraph (a) of this section and § 262.15, if the hazardous wastes are being managed in satellite accumulation areas prior to being moved to a central accumulation area; and

(iii) The large quantity generator must maintain on site at the facility the following records readily available for inspection:

(A) A written description of procedures that are followed to ensure that all wastes are removed from the drip pad and associated collection system at least once every 90 days; and

(B) Documentation of each waste removal, including the quantity of waste removed from the drip pad and the sump or collection system and the date and time of removal.

(4) *Accumulation of hazardous waste in containment buildings.* If the waste is placed in containment buildings, the large quantity generator must comply with of 40 CFR part 265 subpart DD. The generator must label its containment building with the words “Hazardous Waste” in a conspicuous place easily visible to employees, visitors, emergency responders, waste handlers, or other persons on site, and also in a conspicuous place provide an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704). The generator must also maintain:

(i) The professional engineer certification that the building complies with the design standards specified in 40 CFR 265.1101. This certification must be in the generator's files prior to operation of the unit; and

(ii) The following records by use of inventory logs, monitoring equipment, or any other effective means:

(A) A written description of procedures to ensure that each waste volume remains in the unit for no more than 90 days, a written description of the waste generation and management practices for the facility showing that the generator is consistent with respecting the 90 day limit, and documentation that the procedures are complied with; or

(B) Documentation that the unit is emptied at least once every 90 days.

(C) Inventory logs or records with the above information must be maintained on site and readily available for inspection.

(5) *Labeling and marking of containers and tanks—*

(i) *Containers.* A large quantity generator must mark or label its containers with the following:

(A) The words “Hazardous Waste”;

(B) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation

requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704); and

(C) The date upon which each period of accumulation begins clearly visible for inspection on each container.

(ii) *Tanks*. A large quantity generator accumulating hazardous waste in tanks must do the following:

(A) Mark or label its tanks with the words “Hazardous Waste”;

(B) Mark or label its tanks with an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704);

(C) Use inventory logs, monitoring equipment or other records to demonstrate that hazardous waste has been emptied within 90 days of first entering the tank if using a batch process, or in the case of a tank with a continuous flow process, demonstrate that estimated volumes of hazardous waste entering the tank daily exit the tank within 90 days of first entering; and

(D) Keep inventory logs or records with the above information on site and readily available for inspection.

(6) *Emergency procedures*. The large quantity generator complies with the standards in subpart M of this part, Preparedness, Prevention and Emergency Procedures for Large Quantity Generators.

(7) *Personnel training*.

(i)

(A) Facility personnel must successfully complete a program of classroom instruction, online training (e.g., computer-based or electronic), or on-the-job training that teaches them to perform their duties in a way that ensures compliance with this part. The large quantity generator must ensure that this program includes all the elements described in the document required under paragraph (a)(7)(iv) of this section.

(B) This program must be directed by a person trained in hazardous waste management procedures, and must include instruction which teaches facility personnel hazardous waste management procedures (including contingency plan implementation) relevant to the positions in which they are employed.

(C) At a minimum, the training program must be designed to ensure that facility personnel are able to respond effectively to emergencies by familiarizing them with emergency procedures,

emergency equipment, and emergency systems, including where applicable:

- (1) Procedures for using, inspecting, repairing, and replacing facility emergency and monitoring equipment;
 - (2) Key parameters for automatic waste feed cut-off systems;
 - (3) Communications or alarm systems;
 - (4) Response to fires or explosions;
 - (5) Response to ground-water contamination incidents;
- and
- (6) Shutdown of operations.

(D) For facility employees that receive emergency response training pursuant to Occupational Safety and Health Administration regulations 29 CFR 1910.120(p)(8) and 1910.120(q), the large quantity generator is not required to provide separate emergency response training pursuant to this section, provided that the overall facility training meets all the conditions of exemption in this section.

(ii) Facility personnel must successfully complete the program required in paragraph (a)(7)(i) of this section within six months after the date of their employment or assignment to the facility, or to a new position at the facility, whichever is later. Employees must not work in unsupervised positions until they have completed the training standards of paragraph (a)(7)(i) of this section.

(iii) Facility personnel must take part in an annual review of the initial training required in paragraph (a)(7)(i) of this section.

(iv) The large quantity generator must maintain the following documents and records at the facility:

(A) The job title for each position at the facility related to hazardous waste management, and the name of the employee filling each job;

(B) A written job description for each position listed under paragraph (a)(7)(iv)(A) of this section. This description may be consistent in its degree of specificity with descriptions for other similar positions in the same company location or bargaining unit, but must include the requisite skill, education, or other qualifications, and duties of facility personnel assigned to each position;

(C) A written description of the type and amount of both introductory and continuing training that will be given to each person filling a position listed under paragraph (a)(7)(iv)(A) of this section;

(D) Records that document that the training or job experience, required under paragraphs (a)(7)(i), (ii), and (iii) of this section, has been given to, and completed by, facility personnel.

(v) Training records on current personnel must be kept until closure of the facility. Training records on former employees must be kept for at least three years from the date the employee last worked at the facility. Personnel training records may accompany personnel transferred within the same company.

(8) *Closure.* A large quantity generator accumulating hazardous wastes in containers, tanks, drip pads, and containment buildings, prior to closing a unit at the facility, or prior to closing the facility, must meet the following conditions:

(i) *Notification for closure of a waste accumulation unit.* A large quantity generator must perform one of the following when closing a waste accumulation unit:

(A) Place a notice in the operating record within 30 days after closure identifying the location of the unit within the facility; or

(B) Meet the closure performance standards of paragraph (a)(8)(iii) of this section for container, tank, and containment building waste accumulation units or paragraph (a)(8)(iv) of this section for drip pads and notify EPA following the procedures in paragraph (a)(8)(ii)(B) of this section for the waste accumulation unit. If the waste accumulation unit is subsequently reopened, the generator may remove the notice from the operating record.

(ii) *Notification for closure of the facility.*

(A) Notify EPA using form 8700–12 no later than 30 days prior to closing the facility.

(B) Notify EPA using form 8700–12 within 90 days after closing the facility that it has complied with the closure performance standards of paragraph (a)(8)(iii) or (iv) of this section. If the facility cannot meet the closure performance standards of paragraph (a)(8)(iii) or (iv) of this section, notify EPA using form 8700–12 that it will close as a landfill under § 265.310 of this chapter in the case of a container, tank or containment building unit(s), or for a facility with drip pads, notify using form 8700–12 that it will close under the standards of § 265.445(b).

(C) A large quantity generator may request additional time to clean close, but it must notify EPA using form 8700–12 within 75 days after the date provided in paragraph (a)(8)(ii)(A) of this section to request an extension and provide an explanation as to why the additional time is required.

(iii) *Closure performance standards for container, tank systems, and containment building waste accumulation units.*

(A) At closure, the generator must close the waste accumulation unit or facility in a manner that:

(1) Minimizes the need for further maintenance by controlling, minimizing, or eliminating, to the extent necessary to protect human health and the environment, the post-closure escape of hazardous waste, hazardous constituents, leachate, contaminated run-off, or hazardous waste decomposition products to the ground or surface waters or to the atmosphere,

(2) Removes or decontaminates all contaminated equipment, structures and soil and any remaining hazardous waste residues from waste accumulation units including containment system components (pads, liners, etc.), contaminated soils and

subsoils, bases, and structures and equipment contaminated with waste, unless § 261.3(d) of this chapter applies.

(3) Any hazardous waste generated in the process of closing either the generator's facility or unit(s) accumulating hazardous waste must be managed in accordance with all applicable standards of parts 262, 263, 265 and 268 of this chapter, including removing any hazardous waste contained in these units within 90 days of generating it and managing these wastes in a RCRA Subtitle C hazardous waste permitted treatment, storage and disposal facility or interim status facility.

(4) If the generator demonstrates that any contaminated soils and wastes cannot be practicably removed or decontaminated as required in paragraph (a)(8)(ii)(A)(2) of this section, then the waste accumulation unit is considered to be a landfill and the generator must close the waste accumulation unit and perform post-closure care in accordance with the closure and post-closure care requirements that apply to landfills (§ 265.310 of this chapter). In addition, for the purposes of closure, post-closure, and financial responsibility, such a waste accumulation unit is then considered to be a landfill, and the generator must meet all of the requirements for landfills specified in subparts G and H of part 265 of this chapter.

(iv) *Closure performance standards for drip pad waste accumulation units.* At closure, the generator must comply with the closure requirements of paragraphs (a)(8)(ii) and (a)(8)(iii)(A)(1) and (3) of this section, and § 265.445(a) and (b) of this chapter.

(v) The closure requirements of paragraph (a)(8) of this section do not apply to satellite accumulation areas.

(9) *Land disposal restrictions.* The large quantity generator complies with all applicable requirements under 40 CFR part 268.

(b) *Accumulation time limit extension.* A large quantity generator who accumulates hazardous waste for more than 90 days is subject to the requirements of 40 CFR parts 124, 264 through 268, and part 270 of this chapter, and the notification requirements of section 3010 of RCRA, unless it has been granted an extension to the 90-day period. Such extension may be granted by EPA if hazardous wastes must remain on site for longer than 90 days due to unforeseen, temporary, and uncontrollable circumstances. An extension of up to 30 days may be granted at the discretion of the Regional Administrator on a case-by-case basis.

(c) *Accumulation of F006.* A large quantity generator who also generates wastewater treatment sludges from electroplating operations that meet the listing description for the EPA hazardous waste number F006, may accumulate F006 waste on site for more than 90 days, but not more than 180 days without being subject to parts 124, 264 through 267 and 270 of this chapter, and the notification requirements of section 3010 of RCRA, provided that it complies with all of the following additional conditions for exemption:

- (1) The large quantity generator has implemented pollution prevention practices that reduce the amount of any hazardous substances, pollutants, or contaminants entering F006 or otherwise released to the environment prior to its recycling;
- (2) The F006 waste is legitimately recycled through metals recovery;
- (3) No more than 20,000 kilograms of F006 waste is accumulated on site at any one time; and
- (4) The F006 waste is managed in accordance with the following:
 - (i) (A) If the F006 waste is placed in containers, the large quantity generator must comply with the applicable conditions for exemption in paragraph (a)(1) of this section; and/or
 - (B) If the F006 is placed in tanks, the large quantity generator must comply with the applicable conditions for exemption of paragraph (a)(2) of this section; and/or
 - (C) If the F006 is placed in containment buildings, the large quantity generator must comply with subpart DD of 40 CFR part 265, and has placed its professional engineer certification that the building complies with the design standards specified in 40 CFR 265.1101 in the facility's files prior to operation of the unit. The large quantity generator must maintain the following records:
 - (1) A written description of procedures to ensure that the F006 waste remains in the unit for no more than 180 days, a written description of the waste generation and management practices for the facility showing that they are consistent with the 180-day limit, and documentation that the large quantity generator is complying with the procedures; or
 - (2) Documentation that the unit is emptied at least once every 180 days.
 - (ii) The large quantity generator is exempt from all the requirements in subparts G and H of 40 CFR part 265, except for those referenced in paragraph (a)(8) of this section.
 - (iii) The date upon which each period of accumulation begins is clearly marked and must be clearly visible for inspection on each container;
 - (iv) While being accumulated on site, each container and tank is labeled or marked clearly with:
 - (A) The words "Hazardous Waste"; and
 - (B) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704).
 - (v) The large quantity generator complies with the requirements in paragraphs(a)(6) and (7) of this section.

(d) *F006 transported over 200 miles.* A large quantity generator who also generates wastewater treatment sludges from electroplating operations that meet the listing description for the EPA hazardous waste number F006, and who must transport this waste, or offer this waste for transportation, over a distance of 200 miles or more for off-site metals recovery, may accumulate F006 waste on site for more than 90 days, but not more than 270 days without being subject to parts 124, 264 through 267, 270, and the notification requirements of section 3010 of RCRA, if the large quantity generator complies with all of the conditions for exemption of paragraphs (c)(1) through (4) of this section.

(e) *F006 accumulation time extension.* A large quantity generator accumulating F006 in accordance with paragraphs (c) and (d) of this section who accumulates F006 waste on site for more than 180 days (or for more than 270 days if the generator must transport this waste, or offer this waste for transportation, over a distance of 200 miles or more), or who accumulates more than 20,000 kilograms of F006 waste on site is an operator of a storage facility and is subject to the requirements of 40 CFR parts 124, 264, 265, 267, and 270 of this chapter, and the notification requirements of section 3010 of RCRA, unless the generator has been granted an extension to the 180-day (or 270-day if applicable) period or an exception to the 20,000 kilogram accumulation limit. Such extensions and exceptions may be granted by EPA if F006 waste must remain on site for longer than 180 days (or 270 days if applicable) or if more than 20,000 kilograms of F006 waste must remain on site due to unforeseen, temporary, and uncontrollable circumstances. An extension of up to 30 days or an exception to the accumulation limit may be granted at the discretion of the Regional Administrator on a case-by-case basis.

(f) *Consolidation of hazardous waste received from very small quantity generators.* Large quantity generators may accumulate on site hazardous waste received from very small quantity generators under control of the same person (as defined in § 260.10 of this chapter), without a storage permit or interim status and without complying with the requirements of parts 124, 264 through 268, and 270 of this chapter, and the notification requirements of section 3010 of RCRA, provided that they comply with the following conditions. “Control,” for the purposes of this section, means the power to direct the policies of the generator, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate generator facilities on behalf of a different person shall not be deemed to “control” such generators.

(1) The large quantity generator notifies EPA at least thirty (30) days prior to receiving the first shipment from a very small quantity generator(s) using EPA Form 8700-12; and

(i) Identifies on the form the name(s) and site address(es) for the very small quantity generator(s) as well as the name and business telephone number for a contact person for the very small quantity generator(s); and

(ii) Submits an updated Site ID form (EPA Form 8700-12) within 30 days after a change in the name or site address for the very small quantity generator.

(2) The large quantity generator maintains records of shipments for three years from the date the hazardous waste was received from the very small quantity generator. These records must identify the name, site address, and contact information for

the very small quantity generator and include a description of the hazardous waste received, including the quantity and the date the waste was received.

(3) The large quantity generator complies with the independent requirements identified in § 262.10(a)(1)(iii) and the conditions for exemption in this section for all hazardous waste received from a very small quantity generator. For purposes of the labeling and marking regulations in paragraph (a)(5) of this section, the large quantity generator must label the container or unit with the date accumulation started (i.e., the date the hazardous waste was received from the very small quantity generator). If the large quantity generator is consolidating incoming hazardous waste from a very small quantity generator with either its own hazardous waste or with hazardous waste from other very small quantity generators, the large quantity generator must label each container or unit with the earliest date any hazardous waste in the container was accumulated on site.

(g) *Rejected load.* A large quantity generator who sends a shipment of hazardous waste to a designated facility with the understanding that the designated facility can accept and manage the waste and later receives that shipment back as a rejected load or residue in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter may accumulate the returned waste on site in accordance with paragraphs (a) and (b) of this section. Upon receipt of the returned shipment, the generator must:

- (1) Sign Item 18c of the manifest, if the transporter returned the shipment using the original manifest; or
- (2) Sign Item 20 of the manifest, if the transporter returned the shipment using a new manifest.

40 C.F.R. § 262.40. Recordkeeping.

(a) A generator must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until he receives a signed copy from the designated facility which received the waste. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

(b) A generator must keep a copy of each Biennial Report and Exception Report for a period of at least three years from the due date of the report.

(c) See § 262.11(f) for recordkeeping requirements for documenting hazardous waste determinations.

(d) The periods or retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the Administrator.

40 C.F.R. § 264.15. General inspection requirements.

(a) The owner or operator must inspect his facility for malfunctions and deterioration, operator errors, and discharges which may be causing—or may lead to—(1) release of hazardous waste constituents to the environment or (2) a threat to human health. The owner or operator must conduct these inspections often enough to identify problems in time to correct them before they harm human health or the environment.

(b) (1) The owner or operator must develop and follow a written schedule for inspecting monitoring equipment, safety and emergency equipment, security devices, and

operating and structural equipment (such as dikes and sump pumps) that are important to preventing, detecting, or responding to environmental or human health hazards.

(2) He must keep this schedule at the facility.

(3) The schedule must identify the types of problems (e.g., malfunctions or deterioration) which are to be looked for during the inspection (e.g., inoperative sump pump, leaking fitting, eroding dike, etc.).

(4) The frequency of inspection may vary for the items on the schedule.

However, the frequency should be based on the rate of deterioration of the equipment and the probability of an environmental or human health incident if the deterioration, malfunction, or operator error goes undetected between inspections. Areas subject to spills, such as loading and unloading areas, must be inspected daily when in use. At a minimum, the inspection schedule must include the items and frequencies called for in §§ 264.174, 264.193, 264.195, 264.226, 264.254, 264.278, 264.303, 264.347, 264.602, 264.1033, 264.1052, 264.1053, 264.1058, and 264.1083 through 264.1089, where applicable. Part 270 of this chapter requires the inspection schedule to be submitted with part B of the permit application. EPA will evaluate the schedule along with the rest of the application to ensure that it adequately protects human health and the environment. As part of this review, EPA may modify or amend the schedule as may be necessary.

(5) Performance Track member facilities that choose to reduce their inspection frequency must:

(i) Submit a request for a Class I permit modification with prior approval to the Director. The modification request must identify the facility as a member of the National Environmental Performance Track Program and identify the management units for reduced inspections and the proposed frequency of inspections. The modification request must also specify, in writing, that the reduced inspection frequency will apply for as long as the facility is a Performance Track member facility, and that within seven calendar days of ceasing to be a Performance Track member, the facility will revert to the non-Performance Track inspection frequency. Inspections must be conducted at least once each month.

(ii) Within 60 days, the Director will notify the Performance Track member facility, in writing, if the request is approved, denied, or if an extension to the 60-day deadline is needed. This notice must be placed in the facility's operating record. The Performance Track member facility should consider the application approved if the Director does not: deny the application; or notify the Performance Track member facility of an extension to the 60-day deadline. In these situations, the Performance Track member facility must adhere to the revised inspection schedule outlined in its request for a Class 1 permit modification and keep a copy of the application in the facility's operating record.

(iii) Any Performance Track member facility that discontinues their membership or is terminated from the program must immediately notify the Director of their change in status. The facility must place in its operating record a dated copy of this notification and revert back to the non-Performance Track inspection frequencies within seven calendar days.

(c) The owner or operator must remedy any deterioration or malfunction of equipment or structures which the inspection reveals on a schedule which ensures that the

problem does not lead to an environmental or human health hazard. Where a hazard is imminent or has already occurred, remedial action must be taken immediately.

(d) The owner or operator must record inspections in an inspection log or summary. He must keep these records for at least three years from the date of inspection. At a minimum, these records must include the date and time of the inspection, the name of the inspector, a notation of the observations made, and the date and nature of any repairs or other remedial actions.

40 C.F.R. § 264.16. Personnel training.

(a) (1) Facility personnel must successfully complete a program of classroom instruction or on-the-job training that teaches them to perform their duties in a way that ensures the facility's compliance with the requirements of this part. The owner or operator must ensure that this program includes all the elements described in the document required under paragraph (d)(3) of this section.

[Comment: Part 270 of this chapter requires that owners and operators submit with part B of the RCRA permit application, an outline of the training program used (or to be used) at the facility and a brief description of how the training program is designed to meet actual job tasks.]

(2) This program must be directed by a person trained in hazardous waste management procedures, and must include instruction which teaches facility personnel hazardous waste management procedures (including contingency plan implementation) relevant to the positions in which they are employed.

(3) At a minimum, the training program must be designed to ensure that facility personnel are able to respond effectively to emergencies by familiarizing them with emergency procedures, emergency equipment, and emergency systems, including, where applicable:

- (i) Procedures for using, inspecting, repairing, and replacing facility emergency and monitoring equipment;
- (ii) Key parameters for automatic waste feed cut-off systems;
- (iii) Communications or alarm systems;
- (iv) Response to fires or explosions;
- (v) Response to ground-water contamination incidents; and
- (vi) Shutdown of operations.

(4) For facility employees that receive emergency response training pursuant to Occupational Safety and Health Administration (OSHA) regulations 29 CFR 1910.120(p)(8) and 1910.120(q), the facility is not required to provide separate emergency response training pursuant to this section, provided that the overall facility training meets all the requirements of this section.

(b) Facility personnel must successfully complete the program required in paragraph (a) of this section within six months after the effective date of these regulations or six months after the date of their employment or assignment to a facility, or to a new position at a facility, whichever is later. Employees hired after the effective date of these regulations must not work in unsupervised positions until they have completed the training requirements of paragraph (a) of this section.

(c) Facility personnel must take part in an annual review of the initial training required in paragraph (a) of this section.

(d) The owner or operator must maintain the following documents and records at the facility:

(1) The job title for each position at the facility related to hazardous waste management, and the name of the employee filling each job;

(2) A written job description for each position listed under paragraph (d)(1) of this section. This description may be consistent in its degree of specificity with descriptions for other similar positions in the same company location or bargaining unit, but must include the requisite skill, education, or other qualifications, and duties of employees assigned to each position;

(3) A written description of the type and amount of both introductory and continuing training that will be given to each person filling a position listed under paragraph (d)(1) of this section;

(4) Records that document that the training or job experience required under paragraphs (a), (b), and (c) of this section has been given to, and completed by, facility personnel.

(e) Training records on current personnel must be kept until closure of the facility; training records on former employees must be kept for at least three years from the date the employee last worked at the facility. Personnel training records may accompany personnel transferred within the same company.

40 C.F.R. § 264.53. Copies of contingency plan.

A copy of the contingency plan and all revisions to the plan must be:

(a) Maintained at the facility; and

(b) Submitted to all local police departments, fire departments, hospitals, and State and local emergency response teams that may be called upon to provide emergency services.

[Comment: The contingency plan must be submitted to the Regional Administrator with Part B of the permit application under part 270, of this chapter and, after modification or approval, will become a condition of any permit issued.]

40 C.F.R. § 302.8. Continuous releases.

(k) *Documentation supporting notification.* Where necessary to satisfy the requirements of this section, the person in charge may rely on recent release data, engineering estimates, the operating history of the facility or vessel, or other relevant information to support notification. All supporting documents, materials, and other information shall be kept on file at the facility, or in the case of a vessel, at an office within the United States in either a port of call, a place of regular berthing, or the headquarters of the business operating the vessel. Supporting materials shall be kept on file for a period of one year and shall substantiate the reported normal range of releases, the basis for stating that the release is continuous and stable in quantity and rate, and the other information in the initial written report, the followup report, and the annual evaluations required under paragraphs (e), (f), and (i), respectively. Such information shall be made available to EPA upon request as necessary to enforce the requirements of this section.

40 C.F.R. § 312.20. All appropriate inquiries.

(a) All appropriate inquiries” pursuant to CERCLA section 101(35)(B) must be conducted within one year prior to the date of acquisition of the subject property and must include:

- (1) An inquiry by an environmental professional (as defined in §312.10), as provided in §312.21;
- (2) The collection of information pursuant to §312.22 by persons identified under §312.1(b); and
- (3) Searches for recorded environmental cleanup liens, as required in §312.25.

(b) Notwithstanding paragraph (a) of this section, the following components of the all appropriate inquiries must be conducted or updated within 180 days of and prior to the date of acquisition of the subject property:

- (1) Interviews with past and present owners, operators, and occupants (see §312.23);
- (2) Searches for recorded environmental cleanup liens (see §312.25);
- (3) Reviews of federal, tribal, state, and local government records (see §312.26);
- (4) Visual inspections of the facility and of adjoining properties (see §312.27); and
- (5) The declaration by the environmental professional (see §312.21(d)).

(c) All appropriate inquiries may include the results of and information contained in an inquiry previously conducted by, or on the behalf of, persons identified under §312.1(b) and who are responsible for the inquiries for the subject property, provided:

- (1) Such information was collected during the conduct of all appropriate inquiries in compliance with the requirements of CERCLA sections 101(35)(B), 101(40)(B) and 107(q)(A)(viii);
- (2) Such information was collected or updated within one year prior to the date of acquisition of the subject property;
- (3) Notwithstanding paragraph (b)(2) of this section, the following components of the inquiries were conducted or updated within 180 days of and prior to the date of acquisition of the subject property:
 - (i) Interviews with past and present owners, operators, and occupants (see §312.23);
 - (ii) Searches for recorded environmental cleanup liens (see §312.25);
 - (iii) Reviews of federal, tribal, state, and local government records (see §312.26);
 - (iv) Visual inspections of the facility and of adjoining properties (see §312.27); and
 - (v) The declaration by the environmental professional (see §312.21(d)).

(4) Previously collected information is updated to include relevant changes in the conditions of the property and specialized knowledge, as outlined in §312.28, of the persons conducting the all appropriate inquiries for the subject property, including persons identified in §312.1(b) and the environmental professional, defined in §312.10.

(d) All appropriate inquiries can include the results of report(s) specified in §312.21(c), that have been prepared by or for other persons, provided that:

(1) The report(s) meets the objectives and performance factors of this regulation, as specified in paragraphs (e) and (f) of this section; and

(2) The person specified in §312.1(b) and seeking to use the previously collected information reviews the information and conducts the additional inquiries pursuant to §§312.28, 312.29 and 312.30 and the all appropriate inquiries are updated in paragraph (b)(3) of this section, as necessary.

(e) *Objectives.* The standards and practices set forth in this part for All Appropriate Inquiries are intended to result in the identification of conditions indicative of releases and threatened releases of hazardous substances on, at, in, or to the subject property.

(1) In performing the all appropriate inquiries, as defined in this section and provided in the standards and practices set forth this subpart, the persons identified under §312.1(b)(1) and the environmental professional, as defined in §312.10, must seek to identify through the conduct of the standards and practices set forth in this subpart, the following types of information about the subject property:

- (i) Current and past property uses and occupancies;
- (ii) Current and past uses of hazardous substances;
- (iii) Waste management and disposal activities that could have caused releases or threatened releases of hazardous substances;
- (iv) Current and past corrective actions and response activities undertaken to address past and on-going releases of hazardous substances;
- (v) Engineering controls;
- (vi) Institutional controls; and
- (vii) Properties adjoining or located nearby the subject property that have environmental conditions that could have resulted in conditions indicative of releases or threatened releases of hazardous substances to the subject property.

(2) In the case of persons identified in §312.1(b)(2), the standards and practices for All Appropriate Inquiries set forth in this part are intended to result in the identification of conditions indicative of releases and threatened releases of hazardous substances, pollutants, contaminants, petroleum and petroleum products, and controlled substances (as defined in 21 U.S.C. 802) on, at, in, or to the subject property. In performing the all appropriate inquiries, as defined in this section and provided in the standards and practices set forth in this subpart, the persons identified under §312.1(b) and the environmental professional, as defined in §312.10, must seek to identify through the conduct of the standards and practices set forth in this subpart, the following types of information about the subject property:

- (i) Current and past property uses and occupancies;
- (ii) Current and past uses of hazardous substances, pollutants, contaminants, petroleum and petroleum products, and controlled substances (as defined in 21 U.S.C. 802);
- (iii) Waste management and disposal activities;
- (iv) Current and past corrective actions and response activities undertaken to address past and on-going releases of hazardous substances pollutants, contaminants, petroleum and petroleum products, and controlled substances (as defined in 21 U.S.C. 802);
- (v) Engineering controls;
- (vi) Institutional controls; and

(vii) Properties adjoining or located nearby the subject property that have environmental conditions that could have resulted in conditions indicative of releases or threatened releases of hazardous substances, pollutants, contaminants, petroleum and petroleum products, and controlled substances (as defined in 21 U.S.C. 802) to the subject property.

(f) *Performance factors.* In performing each of the standards and practices set forth in this subpart and to meet the objectives stated in paragraph (e) of this section, the persons identified under §312.1(b) or the environmental professional as defined in §312.10 (as appropriate to the particular standard and practice) must seek to:

(1) Gather the information that is required for each standard and practice listed in this subpart that is publicly available, obtainable from its source within reasonable time and cost constraints, and which can practicably be reviewed; and

(2) Review and evaluate the thoroughness and reliability of the information gathered in complying with each standard and practice listed in this subpart taking into account information gathered in the course of complying with the other standards and practices of this subpart.

(g) To the extent there are data gaps (as defined in §312.10) in the information developed as part of the inquiries in paragraph (e) of this section that affect the ability of persons (including the environmental professional) conducting the all appropriate inquiries to identify conditions indicative of releases or threatened releases in each area of inquiry under each standard and practice such persons should identify such data gaps, identify the sources of information consulted to address such data gaps, and comment upon the significance of such data gaps with regard to the ability to identify conditions indicative of releases or threatened releases of hazardous substances [and in the case of persons identified in §312.1(b)(2), hazardous substances, pollutants, contaminants, petroleum and petroleum products, and controlled substances (as defined in 21 U.S.C. 802)] on, at, in, or to the subject property. Sampling and analysis may be conducted to develop information to address data gaps.

(h) Releases and threatened releases identified as part of the all appropriate inquiries should be noted in the report of the inquiries. These standards and practices however are not intended to require the identification in the written report prepared pursuant to §312.21(c) of quantities or amounts, either individually or in the aggregate, of hazardous substances pollutants, contaminants, petroleum and petroleum products, and controlled substances (as defined in 21 U.S.C. 802) that because of said quantities and amounts, generally would not pose a threat to human health or the environment.

41 C.F.R. § 60-1.12. Record retention.

(a) *General requirements.* Any personnel or employment record made or kept by the contractor shall be preserved by the contractor for a period of not less than two years from the date of the making of the record or the personnel action involved, whichever occurs later. However, if the contractor has fewer than 150 employees or does not have a Government contract of at least \$ 150,000, the minimum record retention period shall be one year from the date of the making of the record or the personnel action involved, whichever occurs later. Such records include, but are not necessarily limited to, records pertaining to hiring, assignment, promotion, demotion, transfer, lay off or termination, rates of pay or other terms of compensation, and selection for training or apprenticeship, and other records having to do with requests for reasonable accommodation, the results of any physical examination, job

advertisements and postings, applications, resumes, and any and all expressions of interest through the Internet or related electronic data technologies as to which the contractor considered the individual for a particular position, such as on-line resumes or internal resume databases, records identifying job seekers contacted regarding their interest in a particular position (for purposes of recordkeeping with respect to internal resume databases, the contractor must maintain a record of each resume added to the database, a record of the date each resume was added to the database, the position for which each search of the database was made, and corresponding to each search, the substantive search criteria used and the date of the search; for purposes of recordkeeping with respect to external resume databases, the contractor must maintain a record of the position for which each search of the database was made, and corresponding to each search, the substantive search criteria used, the date of the search, and the resumes of job seekers who met the basic qualifications for the particular position who are considered by the contractor), regardless of whether the individual qualifies as an Internet Applicant under 41 CFR 60-1.3, tests and test results, and interview notes. In the case of involuntary termination of an employee, the personnel records of the individual terminated shall be kept for a period of not less than two years from the date of the termination, except that contractors that have fewer than 150 employees or that do not have a Government contract of at least \$ 150,000 shall keep such records for a period of not less than one year from the date of the termination. Where the contractor has received notice that a complaint of discrimination has been filed, that a compliance evaluation has been initiated, or that an enforcement action has been commenced, the contractor shall preserve all personnel records relevant to the complaint, compliance evaluation or enforcement action until final disposition of the complaint, compliance evaluation or enforcement action. The term "personnel records relevant to the complaint," for example, would include personnel or employment records relating to the complainant and to all other employees holding positions similar to that held or sought by the complainant and application forms or test papers submitted by unsuccessful applicants and by all other candidates for the same position as that for which the complainant unsuccessfully applied. Where a compliance evaluation has been initiated, all personnel and employment records described above are relevant until OFCCP makes a final disposition of the evaluation.

(b) *Affirmative action programs.* A contractor establishment required under § 60-1.40 to develop and maintain a written affirmative action program (AAP) must maintain its current AAP and documentation of good faith effort, and must preserve its AAP and documentation of good faith effort for the immediately preceding AAP year, unless it was not then covered by the AAP requirement.

(c) *Contractor identification of record.* (1) For any record the contractor maintains pursuant to this section, the contractor must be able to identify:

(i) The gender, race, and ethnicity of each employee; and

(ii) Where possible, the gender, race, and ethnicity of each applicant or Internet Applicant as defined in 41 CFR 60-1.3, whichever is applicable to the particular position.

(2) The contractor must supply this information to the Office of Federal Contract Compliance Programs upon request.

(d) *Adverse impact evaluations.* When evaluating whether a contractor has maintained information on impact and conducted an adverse impact analysis under part 60-3 with respect to Internet hiring procedures, OFCCP will require only those records relating to the analyses of the impact of employee selection procedures on Internet Applicants, as defined in 41

CFR 60-1.3, and those records relating to the analyses of the impact of employment tests that are used as employee selection procedures, without regard to whether the tests were administered to Internet Applicants, as defined in 41 CFR 60-1.3.

(e) *Failure to preserve records.* Failure to preserve complete and accurate records as required by paragraphs (a) through (c) of this section constitutes noncompliance with the contractor's obligations under the Executive Order and this part. Where the contractor has destroyed or failed to preserve records as required by this section, there may be a presumption that the information destroyed or not preserved would have been unfavorable to the contractor: Provided, That this presumption shall not apply where the contractor shows that the destruction or failure to preserve records results from the circumstances that are outside of the contractor's control.

42 C.F.R. § 411.357. Exceptions to the referral prohibition related to compensation arrangements

(e) *Physician recruitment.*

(1) Remuneration provided by a hospital to recruit a physician that is paid directly to the physician and that is intended to induce the physician to relocate his or her medical practice to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

- (i) The arrangement is set out in writing and signed by both parties;
- (ii) The arrangement is not conditioned on the physician's referral of patients to the hospital;
- (iii) The amount of remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the physician or other business generated between the parties; and
- (iv) The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment or services contract that complies with § 411.354(d)(4)).

(2)(i) Geographic area served by the hospital—defined. The "geographic area served by the hospital" is the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. The geographic area served by the hospital may include one or more zip codes from which the hospital draws no inpatients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the hospital draws at least 75 percent of its inpatients.

(ii) With respect to a hospital that draws fewer than 75 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the "geographic area served by the hospital" will be deemed to be the area composed of all of the contiguous zip codes from which the hospital draws its inpatients.

(iii) Special optional rule for rural hospitals. In the case of a hospital located in a rural area (as defined at § 411.351), the "geographic area served by the hospital" may also be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. If the hospital draws fewer than 90 percent of its inpatients from all of the contiguous

zip codes from which it draws inpatients, the "geographic area served by the hospital" may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of the hospital's inpatients resides, and continuing to add noncontiguous zip codes in decreasing order of percentage of inpatients.

(iv) A physician will be considered to have relocated his or her medical practice if the medical practice was located outside the geographic area served by the hospital and --

(A) The physician moves his or her medical practice at least 25 miles and into the geographic area served by the hospital; or

(B) The physician moves his medical practice into the geographic area served by the hospital, and the physician's new medical practice derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years, measured on an annual basis (fiscal or calendar year). For the initial "start up" year of the recruited physician's practice, the 75 percent test in the preceding sentence will be satisfied if there is a reasonable expectation that the recruited physician's medical practice for the year will derive at least 75 percent of its revenues from professional services furnished to patients not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years.

(3) The recruited physician will not be subject to the relocation requirement of this paragraph, provided that he or she establishes his or her medical practice in the geographic area served by the recruiting hospital, if --

(i) He or she is a resident or physician who has been in practice 1 year or less;

(ii) He or she was employed on a full-time basis for at least 2 years immediately prior to the recruitment arrangement by one of the following (and did not maintain a private practice in addition to such full-time employment):

(A) A Federal or State bureau of prisons (or similar entity operating one or more correctional facilities) to serve a prison population;

(B) The Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families; or

(C) A facility of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service; or

(iii) The Secretary has deemed in an advisory opinion issued under section 1877(g) of the Act that the physician does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital.

(4) In the case of remuneration provided by a hospital to a physician either indirectly through payments made to another physician practice, or directly to a physician who joins a physician practice, the following additional conditions must be met:

(i) The written agreement in paragraph (e)(1) is also signed by the physician practice if the remuneration is provided indirectly to the physician

through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.

(ii) Except for actual costs incurred by the physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician.

(iii) In the case of an income guarantee of any type made by the hospital to a recruited physician who joins a physician practice, the costs allocated by the physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician. With respect to a physician recruited to join a physician practice located in a rural area or HPSA, if the physician is recruited to replace a physician who, within the previous 12-month period, retired, relocated outside of the geographic area served by the hospital, or died, the costs allocated by the physician practice to the recruited physician do not exceed either --

(A) The actual additional incremental costs attributable to the recruited physician; or

(B) The lower of a per capita allocation or 20 percent of the practice's aggregate costs.

(iv) Records of the actual costs and the passed-through amounts are maintained for a period of at least 6 years and made available to the Secretary upon request.

(v) The remuneration from the hospital under the arrangement is not determined in a manner that takes into account the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.

(vi) The physician practice may not impose on the recruited physician practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital.

(5) Recruitment of a physician by a hospital located in a rural area (as defined at § 411.351) to an area outside the geographic area served by the hospital is permitted under this exception if the Secretary determines in an advisory opinion issued under section 1877(g) of the Act that the area has a demonstrated need for the recruited physician and all other requirements of this paragraph (e) are met.

(6)(i) This paragraph (e) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(6)(ii) The "geographic area served" by a federally qualified health center or a rural health clinic is the area composed of the lowest number of contiguous or noncontiguous zip codes from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients, as determined on an encounter basis. The geographic area served by the federally qualified health center or rural health clinic may include one or more zip codes from which the federally qualified health center or rural health clinic draws no patients, provided that such zip codes are entirely surrounded by

zip codes in the geographic area described above from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients.

42 C.F.R. § 420.302. Requirement for access clause in contracts.

(a) *Applicability.* This subpart applies to contracts—

(1) Between a provider and a subcontractor and, where subject to section 1861(v)(1)(I)(ii) of the Act, between a subcontractor and an organization related to the subcontractor;

(2) Entered into or renewed after December 5, 1980; and

(3) For services the cost or value of which is \$10,000 or more over a 12-month period, including contracts for both goods and services in which the service component is worth \$10,000 or more over a 12-month period.

(b) *Requirement.* Any contract meeting the conditions of paragraph (a) of this section must include a clause that allows the Comptroller General of the United States, HHS, and their duly authorized representatives access to the subcontractor's contract, books, documents, and records until the expiration of four years after the services are furnished under the contract or subcontract. The access must be provided for in accordance with the provisions of this subpart. The clause must also allow similar access by HHS, the Comptroller General, and their duly authorized representatives to contracts subject to section 1861(v)(1)(I)(ii) of the Act between a subcontractor and organizations related to the subcontractor and to books, documents, and records.

(c) *Prohibition against Medicare reimbursement.* If a contract subject to the requirements of this subpart does not contain the clause required by paragraph (b) of this section, CMS will not reimburse the provider for the cost of the services furnished under the contract and will recoup any payments previously made for services under the contract. However, in order to avoid nonreimbursement or recoupment, providers will have until July 30, 1983, to amend those contracts entered into or renewed after December 5, 1980, and before January 31, 1983, that do not conform to the requirements of paragraph (b) of this section.

42 C.F.R. § 424.516. Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

(f) *Maintaining and providing access to documentation.* (1)(i) A provider or a supplier that furnishes covered ordered, certified, referred, or prescribed Part A or B services, items or drugs is required to--

(A) Maintain documentation (as described in paragraph (f)(1)(ii) of this section) for 7 years from the date of service; and

(B) Upon the request of CMS or a Medicare contractor, to provide access to that documentation (as described in paragraph (f)(1)(ii) of this section).

(ii) The documentation includes written and electronic documents (including the NPI of the physician who ordered/certified the home health services and the NPI of the physician or, when permitted, other eligible professional who ordered, certified, referred, or prescribed the Part A or B service, item, or drug) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Part A or B services, items or drugs.

- (2)(i) A physician or, when permitted, an eligible professional who orders, certifies, refers, or prescribes Part A or B services, items or drugs is required to--
- (A) Maintain documentation (as described in paragraph (f)(2)(ii) of this section) for 7 years from the date of the service; and
 - (B) Upon request of CMS or a Medicare contractor, to provide access to that documentation (as described in paragraph (f)(2)(ii) of this section).
- (ii) The documentation includes written and electronic documents (including the NPI of the physician or, when permitted, other eligible professional who ordered, certified, referred, or prescribed the Part A or B service, item, or drug) relating to written orders, certifications, referrals, prescriptions or requests for payments for Part A or B services, items, or drugs.

42 C.F.R. § 424.535. Revocation of enrollment and billing privileges in the Medicare program.

(a) *Reasons for revocation.* CMS may revoke a currently enrolled provider or supplier's Medicare billing privileges and any corresponding provider agreement or supplier agreement for the following reasons:

(10) Failure to document or provide CMS access to documentation. (i) The provider or supplier did not comply with the documentation or CMS access requirements specified in § 424.516(f) of this subpart.

(ii) A provider or supplier that meets the revocation criteria specified in paragraph (a)(10)(i) of this section, is subject to revocation for a period of not more than 1 year for each act of noncompliance.

42 C.F.R. § 455.436. Federal database checks.

The State Medicaid agency must do all of the following:

(a) Confirm the identity and determine the exclusion status of providers and any person with an ownership or control interest or who is an agent or managing employee of the provider through routine checks of Federal databases.

(b) Check the Social Security Administration's Death Master File, the National Plan and Provider Enumeration System (NPPES), the List of Excluded Individuals/Entities (LEIE), the Excluded Parties List System (EPLS), and any such other databases as the Secretary may prescribe.

(c) (1) Consult appropriate databases to confirm identity upon enrollment and reenrollment; and

(2) Check the LEIE and EPLS no less frequently than monthly.

42 C.F.R. § 482.22. Condition of participation: Medical staff.

The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

(a)⁵ *Standard: Eligibility and process for appointment to medical staff.* The medical staff must include doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at § 482.12(c)(1)) and non-physician practitioners who are determined to be eligible for appointment by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.

(3) When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:

(i) The distant-site hospital providing the telemedicine services is a Medicare-participating hospital.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving the telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients and all complaints the hospital has received about the distant-site physician or practitioner.

⁵ NOTE: Effective March 1, 2020 through the end of the COVID-19 public health emergency, CMS has issued a blanket waiver of the requirements of 42 C.F.R. § 482.22(a)(1)-(4) to allow for physicians whose privileges will expire to continue practicing at the hospital and for new physicians to be able to practice before full medical staff/governing body review and approval to address workforce concerns related to COVID-19. See [COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers](#) 5.6 (updated 10/7/21) p. 4.

(4) When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with § 482.12(e), permit the hospital to comply with all applicable conditions of participation for the contracted services. The hospital's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:

(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at § 482.12(a)(1) through (a)(7) and § 482.22(a)(1) through (a)(2).

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides the hospital with a current list of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving such telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients, and all complaints the hospital has received about the distant-site physician or practitioner.

(b) *Standard: Medical staff organization and accountability.* The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:

(i) An individual doctor of medicine or osteopathy.

(ii) A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located.

(iii) A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.

(4) If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:

(i) The medical staff members of each separately certified hospital in the system (that is, all medical staff members who hold specific privileges to practice at that hospital) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital;

(ii) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified hospital (that is, all medical staff members who hold specific privileges to practice at that hospital) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their hospital;

(iii) The unified and integrated medical staff is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and

(iv) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

(c) *Standard: Medical staff bylaws.* The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include a requirement that --

(i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, and except as provided under paragraph (c)(5)(iii) of this section. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oral and maxillofacial

surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(ii) An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under paragraph (c)(5)(iii) of this section. The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(iii) An assessment of the patient (in lieu of the requirements of paragraphs (c)(5)(i) and (ii) of this section) be completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at paragraph (c)(5)(v) of this section, specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services. The assessment must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(iv) The medical staff develop and maintain a policy that identifies those patients for whom the assessment requirements of paragraph (c)(5)(iii) of this section would apply. The provisions of paragraphs (c)(5)(iii), (iv), and (v) of this section do not apply to a medical staff that chooses to maintain a policy that adheres to the requirements of paragraphs of (c)(5)(i) and (ii) of this section for all patients.

(v) The medical staff, if it chooses to develop and maintain a policy for the identification of specific patients to whom the assessment requirements in paragraph (c)(5)(iii) of this section would apply, must demonstrate evidence that the policy applies only to those patients receiving specific outpatient surgical or procedural services as well as evidence that the policy is based on:

(A) Patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure.

(B) Nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures.

(C) Applicable state and local health and safety laws.

(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining privileges and

the procedure for applying the criteria are also subject to the requirements in § 482.12(a)(8) and (a)(9), and § 482.22(a)(3) and (a)(4).

(d) [Reserved by 84 FR 51818]

42 C.F.R. § 482.24. Condition of participation: Medical record services.

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

(b) *Standard: Form and retention of record.* The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

42 C.F.R. § 482.25. Condition of participation: Pharmaceutical services.

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

(a) *Standard: Pharmacy management and administration.* The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

42 C.F.R. § 482.26. Condition of participation: Radiologic services.

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(d) *Standard: Records.* Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

42 C.F.R. § 482.27. Condition of participation: Laboratory services.

The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this chapter.

(a) *Standard: Adequacy of laboratory services.* The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(1) Emergency laboratory services must be available 24 hours a day.

- (2) A written description of services provided must be available to the medical staff.
 - (3) The laboratory must make provision for proper receipt and reporting of tissue specimens.
 - (4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.
- (b) *Standard: Potentially infectious blood and blood components –*
- (1) *Potentially human immunodeficiency virus (HIV) infectious blood and blood components.* Potentially HIV infectious blood and blood components are prior collections from a donor--
 - (i) Who tested negative at the time of donation but tests reactive for evidence of HIV infection on a later donation;
 - (ii) Who tests positive on the supplemental (additional, more specific) test or other follow-up testing required by FDA; and
 - (iii) For whom the timing of seroconversion cannot be precisely estimated.
 - (2) *Potentially hepatitis C virus (HCV) infectious blood and blood components.* Potentially HCV infectious blood and blood components are the blood and blood components identified in 21 CFR 610.47.
 - (3) *Services furnished by an outside blood collecting establishment.* If a hospital regularly uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components. The agreement must require that the blood collecting establishment notify the hospital--
 - (i) Within 3 calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of HIV or HCV infection on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection;
 - (ii) Within 45 days of the test, of the results of the supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required by FDA; and
 - (iii) Within 3 calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available, as set forth at 21 CFR 610.48(b)(3).
 - (4) *Quarantine and disposition of blood and blood components pending completion of testing.* If the blood collecting establishment (either internal or under an agreement) notifies the hospital of the reactive HIV or HCV screening test results, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood components from previous donations in inventory.
 - (i) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood components from quarantine.

(ii) If the blood collecting establishment notifies the hospital that the result of the supplemental, (additional, more specific) test or other follow-up testing required by FDA is positive, the hospital must--

(A) Dispose of the blood and blood components; and

(B) Notify the transfusion beneficiaries as set forth in paragraph (b)(6) of this section.

(iii) If the blood collecting establishment notifies the hospital that the result of the supplemental, (additional, more specific) test or other follow-up testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood components held in quarantine as set forth at 21 CFR 610.46(b)(2) and 610.47(b)(2).

(5) *Recordkeeping by the hospital.* The hospital must maintain--

(i) Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval; and

(ii) A fully funded plan to transfer these records to another hospital or other entity if such hospital ceases operation for any reason.

(6) *Patient notification.* If the hospital has administered potentially HIV or HCV infectious blood or blood components (either directly through its own blood collecting establishment or under an agreement) or released such blood or blood components to another entity or individual, the hospital must take the following actions:

(i) Make reasonable attempts to notify the patient, or to notify the attending physician or the physician who ordered the blood or blood component and ask the physician to notify the patient, or other individual as permitted under paragraph (b)(10) of this section, that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling.

(ii) If the physician is unavailable or declines to make the notification, make reasonable attempts to give this notification to the patient, legal guardian, or relative.

(iii) Document in the patient's medical record the notification or attempts to give the required notification.

(7) *Timeframe for notification* – For donors tested on or after February 20, 2008. For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR 610.46 and 21 CFR 610.47 the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HIV or HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification over a period of 12 weeks unless--

(i) The patient is located and notified; or

(ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 12 weeks.

(8) *Content of notification.* The notification must include the following information:

(i) A basic explanation of the need for HIV or HCV testing and counseling;

(ii) Enough oral or written information so that an informed decision can be made about whether to obtain HIV or HCV testing and counseling; and

(iii) A list of programs or places where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.

(9) *Policies and procedures.* The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for the confidentiality of medical records and other patient information.

(10) *Notification to legal representative or relative.* If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. For possible HIV infectious transfusion beneficiaries that are deceased, the physician or hospital must inform the deceased patient's legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified.

(c) *General blood safety issues.* For lookback activities only related to new blood safety issues that are identified after August 24, 2007, hospitals must comply with FDA regulations as they pertain to blood safety issues in the following areas:

(1) Appropriate testing and quarantining of infectious blood and blood components.

(2) Notification and counseling of beneficiaries that may have received infectious blood and blood components.

42 C.F.R. § 482.41. Condition of participation: Physical environment.

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(d) *Standard: Facilities.* The hospital must maintain adequate facilities for its services.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

42 C.F.R. § 482.42. Condition of participation: Infection control.

The hospital must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the hospital-wide quality assessment and performance improvement (QAPI) program.

(a) *Standard: Infection prevention and control program organization and policies.* The hospital must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;

(2) The hospital infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other institutions and settings;

(3) The infection prevention and control program includes surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and addresses any infection control issues identified by public health authorities; and

(4) The infection prevention and control program reflects the scope and complexity of the hospital services provided.

(b) *Standard: Antibiotic stewardship program organization and policies.* The hospital must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership;

(2) The hospital-wide antibiotic stewardship program:

(i) Demonstrates coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;

(ii) Documents the evidence-based use of antibiotics in all departments and services of the hospital; and

(iii) Documents any improvements, including sustained improvements, in proper antibiotic use;

(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and

(4) The antibiotic stewardship program reflects the scope and complexity of the hospital services provided.

(c) *Standard: Leadership responsibilities.*

(1) The governing body must ensure all of the following:

(i) Systems are in place and operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.

(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with hospital QAPI leadership.

(2) The infection preventionist(s)/infection control professional(s) is responsible for:

(i) The development and implementation of hospital-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

(iii) Communication and collaboration with the hospital's QAPI program on infection prevention and control issues.

(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of infection prevention and control guidelines, policies, and procedures.

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel.

(vi) Communication and collaboration with the antibiotic stewardship program.

(3) The leader(s) of the antibiotic stewardship program is responsible for:

(i) The development and implementation of a hospital-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as with the hospital's infection prevention and control and QAPI programs, on antibiotic use issues.

(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

(d) *Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-hospital systems.* If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:

(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital;

(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the

needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration;

(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed; and

(4) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the hospital as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to hospital staff.

(e) *COVID-19 reporting.* During the Public Health Emergency, as defined in § 400.200 of this chapter, the hospital must report information in accordance with a frequency as specified by the Secretary on COVID-19 in a standardized format specified by the Secretary. This report must include, but not be limited to, the following data elements:

(1) The hospital's current inventory supplies of any COVID-19-related therapeutics that have been distributed and delivered to the hospital under the authority and direction of the Secretary; and

(2) The hospital's current usage rate for any COVID-19-related therapeutics that have been distributed and delivered to the hospital under the authority and direction of the Secretary.

(f) *Standard: Reporting of Acute Respiratory Illness, including Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection.* During the Public Health Emergency, as defined in § 400.200 of this chapter, the hospital must report information, in accordance with a frequency as specified by the Secretary, on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) in a standardized format specified by the Secretary.

42 C.F.R. § 482.53. Condition of participation: Nuclear medicine services.

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

(d) *Standard: Records.* The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(1) The hospital must maintain copies of nuclear medicine reports for at least 5 years.

(2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

(3) The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

(4) Nuclear medicine services must be ordered only by practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

42 C.F.R. § 485.638(c)

(c) *Standard: Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

42 C.F.R. § 489.20(r)(1). Basic commitments.

The provider agrees to the following:

(r) In the case of a hospital as defined in § 489.24(b) (including both the transferring and receiving hospitals), to maintain --

(1) Medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of the transfer;

42 C.F.R. § 493.643(c)(3)(vi)

(3) For purposes of determining a laboratory's classification under this section, the specialties and subspecialties of service for inclusion are: ...

(vi) The specialty of Pathology, which includes the following subspecialties:

- (A) Cytology.
- (B) Histopathology.
- (C) Oral pathology.

42 C.F.R. § 493.801. Condition: Enrollment and testing of samples.

(b) *Standard; Testing of proficiency testing samples.* The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

42 C.F.R. § 493.823

(d)(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

42 C.F.R. § 493.903. Administrative responsibilities.

The proficiency testing program must--

(a)(1) Provide HHS or its designees and participating laboratories with an electronic or a hard copy, or both, of reports of proficiency testing results and all scores for each laboratory's performance in a format as required by and approved by CMS for each CLIA-certified specialty, subspecialty, and analyte or test within 60 days after the date by which the laboratory must report proficiency testing results to the proficiency testing program.

- (2) Provide HHS with reports of PT results and scores of individual performance in cytology and provide copies of reports to participating individuals, and to all laboratories that employ the individuals, within 15 working days of the testing event;
- (b) Furnish to HHS cumulative reports on an individual laboratory's performance and aggregate data on CLIA-certified laboratories for the purpose of establishing a system to make the proficiency testing program's results available, on a reasonable basis, upon request of any person, and include such explanatory information as may be appropriate to assist in the interpretation of the proficiency testing program's results;
- (c) Provide HHS with additional information and data upon request and submit such information necessary for HHS to conduct an annual evaluation to determine whether the proficiency testing program continues to meet the requirements of § § 493.901 through 493.959;
- (d) Maintain records of laboratories' performance for a period of five years or such time as may be necessary for any legal proceedings; and
- (e) Provide HHS with an annual report and, if needed, an interim report which identifies any previously unrecognized sources of variability in kits, instruments, methods, or PT samples, which adversely affect the programs' ability to evaluate laboratory performance.

42 C.F.R. § 493.1105. Standard: Retention requirements.

- (a) The laboratory must retain its records and, as applicable, slides, blocks, and tissues as follows:
 - (1) *Test requisitions and authorizations.* Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.
 - (2) *Test procedures.* Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.
 - (3) *Analytic systems records.* Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in §§ 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:
 - (i) Records of test system performance specifications that the laboratory establishes or verifies under § 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.
 - (ii) Immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d).
 - (4) *Proficiency testing records.* Retain all proficiency testing records for at least 2 years.
 - (5) *Quality system assessment records.* Retain all laboratory quality systems assessment records for at least 2 years.
 - (6) *Test reports.* Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following:
 - (i) Immunohematology reports as specified in 21 CFR 606.160(d).
 - (ii) Pathology test reports for at least 10 years after the date of reporting.

- (7) *Slide, block, and tissue retention --*
- (i) Slides.
 - (A) Retain cytology slide preparations for at least 5 years from the date of examination (see § 493.1274(f) for proficiency testing exception).
 - (B) Retain histopathology slides for at least 10 years from the date of examination.
 - (ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination.
 - (iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.
- (b) If the laboratory ceases operation, the laboratory must make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are retained and available for the time frames specified in this section.

42 C.F.R. § 493.1251. Standard: Procedure manual.

- (a) A written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.
- (b) The procedure manual must include the following when applicable to the test procedure:
- (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in § 493.1242.
 - (2) Microscopic examination, including the detection of inadequately prepared slides.
 - (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.
 - (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.
 - (5) Calibration and calibration verification procedures.
 - (6) The reportable range for test results for the test system as established or verified in § 493.1253.
 - (7) Control procedures.
 - (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.
 - (9) Limitations in the test methodology, including interfering substances.
 - (10) Reference intervals (normal values).
 - (11) Imminently life-threatening test results, or panic or alert values.
 - (12) Pertinent literature references.
 - (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic or alert values.
 - (14) Description of the course of action to take if a test system becomes inoperable.

(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in § 493.1105(a)(2).

45 C.F.R. § 46.115. IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in § 46.109(f)(1).

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in §46.108(a)(2).

(6) Written procedures for the IRB in the same detail as described in §46.108(a)(3) and (4).

(7) Statements of significant new findings provided to subjects, as required by §46.116(c)(5).

(8) The rationale for an expedited reviewer's determination under § 46.110(b)(1)(i) that research appearing on the expedited review list described in § 46.110(a) is more than minimal risk.

(9) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in § 46.103(e).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

45 C.F.R. § 164.528. Accounting of disclosures of protected health information.

(a) *Standard: Right to an accounting of disclosures of protected health information.*

(1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:

- (i) To carry out treatment, payment and health care operations as provided in § 164.506;
- (ii) To individuals of protected health information about them as provided in § 164.502;
- (iii) Incident to a use or disclosure otherwise permitted or required by this subpart, as provided in § 164.502;
- (iv) Pursuant to an authorization as provided in § 164.508;
- (v) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in § 164.510;
- (vi) For national security or intelligence purposes as provided in § 164.512(k)(2);
- (vii) To correctional institutions or law enforcement officials as provided in § 164.512(k)(5);
- (viii) As part of a limited data set in accordance with § 164.514(e); or
- (ix) That occurred prior to the compliance date for the covered entity.

(2)(i) The covered entity must temporarily suspend an individual's right to receive an accounting of disclosures to a health oversight agency or law enforcement official, as provided in § 164.512(d) or (f), respectively, for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required.

- (ii) If the agency or official statement in paragraph (a)(2)(i) of this section is made orally, the covered entity must:
 - (A) Document the statement, including the identity of the agency or official making the statement;
 - (B) Temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and
 - (C) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to paragraph (a)(2)(i) of this section is submitted during that time.

(3) An individual may request an accounting of disclosures for a period of time less than six years from the date of the request.

(b) *Implementation specifications: Content of the accounting.* The covered entity must provide the individual with a written accounting that meets the following requirements.

(1) Except as otherwise provided by paragraph (a) of this section, the accounting must include disclosures of protected health information that occurred during the six years (or such shorter time period at the request of the individual as provided in paragraph (a)(3) of this section) prior to the date of the request for an accounting, including disclosures to or by business associates of the covered entity.

(2) Except as otherwise provided by paragraphs (b)(3) or (b)(4) of this section, the accounting must include for each disclosure:

- (i) The date of the disclosure;
- (ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person;
- (iii) A brief description of the protected health information disclosed;

and

(iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §§ 164.502(a)(2)(ii) or 164.512, if any.

(3) If, during the period covered by the accounting, the covered entity has made multiple disclosures of protected health information to the same person or entity for a single purpose under §§ 164.502(a)(2)(ii) or 164.512, the accounting may, with respect to such multiple disclosures, provide:

(i) The information required by paragraph (b)(2) of this section for the first disclosure during the accounting period;

(ii) The frequency, periodicity, or number of the disclosures made during the accounting period; and

(iii) The date of the last such disclosure during the accounting period.

(4)(i) If, during the period covered by the accounting, the covered entity has made disclosures of protected health information for a particular research purpose in accordance with § 164.512(i) for 50 or more individuals, the accounting may, with respect to such disclosures for which the protected health information about the individual may have been included, provide:

(A) The name of the protocol or other research activity;

(B) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;

(C) A brief description of the type of protected health information that was disclosed;

(D) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;

(E) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and

(F) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.

(ii) If the covered entity provides an accounting for research disclosures, in accordance with paragraph (b)(4) of this section, and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the covered entity shall, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.

(c) *Implementation specifications: Provision of the accounting.* (1) The covered entity must act on the individual's request for an accounting, no later than 60 days after receipt of such a request, as follows.

(i) The covered entity must provide the individual with the accounting requested; or

(ii) If the covered entity is unable to provide the accounting within the time required by paragraph (c)(1) of this section, the covered entity may extend the time to provide the accounting by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (c)(1) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will provide the accounting; and

(B) The covered entity may have only one such extension of time for action on a request for an accounting.

(2) The covered entity must provide the first accounting to an individual in any 12 month period without charge. The covered entity may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12 month period, provided that the covered entity informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.

(d) Implementation specification: Documentation. A covered entity must document the following and retain the documentation as required by § 164.530(j):

(1) The information required to be included in an accounting under paragraph (b) of this section for disclosures of protected health information that are subject to an accounting under paragraph (a) of this section;

(2) The written accounting that is provided to the individual under this section; and

(3) The titles of the persons or offices responsible for receiving and processing requests for an accounting by individuals.

45 C.F.R. § 164.530(j).

(j)(1) *Standard: Documentation.* A covered entity must:

(i) Maintain the policies and procedures provided for in paragraph (i) of this section in written or electronic form;

(ii) If a communication is required by this subpart to be in writing, maintain such writing, or an electronic copy, as documentation; and

(iii) If an action, activity, or designation is required by this subpart to be documented, maintain a written or electronic record of such action, activity, or designation.

(iv) Maintain documentation sufficient to meet its burden of proof under § 164.414(b).

(2) *Implementation specification: Retention period.* A covered entity must retain the documentation required by paragraph (j)(1) of this section for six years from the date of its creation or the date when it last was in effect, whichever is later.

48 C.F.R. § 4.703 Policy.

(a) Except as stated in 4.703(b), contractors shall make available records, which includes books, documents, accounting procedures and practices, and other data, regardless of type and regardless of whether such items are in written form, in the form of computer data, or in any other form, and other supporting evidence to satisfy contract negotiation, administration, and audit requirements of the contracting agencies and the Comptroller General for—

- (1) 3 years after final payment; or
 - (2) For certain records, the period specified in 4.705 through 4.705–3, whichever of these periods expires first.
- (b) Contractors shall make available the foregoing records and supporting evidence for a longer period of time than is required in 4.703(a) if—
- (1) A retention period longer than that cited in 4.703(a) is specified in any contract clause; or
 - (2) The contractor, for its own purposes, retains the foregoing records and supporting evidence for a longer period. Under this circumstance, the retention period shall be the period of the contractor's retention or 3 years after final payment, whichever period expires first.
 - (3) The contractor does not meet the original due date for submission of final indirect cost rate proposals specified in paragraph (d)(2) of the clause at 52.216–7, Allowable Cost and Payment. Under these circumstances, the retention periods in 4.705 shall be automatically extended one day for each day the proposal is not submitted after the original due date.
- (c) Nothing in this section shall be construed to preclude a contractor from duplicating or storing original records in electronic form unless they contain significant information not shown on the record copy. Original records need not be maintained or produced in an audit if the contractor or subcontractor provides photographic or electronic images of the original records and meets the following requirements:
- (1) The contractor or subcontractor has established procedures to ensure that the imaging process preserves accurate images of the original records, including signatures and other written or graphic images, and that the imaging process is reliable and secure so as to maintain the integrity of the records.
 - (2) The contractor or subcontractor maintains an effective indexing system to permit timely and convenient access to the imaged records.
 - (3) The contractor or subcontractor retains the original records for a minimum of one year after imaging to permit periodic validation of the imaging systems.
- (d) If the information described in paragraph (a) of this section is maintained on a computer, contractors shall retain the computer data on a reliable medium for the time periods prescribed. Contractors may transfer computer data in machine readable form from one reliable computer medium to another. Contractors' computer data retention and transfer procedures shall maintain the integrity, reliability, and security of the original computer data. Contractors shall also retain an audit trail describing the data transfer. For the record retention time periods prescribed, contractors shall not destroy, discard, delete, or write over such computer data.

48 C.F.R. § 4.705–1 Financial and cost accounting records.

- (a) Accounts receivable invoices, adjustments to the accounts, invoice registers, carrier freight bills, shipping orders, and other documents which detail the material or services billed on the related invoices: Retain 4 years.
- (b) Material, work order, or service order files, consisting of purchase requisitions or purchase orders for material or services, or orders for transfer of material or supplies: Retain 4 years.

(c) Cash advance recapitulations, prepared as posting entries to accounts receivable ledgers for amounts of expense vouchers prepared for employees' travel and related expenses: Retain 4 years.

(d) Paid, canceled, and voided checks, other than those issued for the payment of salary and wages: Retain 4 years.

(e) Accounts payable records to support disbursements of funds for materials, equipment, supplies, and services, containing originals or copies of the following and related documents: remittance advices and statements, vendors' invoices, invoice audits and distribution slips, receiving and inspection reports or comparable certifications of receipt and inspection of material or services, and debit and credit memoranda: Retain 4 years.

(f) Labor cost distribution cards or equivalent documents: Retain 2 years.

(g) Petty cash records showing description of expenditures, to whom paid, name of person authorizing payment, and date, including copies of vouchers and other supporting documents: Retain 2 years.

48 C.F.R. § 4.705–2 Pay administration records.

(a) Payroll sheets, registers, or their equivalent, of salaries and wages paid to individual employees for each payroll period; change slips; and tax withholding statements: Retain 4 years.

(b) Clock cards or other time and attendance cards: Retain 2 years.

(c) Paid checks, receipts for wages paid in cash, or other evidence of payments for services rendered by employees: Retain 2 years.

48 C.F.R. § 4.705–3 Acquisition and supply records.

(a) Store requisitions for materials, supplies, equipment, and services: Retain 2 years.

(b) Work orders for maintenance and other services: Retain 4 years.

(c) Equipment records, consisting of equipment usage and status reports and equipment repair orders: Retain 4 years.

(d) Expendable property records, reflecting accountability for the receipt and use of material in the performance of a contract: Retain 4 years.

(e) Receiving and inspection report records, consisting of reports reflecting receipt and inspection of supplies, equipment, and materials: Retain 4 years.

(f) Purchase order files for supplies, equipment, material, or services used in the performance of a contract; supporting documentation and backup files including, but not limited to, invoices, and memoranda; e.g., memoranda of negotiations showing the principal elements of subcontract price negotiations (see 52.244–2): Retain 4 years.

(g) Production records of quality control, reliability, and inspection: Retain 4 years.

(h) Property records (see FAR 45.101 and 52.245–1): Retain 4 years.

OFFICIAL CODE OF GEORGIA ANNOTATED**O.C.G.A. § 9-3-23. Sealed instruments**

Actions upon bonds or other instruments under seal shall be brought within 20 years after the right of action has accrued. No instrument shall be considered under seal unless so recited in the body of the instrument.

O.C.G.A. § 9-3-24. Actions on simple written contracts; exceptions

All actions upon simple contracts in writing shall be brought within six years after the same become due and payable. However, this Code section shall not apply to actions for the breach of contracts for the sale of goods under Article 2 of Title 11 or to negotiable instruments under Article 3 of Title 11.

O.C.G.A. § 9-3-25. Open accounts; breach of certain contracts; implied promise; exception.

All actions upon open account, or for the breach of any contract not under the hand of the party sought to be charged, or upon any implied promise or undertaking shall be brought within four years after the right of action accrues. However, this Code section shall not apply to actions for the breach of contracts for the sale of goods under Article 2 of Title 11.

O.C.G.A. § 9-3-27. Actions against fiduciaries.

All actions against executors, administrators, or guardians, except on their bonds, shall be brought within ten years after the right of action accrues.

O.C.G.A. § 9-3-30. Trespass or damage to realty.

(a) All actions for trespass upon or damage to realty shall be brought within four years after the right of action accrues.

(b) (1) The causes of action specified in Code Section 51-1-11 and subsection (a) of Code Section 9-3-51 for recovery of damages to a dwelling due to the manufacture of or the negligent design or installation of synthetic exterior siding shall accrue when the damage to the dwelling is discovered or, in the exercise of reasonable diligence, should have been discovered, whichever first occurs. In any event, such cause of action shall be brought within the time limits provided in Code Sections 51-1-11 and 9-3-51, respectively.

(2) This subsection shall apply to causes of action which had not expired under the former law before March 28, 2000. This subsection shall not revive any cause of action which was barred by former law before March 28, 2000.

O.C.G.A. § 9-3-31. Injuries to personalty.

Actions for injuries to personalty shall be brought within four years after the right of action accrues.

O.C.G.A. § 9-3-32. Recovery of personal property; damages for conversion or destruction; actions involving unauthorized cutting or cutting and carrying away of timber.

Actions for the recovery of personal property, or for damages for the conversion or destruction of the same, shall be brought within four years after the right of action accrues, and actions involving the unauthorized cutting or cutting and carrying away of timber from the property of

another shall be brought within four years after the cutting or cutting and carrying away of timber.

O.C.G.A. § 9-3-33. Injuries to the person; injuries to reputation; loss of consortium; exception.

Actions for injuries to the person shall be brought within two years after the right of action accrues, except for injuries to the reputation, which shall be brought within one year after the right of action accrues, and except for actions for injuries to the person involving loss of consortium, which shall be brought within four years after the right of action accrues.

O.C.G.A. § 9-3-71. General limitation.

(a) Except as otherwise provided in this article, an action for medical malpractice shall be brought within two years after the date on which an injury or death arising from a negligent or wrongful act or omission occurred.

(b) Notwithstanding subsection (a) of this Code section, in no event may an action for medical malpractice be brought more than five years after the date on which the negligent or wrongful act or omission occurred.

(c) Subsection (a) of this Code section is intended to create a two-year statute of limitations. Subsection (b) of this Code section is intended to create a five-year statute of ultimate repose and abrogation.

(d) Nothing contained in subsection (a) or (b) of this Code section shall be construed to repeal Code Section 9-3-73, which shall be deemed to apply either to the applicable statutes of limitation or repose.

O.C.G.A. § 9-3-72. Foreign objects left in body.

The limitations of Code Section 9-3-71 shall not apply where a foreign object has been left in a patient's body, but in such a case an action shall be brought within one year after the negligent or wrongful act or omission is discovered. For the purposes of this Code section, the term "foreign object" shall not include a chemical compound, fixation device, or prosthetic aid or device.

O.C.G.A. § 9-3-73. Certain disabilities and exceptions applicable.

(a) Except as provided in this Code section, the disabilities and exceptions prescribed in Article 5 of this chapter in limiting actions on contracts shall be allowed and held applicable to actions, whether in tort or contract, for medical malpractice.

(b) Notwithstanding Article 5 of this chapter, all persons who are legally incompetent because of mental retardation or mental illness and all minors who have attained the age of five years shall be subject to the periods of limitation for actions for medical malpractice provided in this article. A minor who has not attained the age of five years shall have two years from the date of such minor's fifth birthday within which to bring a medical malpractice action if the cause of action arose before such minor attained the age of five years.

(c) Notwithstanding subsections (a) and (b) of this Code section, in no event may an action for medical malpractice be brought by or on behalf of:

(1) A person who is legally incompetent because of mental retardation or mental illness more than five years after the date on which the negligent or wrongful act or omission occurred; or

(2) A minor:

(A) After the tenth birthday of the minor if such minor was under the age of five years on the date on which the negligent or wrongful act or omission occurred; or

(B) After five years from the date on which the negligent or wrongful act or omission occurred if such minor was age five or older on the date of such act or omission.

(d) Subsection (b) of this Code section is intended to create a statute of limitations and subsection (c) of this Code section is intended to create a statute of repose.

(e) The limitations of subsections (b) and (c) of this Code section shall not apply where a foreign object has been left in a patient's body. Such cases shall be governed by Code Section 9-3-72.

(f) The findings of the General Assembly under this Code section include, without limitation, that a reasonable relationship exists between the provisions, goals, and classifications of this Code section and the rational, legitimate state objectives of providing quality health care, assuring the availability of physicians, preventing the curtailment of medical services, stabilizing insurance and medical costs, preventing stale medical malpractice claims, and providing for the public safety, health, and welfare as a whole.

(g) No action which, prior to July 1, 1987, has been barred by provisions relating to limitations of actions shall be revived by this article, as amended. No action which would be barred before July 1, 1987, by the provisions of this article, as amended, but which would not be so barred by the provisions of this article and Article 5 of this chapter in force immediately prior to July 1, 1987, shall be barred until July 1, 1989.

O.C.G.A. § 10-1-401. Limitation of actions; right to set off damages or penalties not limited.

(a) No private right of action shall be brought under this part:

(1) More than two years after the person bringing the action knew or should have known of the occurrence of the alleged violation; or

(2) More than two years after the termination of any proceeding or action by the State of Georgia, whichever is later.

(b) Damages or penalties to which a person is entitled pursuant to this part may be set off against the allegation of the person to the seller and may be raised as a defense to a suit on the obligation without regard to the time limitations prescribed by this Code section.

O.C.G.A. § 10-11-2. Time period for retention of business records.

Unless a specific period is designated by law for their preservation, business records which persons pursuant to the laws of this state are required to keep or preserve may be destroyed after the expiration of three years from the making of such records without constituting an offense under such laws. This Code section does not apply to minute books of corporations or to records of sales or other transactions involving weapons or poisons capable of use in the commission of crimes.

O.C.G.A. § 10-12-12. Retention of electronic records

(a) If a law requires that a record be retained, such requirement shall be satisfied by retaining an electronic record of the information in the record which:

- (1) Accurately reflects the information set forth in the record after it was first generated in its final form as an electronic record or otherwise; and
- (2) Remains accessible for the retention period required by law.

O.C.G.A. § 11-2-725. Statute of limitations in contracts for sale.

- (1) An action for breach of any contract for sale must be commenced within four years after the cause of action has accrued. By the original agreement the parties may reduce the period of limitation to not less than one year but may not extend it.
- (2) A cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered.
- (3) Where an action commenced within the time limited by subsection (1) of this Code section is so terminated as to leave available a remedy by another action for the same breach such other action may be commenced after the expiration of the time limited and within six months after the termination of the first action unless the termination resulted from voluntary discontinuance or from dismissal for failure or neglect to prosecute.
- (4) This Code section does not alter the law on tolling of the statute of limitations nor does it apply to causes of action which have accrued before January 1, 1964.

O.C.G.A. § 12-8-96.1. Liability of persons contributing to release of hazardous waste, etc., for cost of cleanup; punitive damages.

- (a) Each and every person who contributed to a release of a hazardous waste, a hazardous constituent, or a hazardous substance shall be jointly, severally, and strictly liable to the State of Georgia for the reasonable costs of activities associated with the cleanup of environmental hazards, including legal expenses incurred by the state pursuant to subsection (a) of Code Section 12-8-96, as a result of the failure of such person to comply with an order issued by the director. Any such person shall be so liable notwithstanding the absence of the issuance of an order to such person pursuant to subsection (a) of Code Section 12-8-96 if the director is unable to identify such person prior to the commencement of clean-up action after making a reasonable effort to do so pursuant to such Code section, or if such person contributed to a release which resulted in an emergency action by the director and issuance of such an order would cause a delay in corrective action that could endanger human health and the environment. The person may, in addition, be liable for punitive damages in an amount at least equal to the costs incurred by the state and not more than three times the costs incurred by the state for activities associated with the cleanup of environmental hazards. Costs and damages incurred by the state may be recovered in a civil action instituted in the name of the director. All costs recovered by the state pursuant to this Code section shall be deposited into the hazardous waste trust fund.
- (b) Any action for the recovery of costs and for punitive damages shall be commenced within six years of the date on which all costs have been incurred.

(c) No person shall be liable for costs or damages pursuant to this Code section if he can show by a preponderance of the evidence that the release of a hazardous waste, a hazardous constituent, or a hazardous substance was caused solely by:

- (1) An act of God;
- (2) An act of war;
- (3) An act or omission of a third party other than an employee or agent of the person or other than one whose act or omission occurs in connection with a contractual relationship, existing directly or indirectly, with the person, if the person establishes by a preponderance of the evidence that:

(A) He had no relationship with the third party nor exercised any control over activities of the third party; and

(B) He took precautions against foreseeable acts or omissions of any such third party and the consequences that could foreseeably result from such acts or omissions; or

(4) Any combination of paragraph (1), (2), or (3) of this subsection.

(d) (1) For purposes of paragraph (3) of subsection (c) of this Code section, a contractual relationship may be conclusively established by, but not limited to, land contracts, deeds, or other instruments transferring title or possession, unless the real property on which the disposal or release of hazardous wastes, hazardous constituents, or hazardous substances has occurred or is occurring was acquired by the person after the disposal or release of the hazardous wastes, hazardous constituents, or hazardous substances and one or more of the following circumstances are established by a preponderance of the evidence:

(A) At the time the person acquired the site, the person did not know and had no reason to know that any hazardous waste, hazardous constituent, or hazardous substance had been disposed of or released at the site;

(B) The person is a government entity which acquired the site by escheat, through any other involuntary transfer or acquisition, or through the exercise of eminent domain by purchase or condemnation; or

(C) The person acquired the site by inheritance or bequest and that one or more of the circumstances described in paragraph (1), (2), or (3) of subsection (c) of this Code section are applicable.

(2) To establish that the person had no reason to know as provided in subparagraph (A) of paragraph (1) of this subsection, the person must have undertaken, at the time of acquisition, all appropriate inquiries into the previous ownership and uses of the property consistent with good commercial or customary practice in an effort to minimize liability. For purposes of the preceding sentence, the finder of fact shall take into account any specialized knowledge or experience on the part of the person, the relationship of the purchase price to the value of the property if uncontaminated, commonly known or reasonably ascertainable information about the property, the obviousness of the presence or likely presence of contamination at the property, and the ability to detect such contamination by appropriate inspection.

(3) Nothing in this subsection shall diminish the liability of any previous owner of such property who would otherwise be liable under this part. Notwithstanding this paragraph, if a person obtained actual knowledge of the disposal or release of a hazardous waste, hazardous constituent, or hazardous substance at the site when the person owned the real property and then subsequently transferred ownership of the

property to another person without disclosing such knowledge, the person so transferring the property shall be treated as liable under subsection (a) of this Code section, and no defense under subsection (c) of this Code section shall be available to such person.

Nothing in this subsection shall affect the liability under this part of a person who, by any act or omission, causes or contributes to the disposal or release of a hazardous waste, a hazardous constituent, or a hazardous substance which is the subject of the action relating to the site.

(e) During or following the undertaking of any corrective action, any person may seek contribution from any other person who has contributed or is contributing to any release of a hazardous waste, a hazardous constituent, or a hazardous substance. Such claims for contribution shall be governed by the law of this state. In resolving contribution claims, the court may allocate costs among liable parties using such equitable factors as the court determines to be appropriate. In any action filed by the director for the recovery of costs and damages pursuant to this Code section, any third-party claim for contribution may, upon the motion of the director, be severed and maintained as a separate action.

(f) A person who has voluntarily agreed to perform corrective action pursuant to an administrative consent order with the director shall not be liable for claims for contribution regarding matters addressed in the administrative consent order. Such administrative consent order does not discharge any other person who has contributed or is contributing to a release of hazardous wastes, hazardous constituents, or hazardous substances unless the terms of the administrative consent order so provide, and the other persons remain liable for any corrective action deemed necessary by the director but not agreed to in the administrative consent order.

O.C.G.A. § 14-2-1601. Corporate records.

(a) A corporation shall keep as permanent records minutes of all meetings of its shareholders and board of directors, executed consents evidencing all actions taken by the shareholders or board of directors without a meeting, a record of all actions taken by a committee of the board of directors in place of the board of directors on behalf of the corporation, and waivers of notice of all meetings of the board of directors and its committees.

(b) A corporation shall maintain appropriate accounting records.

(c) A corporation or its agent shall maintain a record of its shareholders, in a form that permits preparation of a list of the names and addresses of all shareholders, in alphabetical order by class of shares showing the number and class of shares held by each.

(d) A corporation shall maintain its records in written form or in another form capable of conversion into written form within a reasonable time.

O.C.G.A. § 16-13-39. Manufacturers, distributors, and dispensers to maintain records of controlled substances.

Persons registered to manufacture, distribute, or dispense controlled substances under this article shall keep a complete and accurate record of all controlled substances on hand, received, manufactured, sold, dispensed, or otherwise disposed of and shall maintain such records and inventories in conformance with the record-keeping and inventory requirements of federal law and with any rules issued by the State Board of Pharmacy.

O.C.G.A. § 16-13-72. Sale, distribution, or possession of dangerous drugs.

Except as provided for in this article, it shall be unlawful for any person, firm, corporation, or association to sell, give away, barter, exchange, distribute, or possess in this state any dangerous drug, except under the following conditions:

(6) Such person, firm, corporation, or association shall keep a complete and accurate record of all dangerous drugs received, purchased, manufactured, sold, dispensed, or otherwise disposed of and shall maintain such records for at least two years or in conformance with any other state or federal law or rule issued by the State Board of Pharmacy.

O.C.G.A. § 16-14-8. Period of limitations as to criminal or civil proceedings under this chapter.

Notwithstanding any other provision of law, a criminal or civil action or proceeding under this chapter may be commenced up until five years after the conduct in violation of a provision of this chapter terminates or the cause of action accrues. If a criminal prosecution or civil action is brought by the state to punish or prevent any violation of this chapter, then the running of this period of limitations, with respect to any cause of action arising under subsection (b) or (c) of Code Section 16-14-6 which is based upon any matter complained of in such prosecution or action by the state, shall be suspended during the pendency of the prosecution or action by the state and for two years thereafter.

O.C.G.A. § 26-4-83. Patient record systems.

(a) The board of pharmacy may refuse to renew or may suspend, revoke, or restrict the licenses of or fine any person or pharmacy pursuant to the procedures set forth in this Code section and rules and regulations established by the board upon the failure to maintain an appropriate patient record system.

(b) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary by the pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist or the pharmacist's designee shall make a reasonable effort to obtain, record, and maintain the following information:

- (1) The full name of the patient for whom the drug is intended;
- (2) The address and telephone number of the patient;
- (3) The date of birth of the patient; and
- (4) The gender of the patient.

(c) The pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and identify any other drugs, including over-the-counter drugs or devices, currently being used by the patient which may relate to prospective drug use review unless the patient or the patient's agent refuses to provide such information. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

- (1) A list of all prescription drug orders obtained by the patient at the pharmacy where the prescription drug order is being filled for at least the preceding two

years, showing the prescription number, the name and strength of the drug, the quantity and date dispensed, and the name of the prescribing practitioner; and

(2) Comments from the pharmacist relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(d) A patient record shall be maintained for a period of not less than two years from the date of the last entry in the profile record. This record may be a hard copy of a computerized form.

O.C.G.A. § 26-4-160. Sales and labeling.

No person shall furnish by retail sale any poison enumerated in this Code section without distinctly labeling the bottle, box, vessel, or paper in which the poison is contained, and also the outside wrapper or cover thereof, with the name of the article, the word "Poison," and the name and place of business of the person who furnishes the same; and no poison shall be furnished unless upon due inquiry it shall be found that the person to whom it is delivered is aware of its poisonous character and shall represent that it is to be used for a legitimate purpose:

(1) Schedule "A." Arsenic and its preparations, corrosive sublimate, white precipitate, red precipitate, biniodide of mercury, cyanide of potassium, hydrocyanic acid, strychnia, and all other poisonous vegetable alkaloids and their salts; essential oil of bitter almonds, opium and its preparations, except paregoric and other preparations of opium containing less than two grains to the ounce; and

(2) Schedule "B." Aconite, belladonna, colchicum, conium, nux vomica, henbane, creosote, digitalis, and their pharmaceutical preparations; croton oil, chloroform, chloral hydrate, sulfate of zinc, mineral acids, carbolic acid, and oxalic acid.

O.C.G.A. § 26-4-161. Procedure on sale or delivery of listed poisons.

No licensed pharmacist shall sell or deliver any of the poisons included in paragraph (1) of Code Section 26-4-160 without first making an entry in a book for that purpose, stating the date of the delivery, the name and address of the person receiving the poison, the name and quantity of the poison, the purpose for which it is represented by such person to be required, and the name of the dispenser. Such book shall always be open for inspection by the proper authorities and shall be preserved for reference for at least five years.

O.C.G.A. § 31-7-22. Required posting of documents to hospital websites.

(a) As used in this Code section, the term "hospital" means a nonprofit hospital, a hospital owned or operated by a hospital authority, or a nonprofit corporation formed, created, or operated by or on behalf of a hospital authority.

(b) Beginning October 1, 2019, each hospital in this state shall post a link in a prominent location on the main page of its website to the most recent version of the following documents:

(1) Federal related disclosures:

(A) Copies of audited financial statements that are general purpose financial statements, which express the unqualified opinion of an independent certified public accounting firm for the most recently completed fiscal year for the hospital; each of its affiliates, except those affiliates that were inactive or that had an immaterial amount of total assets; and the hospital's parent corporation that include the following:

(i) A PDF version of all audited financial statements;

(ii) A note in the hospital's audited financial statements that identifies individual amounts for such hospital's gross patient revenue, allowances, charity care, and net patient revenue;

(iii) Audited consolidated financial statements for hospitals with subsidiaries and consolidating financial statements that at a minimum contain a balance sheet and statement of operations and that provide a breakout of the hospital's and each subsidiary's numbers with a report from independent accountants on other financial information; and

(iv) Audited consolidated financial statements for the hospital's parent corporation and consolidating financial statements that at a minimum contain a balance sheet and statement of operations and that provide a breakout of the hospital's and each affiliate's numbers with a report from independent accountants on other financial information; and

(B) Copy of audited Internal Revenue Service Form 990, including Schedule H for hospitals and other applicable attachments; provided, however, that for any hospital not required to file IRS Form 990, the department shall establish and provide a form that collects the same information as is contained in Internal Revenue Service Form 990, including Schedule H for hospitals, as applicable; and

(2) Georgia supplemental disclosures:

(A) Copy of the hospital's completed annual hospital questionnaire, as required by the department;

(B) The community benefit report prepared pursuant to Code Section 31-7-90.1, if applicable;

(C) The disproportionate share hospital survey, if applicable;

(D) Listing of all real property holdings of the hospital, including the location and size, parcel ID number, purchase price, current use, and any improvements made to such property;

(E) Listing of any ownership or interest the nonprofit hospital has in any joint venture, partnership, subsidiary holding company, or captive insurance company; where any such entity is domiciled; and the value of any such ownership or interest;

(F) Listing of any bonded indebtedness, outstanding loans, and bond defaults, whether or not in forbearance; and any bond disclosure sites of the hospital;

(G) A report that identifies by purpose, the ending fund balances of the net assets of the hospital and each affiliate as of the close of the most recently completed fiscal year, distinguishing between donor permanently restricted, donor temporarily restricted, board restricted and unrestricted fund balances. The hospital's interest in its foundation shall be deducted from the foundation's total fund balance;

(H) Copy of all going concern statements regarding the hospital;

(I) The most recent legal chart of corporate structure, including the hospital, each of its affiliates and subsidiaries, and its parent corporation, duly dated;

(J) Report listing the salaries and fringe benefits for the ten highest paid administrative positions in the hospital. Each position shall be identified by its complete, unabbreviated title. Fringe benefits shall include all forms of compensation, whether actual or deferred, made to or on behalf of the employee, whether full or part-time;

(K) Evidence of accreditation by accrediting bodies, including, but not limited to, the Joint Commission and DNV; and

(L) Copy of the hospital's policies regarding the provision of charity care and reduced cost services to the indigent, excluding medical assistance recipients, and its debt collection practices.

(c) Each hospital shall update the documents in the links posted pursuant to subsection (b) of this Code section on July 1 of each year or more frequently at its discretion. Noncurrent documents shall remain posted and accessible on the hospital's website indefinitely.

(d) All documents listed in subsection (b) of this Code section shall be prepared in accordance with generally accepted accounting principles, as applicable.

(e) The department shall also post a link in a prominent location on its website to the documents listed in subsection (b) of this Code section for each hospital in this state.

(f) Any hospital that fails to post the documents required pursuant to subsection (b) of this Code section within 30 days of the dates required in this Code section shall be suspended from receiving any state funds or any donations pursuant to Code Section 48-7-29.20; provided, however, that the department shall provide a hospital notice of any deficiency and opportunity to correct such deficiency prior to any suspension of funds pursuant to this subsection.

(g) The department shall have jurisdiction to enforce this Code section and to promulgate rules and regulations required to administer this Code section.

(h) Any person who knowingly and willfully includes false, fictitious, or fraudulent information in any documents required to be posted pursuant to this Code section shall be subject to a violation of Code Section 16-10-20.

O.C.G.A. § 31-10-9. Registration of births.

(a) A certificate of birth for each live birth which occurs in this state shall be filed with the State Office of Vital Records within five days after such birth and filed in accordance with this Code section and regulations of the department.

(b) When a birth occurs in an institution or en route thereto, the person in charge of such institution or that person's designated representative shall obtain the personal data, prepare the birth certificate, certify, either by signature or by an electronic process established or approved by the State Office of Vital Records, that the child was born alive at the place and time and on the date stated and file the certificate with the State Office of Vital Records. The physician or other person in attendance shall provide the medical information required by the certificate within 72 hours after the birth occurs.

(c) Except as provided in subsection (b) of this Code section, when a birth occurs outside an institution, the certificate shall be prepared and filed by one of the following in the indicated order of priority:

(1) The physician or certified nurse midwife in attendance at or immediately after the birth; or in the absence of such person:

(2) Any other person in attendance at or immediately after the birth; or in the absence of such a person:

(3) The father or the mother; or in the absence of the father and inability of the mother:

(4) The person in charge of the premises where the birth occurred.

(d) When a birth occurs on a moving conveyance within the United States and the child is first removed from the conveyance in this state, the birth shall be registered in this state and the place where it is first removed shall be considered the place of birth. When a birth occurs on a moving conveyance while in international waters or airspace or in a foreign country or its airspace and the child is first removed from the conveyance in this state, the birth shall be registered in this state but the certificate shall show the actual place of birth insofar as can be determined.

(e) The name of the natural father or putative father shall be entered on the certificate of live birth as follows:

(1) If the mother was married either at the time of conception or at the time of birth, the name of the husband shall be entered on the certificate as the father of the child unless paternity has been determined otherwise by a court having jurisdiction, in which case the name of the father as determined by the court shall be entered;

(2) If the mother is not married at either the time of conception or at the time of birth, the name of the putative father shall not be entered on the certificate of birth without the written consent of the mother and the person to be named as father;

(3) In any case in which paternity of a child is determined by a court of competent jurisdiction, the name of the father and the surname of the child shall be entered on the certificate of birth in accordance with the finding and order of the court;

(4) If the father is not named on the certificate of birth, no other information about the father shall be entered on the certificate; or

(5) Except as provided in paragraph (3) of this subsection, in all other cases, the surname of the child shall be the legal surname of the mother at the time of the birth entered on the certificate as designated by the mother. When a paternity acknowledgment is completed, the surname of the child shall be entered as designated by both parents.

(f) The birth certificate of a child born to a married woman as a result of artificial insemination, with consent of her husband, shall be completed in accordance with the provisions of subsection (e) of this Code section.

(g) Either of the parents of the child, or other informant, shall verify the accuracy of the personal data entered on the certificate in time to permit the filing of the certificate within the time period prescribed in subsection (a) of this Code section.

(h) All birth certificates filed and registered must identify the recorded person by name and the name of each legal parent of such person and the name of all other persons required by this Code section or by regulation. No obscenities, numbers, symbols, or other such nonidentifying name information will be accepted. If a legal parent has not decided upon a first or middle name for the child before the time limits established in this Code section, the birth record shall be registered without the child's first or middle name, or both, unless a court order provides otherwise.

O.C.G.A. § 31-10-15. Death certificate; filing; medical certification; forwarding death certificate to decedent's county of residence; purging voter registration list.

(a) A certificate of death for each death which occurs in this state shall be filed with the local registrar of the county in which the death occurred or the body was found within ten days after the death as follows:

(1) If the place of death is unknown but the dead body is found in this state, the certificate of death shall be completed and filed in accordance with this Code section. The place where the body is found shall be shown as the place of death. If the date of death is unknown, it shall be the date the body was found and the certificate marked as such; or

(2) When death occurs in a moving conveyance in the United States and the body is first removed from the conveyance in this state, the death shall be registered in this state and the place where it is first removed shall be considered the place of death. When a death occurs on a moving conveyance while in international waters or airspace or in a foreign country or its airspace and the body is first removed from the conveyance in this state, the death shall be registered in this state but the certificate shall show the actual place of death insofar as can be determined.

(b) The funeral director or person acting as such who first assumes custody of the dead body shall file the certificate of death within 72 hours. Such director or person shall obtain the personal data from the next of kin or the best qualified person or source available and shall obtain the medical certification from the person responsible therefor.

(c) (1) The medical certification as to the cause and circumstances of death shall be completed, signed, and returned to the funeral director or person acting as such within 72 hours after death by the physician in charge of the patient's care for the illness or condition which resulted in death, except when inquiry is required by Article 2 of Chapter 16 of Title 45, the "Georgia Death Investigation Act." In the absence of said physician or with that physician's approval the certificate may be completed and signed by an associate physician, the chief medical officer of the institution in which death occurred, or the physician who performed an autopsy upon the decedent, provided that such individual has access to the medical history of the case, views the deceased at or after death, and death is due to natural causes. If, 30 days after a death, the physician in charge of the patient's care for the illness or condition which resulted in death has failed to complete, sign, and return the medical certification as to the cause and circumstances of death to the funeral director or person acting as such, the funeral director or person acting as such shall be authorized to report such physician to the Georgia Composite Medical Board for discipline pursuant to Code Section 43-34-8.

(2) In any area in this state which is in a state of emergency as declared by the Governor due to an influenza pandemic, in addition to any other person authorized by law to complete and sign a death certificate, any registered professional nurse employed by a long-term care facility, advanced practice nurse, physician assistant, registered nurse employed by a home health agency, or nursing supervisor employed by a hospital shall be authorized to complete and sign the death certificate, provided that such person has access to the medical history of the case, such person views the deceased at or after death, the death is due to natural causes, and an inquiry is not required under Article 2 of Chapter 16 of Title 45, the "Georgia Death Investigation Act." In such a state of emergency, the death certificate shall be filed by the funeral director in accordance with subsection (b) of this Code section; or, if the certificate is not completed and signed by an

appropriate physician or coroner, the public health director of preparedness shall cause the death certificate to be completed, signed, and filed by some other authorized person within ten days after death.

(d) When death occurs without medical attendance as set forth in subsection (c) of this Code section or when inquiry is required by Article 2 of Chapter 16 of Title 45, the "Georgia Death Investigation Act," the proper person shall investigate the cause of death and shall complete and sign the medical certification portion of the death certificate within 30 days after being notified of the death.

(e) If the cause of death cannot be determined within 48 hours after death, the medical certification shall be completed as provided by regulation. The attending physician or coroner shall give the funeral director or person acting as such notice of the reason for the delay, and final disposition of the body shall not be made until authorized by the attending physician, coroner, or medical examiner.

(f) When death occurs on or after July 1, 1985, in a county other than the county of the residence of the deceased person, a copy of such person's death certificate shall be forwarded as soon as practicable by the department to the custodian of records of the county of the residence of such deceased person. The custodian of records shall file such death certificate as a part of the permanent records of such office.

(g) Any other provision of this chapter or Chapter 16 of Title 45 notwithstanding, when the death of a nonresident burn victim occurs in a treatment facility following the transportation of such victim from an incident occurring in another state, only the attending physician shall be required to complete and sign the death certificate.

(h) On or before the tenth day of each month, the state registrar shall furnish to the Secretary of State's office, in a format prescribed by the Secretary's office, a list of those persons for whom death certificates have been filed during the preceding month. Such list shall be used by the Secretary of State to notify local registration officers for the purpose of purging the voter registration list of each county.

O.C.G.A. § 31-12-2. Reporting disease; confidentiality; reporting required of pharmacists; immunity from liability as to information supplied; notification of potential bioterrorism.

(a) The department is empowered to declare certain diseases, injuries, and conditions to be diseases requiring notice and to require the reporting thereof to the county board of health and the department in a manner and at such times as may be prescribed. The department shall require that such data be supplied as are deemed necessary and appropriate for the prevention of certain diseases, injuries, and conditions as are determined by the department. All such reports and data shall be deemed confidential and shall not be open to inspection by the public; provided, however, the department may release such reports and data in statistical form or for valid research purposes.

(a. 1)(1) As used in this subsection, the term "neonatal abstinence syndrome" means a group of physical problems that occur in a newborn infant who was exposed to addictive illegal or prescription drugs while in the mother's womb.

(2) The department shall require notice and reporting of incidents of neonatal abstinence syndrome. A health care provider, coroner, or medical examiner, or any other person or entity the department determines has knowledge of diagnosis or health outcomes related, directly or indirectly, to neonatal abstinence syndrome shall report incidents of neonatal abstinence syndrome to the department. The

department shall provide an annual report to the President of the Senate, the Speaker of the House of Representatives, the chairperson of the House Committee on Health and Human Services, and the chairperson of the Senate Health and Human Services Committee. Such annual report shall include any department findings and recommendations on how to reduce the number of infants born with neonatal abstinence syndrome.

(b) A health care provider, coroner, or medical examiner shall report to the department and the county board of health all known or presumptively diagnosed cases of persons harboring any illness or health condition that may be caused by bioterrorism, epidemic or pandemic disease, or novel and highly fatal infectious agents or toxins and that may pose a substantial risk of a public health emergency. Reportable illnesses and conditions include, without limitation, diseases caused by biological agents listed at 42 C.F.R. Part 72, app. A (2000) and any illnesses or conditions identified by the department as potential causes of a public health emergency.

(c) A pharmacist shall report to the department and the county board of health any unusual or increased prescription rates, unusual types of prescriptions, or unusual trends in pharmacy visits that may reasonably be believed to be caused by bioterrorism, epidemic or pandemic disease, or novel and highly fatal infectious agents or toxins and that may pose a substantial risk of a public health emergency.

(d) Any person, including but not limited to practitioners of the healing arts, submitting in good faith reports or data to the department or county boards of health in compliance with the provisions of this Code section shall not be liable for any civil damages therefor.

(e) Whenever the department learns of any case of an unusual illness, health condition, or death, or an unusual cluster of such events, or any other suspicious health related event that it reasonably believes has the potential to be caused by bioterrorism, it shall immediately notify the Department of Public Safety and other appropriate public safety authorities.

O.C.G.A. § 31-33-2. Furnishing copy of records to patient, provider, or other authorized person.

(a) (1) (A) A provider having custody and control of any evaluation, diagnosis, prognosis, laboratory report, or biopsy slide in a patient's record shall retain such item for a period of not less than ten years from the date such item was created.

(B) The requirements of subparagraph (A) of this paragraph shall not apply to:

(i) An individual provider who has retired from or sold his or her professional practice if such provider has notified the patient of such retirement or sale and offered to provide such items in the patient's record or copies thereof to another provider of the patient's choice and, if the patient so requests, to the patient; or

(ii) A hospital which is an institution as defined in subparagraph (A) of paragraph (4) of Code Section 31-7-1, which shall retain patient records in accordance with rules and regulations for hospitals as issued pursuant to Code Section 31-7-2.

(2) Upon written request from the patient or a person authorized to have access to the patient's record under an advance directive for health care or a durable

power of attorney for health care for such patient, the provider having custody and control of the patient's record shall furnish a complete and current copy of that record, in accordance with the provisions of this Code section. If the patient is deceased, such request may be made by the following persons:

- (A) The executor, administrator, or temporary administrator for the decedent's estate if such person has been appointed;
- (B) If an executor, administrator, or temporary administrator for the decedent's estate has not been appointed, by the surviving spouse;
- (C) If there is no surviving spouse, by any surviving child; and
- (D) If there is no surviving child, by any parent.

(b) Any record requested under subsection (a) of this Code section shall within 30 days of the receipt of a request for records be furnished to the patient, any other provider designated by the patient, any person authorized by paragraph (2) of subsection (a) of this Code section to request a patient's or deceased patient's medical records, or any other person designated by the patient. Such record request shall be accompanied by:

- (1) An authorization in compliance with the federal Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. Section 1320d-2, et seq., and regulations implementing such act; and
- (2) A signed written authorization as specified in subsection (d) of this Code section.

(c) If the provider reasonably determines that disclosure of the record to the patient will be detrimental to the physical or mental health of the patient, the provider may refuse to furnish the record; however, upon such refusal, the patient's record shall, upon written request by the patient, be furnished to any other provider designated by the patient.

(d) A provider shall not be required to release records in accordance with this Code section unless and until the requesting person has furnished the provider with a signed written authorization indicating that he or she is authorized to have access to the patient's records by paragraph (2) of subsection (a) of this Code section. Any provider shall be justified in relying upon such written authorization.

(e) Any provider or person who in good faith releases copies of medical records in accordance with this Code section shall not be found to have violated any criminal law or to be civilly liable to the patient, the deceased patient's estate, or to any other person.

O.C.G.A. § 34-2-11. Employer's duty to keep records.

Every employer shall keep a true and accurate record of the name, address, and occupation of each person employed by him, and of the daily and weekly hours worked by each such person and of the wages paid during each pay period to each such person. Such records shall be kept on file for at least one year after the date of the record. No employer shall make or cause to be made any false entries in any such record.

O.C.G.A. § 34-9-80. Procedure for giving notice of accident; requirements of written notice; effect of failure to give notice.

Every injured employee or his representative shall, immediately on the occurrence of any accident or as soon thereafter as practicable, give or cause to be given to the employer, his agent, representative, or foreman, or the immediate superior of the injured employee a notice of the accident. This notice shall be given by the employee either in person or by his representative, and

until such notice is given the employee shall not be entitled to any physician's fees nor to any compensation which may have accrued under the terms of this chapter prior to the giving of such notice. In the event that, within 30 days after the accident, neither the employee nor his representative has given a notice in person to the employer, his agent, representative, or foreman, or to the immediate superior of the injured employee, a written notice must be given. This written notice will not be required where an injured employee or his representative has given notice in person to the employer, his agent, representative, or foreman, or to the immediate superior of the injured employee. No compensation will be payable unless such notice, either oral or written, is given within 30 days after the occurrence of an accident or within 30 days after death resulting from an accident unless it can be shown that the employee had been prevented from doing so by reason of physical or mental incapacity, or by fraud or deceit, or that the employer, his agent, representative, or foreman, or the immediate superior of the injured employee had knowledge of the accident, or unless a reasonable excuse is made to the satisfaction of the board for not giving such notice and it is reasonably proved to the satisfaction of the board that the employer had not been prejudiced thereby.

O.C.G.A. § 34-9-82. Limitation period and procedure for filing claims.

(a) The right to compensation shall be barred unless a claim therefor is filed within one year after injury, except that if payment of weekly benefits has been made or remedial treatment has been furnished by the employer on account of the injury the claim may be filed within one year after the date of the last remedial treatment furnished by the employer or within two years after the date of the last payment of weekly benefits.

O.C.G.A. § 43-34-174. License to be property of board; display of license; surrender of license; renewal; expired license.

- (b) The license holder shall:
- (1) Display the license in an appropriate and public manner; or
 - (2) Maintain on file at all times during which the license holder provides services in a health care facility a true and correct copy of the license certificate in the appropriate records of the facility and keep the board informed of any change of address.

O.C.G.A. § 44-12-228. Retention of books and records.

(a) Every financial institution, banking organization, and business association and all other holders required to file a report under Code Section 44-12-214 shall retain all books, records, and documents necessary to establish the accuracy and compliance of such report for ten years after the property becomes reportable, except to the extent that shorter time is provided in accordance with Article 5 of Chapter 18 of Title 50, the "Georgia Records Act," or in subsection (b) of this Code section or by rule of the commissioner. As to any property for which it has obtained the last known address of the owner, the holder shall maintain a record of the name and last known address of the owner for the same ten-year period.

O.C.G.A. § 48-7-111. Employer's records; contents; period of preservation.

(a) Each employer required to deduct and withhold taxes under this article shall keep accurate records of all remuneration paid to his employees, including, but not limited to, remuneration paid in forms other than cash. The records shall contain the information required by rules issued by the commissioner.

(b) The records required to be kept pursuant to subsection (a) of this Code section and records relating to refunds shall be preserved and maintained for a period of at least four years after the date the tax to which they relate becomes due or the date the tax is paid, whichever is later.

O.C.G.A. § 51-1-11. When privity required to support action; product liability action and time limitation therefore; industry-wide liability theories rejected.

(a) Except as otherwise provided in this Code section, no privity is necessary to support a tort action; but, if the tort results from the violation of a duty which is itself the consequence of a contract, the right of action is confined to the parties and those in privity to that contract, except in cases where the party would have a right of action for the injury done independently of the contract and except as provided in Code Section 11-2-318.

(b) (1) The manufacturer of any personal property sold as new property directly or through a dealer or any other person shall be liable in tort, irrespective of privity, to any natural person who may use, consume, or reasonably be affected by the property and who suffers injury to his person or property because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained.

(2) No action shall be commenced pursuant to this subsection with respect to an injury after ten years from the date of the first sale for use or consumption of the personal property causing or otherwise bringing about the injury.

(3) A manufacturer may not exclude or limit the operation of this subsection.

(c) The limitation of paragraph (2) of subsection (b) of this Code section regarding bringing an action within ten years from the date of the first sale for use or consumption of personal property shall also apply to the commencement of an action claiming negligence of a manufacturer as the basis of liability, except an action seeking to recover from a manufacturer for injuries or damages arising out of the negligence of such manufacturer in manufacturing products which cause a disease or birth defect, or arising out of conduct which manifests a willful, reckless, or wanton disregard for life or property. Nothing contained in this subsection shall relieve a manufacturer from the duty to warn of a danger arising from use of a product once that danger becomes known to the manufacturer.

(d) Irrespective of privity, a manufacturer shall not be held liable for the manufacture of a product alleged to be defective based on theories of market share or enterprise, or other theories of industry-wide liability.

(e) Irrespective of privity, a manufacturer of a product alleged to be defective shall not be held liable for a public nuisance based on theories of market share or enterprise, or other theories of industry-wide liability.

GEORGIA COMPOSITE RULES AND REGULATIONS**Ga. Comp. R. & Regs. 111-8-10-.06. Laboratory Personnel Requirements, Personnel Qualifications and Personnel Records.**(h) *Personnel Records:*

1. Personnel records shall be kept current. They shall include a complete resume of each employee's training, experience, duties, competency evaluation and date or dates of employment. Personnel forms shall be submitted to the Department in a timely manner.

2. The laboratory is responsible for maintaining written documentation (in the personnel file of each employee performing testing) which demonstrates that the employee meets the personnel qualifications as set forth in these rules.

Ga. Comp. R. & Regs. 111-8-10-.09. General Quality Control Requirements.

Each laboratory shall establish and follow written policies and procedures for a quality assurance program, comprehensive in scope and specific to that laboratory. The program shall monitor and evaluate the ongoing and overall quality of the total testing process from specimen collection to reporting of test results. The program shall identify and correct problems, assure the accurate, reliable and prompt reporting of test results and assure adequacy and competency of laboratory staff. Written procedures shall be revised when evaluation results indicate the need. There must be documentation of the ongoing quality assurance program as well as corrective action taken when necessary. The laboratory director is responsible for ensuring that the following quality controls are employed for all clinical testing authorized under the laboratory's license:

(a) Preventive maintenance, periodic inspection or testing for proper operation of equipment and instruments, based on but not limited to manufacturers' instructions. The laboratory must confirm the effectiveness of its preventive maintenance program;

(b) Each quantitative method shall be validated prior to placing into routine use. Such validation shall include reportable range, sensitivity, specificity, accuracy and precision. Documentation of validation shall be maintained for the period the method is used, or for at least two years, whichever is longer;

(c) Evaluation of reagents and volumetric equipment;

(d) Maintenance of documentation verifying that test systems perform according to laboratory specification; such documentation must be available to the authorized persons ordering or receiving test results, and to the Department; the laboratory must establish its reference range for each method before reporting patient test results;

(e) Establishment and employment of policies/procedures for remedial action to be taken in response to quality control outside acceptable limits, equipment or methodology performance outside established operating limits, test results outside acceptable limits, tests not performed within laboratory established time frames, proficiency test results outside acceptable limits or errors detected in reported patient results;

(f) Adequacy of space, ventilation, facilities, equipment, instruments, and methods of performance of the procedures or categories of procedures for which a license application is filed or granted; proper lighting for accuracy and precision; convenient location of essential utilities; monitoring of temperature controlled spaces and equipment to assure proper performance of equipment and storage of specimens, tissues, reagents and supplies; the evaluation of analytical

measuring devices, with respect to all critical operating characteristics, and the laboratory shall not report test results unless such operating characteristics are within defined acceptable ranges;

(g) Labeling of all reagents and solutions to indicate identity, and when significant, titer, strength or concentration, recommended storage and preparation or expiration date, and other pertinent information. Material of substandard reactivity, expired, or deteriorated materials may not be used;

(h) Availability at all times, in the immediate bench area of personnel engaged in examining specimens and performing related procedures within a category, of laboratory manuals or other complete written descriptions and instructions (properly designated and dated to reflect an initial and periodic review by the current director) relating to the current analytical methods, specimen processing procedures, reagents, control and calibration procedures, microscopic examinations, remedial action procedures, limitations in methodologies, pertinent literature references and the date each procedure was placed into use. Textbooks may be used as supplements to such written descriptions but may not be used in lieu thereof;

(i) Written approval by the director of any and all changes in laboratory procedures; a copy of each procedure must be retained for two years after the procedure has been discontinued;

(j) Maintenance and availability to laboratory personnel, and to the Department, of records, reflecting dates, and where appropriate, the nature of inspection, validation, remedial action, monitoring, evaluation, and alternative test methods;

(k) Written materials designed to provide instruction for proper collection, labeling, preservation and transportation of specimens to assure accurate results suitable for clinical interpretation.

Ga. Comp. R. & Regs. 111-8-10-.15. Quality Control for Exfoliative Cytology; Histopathology; and Oral Pathology.

(1) *Exfoliative Cytology.*

(c) The laboratory must develop and implement procedures to detect inadequately prepared slides, assuring no diagnosis is reported on such cases. Such procedures must include a plan for promptly notifying referring physicians of inadequately prepared slides. The report must clearly distinguish specimens, or smears, or both, that are unsatisfactory for diagnosis interpretation. Documentation of unsatisfactory specimens and notifications must be retained by the laboratory for a minimum of five years.

(f) Records shall be maintained by the laboratory of the total number of slides examined by cytotechnologist during each twenty-four and eight hour period. It shall be the responsibility of each laboratory to maintain records of the number of slides read on and off the premises of the laboratory by cytotechnologists when such slides are assigned by that laboratory. All slides must be read on the premises of the licensed laboratory unless referred to another licensed laboratory.

(g) All gynecological smears interpreted to be in the “suspicious” or “positive” categories by cytotechnologists shall be confirmed by the laboratory director or supervisor, who is qualified in Exfoliative Cytology as specified in Rule 111-8-10-.06(1)(a)2. or (3)(b), and who shall personally sign all such suspicious or positive reports. All nongynecological cytological preparations, positive and negative, shall be reviewed by such a director or supervisor qualified in cytology. All slides for exfoliative cytology

must be retained as long as required by applicable federal law and regulations, but not less than five years from the date of examination.

(h) The laboratory must review, for each patient with premalignant or malignant gynecologic cytology results, all gynecologic cytology specimens received within the previous five years, if available. If significant discrepancies are found that would affect patient care, the laboratory must notify the patient's physician and issue an amended report.

(2) *Histopathology and Oral Pathology.* Special stains on tissue sections must be checked for intended reactivity by use of positive preparations, and results of reactions must be documented. Stained slides and tissue blocks shall be retained as long as required by applicable federal law and regulations, but not less than ten years for slides or two years for tissue blocks. Remnants of tissue specimens shall be retained in a fixative solution until those portions submitted for microscopy have been examined and a diagnosis made by a pathologist.

Ga. Comp. R. & Regs. 111-8-10-16. Quality Control for Tissue Banks.

Tissue banks which procure, store, or process human or animal tissue designed to be used for medical purposes in human beings shall conform to the procurement, storage and processing requirements listed in this section. The tissue bank must maintain donor and patient recipient records and communications. These records must be retained for not less than seven years after the distribution of the tissue material. These records shall be evaluated and reviewed by the director to ensure the suitability of the donated tissue for its intended use. Records must include the following:

(a) Each step in collection, preparation, testing, storage and distribution of the tissue must be documented concurrent with the performance of each step.

(b) Records must be legible and indelible and must include dates of testing, testing results, interpretations, assigned expiration date, if applicable, and the identity of the person performing the work.

(c) Donor identification and documentation of the pathological and microbiological evaluation of the donor shall be recorded.

(d) Each tissue and any component must be given a generic designation and a unique identification number which shall be used as the lot number throughout the collection, processing, distribution and utilization processes.

(e) All records concerning donor history, tissue processing and any other details deemed necessary (within the bounds of medical-legal and donor confidentiality) shall be available to authorized personnel upon request.

1. An adverse reaction file must be maintained.

2. An accurate inventory of all tissues (unprocessed, processed, and distributed) must be maintained.

3. There must be verification of step by step procedures under which tissue is procured, processed, tested and stored. Final disposition of the transplanted tissue must be recorded.

(f) Air drains, surfaces and water faucets shall include periodic sampling to ensure the tissue bank environment is maintained.

(g) The tissue bank shall have a system to prevent unauthorized entry either by physical configuration and/or an adequate security system.

- (h) Procedures for recruiting donors shall be established and approved by appropriate officials.
- (i) Permission to obtain tissues from living or non-living donors shall be documented through informed consent. Tissue banks must comply with Georgia Rules and Regulations for Anatomical Gifts, Chapter 111-8-5, as may be applicable.
- (j) Tissues shall be processed by procedures which are appropriate for the type of tissue and the manner in which it is retrieved. Processing shall not change the physical properties of the tissues.
- (k) Tissue preservation and types of storage containers shall ensure that the biological and biochemical properties are retained.
- (l) Tissues shall be sent only to licensed and approved facilities that have accepted responsibility for proper handling and use. There shall be an agreement for notifications of the tissue bank if tissues are received in defective packaging, have been removed from sterile containers but not used, or have been lost. The following criteria for distribution must be met:
 - 1. Transportation methods shall maintain proper environmental conditions during transit.
 - 2. Excess product remaining after use shall be discarded unless the tissue bank retains control of the product and the product remains sterile.
 - 3. Upon receipt of tissue, a record shall be made of its description, date received, and the tissue supplier and, if applicable, expiration dates.
 - 4. Tissue shall not be dispensed without a documented order from the physician or other authorized health professional, and records of the person to whom this tissue was dispensed, and the integrity of the container and label.
- (m) Records must be retained indefinitely to permit tracing of any tissue from the donor to all recipients or other final dispositions. Records must include the following:
 - 1. Receipt, storage, and transportation information;
 - 2. Identity of the source facility;
 - 3. Type of tissue and the numeric or alphanumeric identification;
 - 4. Name(s) of the recipient(s);
 - 5. Personnel who prepared the tissue for dispensing;
 - 6. Personnel who dispensed the tissue;
 - 7. Personnel who accepted the tissue for use;
 - 8. Dates of dispensing and transportation;
 - 9. Identification of the ordering physician or other authorized health professional;
- (n) Storage temperature records must be retained for five years.
- (o) Container labels must include:
 - 1. Name of product;
 - 2. Name and address of tissue bank; and
 - 3. Tissue identification number.
- (p) Package labels must include:
 - 1. Product name;
 - 2. Name and address of the tissue bank;
 - 3. Unique tissue identification number;
 - 4. Expiration date of contents, if applicable;
 - 5. Method of sterilization, if applicable;

6. Preservation and concentration or “no preservative” if preservative presents a safety factor;
 7. Number of containers, if applicable;
 8. Amount of product by weight;
 9. Storage and handling instructions, including recommended storage temperature and special handling instructions relative to the product;
 10. Sensitizing substances known to be present;
 11. Antibiotics added during processing: type and calculated amount;
 12. Product source, if a factor in safety of administration; and
 13. A statement that the tissue donor was tested for HIV antibody and Hepatitis B surface antigen (HBsAg) using FDA approved tests and found to be nonreactive.
- (q) Final container shall be packaged in a manner that ensures the integrity and sterility of the contents.
- (r) A product insert must accompany all tissues.
- (s) There shall be written procedures for tissue recall and notification of recipient centers of possible tissue contamination, errors detected in the processing, preparation or distribution process or other factors which may render the tissue unsuitable for its intended application.
- (t) Standard nomenclature and units of measure shall be used to describe tissues and the processing they have undergone.

Ga. Comp. R. & Regs. 111-8-10-.17. Quality Control for Sperm Banks/Embryology and Assisted Reproductive Technology (ART).

- (1) *Sperm Banks*. Facilities collecting semen specimens shall comply with the following:
- (a) Sperm banks shall be staffed with personnel trained in the most current methods of cryobanking and who meet the personnel requirements of these rules.
 - (b) Records must contain a donor release and a complete history.
 - (c) Donor semen shall have specific identification codes for use during the freezing and storage processes. Codes shall in no way be linked to the donor or the recipient.
 - (d) Donor history shall include the following:
 1. Interview;
 2. Examination including personal, physical, sexual and genetic histories;
 3. Examination of semen to ensure viability and motility, freedom from infection and/or foreign cells and freezing survival capabilities.
 - (e) Semen specimens shall be collected at the sperm bank and processing shall be initiated within one hour of collection. Test results and measurements shall be documented concurrent with evaluation.
 - (f) An appropriate method of cryopreservation shall be chosen which ensures maximum viability and freedom from contamination. Documentation shall be available which validates the method chosen.

(g) Storage and handling instructions shall be made available to the requesting physician. Such instructions shall include handling and disposition of unused specimen. Donor semen shall not be refrozen or redistributed.

(2) *Assisted Reproductive Technology (ART)*. Facilities providing ART shall comply with the following:

(a) The laboratory director must meet requirements at Rule 111-8-10-.06(2)(b) of these regulations; in addition, the director must have two years of documented experience in a laboratory performing ART procedures, have documented training of at least six months in an embryo laboratory which includes performing, at a minimum, each ART laboratory procedure 60 times. Included in the responsibilities of the director of the laboratory performing these procedures shall be:

1. To establish and monitor a program to ensure that aseptic conditions are maintained in the laboratory;
2. To assure that procedure manuals meet requirements at Rule 111-8-10-.09(2)(h);
3. Establish and monitor a quality assurance program that meets requirements at Rule 111-8-10-.06(3)(a), as applicable.

(b) An ART supervisor shall meet the requirements at Rule 111-8-10-.06(3)(b)1., 2., 3., or .06(4)(b)1., or 3., and have documented training which includes performing, at a minimum, each ART laboratory procedure sixty (60) times.

1. An ART supervisor must be accessible to laboratory personnel when ART procedures are performed, either on-site or via electronic means; and
2. An ART supervisor may perform director responsibilities as authorized, in writing, by the director.

(c) A reproductive biologist in an ART must meet the requirements for director, supervisor, or meet the following:

1. Requirements at Rule 111-8-10-.06(4)(b)1., or 3.;
2. Have documented ART training for laboratory procedures; and
3. Training must include the performance of ART procedures at least 30 times under director and constant supervision.

(d) In addition to meeting all safety requirements at Rule 111-8-10-.08, an ART laboratory must also:

1. Be located in a secure place with access limited to authorized personnel;
2. Conduct laboratory activities under aseptic conditions; and
3. Use no radioisotopes in the laboratory where ART procedures are performed.

(e) In addition to meeting all quality assurance requirements at Rule 111-8-10-.09, an ART laboratory must also:

1. Verify that materials which come in contact with sperm, oocytes, and embryos have been tested and found to be non-toxic to the sperm, oocytes and embryos;
2. Ensure patient confidentiality throughout the testing phase; and
3. Require that an authorized person's request for testing must be written or electronic; and that an oral request must be followed within 24 hours by a written or electronic request.

(f) In addition to meeting all quality control requirements, as applicable, at Rule 111-8-10-.09, an ART laboratory must also:

1. Have documented criteria for assessment of oocyte morphology, maturity, fertilization, and embryo quality;
2. Document the insemination schedule relative to oocyte maturity;
3. Document volume, numbers, and quality of sperm used for insemination of each oocyte;
4. Document disposition of oocytes with an abnormal number of pronuclei; disposition of excess oocytes; and
5. Document critical time periods for various procedures.

(g) In addition to meeting specimen, reporting and records requirements at Rules 111-8-10-.11, .12, and .13, an ART laboratory must also:

1. Keep records for the pre- and post-washing and concentration for insemination, the outcome of insemination and culture, and quality of all embryos at transfer, and the identity of testing personnel;
2. Use a reliable tracking method for cryopreserved specimens;
3. Use permanent labeling of containers; and
4. Assure that records are indelible and legible, retained for two years on-site and for ten years beyond the date of final disposition or disposal of all specimens obtained during each patient's ART cycle.

(h) If the ART laboratory ceases operation, it must make provisions for records to be maintained for the required time frames.

Ga. Comp. R. & Regs. 111-8-10-.20. Quality Control for Screening and Monitoring Tests.

(1) Facilities performing only screening and monitoring tests shall establish a training program with written guidelines and must keep documentation of the training of those personnel designated for performance of specific tests.

(2) Quality control procedures for screening and monitoring tests shall be performed for each test, if available. Controls and control frequency shall be according to published guidelines. Only tests approved by the Department may be performed; a list of approved tests shall be available from the Department. Proficiency testing is required for all tests, where such is available and graded.

(3) Results of exempt screening and monitoring tests, including all quality control records, shall be maintained separate from the patient's medical record for two years. The records must include the test date, time, patient's first and last name or unique identifier, test site, control/calibration results, lot numbers of reagents/controls, and identification of testing personnel.

(4) Reports of test results provided to non-physicians shall contain a statement which recommends that the results of the test be reviewed by a physician or that medical advice be obtained.

(5) The results of the tests shall be clearly identified as being performed by a nonlicensed facility and shall be displayed in a manner which will clearly differentiate them from results of a licensed laboratory.

(6) Screening test results which indicate abnormal conditions shall be noted with a recommendation that the abnormal results be confirmed by a definitive laboratory test performed in a licensed laboratory.

(7) Safety instruction using CDC's universal precaution guide lines for handling blood and instructions for packaging, labeling and disposal of potentially infectious waste materials and sharps, must be available to and practiced by the facility personnel.

(8) Each facility, performing whole blood cholesterol, HDL or other approved screening procedures, shall establish a training program with written guidelines and retain documentation of the training of those personnel designated for performing these procedures. The training shall include all areas of the testing process including the use of the instrument.

(a) Prior to performing cholesterol testing, the facility must evaluate the procedure for accuracy and precision. Maintenance and testing for proper operation of any analyzers shall be performed with the frequency specified by the manufacturer.

(b) Two levels of control must be performed at the beginning of each day of testing and one level of control must be performed if testing equipment is moved from site to site.

(c) Maintenance, quality control, current procedure manuals and test participant records shall be available at each test site or with each instrument in use.

(d) The screening facility shall recommend referrals for further cholesterol testing in accordance with the National Cholesterol Education Program (NCEP) published guidelines.

(e) Reports shall show the name, telephone number, street address, city and state of the screening facility/agency. The screening facility/agency shall provide privacy for blood sampling and confidential counseling about test results.

(f) Each screening entity shall have a medical review officer who is licensed to practice medicine in Georgia. This officer may authorize testing.

Ga. Comp. R. & Regs. 111-8-10-.23. Evaluation.

(d) Proficiency testing must be conducted in the laboratory being evaluated, by regular employees of that laboratory and in the same manner as patient testing. If a laboratory is found to have intentionally sent proficiency testing samples to another laboratory for analysis prior to receiving results back from the testing agency, it shall have its license revoked for a minimum of one year or a period that is equal to or more stringent than current federal law and regulations and, shall be subject to other appropriate sanctions as provided for in Chapter 111-8-25 of the Georgia Rules and Regulations for General Licensing and Enforcement Requirements; all records of proficiency testing must be retained and available for inspection for a period of not less than two years.

Ga. Comp. R. & Regs. 111-8-10-.26. Records.

Records of all clinical laboratory services, including records of laboratory test requests and reports, shall be retained by the laboratory for as long as required by federal law and regulations, and:

(a) For general laboratory records and quality control records, kept at least two (2) years,

(b) For records of immunohematology and cytology, kept at least five (5) years, and

(c) For records of surgical pathology, kept at least ten (10) years.

Ga. Comp. R. & Regs. 111-8-28-.07. Records.

- (1) All records of the eye bank shall be confidential and shall be made available only to duly authorized persons.
- (2) The following records shall be kept by each eye bank:
 - (a) donor record; the signed and witnessed duplicate donor card of every intended donor as well as the consent form for every eye received in the eye bank must be kept on file. The consent form shall be witnessed by two (2) persons of legal majority.
 - (b) history record; this shall be a record of the enucleation, identification and condition of the eye or eyes. It shall include a full medical history, the cause of death, time of death, recorded time of enucleation, and when available, gross and slit lamp examination of the enucleated eye.
- (3) These records shall be retained for a minimum of six (6) years.
- (4) If the eye bank ceases operation, provision must be made for the retention of records in a manner acceptable to the Department.

Ga. Comp. R. & Regs. 111-8-40-.03. Hospital Permit Requirement.

No person, corporation, association, or other entity shall establish, operate, or maintain a hospital in Georgia without a permit or provisional permit.

- (a) A permit is required for each hospital. Multi-building hospitals may request a single permit to include all buildings provided that the hospital buildings are in close proximity to each other, the facilities serve patients in the same geographical area, and the facilities are operated under the same ownership, control, and bylaws.
 1. Services offered in separate buildings or on separate premises, which do not by themselves meet the definition of a hospital, including, but not limited to, satellite urgent care centers, outpatient or mammography clinics, or hospital-owned physicians' offices, shall be considered organized services of the hospital for the purposes of these rules.
 2. Only those services operated by the hospital under the permit as approved by the Department shall be presented to the public as a service of the hospital.
- (b) A permit, either continuing or provisional, is required prior to the admission of any patients or initiation of any patient care services in the hospital. A provisional permit may be issued for a limited time to a newly established hospital to allow the hospital to demonstrate that its operational procedures equal standards specified by the rules.
- (c) The permit shall designate the classification of the hospital as determined by the Department following evaluation of the hospital's services and in accordance with the Certificate of Need.
 1. The classification shall be one of the following:
 - (i) Classification as a general hospital means a facility meets the definition of a hospital and provides continuous care for a variety of patients who have a variety of medical conditions. A critical access hospital shall fall under the general hospital classification; or
 - (ii) Classification as a specialized hospital means a facility that meets the definition of a hospital and provides care to a specialized or specified group of patients and/or patients who have specified conditions. The type of specialization shall be designated on the hospital permit.

2. If changes occur in the organized services offered by the hospital, including the addition of any services requiring CON review or off-campus service locations, the hospital's administrator or governing body shall submit to the Department a new description of services at least thirty (30) days prior to the change. Change in the classification of the hospital shall require application for a new permit.

(d) To be eligible for a permit the hospital shall be in substantial compliance with these rules and regulations and any provisions of law as applicable to the construction and operation of the hospital. In its discretion, the Department may issue a provisional permit for a limited time to compliance with these rules provided the Department has received an acceptable plan of correction.

(e) The permit issued to the hospital shall be prominently displayed in a public area of the hospital at all times.

(f) A permit is not transferable from one governing body to another nor from one hospital location to another.

(g) If the hospital anticipates that it will close or cease to operate, the governing body shall notify the Department at least thirty (30) days prior to the anticipated closure.

1. Prior to hospital closure, the hospital shall inform the Department of the planned storage location for patients' medical records, medical staff information, and other critical information after closure. The hospital shall publish in a widely circulated newspaper(s) in the hospital's service area a notice indicating where medical records and other critical information can be retrieved and shall notify the Department of Transportation of the anticipated date of closure for removal of the hospital locator signs. Following closure, the Department shall be notified of any change in location of the patients' medical records, medical staff information, and other critical information from the published location.

2. When the hospital ceases to operate, the permit shall be returned to the Department within ten (10) days of closure. The permit shall be considered revoked, unless placed on inactive status as described in these rules.

3. If the hospital is closing for a period of less than twelve (12) months, and plans to reopen under the same ownership, name, classification, and bed capacity, the hospital may request to have the permit placed on temporary inactive status.

(i) When placed on temporary inactive status, the permit shall be returned to the Department within ten (10) days of closure and the hospital shall not operate until the permit has been reactivated. The hospital shall notify the Department of Transportation of the intended closure.

(ii) The hospital shall request in writing that the permit be reactivated at least thirty (30) days prior to the desired date of re-opening. Prior to reactivation of the permit, the hospital may be subject to inspection by the Department. If the permit is not reactivated within twelve (12) months, the permit shall be considered revoked.

(h) A new permit may be obtained by application to the Department and is required if the hospital is moved to another location, has a change in operational or trade name, has a change in ownership or classification, or has a change in the authorized bed capacity. The former permit shall be considered revoked upon the issue of a new permit and the former permit shall be returned to the Department.

(i) A permit shall remain in effect unless suspended or revoked or otherwise rescinded or removed as provided in these rules. Authority: O.C.G.A. §§ 31-7-1, 31-7-2, 31-7-

Ga. Comp. R. & Regs. 111-8-40-.05

An application for a permit to operate a hospital shall be submitted on forms provided by the Department. The application submitted to the Department shall be an original document. No application shall be considered by the Department unless it is complete and accompanied by all required attachments...

Ga. Comp. R. & Regs. 111-8-40-.12. Human Resources Management.

The hospital shall select and organize sufficient qualified and competent personnel to meet patients' needs and in a manner appropriate to the scope and complexity of the services offered.

(a) The hospital shall establish and implement human resources policies and procedures to include at least:

1. Procedures for selecting qualified personnel;
2. A system for documenting the current licensure and/or certification status for those personnel whose positions or functions require such licensure or certification;
3. A system for assessing competency of all personnel providing health care services, on a time schedule defined by hospital policy; and
4. Policies and procedures regarding the hospital-approved method for identification of personnel to patients, other staff, and visitors.

(b) *Written Job Descriptions.* The hospital shall have a written description of responsibilities and job duties, with qualification requirements, for each position or job title at the hospital.

(c) *Health Screenings.* The hospital shall have in place a mechanism and requirement for initial, regular, and targeted health screenings of personnel who are employed or under contract with the hospital or providing patient care services within the hospital setting. The screening shall be sufficient in scope to identify conditions that may place patients or other personnel at risk for infection, injury, or improper care. The health-screening program shall be developed in consultation with hospital administration, medical staff, occupational health, and infection control/safety staff.

(d) *Personnel Training Programs.* The hospital shall have and implement a planned program of training for personnel to include at least:

1. Hospital policies and procedures;
2. Fire safety, hazardous materials handling and disposal, and disaster preparedness;
3. Policies and procedures for maintaining patients' medical records;
4. The infection control program and procedures; and
5. The updating of job-specific skills or knowledge.

(e) Personnel records shall be maintained for each employee of the hospital and shall contain, at a minimum:

1. The employment application or resume;
2. Dates of hire and position changes since hiring;
3. The job or position description(s) for the employee;
4. All evaluations of performance or competencies for the employee since the date of hire or at least the last five (5) years;

5. Credible evidence of current registration, licensure, or certification as required for that position by state law;
6. Evidence of completion of in-service training as required by hospital policy; and
7. Evidence of completion of any requirements of the occupational health program at the hospital.

Ga. Comp. R. & Regs. 111-8-40-.14. Physical Environment.

The hospital shall be equipped and maintained to provide a clean and safe environment for patients, employees, and visitors.

(a) *Safety.* The hospital shall develop and implement an effective hospital-wide safety program that includes the following components:

1. A fire safety program including compliance with the applicable provisions of the Life Safety Code (NFPA 101), as enforced by the state fire marshal;
2. An incident monitoring system that promptly identifies, investigates, and takes effective action regarding all incidents that involve injury to patients, employees, or visitors or that involve significant damage to property;
3. A program to inspect, monitor, and maintain biomedical equipment, electrical equipment, and emergency power generators;
4. A program for the monitoring and maintenance of electrical safety;
5. Security procedures for controlling access to sensitive areas, as defined by the hospital, for patients, employees, and visitors;
6. Procedures for the safe management of medical gases;
7. A system for patients or staff to summon assistance, when needed, from patient rooms, bathrooms, and treatment areas;
8. Policies regarding smoking which apply to employees, patients, and visitors; and
9. Procedures for storage and disposal of biohazardous medical waste in accordance with applicable laws.

(b) *Cleanliness and Sanitation.* The hospital shall maintain an environment that is clean and in good repair, through a program that establishes and maintains:

1. Standardized daily, interim, and terminal cleaning routines for all areas;
2. Facilities for convenient and effective hand washing throughout the hospital;
3. Systems for management of linens, including collection, sorting, transport, and washing of soiled linens, and storage and distribution of clean linens;
 - (i) Collection and sorting procedures shall be designed to prevent contamination of the environment and personnel. Collection procedures shall include bagging of soiled linen at site of use. Sorting and rinsing of soiled linens shall not take place in patient care areas;
 - (ii) Clean and soiled linens shall be transported in separate containers or carts;
 - (iii) The laundering process for soiled linens shall be sufficient to remove organic soil and render the linen incapable of causing human illness; and

- (iv) Any soiled linen processing area shall be separate from the area used for clean linen storage, from patient care areas, and from areas where clean or sterilized supplies and equipment are stored;
- 4. Standards regarding the use of hospital disinfectants;
- 5. Systems for the storage and disposal of garbage, trash, and waste in a manner that will not permit the transmission of disease, create a nuisance, or provide a breeding place for insects or rodents; and
- 6. Procedures for the prevention of infestation by insects, rodents, or other vermin or vectors.

(c) *Light, Temperature, and Ventilation.* The hospital shall provide adequate lighting, ventilation, and control of temperature and air humidity for optimal patient care and safety of the hospital's patients and staff and shall monitor and maintain such systems to function at least minimally to the design standards current at the time of approved facility construction or renovation.

(d) *Space.* The hospital shall provide sufficient space and equipment for the scope and complexity of services offered.

Ga. Comp. R. & Regs. 111-8-40-.15. Disaster Preparedness.

The hospital shall prepare for potential emergency situations that may affect patient care by the development of an effective disaster preparedness plan that identifies emergency situations and outlines an appropriate course of action. The plan must be reviewed and revised annually, as appropriate, including any related written agreements.

(a) The disaster preparedness plan shall include at a minimum plans for the following emergency situations:

- 1. Local and widespread weather emergencies or natural disasters, such as tornadoes, hurricanes, earthquakes, ice or snowstorms, or floods;
- 2. Manmade disasters such as acts of terrorism and hazardous materials spills;
- 3. Unanticipated interruption of service of utilities, including water, gas, or electricity, either within the facility or within a local or widespread area;
- 4. Loss of heat or air conditioning;
- 5. Fire, explosion, or other physical damage to the hospital; and
- 6. Pandemics or other situations where the community's need for services exceeds the availability of beds and services regularly offered by the hospital.

(b) There shall be plans to ensure sufficient staffing and supplies to maintain safe patient care during the emergency situation.

(c) There shall be plans for the emergency transport or relocation of all or a portion of the hospital patients, should it be necessary, in vehicles appropriate to the patient's condition(s) when possible, including written agreements with any facilities which have agreed to receive the hospital's patients in these situations.

(d) The hospital shall document participation of all areas of the hospital in quarterly fire drills.

(e) In addition to fire drills, the hospital shall have its staff rehearse portions of the disaster preparedness plan, with a minimum of two (2) rehearsals each calendar year either in response to an emergency or through planned drills, with coordination of the drills with the local Emergency Management Agency (EMA) whenever possible.

(f) The plan shall include the notification to the Department of the emergency situation as required by these rules.

(g) The hospital shall provide a copy of the internal disaster preparedness plan to the local Emergency Management Agency (EMA) and shall include the local EMA in development of the hospital's plan for the management of external disasters.

(h) The hospital's disaster preparedness plan shall be made available to the Department for inspection upon request.

(i) The Department may suspend any requirements of these rules and the enforcement of any rules where the Governor of the State of Georgia has declared a public health emergency.

Ga. Comp. R. & Regs. 111-8-40-.18. Medical Records.

(1) *Management of Patients' Medical Records.* The hospital shall have an efficient and organized medical records service that establishes the policies and procedures for the maintenance of the medical records for all patients and that is administratively responsible for the management of those records.

(h) The hospital shall retain all patients' medical records at least until the fifth anniversary of the patients' discharges. If the patient is a minor, the records must be retained for at least five (5) years past the age of majority. Records may be preserved in the hospital's format of choice, including but not limited to paper or electronic format, so long as the records are readable and capable of being reproduced in paper format upon request.

(3) *Minimum Requirements for Patients' Medical Records.* Upon completion, medical records for inpatients and outpatients shall contain, at minimum, the documents as specified below. Records for patients at the hospital for other specialized services, such as emergency services or surgical services, shall contain such additional documentation as required for those services.

(a) *Inpatient Records.* Medical records for inpatients shall contain at least the following:

1. A unique identifying number and a patient identification form, which includes the following when available: name, address, date of birth, sex, and person to be notified in an emergency;
2. The date and time of the patient's admission;
3. The admitting diagnosis and clinical symptoms;
4. The name of the attending physician;
5. Any patient allergies;
6. Documentation regarding advanced directives;
7. The report from the history and physical examination;
8. The report of the nursing assessment performed after admission;
9. Laboratory, radiological, electrocardiogram, and other diagnostic assessment data or reports as indicated;
10. Reports from any consultations;
11. The patient's plan of care;
12. Physician's orders or orders from another practitioner authorized by law to give medical or treatment orders;

13. Progress notes from staff members involved in the patient's care, which describe the patient's response to medications, treatment, procedures, anesthesia, and surgeries;
14. Data, or summary data where appropriate, from routine or special monitoring;
15. Medication, anesthesia, surgical, and treatment records;
16. Documentation that the patient has been offered the opportunity to consent to procedures for which consent is required by law;
17. Date and time of discharge;
18. Description of condition, final diagnosis, and disposition on discharge or transfer;
19. Discharge summary with a summary of the hospitalization and results of treatment; and
20. If applicable, the report of autopsy results.

Ga. Comp. R. & Regs. 111-8-40-.24. Imaging and Therapeutic Radiology Services.

(2)(c) Films, scans, and other images shall be retained by the hospital for at least five years after the date of the procedure unless the release of the original images is required for the care of the patient. When original images are released, documentation of the disposition of the original images shall be retained for the applicable five-year period. If the patient is a minor, the records shall be retained for at least five years past the age of majority.

Ga. Comp. R. & Regs. 111-8-41-.04. Required Documentation.

Beginning October 1, 2019, each Hospital in this state shall make public the most recent version of the following subject documents:

(1) Federal related disclosures:

(A) Copies of audited financial statements that are general purpose financial statements, which express the unqualified opinion of an independent certified public accounting firm for the most recently completed fiscal year for the Hospital; each of its Affiliates, except those Affiliates that were inactive or that had an immaterial amount of total assets; and the Hospital's parent corporation that include the following:

(i) A PDF version of all audited financial statements;

(ii) A note in the Hospital's audited financial statements that identifies individual amounts for such Hospital's gross patient revenue, allowances, charity care, and net patient revenue;

(iii) Audited consolidated financial statements for Hospitals with subsidiaries and consolidating financial statements that at a minimum contain a balance sheet and statement of operations and that provide a breakout of the Hospital's and each Subsidiary's numbers with a report from independent accountants on other financial information; and

(iv) Audited consolidated financial statements for the Hospital's parent corporation and consolidating financial statements that at a minimum contain a balance sheet and statement of operations and that provide a breakout of the Hospital's and each Affiliate's numbers with a report from independent accountants on other financial information; and

(B) Copy of audited Internal Revenue Service Form 990, including Schedule H for hospitals and other applicable attachments; provided, however, that for any Hospital not required to file IRS Form 990, the department shall establish and provide a form that collects the same information as is contained in Internal Revenue Service Form 990, including Schedule H for hospitals, as applicable; and

(2) Georgia supplemental disclosures:

(A) Copy of the Hospital's completed annual hospital questionnaire, as required by the department;

(B) The community benefit report prepared pursuant to O.G.C.A. § 31-7-90.1, if applicable;

(C) The disproportionate share hospital survey, if applicable;

(D) Listing of all Real Property Holdings of the Hospital, including the location and size, parcel ID number, purchase price, current use, and any improvements made to such property;

(E) Listing of any ownership or interest the nonprofit Hospital has in any Joint Venture, partnership, Subsidiary Holding Company, or Captive Insurance Company; where any such entity is domiciled; and the value of any such ownership or interest;

(F) Listing of any bonded indebtedness, outstanding loans, and bond defaults, whether or not in forbearance; and any bond disclosure sites of the Hospital;

(G) A report that identifies by purpose, the ending fund balances of the net assets of the Hospital and each Affiliate as of the close of the most recently completed fiscal year, distinguishing between donor permanently restricted, donor temporarily restricted, board restricted and unrestricted fund balances. The Hospital's interest in its foundation shall be deducted from the foundation's total fund balance;

(H) Copy of all going concern statements regarding the Hospital;

(I) The most recent legal chart of corporate structure, including the Hospital, each of its Affiliates and Subsidiaries, and its Parent Corporation, duly dated;

(J) Report listing the salaries and fringe benefits for the ten highest paid Administrative Positions in the Hospital. Each position shall be identified by its complete, unabbreviated title. Fringe benefits shall include all forms of compensation, whether actual or deferred, made to or on behalf of the employee, whether full or part-time;

(K) Evidence of accreditation by accrediting bodies, including, but not limited to, the Joint Commission and DNV; and

(L) Copy of the Hospital's policies regarding the provision of charity care and reduced cost services to the indigent, excluding medical assistance recipients, and its debt collection practices.

Ga. Comp. R. & Regs. 111-8-41-.05. Posting Requirements.

(1) Each Hospital shall post a Link entitled "Hospital Transparency Information" in a prominent location on the main page of its website to the documents listed in Rule 111-8-41-.04 on July 1 of each year or more frequently at its discretion. Documents from prior years shall remain posted and accessible on the Hospital's website indefinitely.

(2) All documents listed in Rule 111-8-41-.03 shall be prepared in accordance with generally accepted accounting principles, as applicable.

(3) Each Hospital shall provide the Link to the department annually and in the manner requested.

(4) The department shall post the Link in a prominent location on its website for each Hospital in this state.

Ga. Comp. R. & Regs. 111-8-41-.06. Enforcement.

(1) Any Hospital that fails to post the documents required by these Rules within 30 days of the dates required in this Rule section shall be suspended from receiving any State Funds or any donations pursuant to O.C.G.A. § 48-7-29.20; provided, however, that the department shall provide a hospital notice of any deficiency and opportunity to correct such deficiency prior to any suspension of funds pursuant to this subsection.

(2) Any hearing under these Rules shall be held in accordance with the Georgia Administrative Procedure Act.

(3) Any person who knowingly and willfully includes false, fictitious, or fraudulent information in any documents required to be posted pursuant to O.C.G.A. § 31-7-22 and these Rules shall be subject to a violation of O.C.G.A. § 16-10-20 and be referred by the department to the Office of the Attorney General for investigation.

Ga. Comp. R. & Regs. 11-8-90-.07. Records, Reports and Notification. Amended.

(1) *Records and Reports*

(c) Records of individual radiation exposure which must be maintained pursuant to the provisions of .07(1)(a) of this Chapter shall be preserved until a date five (5) years after termination of the individual's employment or association with the registrant, or such other time as the Department may determine.

(f) Each person who possesses a radiation machine shall keep records showing the receipt, transfer, or disposal of such radiation machine and shall make such records available for inspection by the Department upon request.

(g) The registrant shall keep a record of all major maintenance and/or modifications performed on each radiation machine during the period it is under his control. Such record shall be transferred to any subsequent owner of the equipment. Records shall include, but not be limited to, tube housing or x-ray tube insert replacement, any reorientation of the machine, repair or change of the console or high-voltage supply, or collimator repair.

Ga. Comp. R. & Regs. 360-3-.02(16)

O.C.G.A. §§ 43-1-19 and 43-34-37 authorize the Board to take disciplinary action against licensees for unprofessional conduct. "Unprofessional conduct" shall include, but not be limited to, the following: ...

(16) Failing to maintain patient records documenting the course of the patient's medical evaluation, treatment, and response.

(a) A physician shall be required to maintain a patient's complete medical record, which may include, but is not limited to, the following: history and physical, progress notes, X-ray reports, photographs, laboratory reports, and other reports as may be required by provision of the law. A physician shall be required to maintain a patient's

complete treatment records for a period of no less than 10 years from the patient's last office visit.

(b) The requirements of this rule shall not apply to a physician who has retired from or sold his or her medical practice if:

1. such physician has notified his or her active patients of retirement from or sale of practice by mail, at the last known address of his or her patients, offering to provide the patient's records or copies thereof to another provider of the patient's choice and, if the patient so requests, to the patient;

2. has caused to be published, in the newspaper of greatest circulation in each county in which the physician practices or practiced and in a local newspaper that serves the immediate practice area, a notice which shall contain the date of such retirement or sale that offers to provide the patient's records or copies thereof to another provider of the patient's choice, and if the patient so requests, to the patient; and

3. has placed in a conspicuous location in or on the façade of the physician's office, a sign announcing said retirement or sale of the practice. The sign shall be placed 30 days prior to retirement or the sale of the practice and shall remain until the date of retirement or sale.

4. Both the notice and sign required by rule 360-3-.02 shall advise the physician's patients of their opportunity to transfer or receive their records.

(c) The period specified in this rule may be less than the length of time necessary for a physician to protect himself or herself against other adverse actions. Therefore, physicians may wish to seek advice from private counsel or their malpractice insurance carrier.

Ga. Comp. R. & Regs. 391-3-4-.15. Biomedical Waste. Amended.

(1) All persons subject to regulation under Rule .15 shall, in addition to the requirements of Rule .15, handle biomedical waste in accordance with the provisions of O.C.G.A. 12-8-20, et seq., and the Rules for Solid Waste Management, Chapter 391-3-4 applicable to solid waste.

(2) Biomedical waste shall mean and include the following:

(a) Pathological waste, which means all recognizable human tissues and body parts except teeth which are removed during surgery, obstetrical procedures, autopsy, and laboratory procedures.

(b) Biological waste, which means blood and blood products, exudates, secretions, suctionings, and other body fluids which contains free liquids and cannot be or are not directly discarded into a municipal sewer system.

(c) Cultures and stocks of infectious agents and associated biologicals including cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures.

(d) Contaminated animal carcasses, body parts, their bedding, and other wastes from such animals which are infected with or which have been exposed to infectious agents, capable of causing disease in man.

(e) Sharps, which means any discarded article that may cause punctures or cuts. Such waste includes, but is not limited to, items such as needles, IV tubing and syringes with needles attached, and scalpel blades.

(f) Chemotherapy waste, which means any disposable material which has come in contact with cytotoxic/antineoplastic agents (agents toxic to cells) and/or antineoplastic agents (agents that inhibit or prevent the growth and spread of tumors or malignant cells) during the preparation, handling, and administration of such agents. Such waste includes, but is not limited to, masks, gloves, gowns, empty IV tubing bags and vials, and other contaminated materials. The above waste must first be classified as empty which means such quantity that it is not subject to other federal or state waste management regulations prior to being handled as biomedical waste.

(g) Discarded medical equipment and parts, excluding expendable supplies and materials included in paragraphs (a) through (f) of this Rule, which have not been decontaminated, and that were in contact with infectious agents.

(3) *Generation of Biomedical Waste.*

(a) Unless otherwise exempted, Rule 391-3-4-.15 shall apply to all persons generating or handling biomedical waste, including but not limited to: ambulatory service centers, blood banks, clinics, county health departments, dental offices, funeral homes, health maintenance organizations (HMOs), hospitals, laboratories, medical buildings, physicians offices, veterinary offices, research and manufacturing facilities, nursing homes, and biomedical waste transportation, storage, treatment, and disposal facilities.

(b) Partial exemption: facilities which generate less than 100 pounds per month of biomedical waste shall be exempt from all provisions of Rule 391-3-4-.15 except that they shall comply fully with the provisions of Rule 391-3-4-.15(4)(a), (4)(b), (4)(b)1., (4)(b)2., (4)(c), (6)(c), and (7)(b). For purposes of this Rule, a facility is defined as one or more persons generating biomedical waste who share common waste management services including, but not limited to, bulk storage containers.

(c) Total exemption: in no case shall a person be a generator of biomedical waste if those wastes are generated from single-family residential premises or a single-family dwelling unit in the self-care and treatment of family members living in those premises or units and disposed of as residential solid waste. Home health care organizations or physicians treating patients in a home are not exempt unless otherwise exempted in (b) above.

(d) All requirements of this Rule shall apply to persons or facilities who generate 100 pounds or more biomedical waste per month.

(4) *Storage and Containment of Biomedical Waste.*

(a) Containment of biomedical waste shall be in a manner and location which affords protection from animals, rain and wind, does not provide a breeding place or a food source for insects and rodents, and minimizes exposure to the public.

(b) Biomedical waste shall be segregated by separate containment from other waste at the point of origin.

1. Biomedical waste, except for sharps, shall be placed in containers which are impervious to moisture and have a strength sufficient to preclude ripping, tearing, or bursting under normal conditions of use. The containers shall be securely closed so as to prevent leakage or expulsion of solid or liquid wastes during storage, handling, or transport.

2. Sharps shall be contained for storage, transportation, treatment and subsequent disposal in leakproof, rigid, puncture-resistant containers which are taped closed or tightly lidded to preclude loss of contents.

(c) Rigid containers of discarded sharps and all other disposable containers used for containment of biomedical waste shall be red or orange in color or clearly identified with the universal biohazard symbol or clearly marked with the word "Biohazard".

(d) Biomedical waste contained in disposable containers as prescribed above, shall be placed for storage, handling, or transport in disposable or reusable pails, cartons, boxes, drums, dumpsters, or portable bins. The containment system shall have a tight fitting cover and be kept clean and in good repair. The containers may be of any color and shall be conspicuously labeled with the universal biohazard symbol and the word "Biohazard" on the sides so as to be readily visible from any lateral direction when the container is upright.

1. Reusable containers used for shipment of biomedical waste shall be thoroughly washed and decontaminated each time they are emptied.

2. Reusable pails, drums, dumpsters or bins used for containment of biomedical waste shall not be used for other purposes except after being decontaminated by procedures as described in (4)(d)1. above and after the universal biohazard symbol and word "Biohazard" are removed.

(5) *Transfer of Biomedical Waste to Off-Site Treatment or Disposal Facilities.*

(a) Any generator of biomedical waste shall transfer custody of the waste only to a collector who is operating under authority of these Rules.

(b) Biomedical waste shall not be transported in the same vehicle with other solid waste unless the biomedical waste is contained in a separate, fully enclosed leakproof container within the vehicle compartment or unless all of the waste is to be treated as biomedical waste in accordance with the requirements of these Rules.

(c) Biomedical waste shall be delivered for storage, including intermediate transfer, and treatment only to a facility or location for which there is a valid and appropriate operating permit as set forth in these Rules.

(d) Surfaces of transport vehicles that have contacted spilled or leaked biomedical waste shall be decontaminated.

(e) Equipment used to transport waste from the generator to the off-site treatment or disposal facility may not destroy the integrity of the container.

(f) Vehicles used for the transport of biomedical waste shall not be used for transportation of food or food products.

(6) *Treatment of Biomedical Waste.*

(a) If treated in accordance with the following procedures, the waste shall no longer be considered biomedical waste and may be combined and handled with regular solid waste. Biomedical waste shall be treated by one of the following methods prior to disposal at a permitted solid waste disposal facility.

1. Incineration in the thermal treatment technology facility which provides complete combustion of waste to render it nonpathogenic.

(i) Biomedical waste thermal treatment technology facilities shall be capable of maintaining a minimum temperature in the primary chamber sufficient to destroy infectious agents and produce a residue

essentially free of odors and unstable organic matter. If chemotherapy wastes are incinerated, the facility must be capable of maintaining a minimum of 1,800 degrees Fahrenheit in the secondary combustion chamber and a minimum residence time of two seconds.

(ii) Atmospheric emissions shall be controlled so as not to exceed air quality standards of the Division.

2. Decontamination by heating with steam under pressure (autoclave) so as to render the biomedical waste noninfectious.

(i) A recording thermometer shall be used during each complete cycle to ensure the attainment of a temperature of 121 degrees Centigrade (250 degrees Fahrenheit) for one-half hour or longer in order to achieve decontamination of the entire load.

(ii) Monitoring of the steam sterilization process shall be required in order to confirm the attainment of decontamination.

(iii) Monitoring may be through the use of biological indicators or other methods as approved by the Director. Indicators used to ensure the attainment of the proper temperature during steam sterilization shall be placed at the point of the load where the rate of thermal penetration is at a minimum.

3. Other methods as may be approved by the Director.

(b) Fluid or semisolid waste specified in (2)(b) of this Rule may be discharged to a sewage treatment system that provides secondary treatment of waste if approved by the agency responsible for the operation of the sewage treatment system.

(c) Biomedical wastes consisting of recognizable human anatomical remains shall not be disposed of by landfilling.

(d) Chemotherapy waste, as defined in (2)(f), shall be treated at a permitted thermal treatment technology facility or other facility approved by the Director. Steam decontamination may not be used for treatment of chemotherapy waste.

(e) All facilities treating regulated quantities of biomedical waste must, at a minimum, comply with the above criteria. Commercial biomedical waste treatment facilities may not construct or operate a biomedical waste treatment facility without first obtaining a solid waste handling permit under these Rules. On-site biomedical waste treatment facilities are required to obtain a solid waste permit-by-Rule, and must comply with the provisions of paragraph (6)(a)-(d) of this Rule, in addition to Rule 391-3-4-.06. For purposes of this Rule, "Commercial biomedical waste treatment facility" means a facility which accepts over 25 percent of its biomedical waste from other, off-site, facilities, which are not owned by the facility owning the treatment or disposal facility, generally for a fee.

(7) *Disposal of Biomedical Waste.*

(a) Biomedical wastes treated in accordance with the provisions in Rule 391-3-4-.15(6), shall be properly disposed of at a facility permitted under the authority of these Rules unless otherwise approved by the Director.

(b) Biomedical waste from generators of less than 100 pounds per month shall be properly disposed of at a municipal solid waste landfill or treatment facility permitted under authority of these Rules or other facilities approved by the Director.

(c) The disposal of untreated biomedical waste, from generators of more than 100 pounds per month, by landfilling is prohibited.

Ga. Comp. R. & Regs. 391-3-11-.08. Standards Applicable to Generators of Hazardous Waste. Amended.

- (1) 40 C.F.R. Part 262 is hereby incorporated by reference.
- (2) Hazardous Waste Manifests shall be on EPA forms and shall be completed as required by the instructions supplied.
- (3) Weekly inspections of hazardous waste central accumulation areas shall be documented and maintained onsite for three years.

Ga. Comp. R. & Regs. 391-3-17-.02. Licensing of Radioactive Material.

- (6) *General Licenses - Radioactive Materials Other Than Source Material.*
 - (c) Certain Measuring, Gauging, or Controlling Devices and Certain Devices for Producing Light or an Ionizing Atmosphere.

3. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in (6)(c)1.:

(i) Shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(ii) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on/off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however,

(I) Devices containing only krypton need not be tested for leakage of radioactive material, and

(II) Devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta- and/or gamma-emitting material or ten microcuries (0.37 MBq) of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(iii) Shall assure that the tests required by (6)(c)3.(ii) and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

(I) In accordance with the instructions provided by the labels, or

(II) By a person holding an applicable specific license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform such activities;

(iv) Shall maintain records showing compliance with the requirements of (6)(c)3.(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding, or

containment. Records of tests for leakage of radioactive material required by (6)(c)3.(ii) shall be maintained for three years after the next required leak test is performed. Records of tests of the on/off mechanism and indicator required by (6)(c)3.(ii) shall be maintained for three years after the next required test of the on/off mechanism and indicator is performed. Records which are required by (6)(c)3.(iii) shall be maintained for three years. In case of transfer or disposal, records required by this paragraph (iv) shall be maintained for three years after the transfer or disposal.

(v) Shall, upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on/off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, immediately suspend operation of the device. The device may not be operated until it has been repaired by the manufacturer or other person holding an applicable specific license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to repair such devices. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device or as otherwise approved by the Department. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie (185 Bq) or more of removable radioactive material, or failure or damage to a source likely to result in contamination of the premises or environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Department within 30 days. Under these circumstances, the criteria set out in Rule .03(7)(b) "Radiological requirements for unrestricted use" may be applicable, as determined by the Department on a case-by-case basis;

(vi) Shall not abandon the device containing radioactive material;

(vii)

(I) Shall transfer or dispose of the device containing radioactive material only by export as provided in (6)(c)3.(xiv), by transfer to another general licensee as specified in (6)(c)3.(viii) or equivalent regulations of the NRC or another Agreement State, by transfer to a specific licensee of the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State whose specific license authorizes him to receive the device or authorizes him to collect waste, or as otherwise approved under (6)(c)3.(vii)(III).

(II) Within 30 days after transfer of a device to a specific licensee or export, the licensee shall furnish to the Department a report containing identification of the device by manufacturer's (or initial transferor's) name, model number, serial number, the name and address and license number (license number

not applicable if exported) of the person receiving the device and the date of transfer;

(III) If transfer is to any other licensee not identified in (vii)(I), the licensee shall obtain written approval from the Department before transferring the device to any other person; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

I. Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

II. Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by Rule .02(6)(c)3.(i) so that the device is labeled in compliance with Rule .03(12)(d); however the manufacturer, model number, and serial number must be retained;

III. Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

IV. Reports the transfer under Rule .02(6)(c)3.(vii)

(viii) Shall transfer the device to another general licensee only:

(I) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this Regulation and any safety documents identified in the label on the device. Within 30 days of the transfer, report to the Department the manufacturer's (or initial transferor's) name, model number, serial number of the device transferred, the name and mailing address for place of use of the transferee, and the name, title and telephone number of a person identified by the transferee as the individual responsible for having knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(II) Where the device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee;

(ix) Shall comply with the provisions of Rule .03(15) of this Chapter for reporting radiation incidents, or the theft or loss of licensed material, but shall be exempt from the other requirements contained in Rules .03 and .07 of this Chapter;

(x) Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate

regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

(xi) (I) Shall register, in accordance with paragraphs (6)(c).3(xi)(II) and (III), devices containing at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37 MBq) of cobalt-60, 10 mCi (370 MBq) of cadmium-109, or 1 mCi (37 MBq) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph 3.(xi)(III)IV. of this section, represents a separate general licensee and requires a separate registration.

(II) If in possession of a device meeting the criteria of paragraph (6)(c)3.(xi)(I), shall register these devices annually with the Department. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Department. The registration information must be submitted to the Department within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of (6)(c)3.(xi)(I) is subject to the bankruptcy notification requirement in (13)(e) of this rule.

(III) In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Department;

I. Name and mailing address of the general licensee.

II. Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).

III. Name, title, and telephone number of the responsible person designated as a representative of the general licensee under (6)(c)3.(x).

IV. Address or location at which the device(s) are used and/or stored.

V. Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

VI. Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(IV) Persons generally licensed by the NRC, an Agreement State, or Licensing State are not eligible for reciprocity.

(xii) Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Department within 30 days of the effective date of the change; and

(xiii) May not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by (6)(c)3.(ii) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(xiv) Shall not export the device containing byproduct material except in accordance with the requirements of 10 CFR Part 110.

(xv) Shall respond to written requests from the Program to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Program a written justification for the request.

4. The general license in (6)(c)1. does not authorize the manufacture or import of devices containing radioactive material.

5. The general license provided in (6)(c)1. is subject to the provisions of (13), (18), and (19) of this rule, of paragraphs (4), (5), (6), (7), (8), (9) and (10) of Rule .01, and of Rule .06 of this Chapter.

Ga. Comp. R. & Regs. 391-3-17-.03. Standards for Protection Against Radiation.

(14) *Records.*

(b) *Records of Radiation Protection Programs.*

1. Each licensee shall maintain records of the Radiation Protection Program required pursuant to (4) of this Rule, including:

(i) The provisions of the Program; and

(ii) Audits and other reviews of Program content and implementation.

2. The licensee shall retain the records required by (14)(b)1.(i) of this Rule until the Department terminates each pertinent license requiring the record. The licensee shall retain each of the records required by (14)(b)1.(ii) of this Rule for three years after the record is made.

(c) *Records of Surveys.*

1. Each licensee shall maintain records showing the results of surveys and calibrations required by (8)(a) and (12)(f)2. of this Rule. The licensee shall retain each of these records for three years after the record is made.

2. The licensee shall retain each of the following records until the Department terminates each pertinent license requiring the record:

(i) Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;

(ii) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;

(iii) Records showing the results of air sampling, surveys, and bioassays required pursuant to (10)(d)1.(iii)(I) and (II) of this Rule; and

(iv) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

3. Upon termination of the license, the licensee shall permanently store records on Department Form "Occupational Radiation Exposure History" or equivalent or shall make provision with the Department for their transfer to the Department.

(d) *Records of Tests for Leakage or Contamination of Sealed Sources.*

Records of tests for leakage or contamination of sealed sources required by (6) of this Rule shall be kept in units of microcuries or becquerels and maintained for inspection by the Department for three years after the record is made.

(e) *Records of Prior Occupational Dose.*

1. The licensee shall retain the records of prior occupational dose and of exposure history as specified in (5)(e) of this Rule on Department Form "Occupational Radiation Exposure History" or equivalent until the Department terminates each pertinent license requiring this record. The licensee shall retain records used in preparing Department Form "Occupational Radiation Exposure History" for three years after the record is made.

2. Upon termination of the license, the licensee shall permanently store records on Department Form "Occupational Radiation Exposure History" or equivalent or shall make provision with the Department for their transfer to the Department.

(f) *Records of Planned Special Exposures.*

1. For each use of the provisions of (5)(e) of this Rule for planned special exposures, the licensee shall maintain records that describe:

(i) The exceptional circumstances requiring the use of a planned special exposure;

(ii) The name of the management official who authorized the planned special exposure and a copy of the signed authorization;

(iii) What actions were necessary;

(iv) Why the actions were necessary;

(v) What precautions were taken to assure that doses were maintained ALARA;

(vi) What individual and collective doses were expected to result; and

(vii) The doses actually received in the planned special exposure.

2. The licensee shall retain the records until the Department terminates each pertinent license requiring these records.

3. Upon termination of the license, the licensee shall permanently store records on Department Form "Occupational Radiation Exposure History" or equivalent or shall make provision with the Department for their transfer to the Department.

(g) *Records of Individual Monitoring Results.*

1. Record-keeping Requirement. Each licensee shall maintain records of doses received by all individuals for whom monitoring was required pursuant to (8)(b) of this Rule and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994, need not be changed. These records shall include when applicable:

(i) The deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;

(ii) The estimated intake of radionuclides (see (5)(b) of this Rule);

(iii) The committed effective dose equivalent assigned to the intake of radionuclides;

(iv) The specific information used to calculate the committed effective dose equivalent pursuant to (5)(d)3. of this Rule;

(v) The total effective dose equivalent when required by (5)(b) of this Rule; and

(vi) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

2. Record-keeping Frequency. The licensee shall make entries of the records specified in (14)(g)1. of this Rule at intervals not to exceed one year.

3. Record-keeping Format. The licensee shall maintain the records specified in (14)(g)1. of this Rule on Department Form "Occupational Radiation Exposure History" in accordance with the instructions or in clear and legible records containing all the information required by the Department Form.

4. The licensee shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

5. The licensee shall retain each required form or record until the Department terminates each pertinent license requiring the record.

6. Upon termination of the license, the licensee shall permanently store records on Department Form "Occupational Radiation Exposure History" or equivalent or shall make provisions with the Department for their transfer to the Department.

7. Privacy Protection. The records required pursuant to (14)(g) should be protected from public disclosure because of their personal privacy nature.

(h) *Records of Dose to Individual Members of the Public.*

1. Each licensee shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See (5)(i) of this Rule.

2. The licensee shall retain the records required by (14)(h)1. of this Rule until the Department terminates each pertinent license requiring the record.
(i) *Records of Waste Disposal.*

1. Each licensee shall maintain records of the disposal of licensed materials made pursuant to (13)(b), (13)(c), (13)(d), (13)(e), and (13)(k) of this Rule and of disposal of licensed materials by burial in soil, including burials authorized before July 12, 1982. [FN6]

2. The licensee shall retain the records required by (14)(i) of this Rule until the Department terminates each pertinent license requiring the record.
(j) *Records of Testing Entry Control Devices for Very High Radiation Areas.*

1. Each licensee shall maintain records of tests made on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

2. The licensee shall retain the records required by (14)(j)1. of this Rule for three years after the record is made.

(k) *Form of Records.* Each record required by this Rule shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period; or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Ga. Comp. R. & Regs. 391-3-17-.05. Use of Radionuclides in the Healing Arts.

(19) *Written Directives.*

(a) A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerel (30 μ Ci), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.

1. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

2. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

3. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's

record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

(b) The written directive must contain the patient or human research subject's name and the following:

1. For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of administration;
2. For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;
3. For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;
4. For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;
5. For all other brachytherapy including LDR, MDR, and PDR:
 - (i) Prior to implantation: treatment site, the radionuclide, and dose; and
 - (ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, total source strength and exposure time (or, the total dose), and date Or
6. For permanent implant brachytherapy:
 - (i) Before implantation: The treatment site, the radionuclide, and the total source strength; and
 - (ii) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date.

(c) The licensee shall retain the written directive in accordance with Rule .05(88)...

(49) Safety Instruction. In addition to the requirements of Rule .07(3) of this Chapter:

(a) A licensee shall provide radiation safety instruction to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released in accordance with Rule .05(37). The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:

1. Patient or human research subject control;
2. Visitor control to include the following:
 - (i) Routine visitation to hospitalized individuals in accordance with Rule .03 of this Chapter;
 - (ii) Contamination control;
 - (iii) Waste control; and
 - (iv) Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with Rule .05(101)...

- (58) *Safety Instruction.* In addition to the requirements of Rule .07(3) of this Chapter:
- (a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with Rule .05(37). Instruction must be commensurate with the duties of the personnel and shall include the following:
1. Size and appearance of the brachytherapy sources;
 2. Safe handling and shielding instructions;
 3. Patient or human research subject control;
 4. Visitor control, including both:
 - (i) Routine visitation of hospitalized individuals in accordance with Rule .03(5)(i)1.(i) of this Chapter; and
 - (ii) Visitation authorized in accordance with Rule .03(5)(i)2. of this Chapter; and
 5. Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject dies or has a medical emergency. The licensee shall also notify the Department in accordance with Rule .05(119) if it is possible for any individual to receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body.
- (b) A licensee shall retain a record of individuals receiving instruction in accordance with Rule .05(101)...

(70) *Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.*

- (a) A licensee shall:
1. Secure the unit, the console, the console keys, and the treatment room when not in use or when unattended;
 2. Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);
 3. Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and
 4. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:
 - (i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
 - (ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
 - (iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
- (b) A copy of the procedures required by Rule .05(70)(a)4. must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of:

1. The location of the procedures required by Rule .05(70)(a)4.; and
2. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d) 1. Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

2. A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in:

- (i) The procedures identified in Rule .05(70)(a)4.; and
- (ii) The operating procedures for the unit.

A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

1. The procedures identified in Rule .05(70)(a)4.; and
2. The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by Rule .05(70)(d), in accordance with Rule .05(101)...

(86) *Records of Authority and Responsibilities for Radiation Protection Programs.*

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with Rule .05(15)(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by Rule .05(15)(d), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by Rule .05(15)(b). The record must include the signature of the Radiation Safety Officer and licensee management.

(c) The minutes of each Radiation Safety Committee meeting held in accordance with Rule .05(15)(g) shall include:

1. The date of the meeting;
2. Members present;
3. Members absent; and
4. Summary of deliberations and discussions.

(87) *Records of Radiation Protection Program Safety Changes.* A licensee shall retain a record of each radiation protection program change made in accordance with Rule .05(16)(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of

the change; and the signature of the licensee management that reviewed and approved the change.

(88) *Records of Written Directives.* A licensee shall retain a copy of each written directive as required by Rule .05(19) for 3 years.

(89) *Records of Misadministrations.* A licensee shall retain a record of misadministrations reported in accordance with Rule .05(115) for 3 years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(90) *Record of a Dose to an Embryo/Fetus or a Nursing Child.* A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with Rule .05(116) for 3 years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(91) *Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material.* A licensee shall maintain a record of instrument calibrations required by Rule .05(29) for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(92) *Records of Survey Instrument Calibrations.* A licensee shall maintain a record of instrument calibrations required by Rule .05(30) for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(93) *Records of Dosages of Unsealed Radioactive Material for Medical Use.* A licensee shall maintain a record of dosage determinations required by Rule .05(31) for 3 years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.11 MBq (30 μ Ci); the date and time of the dosage determination; and the name of the individual who determined the dosage.

(94) *Records of Possession of Sealed Sources and Brachytherapy Sources.* A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by Rule .05(33)(d) for 3 years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(95) *Records of Surveys for Ambient Radiation Exposure Rate.* A licensee shall retain a record of each survey required by Rule .05(36) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(96) *Records of the Release of Individuals Containing Radioactive Drugs or Implants Containing Radioactive Material.*

(a) A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for 3 years after the date of release,

(b) A licensee shall retain a record, for 3 years after the date of release, that the instructions required by Rule .05(37)(b) were provided to a breast-feeding woman.

(97) *Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services.*

(a) A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by Rule .05(9)(b), for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by Rule .05(38)(f) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(98) *Records of Decay-in-Storage.* A licensee shall maintain records of the disposal of licensed materials, as required by Rule .05(40), for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

(99) *Records of Radionuclide Purity.* A licensee shall maintain a record of the radionuclide contaminant concentration tests required by Rule .05(45) for 3 years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcurie/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

(100) *Records of Training.* A licensee shall maintain records of training required by Rule .05(25) for 3 years after the last date an individual was authorized to act as a nuclear medicine technologist or radiation therapist at the licensee's facility.

(101) *Records of Safety Instruction and Training.* A licensee shall maintain a record of safety instructions and training required by Rules .05(49), (58) and (70) for 3 years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

(102) *Records of Radiation Surveys of Patients and Human Research Subjects.* A licensee shall maintain a record of the surveys required by Rule .05(56) and (68) for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

(103) *Records of Brachytherapy Source Inventory.*

(a) A licensee shall maintain a record of brachytherapy source accountability required by Rule .05(57) for 3 years.

(b) For temporary implants, the record must include:

1. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use;

2. The number and activity of unused sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage; and

3. The number and activity of temporarily implanted sources removed from the patient or human research subject, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include:

1. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

2. The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and

3. The number and activity of sources permanently implanted in the patient or human research subject.

(104) *Records of Calibration Measurements on Brachytherapy Sources.* A licensee shall maintain a record of the calibrations on brachytherapy sources required by Rule .05(60) for 3 years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(105) *Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.* The licensee shall maintain a record of the activity of a strontium 90 source required by Rule .05(60) for the life of the source. The record must include the date and initial activity of the source as determined under Rule .05(60), and for each decay calculation, the date, and the source activity and the signature of the authorized medical physicist.

(106) *Records of Installation, Maintenance, Adjustment, and Repair.* A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by Rule .05(69) for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

(107) *Records of Dosimetry Equipment.*

(a) A licensee shall retain a record of the calibration, inter-comparison, and comparisons of its dosimetry equipment done in accordance with Rule .05(72) for the duration of the license.

(b) For each calibration, inter-comparison, or comparison, the record must include:

1. The date;

2. The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by Rule .05(72)(a) and (72)(b);

3. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an inter-comparison; and

4. The names of the individuals who performed the calibration, inter-comparison, or comparison.

(108) *Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.*

(a) A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by Rule .05(73), (74) and (75) for 3 years.

(b) The record must include:

1. The date of the calibration;
2. The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;
3. The results and assessments of the full calibrations;
4. The results of the autoradiograph required for low dose-rate remote afterloader units; and
5. The signature of the authorized medical physicist who performed the full calibration.

(109) *Records of Periodic Spot-Checks for Teletherapy Units.*

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by Rule .05(76) for 3 years.

(b) The record must include:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
3. An assessment of timer linearity and constancy;
4. The calculated on-off error;
5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
6. The determined accuracy of each distance measuring and localization device;
7. The difference between the anticipated output and the measured output;
8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and
9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(110) *Records of Periodic Spot-Checks for Remote Afterloader Units.*

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by Rule .05(77) for 3 years.

(b) The record must include, as applicable:

1. The date of the spot-check;
2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
3. An assessment of timer accuracy;

4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
 5. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.
- (111) *Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.*
- (a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by Rule .05(78) for 3 years.
 - (b) The record must include:
 1. The date of the spot-check;
 2. The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
 3. An assessment of timer linearity and accuracy;
 4. The calculated on-off error;
 5. A determination of trunnion centricity;
 6. The difference between the anticipated output and the measured output;
 7. An assessment of source output against computer calculations;
 8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
 9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.
- (112) *Records of Additional Technical Requirements for Mobile Remote Afterloader Units.*
- (a) A licensee shall retain a record of each check for mobile remote afterloader units required by Rule .05(79) for 3 years.
 - (b) The record must include:
 1. The date of the check;
 2. The manufacturer's name, model number, and serial number of the remote afterloader unit;
 3. Notations accounting for all sources before the licensee departs from a facility;
 4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and
 5. The signature of the individual who performed the check.
- (113) *Records of Surveys of Therapeutic Treatment Units.*

- (a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with Rule .05(80) for the duration of use of the unit.
- (b) The record must include:
 - 1. The date of the measurements;
 - 2. The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
 - 3. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
 - 4. The signature of the individual who performed the test.

(114) *Records of Five-Year Inspection for Teletherapy and Gamma Stereotactic Surgery Units.*

- (a) A licensee shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by Rule .05(81) for the duration of use of the unit.
- (b) The record must contain:
 - 1. The inspector's radioactive materials license number;
 - 2. The date of inspection;
 - 3. The manufacturer's name and model number and serial number of both the treatment unit and source;
 - 4. A list of components inspected and serviced, and the type of service; and
 - 5. The signature of the inspector.

Ga. Comp. R. & Regs. 480-7-.07. Credit for Returned Expired Drugs.

(4) In order to be eligible for full credit or replacement, the drug must be received by the wholesale drug distributor, or if not the wholesale drug distributor, its agent designated in its return policy, no later than the sixth month from the labeled expiration date. A signed delivery receipt shall constitute evidence of the drugs having been returned.

Ga. Comp. R. & Regs. 480-10-.19. Use of Automated and or Robotic Pharmacy Systems.

(d) The filling/stocking of all medications in the APS or RPS shall be performed by licensed pharmacist, licensed pharmacy intern or a registered pharmacy technician under the direct, on-site supervision of a licensed pharmacist. An electronic or hard copy record of medications produced by the system shall be maintained for 2 years, and shall include identification of the person stocking/filling the system, and if a pharmacy intern or registered pharmacy technician, the name of the pharmacist providing the supervision.

Ga. Comp. R. & Regs. 480-13-.01. Definitions.

For purposes of these Rules and Regulations, the following definitions apply:

(i) *Standard ward inventory.* The Director of Pharmacy or his/her pharmacist designee may, in the best interest of the patients served, establish one or more lists of the kind and quantity of legend drugs to be kept at one or more locations at all times within said hospital and such stocks of legend drugs shall be known as standard ward inventory. The use of standard ward inventory shall be minimized. A copy of the list of items on standard ward inventory must be kept by the Director of Pharmacy or his/her pharmacist designee. A standard ward inventory may be placed on an emergency vehicle licensed with the State Department of Human

Resources. A contract or agreement must be signed between the hospital and the ambulance service and filed with the Department of Human Resources Licensure Division and the Georgia Drugs and Narcotics Agency (GDNA) before any legend drugs may be placed on said licensed vehicle. An agreement can be made with only one hospital.

Ga. Comp. R. & Regs. 480-13-.04. Absence of Pharmacist.

(5) Each remote entry record must comply with all recordkeeping requirements and shall identify, by name or other unique identifier, the pharmacist involved in the preview and verification of the order. The remote entry pharmacist shall maintain records of any and all records entered for the hospital for a minimum of two (2) years, and such records shall be readily available for inspection, copying by, or production of upon request by the Board, its designee, or a representative for the Georgia Drugs and Narcotics Agency (GDNA), upon request.

Ga. Comp. R. & Regs. 480-13-.06. Drug Distribution and Control.

(2) *Responsibility.* The Director of Pharmacy shall be responsible for the safe and efficient distribution, control, and accountability for drugs, including IV solutions and irrigation solutions. The other professional staff of the hospital shall cooperate with the Director of Pharmacy in meeting this responsibility and in ordering, administering, and accounting for the pharmaceutical materials to achieve this purpose. The Director of Pharmacy shall establish written procedures for the distribution of parenteral medications to achieve this goal.

Accordingly, the Director of Pharmacy shall be responsible for, at a minimum, the following:

(d) *Utilization of a pharmacy-generated patient profile.* The patient profile shall be the official record of medications dispensed to the patient. The patient profile or the ability to generate such profile electronically shall be under the control of the Director of Pharmacy for a period of two (2) years. The patient profile shall contain at a minimum:

1. Given and last name of the patient;
2. Age;
3. Sex;
4. Provisional diagnosis;
5. Room number;
6. Drug product dispensed, date dispensed, strength, dosage form, quantity and directions, and identification of dispensing pharmacist;
7. Identification or differentiation of controlled substances;
8. Intravenous therapy;
9. Selected medical data;
10. Drug history interview (when possible); and
11. Sensitivities and allergies to drugs and foods;

(k) Records of all transactions of the hospital pharmacy as may be required by law, and as may be necessary to maintain accurate control over the accountability for all pharmaceutical drugs, devices and materials. Nothing in this section shall prohibit the use of computer hard copy, where such copy meets all other requirements of the law;

(6) *Accountability of controlled drugs.*

(a) Proof of use of controlled drugs on standard ward inventory. Proof of use of controlled substances and such other drugs as may be specified by the appropriate committee of the hospital, shall be submitted to the pharmacy, on forms provided by the pharmacy. Proof of use forms shall specify at a minimum:

1. Name of drug, strength, and dosage form;
2. Dose administered;
3. Name of authorized practitioner. This shall include, at a minimum, the initial and last name;
4. Given and last name of the patient;
5. Date and time of administration to the patient;
6. Signature of the individual administering, which shall include at a minimum, the initial, last name, and title;
7. Documentation of the destruction of any and all unused portions by two signature verifications;
8. Proof of receipt of the medications that bears identifying serial numbers; and
9. Date the medication was issued and the date that the proof of use form was returned to the pharmacy.

(e) Perpetual inventory of Schedule II substances shall be required and accountability of said drugs shall be by a proof of use form.

(9) *Records and reports.* The Director of Pharmacy shall maintain access to and submit, as appropriate, such records and reports as are required to insure the patient's health, safety and welfare. Such records shall be readily available and subject to inspections by the Board of Pharmacy, the GDNA or its employees. These shall include, at a minimum, the following:

- (a) Patient profile;
- (b) Proof of use;
- (c) Reports of suspected adverse drug reactions;
- (d) Inventories of night cabinets and emergency kits/crash carts;
- (e) Inventories of the pharmacy;
- (f) Biennial controlled substances inventories;
- (g) Alcohol and flammables reports; and
- (h) Such other records and reports as may be required by state Law and the Rules and Regulations of the Board of Pharmacy.

(10) *Standard ward inventory (floor stock).* The pharmacy department may distribute drugs within a hospital for the purpose of establishing and/or maintaining a standard ward inventory. Such drugs may be distributed only upon a signed requisition from a nurse or other authorized representative of said hospital or by an inventory replacement system. These drugs may be administered only pursuant to a practitioner's order. This practitioner's order will be forwarded to the pharmacy and these medications will be recorded on the pharmacy patient profile. A record of administration of drugs administered to patients in ancillary areas such as but not limited to the operating room, emergency room, anesthesiology, and x-ray shall be forwarded to the pharmacy and these medications shall be recorded on the patient profile. A survey of usage trends of each standard ward inventory shall be prepared monthly. Such records shall be retained for a period of two years.

Ga. Comp. R. & Regs. 480-13-.10. Inspections. Amended.

(1) *Monthly.* The Director of Pharmacy shall no less than once per month, personally or by qualified designee, inspect all matters within his/her jurisdiction and responsibility and

make appropriate written records of such inspections. Such inspections shall, at a minimum, verify that:

- (a) Drugs are dispensed only by licensed pharmacists or licensed pharmacy interns acting under the direct supervision of a licensed pharmacist;
- (b) Non-licensed pharmacy personnel are properly directed and supervised;
- (c) Drugs for external use are stored separately, and apart from drugs for internal use or injection;
- (d) Drugs requiring special storage conditions to insure their stability are properly stored ;
- (e) No outdated drugs are stocked in the hospital pharmacy or the facility it serves;
- (f) Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and other licensed medical personnel;
- (g) Standard ward inventory (floor stock). Verification of standard ward inventory lists and accountability, including such updating, if applicable, are maintained;
- (h) All necessary and required security and storage standards are met;
- (i) Metric-apothecaries' weight and measure conversion tables and charts are available;
- (j) All policies and procedures of the Director of Pharmacy and of appropriate committees of the hospital relevant to the pharmacy are followed;
- (k) All discounted and out-dated medications are returned to the pharmacy for proper disposition; and
- (l) Disinfectants and other similar supplies intended for external use are stored separately and apart from drugs intended for internal (oral) or parenteral use.

(2) *Board Inspection.* The Board of Pharmacy inspections shall be conducted by representatives of the Georgia Drugs and Narcotics Agency (GDNA) no less than once every two (2) years. Such inspections shall include all aspects of the management and operation of all hospital pharmacies in this State to verify compliance with the Pharmacy Laws, the Rules and Regulations of the Board of Pharmacy, and such other standards as may be appropriate to insure that the health, safety and welfare of patients of the hospital serviced by the pharmacy are protected. A written report shall be filed with the GDNA, the Director of Pharmacy, and the hospital administrator. Any discrepancies or deficiencies noted shall be corrected within a reasonable time. Written notice of such corrections shall be filed with the GDNA within thirty (30) days after receipt of the inspection notice.

- (a) The Director of Pharmacy of each hospital pharmacy shall obtain a copy of the current Board permit of every drug wholesaler and/or reverse distributor from which controlled substances and/or dangerous drugs are purchased and/or returned. Such copies shall be made available during the GDNA's inspection.

Ga. Comp. R. & Regs. 480-19-.01. Excepted Sales of Non-Pseudoephedrine Schedule V Controlled Substances.

- (b) A licensed pharmacist, or intern acting under the immediate and direct supervision of a licensed pharmacist, may sell, dispense or otherwise dispose of without prescription not more than 4 oz. or 32 dosage units of an exempted non-pseudoephedrine Schedule V controlled substance within any 48 hour period of time, but only:

2. After the purchaser has written his/her signature, date of birth, address, city, state and zip code upon a register which records and reflects the date of such transaction, the name, kind, quantity and intended use of such Schedule V substance sold, dispensed, or otherwise disposed of, and such records shall be maintained as required by Schedule V records.

Ga. Comp. R. & Regs. 480-19-.03. Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine.

(d) All logbooks must be retained for a minimum period of 2 years from the date of the last recorded sale.

Ga. Comp. R. & Regs. 480-27-.03. Records of Dispensing.

Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for two years and shall include, but not be limited to:

- (a) Quantities dispensed;
- (b) Date of dispensing;
- (c) Serial number (or equivalent if an institution);
- (d) The identification of the pharmacist responsible for dispensing;
- (e) Documentation of satisfaction of state requirements for drug product selection;
- (f) Records of refills to date to include date(s) of refills, and identification of pharmacist(s) dispensing refills.

Ga. Comp. R. & Regs. 480-27-.05. Record-Keeping When Utilizing an Automated Electronic Data Processing System.

In order to comply with the record keeping requirements of this Chapter, an automated electronic data processing system may be utilized for the record keeping system if the following conditions have been met:

- (a) Except as otherwise provided herein, all original prescriptions, those hard copies written by a practitioner, telephoned to the pharmacist by a practitioner and reduced to writing, or sent via facsimile machine or other electronic means must be retained as a permanent record for two years in the usual consecutively serial numbered prescription file. Any refill information subsequently authorized by a practitioner must be maintained in the manner required by O.C.G.A. § 26-4-80(e).
- (b) The system shall at a minimum produce sight-readable printouts for all dangerous drug and controlled substance prescriptions for each 24 hour period. The term sightreadable means that a representative of the Board or GDNA shall be able to readily retrieve and examine the record and read the information during any on-site visit to the pharmacy. These print-outs must be generated at least once weekly by the pharmacy and maintained for at least two years after the last date on which the prescription was filled or refilled. If not readily retrievable, any such printouts shall be generated as soon as possible upon the verbal request from the Board or GDNA representative.
- (c) The information maintained by the automated electronic data processing system shall include, but not be limited to the following:
 1. Date of dispensing;
 2. Prescription number;
 3. Patient's name;

4. Patient's address;
5. Drug name, strength and dosage form;
6. Quantity prescribed, and if the quantity dispensed is different from the quantity prescribed, the quantity dispensed;
7. Prescriber's name;
8. Identification of dispensing pharmacist;
9. Indication whether drugs are being dispensed pursuant to a new prescription or for a refill order;
10. In case of a controlled substance as allowed by federal law, the name, address and DEA registration of the practitioner and the schedule of the drug;
11. Directions for administration of the prescription to the patient;
12. Total number of refills authorized; and
13. NPI of the prescriber as assigned under federal law.

(d) Permanent records of electronic prescriptions for dangerous drugs and controlled substances do not have to be reduced to hard copy provided the following requirements are met:

1. Electronic prescription data must be maintained in the original format received for a minimum of two years; and
2. Reliable backup copies of the information are readily retrievable and stored in a secure and fireproof (minimum 1 hr UL approved) container, stored in a secured offsite location or backed up to a documented offsite secure storage device within 48 hours following each work day.

(e) The individual pharmacist responsible for completeness and accuracy of the entries to the system must provide documentation that prescription information entered into the computer is correct, by dating and signing the print-out in the same manner as signing a check or legal document (e.g., Mary A. Smith or M. A. Smith).

(f) An auxiliary record-keeping system shall be established for the documentation of filling new prescriptions, refills, and transfers if the automated electronic data processing system is inoperative for any reason. The auxiliary system shall insure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded. When this automated electronic data processing system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated electronic data processing system as soon as possible. However, nothing in this section shall preclude the pharmacist from using his/her professional judgment for the benefit of a patient's health and safety.

(g) Any pharmacy using an automated electronic data processing system must comply with all applicable State and Federal laws and regulations.

(h) A pharmacy shall make arrangements with the supplier of data processing services or materials to insure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with such supplier.

Ga. Comp. R. & Regs. 480-27-.06. Security.

The computerized information provided by the system shall be used only by the pharmacy in which the data has been entered or a pharmacy sharing a common database. To maintain the confidentiality of patients' prescriptions, there must exist adequate safeguards or security of the records.

Ga. Comp. R. & Regs. 480-31-.01(a)(3)

3. A patient record shall be maintained for a period of not less than two years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

Ga. Comp. R. & Regs. 480-35-.05. Recordkeeping.

(2) All such patient records must be maintained for a period of ten (10) years following the date the protocol is terminated;

OTHER SOURCES**FEDERAL REGISTER****76 Fed. Reg. 5,861, 5,898 (Feb. 2, 2011).**

Comment: One commenter asked whether it was our intention to require providers also to check their employees for exclusions on a monthly basis. The proposed regulation at § 455.436 does not require providers to check their employees for exclusions.

Response: We issued guidance on June 12, 2008, to State Medicaid Directors recommending that they check their enrolled providers for exclusions on a monthly basis. We followed up that guidance on January 16, 2009, with guidance to State Medicaid Directors recommending that they require their enrolled providers to check the providers' employees and contractors for exclusions on a monthly basis. Those letters are available at: <http://www.cms.gov/smdl/downloads/SMD061208.pdf> and <http://www.cms.gov/SMDL/downloads/SMD011609.pdf>. Many States made our recommendations their policy. Section 455.436 does not mandate that States require their providers to check the LEIE and EPLS on a monthly basis to determine whether the providers' employees and contractors have been excluded. We do, however, recommend that States consider making this a requirement for all providers and contractors, including managed care contractors in their Medicaid programs and CHIP.

MEDICARE AND MEDICAID MANUALS**Medicare Claims Processing Manual, Ch. 1, 110 - Provider Retention of Health Insurance Records**

(Rev. 1, 10-01-03)

HO-413, HH-480, SNF-545

The provider must maintain health insurance materials related to services rendered under title XVIII for the retention periods outlined below unless State law stipulates a longer period. It must keep them available for reference by CMS, carrier, or FI, DHHS audit, or specially designated components for bill review, audit, and other references.

110.1 - Categories of Health Insurance Records to Be Retained

(Rev. 1, 10-01-03)

HO-413, HH-480, SNF-545.1

Providers retain records in all categories as applicable:

A. Billing Material

Provider copies of Form CMS-1450 and any other supporting documents, e.g., charge slips, daily patient census records, and other business and accounting records referring to specific claims.

B. Cost Report Material

All data necessary to support the accuracy of the entries on the annual cost reports, including original invoices, cancelled checks, and provider copies of material used in preparing them. Also include other similar cost reports, schedules, and related worksheets and contracts or records of dealings with outside sources of medical supplies and services or with related organizations.

C. Medical Record Material

For hospitals, utilization review committee reports and discharge summaries. For hospitals and home health agencies, physicians' certifications, and recertifications, and clinical and other medical records relating to health insurance claims.

D. Provider Physician Materials

Provider physician agreements upon which Part A and Part B allocations are based. After payment of the bill, the provider should not retain administrative and billing work records if the material does not represent critical detail in support of summaries related to these records. These include punch cards, adding machine tapes, or other similar material not required for record retention. ...

110.3 - Retention Period

(Rev. 1, 10-01-03)

The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The provider must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

The provider (hospital, skilled nursing facility, and home health agency) must retain medical records in their original or legally reproduced form for a period of at least five years after it files with its FI the cost report to which the records apply, unless State law stipulates a longer period of time.

After payment of the bill, the provider need not retain administrative and billing work records provided that, and only to the extent that, such material does not represent critical detail in support of summaries related to the records outlined in §110.2. These records include punch cards, adding machine tapes, internal controls, or other similar material not required for record retention.

Providers must retain clinical records as follows:

- The period of time required by State law;
- Five years from the date of discharge when there is no requirement in State law; or
- For a minor, three years after a resident reaches legal age under State law.

Medicare Program Integrity Manual (“MPIM”), 15.18 – Ordering and Certifying Documentation – Maintenance Requirements.

[MPIM, Ch. 15 § 18 (available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/pim83c15.pdf> (last visited January 14, 2021)) provided guidance on 42 C.F.R. § 424.516(f) before that regulation's amendment effective November 14, 2019. Because the

guidance language, which was implemented in July 2015, is now inconsistent with the regulation as amended, it has been omitted from this edition of the Document Retention Schedule.]

CMS State Operations Manual, Appendix A – Regulations and Interpretive Guidelines § 482.42, Tag A-0747.

Guidance is pending and will be updated in a future release.

CMS State Operations Manual, Appendix V – Part II – Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases, Tag A-2403/C-2403.

The medical records of individuals transferred to or from the hospital must be retained in their original or legally reproduced form in hard copy, microfilm, microfiche, optical disks, computer disks, or computer memory for a period of 5 years from the date of transfer.

Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(R).

[Enrolled providers must]: Maintain such written records for Medicaid/PeachCare for Kids members as necessary to disclose fully the extent of services provided and the medical necessity for the provision of such services, for a minimum of six (6) years after the date of service. Providers should ensure that member records are forwarded to a member's new provider during a change of ownership, voluntary or involuntary termination, transfer of a member to a new provider or any other action that requires the review of member records to determine course of treatment. Member records must, at a minimum, reflect the date of service, member name and medical history, the service provided, the diagnosis and the prescribed drugs or treatment ordered, and the signature of the treating provider. **The Department will accept secure electronic signatures as defined in the Definitions section of this Manual. Please refer to Part II for more stringent documentation and secure electronic signature requirements applicable to different categories of service.**

Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(W).

[Enrolled providers must]: **Not employ or contract with a person, provider, owner, managing employee, partnership, or corporation previously terminated or suspended from the Program, barred from enrollment, previously or currently placed on the Department of Health and Human Services, Office of the Inspector General's sanction or exclusions lists, General Service Administration's Excluded Parties List System (EPLS), the Social Security Administration's Death Master File or a person, owner, managing employee, partnership, or corporation that has ever been convicted of any offense as described in §404(J) of this Manual.** Medicaid payments cannot be made for any items or services directed or prescribed by an excluded physician or other authorized person when the individual or entity furnishing the services knew or should have known of the exclusion. This prohibition applies even when the Medicaid payment itself is made to another provider, practitioner or supplier that is not excluded. (42 CFR Section 1001.19019(b)). The exclusion includes administrators, billing agents, accountants, claims processors or utilization reviewers that are related to and reimbursed, directly or indirectly by a Medicaid program. Providers can search by individual names or entity name on the HHS-OIG, EPLS, and the Social Security Administration's Death Master File websites. Providers are required to search the HHS-OIG and EPLS websites monthly to capture exclusions and reinstatements that have occurred since the last search. Providers are required to

report to the Department of Community Health Provider Enrollment Section immediately any exclusion information discovered among employees or contractors.

Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106(Z).

[Enrolled providers must]: Furnish to the Division and to the Secretary of the U.S. Department of Health and Human Services, within thirty-five (35) days of the date of a request, full and complete information about the ownership of any subcontractor with whom the provider had business transactions totaling more than Twenty-Five Thousand Dollars (\$25,000) during the twelve (12) month period ending on the date of the request, and any significant business transactions between the provider and wholly-owned supplier, or between the provider and any subcontractor, during the six (6) year period ending on the date of the request.

Part II: Policies and Procedures for Hospital Services, § 1002.

1002.1 Each participating (enrolled) hospital must submit a cost report using the appropriate Form HCFA-2552. The Division requires hospitals to list inpatient and outpatient costs and charges separately on Worksheet E-3 Part III or other revised forms as appropriate.

1002.2 A hospital with a cost reporting period ending on or after June 27, 1995, must furnish its cost report within five months after its fiscal year end. If the report has not been received after this five-month period and a request for extension has not been granted, a written warning will be issued. This warning will indicate if, after an additional month (total six months), the cost report has not been received, a one hundred percent reduction will be imposed on all payments made during the period that the cost report is late.

These payments will be withheld until an acceptable Medicaid cost report is received. After the cost report is received and is determined to be acceptable, the withheld funds will be released. If the cost report is not received after a total of seven months from a hospital's fiscal year end, the hospital's agreement of participation will be subject to suspension or termination.

When a hospital undergoes a change of ownership or voluntarily or involuntarily terminates from the Medicare/Medicaid program, the hospital must notify the Division and file a terminating cost report within five (5) months of the date of termination. If a cost report is not received within this period, all Medicaid payments will be withheld until an acceptable cost report is received and accepted by the Division. The Department may sanction a hospital for failure to submit the required cost report as outlined in Section 1002.

1002.3 The Division has entered into a “common audit” agreement with Myers and Stauffer, LC. The hospital’s Medicaid cost report should be sent to the following address:
John D. Kraft, CPA, CHFP
MYERS AND STAUFFER, LC
10200 Grand Central
Avenue, Suite 200
Owings Mills, MD 21117
PH 410. 581. 4643 (Direct)
PH 800. 505. 1698 (Main)
FX 410.0356. 0188
www.mslc.com

In addition to the cost report, the following listing of items must also be submitted along with the cost report in electronic format if possible.

1. ECR files of submitted cost report
2. Working Trial Balance
3. Expense mapping for Worksheet A
4. Revenue mapping for Worksheet C
5. Supporting work papers for A-6 reclassifications
6. Supporting work papers for A-8 adjustments
7. CMS Form 339
8. Medicaid charge mapping Worksheets for D-4 and D Part V
9. Audited Financial Statements (if available)

1002.4 As part of the cost report review process, a hospital must make available to authorized representatives of the Division all medical and fiscal records, including Medicare cost reports and work papers prepared by Medicare fiscal intermediary auditors.

GEORGIA INTERPRETIVE GUIDELINES AND GUIDANCE DOCUMENTS

Interpretive Guideline citing Ga. Comp. R. & Regs. 290-9-7-.05, recodified to Ga. Comp. R. & Regs. 111-8-40-.05.

Hospitals should keep a copy of the application submitted and any supporting documents.

Interpretive Guideline citing Ga. Comp. R. & Regs. 290-9-7-.18, recodified to Ga. Comp. R. & Regs. 111-8-40-.18.

Records can be preserved in the format of choice: paper, electronic, etc. All data pertaining to a patient’s diagnosis or treatment must be retained, including x-rays, films, monitoring data, etc. The age of majority in Georgia is eighteen (18) years.

Georgia EPD, Hazardous Waste Management Guide for Georgia Hospitals (September 2003)

Available at: <https://gecap.org/pdf/EPD%20gahospguide.pdf>.

Georgia Comprehensive Cancer Registry – Policy and Procedure Manual for Reporting Facilities

Available at <https://dph.georgia.gov/document/document/gccr-policy-and-procedure-manual/download>.

MISCELLANEOUS SOURCES:**AICPA Employee Benefit Plan Audit Quality Center Advisory on the Importance of Retaining and Protecting Employee Benefit Records (2019)**

Available at: <https://www.aicpa.org/resources/download/the-importance-of-retaining-ebp-records>

CDC Guideline for Disinfection and Sterilization in Healthcare Facilities (2008) (Update: May 2019)

Available at: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf>

CMS COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers

Available at: <https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf>

Corporate Integrity Agreements

Available at: <http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp>.

DEA Pharmacist's Manual, Section VI

Available at: [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-046\)\(EO-DEA154\)_Pharmacist_Manual.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046)(EO-DEA154)_Pharmacist_Manual.pdf).

Every pharmacy must maintain complete and accurate records on a current basis for each controlled substance received, stored, distributed, dispensed, or otherwise disposed of. 21 CFR 1304.21(a). These records are required to provide accountability of all controlled substances from the manufacturing process through the dispensing pharmacy and to the ultimate user. The closed system reduces the potential for diversion of controlled substances.

All required records concerning controlled substances must be maintained for at least two years for inspection and copying by duly authorized DEA officials. 21 U.S.C. 827(b) and 21 CFR 1304.04(a). Records and inventories of schedule II controlled substances must be maintained separately from all other records of the registrant. All records and inventories of schedules III, IV, and V controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business records. 21 CFR 1304.04(h)(3). Recordkeeping requirements for prescriptions are detailed in Section VII, Valid Prescription Requirements.

Under 21 CFR 1300.01(b), readily retrievable is defined as:

1. Records kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time, and/or
2. Records kept in such a manner that certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records. ...

Georgia Environmental Compliance Assistance Program Guidance on Underground Storage Tanks

Available at: <http://www.gecap.org/pdf/USTs.pdf>.

HHS-OIG Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (May 8, 2013)

Available at: <https://oig.hhs.gov/exclusions/advisories.asp>.

Joint Commission, Comprehensive Accreditation Manual

Available for purchase at: <https://www.jcrinc.com/products-and-services/publications/manuals/>.

Office of Federal Contract Compliance Programs, Frequently Asked Questions – Jurisdiction

Available at: <http://www.dol.gov/ofccp/regs/compliance/faqs/juristn.htm>.

O.M.B. Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations § 200(a).

Audit Required. Non-Federal entities that expend \$300,000 (\$500,000 for fiscal years ending after December 31, 2003) or more in a year in Federal awards shall have a single or program-specific audit conducted for that year in accordance with the provisions of this part. Guidance on determining Federal awards expended is provided in § ____.205.

O.M.B. Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations § 320(g).

Report retention requirements. Auditees shall keep one copy of the data collection form described in paragraph (b) of this section and one copy of the reporting package described in paragraph (c) of this section on file for three years from the date of submission to the Federal clearinghouse designated by OMB. Pass-through entities shall keep subrecipients' submissions on file for three years from date of receipt.

Available at:

https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A133/a133_revised_2007.pdf.

U.S. Army Corps of Engineers, Regulatory Guidance Letter No. 16-01 (October 2016).

Available at: <http://www.usace.army.mil/Missions/CivilWorks/RegulatoryProgramandPermits/GuidanceLetters.aspx>.