

HEALTH CARE RECORDS RETENTION MANUAL

JUNE 2013



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**STATE BAR OF MICHIGAN
HEALTH CARE LAW SECTION**

Health Care Records Retention Manual

FOREWORD

The Publications Committee, a Committee of the State Bar of Michigan, Health Care Law Section, is extremely pleased to offer the 2013 Edition of the Health Care Records Retention Manual. The 2013 Edition is the third edition of this Manual, having been first created in 2002 and then updated in 2009.

The 2013 Edition was updated by Publications Committee Member **Sheerin Siddique**, who devoted substantial time and resources to this project. Sheerin was assisted by earlier versions of this Manual, which provided an important starting point for the 2013 Edition, and was supported in her efforts by the Publications Committee of the Health Law Section, whose members include:

Monica P. Navarro, Chair
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One of the Health Care Law Section's primary goals is to help lawyers serve their health care clients more effectively through education and information. We hope this Health Care Records Retention Manual will be a lasting contribution to achieving that goal.

Monica P. Navarro
Council Member of the Health Law Section and
Publications Committee Chair

INTRODUCTION

The 2013 Edition of the Health Care Records Retention Manual, like the previous editions, was prepared to assist lawyers of the State of Michigan in researching the retention requirements for the types of records prepared by health care facilities and providers such as hospitals, clinical laboratories, health maintenance organizations, and pharmacies. In their efforts to abide by sound health care business practices and to comply with state and federal statutes, rules and regulations and accreditation and contractual requirements, health care facilities and providers prepare countless records pertaining to almost every aspect of their operations. Record keeping is tremendously expensive due to the cost of equipment and space and the time spent by health care professionals, administrative staff and executives in preparing, organizing, developing, managing, accessing and storing patient clinical records and other documents. Faced with burgeoning files, limited storage space, and administrative cost restraints, health care clients often ask their attorneys how long they must retain records. To help members of the Health Care Law Section and other lawyers answer these questions, this Manual, as updated, provides a reference to record retention laws.

The editors of the Manual endeavored to be thorough in researching federal and state statutes, rules, and regulations. In using the Manual as a research aid, attorneys should be aware that record retention requirements are often contained in contracts, policies and procedures of third-party payers and other entities with whom a health care provider transacts business. For example, a hospital's contract with a health maintenance organization or Blue Cross Shield of Michigan may require the hospital to retain certain records for longer periods than the periods prescribed by the state and the federal statutes, or rules and regulations applicable to the hospital. In addition, accrediting and other professional and industry organizations may recommend different retention periods. For this reason, the authors and editors decided *not* to make recommendations concerning appropriate retention periods. With respect to many records, however, experience in a particular case or cases may dictate longer retention periods than mandated by statutes, regulations, or written standards and guidelines. Records relating to the Medicare and Medicaid programs and physical plant are examples of such records.

The Manual covers patient medical records and other selected topics thought to be appropriate and helpful. The Manual does not address general business and financial records.

Previous versions of the Manual contained a separate section entitled “Impact of Statutes of Limitations on Record Retention.” That section is currently being updated and will be provided as a supplement to this Manual when the update is completed.

Because health care providers often are plaintiffs, petitioners, defendants or respondents in civil and criminal actions before state and federal courts and regulatory agencies, their attorneys should consider record retention requirements in the context of potential investigations or litigation. The minimum record retention periods prescribed by state licensing laws may not be sufficient to ensure that adequate records will be available to a health care provider defending against, for example, an alleged violation of the state or federal fraud and abuse laws, or a medical malpractice action by an individual who allegedly suffered an injury at birth.

The Manual is a tool to assist in researching record retention questions and requires the user’s skillful application. The Health Care Law Section makes no representation or guarantee with respect to the contents herein and specifically disclaims any implied guarantee of suitability for any specific purpose. The Health Care Law Section has no liability or responsibility to any person or entity for loss or damage caused by the use of this Manual.

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CLINICAL INFORMATION

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Electrocardiograms, Electroencephalograms, and Electromyograms	42 CFR § 482.26(d)(2): Hospital must retain records of radiologic services for at least five (5) years: (i) copies of reports and printouts; (ii) films, scans, and other image records, as appropriate.	Not found.	None.
Emergency Room Central Logs	42 CFR § 489.20(r)(3): Hospitals must maintain a central log on each individual who comes to the emergency department (as defined in Sec. 489.24(b)) seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred or discharged. These records likely must be retained for five (5) years. (See 489.20(r)(1)).	Not found.	None.
Emergency Room Physician-On-Call Lists	42 CFR § 489.20(r)(2): Hospitals must maintain a list of physicians who are on-call for duty after the initial examination to provide treatment necessary to stabilize individuals with emergency medical condition. These records likely must also be maintained for 5 years. (See 489.20(r)(1)).	Not found.	None.
Emergency Room – Transfer	42 CFR§ 489.20(r)(1): Hospitals must maintain medical and other records related to individuals transferred to or from the hospital for a period of five (5) years from the date of transfer.	Not found.	None.
Fetal Heart Monitor Strips	42 CFR § 482.24(b)(1): Medical records	American Health Information	

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	must be retained in their original or legally reproduced form for at least five (5) years.	Management Association Position Statement (June 1999): The AHIMA recommends that fetal heart monitor strips be retained for ten (10) years after infant reaches age of majority.	
Laboratory, Blood and Pathology Reports	42 CFR § 493.1107; 42 CFR § 493.1109: Preliminary and final test reports, including, if applicable, instrument printout, must be retained by the testing laboratory for at least two (2) years after date of report. Immunohematology records and transfusion records must be retained by the laboratory for at least five (5) years in accordance with 21 CFR part 606, subpart I. Records of blood and blood product testing must be retained for at least five (5) years after completion of processing records or six (6) months after latest expiration date, whichever is later, in accordance with 21 CFR § 606.160(d). Pathology test reports must be retained for at least ten (10) years after date of report. This information may be maintained as part of patient's chart or medical record which must be readily available to lab and HHS.	Not found.	The record system must provide documentation of information specified in Sec. 493.1105(a) through (f) and include the information specified in Sec. 493.1107(a) through (d).
Mammograms	42 USC § 263b(f)(1)(G); 21 CFR § 900.12(c)(4)(i): Mammography facilities must maintain original mammography reports in permanent medical record for not less than five (5) years, or not less than ten (10) years if no additional mammograms	Not found.	Note: There are also very specific training and continuing education requirements and records should probably be kept demonstrating compliance.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>are performed, or longer if State or local law mandates.</p> <p>MCL § 333.13523: (i) The facility which has authorized a radiation machine to be used for mammography must at least annually have a qualified radiation physicist provide on-site consultation to the facility, including, but not limited to, a complete evaluation of the entire mammography system to ensure compliance with this part of the rules. The records of the consultation required under (i) and the findings must be maintained for seven (7) years.</p> <p>MCL § 333.13523(2)(g)(v): Facility maintains annual reports concerning outcome data for correlation of positive mammograms to biopsies done and the number of cancers detected.</p> <p>MCL 333.20175: A health facility or agency must keep and maintain a record for each patient, including a full and complete record of tests and examinations performed, observations made, treatments provided, and in the case of a hospital, the purpose of hospitalization. Unless a longer retention period is otherwise required under federal or state laws or regulations or by generally accepted standards of medical practice, a health facility or agency shall keep and</p>		

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>retain each record for a minimum of seven (7) years from the date of service to which the record pertains.</p> <p>Mich. Admin. Code R 325.5657: Mammography facilities must maintain original mammography reports in permanent medical record for not less than seven (7) years.</p>		
Medical Records: Health Facilities Generally	<p>42 CFR § 482.24(b)(1): Inpatient and outpatient records must be retained in their original or legally reproduced form for at least five (5) years.</p> <p>MCL § 333.20175(1): A health facility or agency must keep and maintain a record for each patient, including a full and complete record of tests and examinations performed, observations made, treatments provided and, in the case of a hospital, the purpose of hospitalization. Unless a longer retention period is otherwise required under federal or state laws or regulations or by generally accepted standards of medical practice, a health facility or agency shall keep and retain each record for a minimum of seven (7) years from the date of service to which the record pertains.</p> <p>MCL § 400.111b(8): Providers must retain records necessary to document fully the extent and cost of services, supplies or</p>	<p>American College of Obstetricians and Gynecologists, Guidelines for Women's Health Care (1996); American Academy of Pediatrics, American College of Obstetricians and Gynecologists, Guidelines for Perinatal Care (3d ed. 1992): Retain records in accordance with law and good medical practice.</p> <p>American Hospital Association, Management Advisory (1990):</p> <p>Retention period varies depending on purpose for which record is being kept.</p> <p>Such purposes include a health care institution's needs relating to patient care, clinical and/or scientific research, assessment</p>	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>equipment provided to a medically indigent individual for (seven) 7 years after the date of service.</p> <p>MCL § 750.492a: A healthcare provider or other person, knowing that information is misleading or inaccurate, shall not intentionally, willfully or recklessly place or direct another to place in a patient's medical record or chart misleading or inaccurate information regarding the diagnosis, treatment or cause of a patient's condition. The above does not apply to either of the following:</p> <p>(a) All information contained in the medical record or chart is otherwise retained by means of photography, mechanical or electronic recording, chemical reproduction, or other equivalent techniques which accurately reproduce all information contained in original;</p> <p>(b) Supplementation or correction of an error in a patient's medical record or chart in a manner that reasonably discloses the supplementation or correction was performed and that does not conceal or alter prior entries.</p> <p>Mich. Admin. Code R 325.1028(5): A hospital shall require accurate and complete</p>	<p>activities pertaining to the quality of patient care, and the possibility of future patient litigation.</p> <p>The appropriate period of retention may also be affected by state or local statutes relating to the retention of medical records as well as the statute of limitations for bringing a legal action for an injury or breach of contract.</p> <p>Because a health care institution is seldom requested to produce medical records older than ten (10) years, it is recommended that complete patient medical records be retained, either in the original or reproduced form, for ten (10) years after the most recent date of patient care, in the absence of legal considerations and unless destruction of the original/reproduced record is specifically prohibited by statute, ordinance, regulation, or laws.</p> <p>After ten (10) years, at least the following information should be retained:</p>	

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>medical records be preserved as original records, abstracts, microfilms or otherwise so as to afford a basis for a complete audit of professional information.</p>	<ul style="list-style-type: none"> (i) dates of all visits; (ii) admission and discharge dates; (iii) names of responsible physicians; (iv) records of diagnoses and procedures, including any applicable physician attestations; (v) history and physical records; (vi) operative and pathology reports; and (vii) discharge summaries. <p>Additionally, the complete medical records of minors should be retained for the period of minority plus any applicable period of time specified in state statutes relating to retention of records of minors and/or the statute of limitations.</p> <p>Complete medical records may be retained longer when</p>	

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
		<p>requested in writing by any of the following individuals:</p> <ul style="list-style-type: none"> (i) an attending or consulting physician of the patient; (ii) the patient or someone acting legally on the patient's behalf; or (iii) legal counsel for an individual having an interest affected by the medical records. <p>Medical records shall be retained for a period of time established by the statutes of limitation in the state.</p> <p>American Medical Association, 1994 Code of Medical Ethics, 7.05(2):</p> <ul style="list-style-type: none"> (1) AMA has actively supported and advocated the implementation of E-7.05. (2) Medical considerations are the primary basis for deciding how long to retain medical records. For example, operative notes and chemotherapy should 	

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
		<p>always be part of a patient's chart. In deciding whether to keep certain parts of the record, an appropriate criteria is whether the physician would want the information if he/she were seeing the patient for the first time.</p> <p>(3) If a particular record no longer needs to be kept for medical reasons, the physician should check state laws to see if there is a requirement that records be kept for a minimum length of time. Most states will not have such a provision. If they do, it will be part of the statutory code or state licensing board.</p> <p>(4) In all cases, if a particular record is no longer needed for medical purposes, medical records should be kept for at least as long as the length of time of the statute of limitations for medical malpractice.</p> <p>(5) Whatever the statute of limitations, a physician should measure time from the last professional contact with the patient.</p>	

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
		<p>(6) If the patient is a minor, the statute of limitations may not apply until the patient reaches the age of majority.</p> <p>(7) In order to preserve confidentiality when discarding old records, all documents should be destroyed.</p> <p>(8) Before discarding old records, patients should be given the opportunity to claim them or have them sent to another physician.</p> <p>Joint Commission Accreditation Manual for Hospitals, IM.6.1: Retention time of record is determined by the hospital, based on law and regulation and the information's use for patient care, legal, research, and educational purposes.</p> <p>1999 Accreditation Handbook for Ambulatory Care, Accreditation Association for Ambulatory Health Care (AAAHC): Requires organization to have policies that</p>	

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
		<p>address retention of active clinical records and the retirement of inactive clinical records and the retention of diagnostic images.</p> <p>American Health Information Management Association Position Statement (June 1999): Retain adult patient medical records for ten (10) years after most recent encounter and minor patient medical records until the age of majority plus the statute of limitations.</p>	
Immunization/Vaccines	42 USC § 300aa-25: Retention periods are not specified. However, each healthcare provider who administers a vaccine set forth in the Vaccine Injury Table (42 CFR 100.3) to any person shall, within seven (7) days of administering the vaccine, record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine the date of administration of the vaccine, the vaccine manufacturer and lot number of the vaccine, the name and address and, if appropriate, the title of the healthcare provider administering the vaccine required pursuant to regulation promulgated by the	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	Secretary.		
Nuclear Medicine	42 CFR § 482.53(d)(1): Retain copies of nuclear medicine reports for at least five (5) years.	Not found.	None.
Surgery Log Book	Not found.	American Health Information Management Association: The AHIMA recommends that surgery log books be retained permanently and the operative index be retained for ten (10) years.	None.
Video and Audio Tapes, Including Diagnostic Procedures	42 CFR § 482.26(d)(2): Hospital must retain records of radiologic services for at least five (5) years: (i) copies of reports and printouts; (ii) films, scans, and other image records, as appropriate.	American Hospital Association, Management Advisory (1990): Video and audio tapes are sometimes made during the patient's stay in the facility. The purposes for which these tapes are made vary and the hospital should establish retention requirements for them based upon the purposes for which they were made. There is no definitive standard that requires them to be treated as a part of the medical record.	None.
X-ray Films	42 CFR § 482.26(d)(2): Hospital must retain records of radiologic services for at least five (5) years: (i) copies of reports and printouts; (ii) films, scans, and other image records, as appropriate.	American Health Information Management Association (AHIMA): The AHIMA recommends retaining x-rays for five (5) years for adults and five (5) years after the	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
		age of majority for minors.	
Abortions and Related Medical Services Documentation	42 CFR § 36.56: Medical Records for abortions received under federal programs (Indian health or research grant fund) must be retained for three (3) years.	Not found.	None.
Maternity Hospitals and Departments	Mich. Admin. Code R 325.1056(j): Records of the bacteriologic check of infant formulas and water solutions prepared in the formula room and the attached nipples shall be maintained for 1 year from the date of the bacteriologic check.	Not found.	None.
Transplantation of Human Tissue	21 CFR § 1270.33(h): All persons or establishments that generate records used in determining the suitability of the donor of human tissue for transplantation shall retain the records for at least ten (10) years beyond the date of transplantation, if known, distribution, disposition or expiration of the tissue.	Not found.	None.
Local Health Department Venereal Disease	Mich. Admin. Code R 325.177: Shall retain records for not less than five (5) years, as required under the Administrative Code, after the last reactive test in Syphilis cases; for not less than one (1) year for other venereal diseases, and for not less than three (3) calendar years after the termination of pregnancy.	Not found.	None.

CLINICAL LABORATORY/PATHOLOGY

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
General Laboratory	<p>42 § 493.1105(a): The laboratory must retain its records and, as applicable, slides, blocks, and tissues as follows:</p> <p>(1) Test requisitions and authorizations. At least two (2) years.</p> <p>(2) Test procedures. At least two (2) years after a procedure has been discontinued.</p> <p>(3) Analytic systems records. At least two (2) years.</p> <p>(4) Proficiency testing records. At least two (2) years.</p> <p>(5) Laboratory quality systems assessment records. At least two (2) years.</p> <p>(6) Test reports. At least two (2) years.</p> <p>(7) Slide, block, and tissue retention as:</p> <p>(i)(A) Retain cytology slide preparations for at least five (5) years from the date of examination.</p> <p>(B) Retain histopathology slides for at least ten (10) years from the date of examination.</p>	<p>Clinical Laboratory Improvement Amendments of 1988 (CLIA 88): The College of American Pathologists makes the following recommendations for the minimum requirements for the retention of laboratory records and materials:</p> <p>Accession Log: Two (2) years.</p> <p>Maintenance/Instrument Maintenance Records: Two (2) years.</p> <p>Quality Control Records: Two (2) years.</p>	<p>The College of American Pathologists' recommendations meet or exceed the regulatory requirements specified in the Clinical Laboratory Improvement Amendments of 1988. It may be appropriate for laboratories to retain records and/or materials for a longer period of time when required for patient care, education, quality improvement, or other needs. Some state regulations as well as other federal mandates may require retention of records and/or materials for a longer time period than that specified in the CLIA 88 regulations; therefore any applicable state or federal laws should be reviewed carefully when individual laboratories develop their record retention policies.</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>(ii) Blocks. Retain pathology specimen blocks for at least two (2) years from the date of examination.</p> <p>(iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made.</p>		
Surgical Pathology (Including Bone Marrows)	42 CFR § 493.1257(g): The laboratory must retain all slide preparations for five (5) years from the date of examination, or slides may be loaned to proficiency testing programs, in lieu of maintaining them for this time period, provided the laboratory receives written acknowledgment of the receipt of slides by the proficiency testing program and maintains the acknowledgement to document the loan of such slides. Documentation for slides loaned or referred for purposes other than proficiency testing must also be maintained. All slides must be retrievable upon request.	<p>Clinical Laboratory Improvement Amendments of 1988 (CLIA 88): The College of American Pathologists makes the following recommendations for the minimum requirements for the retention of laboratory records and materials:</p> <p>Wet Tissue: Two (2) weeks after final report.</p> <p>Paraffin Blocks: Ten (10) years.</p> <p>Slides: Ten (10) years.</p> <p>Reports: Ten (10) years.</p>	42 CFR § 493.1103: Laboratory must have available written policies and procedures for specimen collection, specimen labeling, specimen preservation, conditions for specimen transportation and specimen processing.
Cytology	42 CFR § 493.1257(g): The laboratory must retain all slide preparations for five (5) years from the date of examination, or slides may be loaned to proficiency testing programs, in lieu of maintaining them for this time period, provided the laboratory receives written acknowledgment of the receipt of slides by the proficiency testing	Clinical Laboratory Improvement Amendments of 1988 (CLIA 88): The College of American Pathologists makes the following recommendations for the minimum requirements for the retention of laboratory records and materials:	42 CFR § 493.1221: The laboratory must retain all records and slide preparations as specified in § 493.1105.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	program and maintains the acknowledgement to document the loan of such slides. Documentation for slides loaned or referred for purposes other than proficiency testing must also be maintained. All slides must be retrievable upon request.	<p>Slides (Negative-Unsatisfactory): Five (5) years.</p> <p>Slides (Suspicious-Positive): Five (5) years.</p> <p>Fine-Needle Aspiration Slides: Ten (10) years.</p> <p>Reports: Ten (10) years.</p>	
Non-Forensic Autopsy Records	Not found.	<p>Clinical Laboratory Improvement Amendments of 1988 (CLIA 88): The College of American Pathologists makes the following recommendations for the minimum requirements for the retention of laboratory records and materials:</p> <p>Wet Tissue: Three (3) months after final report.</p> <p>Paraffin Blocks: Ten (10) years.</p> <p>Slides: Ten (10) years.</p> <p>Reports: Ten (10) years.</p>	None.
Histopathology	42 CFR § 493.1259(b): The laboratory must retain stained slides for at least ten (10) years from the date of examination and retain specimen blocks at least two (2) years from date of examination.	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Immunochemistry	<p>42 CFR § 493.1107; 42 CFR § 493.1109: The laboratory must retain immunochemistry records for not less than five (5) years.</p> <p>42 CFR § 606.160(d): Records must 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. Individual product records must be retained for not less than ten (10) years after the records of processing are completed or six (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.</p>	Not found.	None.
Forensic Autopsy Records	Not found.	<p>Clinical Laboratory Improvement Amendments of 1988 (CLIA 88): The College of American Pathologists makes the following recommendations for the minimum requirements for the retention of laboratory records and materials:</p> <p>Wet Stock Tissue: One (1) year.</p> <p>Paraffin Blocks: Indefinitely.</p> <p>Reports: Indefinitely.</p>	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
		<p>Slides: Indefinitely.</p> <p>Gross Photographs/Negatives: Indefinitely.</p> <p>Accession Log: Indefinitely.</p> <p>Body fluids and tissues for toxicology: One (1) year.</p> <p>Representative tissue suitable for DNA Analysis: Indefinitely.</p>	
Clinical Pathology Records	<p>42 CFR § 493.1107; 42 CFR § 493.1109: Records of patient testing, including, if applicable, instrument printouts, must be retained by the testing laboratory for at least two (2) years. Immunohematology records and transfusion records must be retained by the laboratory for at least five (5) years in accordance with 21 CFR part 606, subpart 1. In addition, records of blood and blood product testing must be maintained for at least five (5) years after completion of processing records or six (6) months after latest expiration date, whichever is later, in accordance with 21 CFR § 606.160(d). Pathology test reports must be retained for at least ten (10) years after the date of report. This information may be maintained as part of patient's chart or medical record which must be readily available to the lab</p>	<p>Clinical Laboratory Improvement Amendments of 1988 (CLIA 88): The College of American Pathologists makes the following recommendations for the minimum requirements for the retention of laboratory records and materials:</p> <p>Patient Test Records: Two (2) years.</p> <p>Serum/Heparinized or EDTA Plasma/CSF/Body Fluids (except urine): Forty-eight (48) hours.</p> <p>Urine: Twenty-four (24) hours.</p> <p>Peripheral Blood Smears/Body</p>	<p>42 CFR § 493.1107: The record system must provide documentation of information specified in Sec. 493.1105(a) through (f) and include the information specified in Sec. 493.1107(a) through (d).</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	and HHS.	<p>Fluid Smears: Seven (7) days.</p> <p>Permanently Stained Slides-Microbiology (gram, trichrome, etc.): Seven (7) days.</p>	
Cytogenetic Records	Not found.	<p>Clinical Laboratory Improvement Amendments of 1988 (CLIA 88): The College of American Pathologists makes the following recommendations for the minimum requirements for the retention of laboratory records and materials:</p> <p>Permanently-Stained Slides: Three (3) years.</p> <p>Fluorochrome-Stained Slides: At the discretion of the laboratory director.</p> <p>Wet Specimen/Tissue: Until adequate metaphase cells obtained.</p> <p>Fixed Cell Pellet: Two (2) weeks after final report.</p> <p>Final Reports: Twenty (20) years.</p> <p>Diagnostic Images (digitized or</p>	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
		negatives):	
Flow Cytometry	Not found.	<p>Clinical Laboratory Improvement Amendments of 1988 (CLIA 88): The College of American Pathologists makes the following recommendations for the minimum requirements for the retention of laboratory records and materials:</p> <p>Gated Dot Plots and Histograms: Ten (10) years.</p>	None.
Blood Bank Records	<p>42 CFR § 606.160(d): Records must 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. Individual product records must be retained for not less than ten (10) years after the records of processing are completed or six (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.</p> <p>42 CFR § 493.1107: Clinical laboratories must retain records of blood and blood product testing for not less than five (5) years after processing records have been completed, or six (6) months after latest expiration date, whichever date is later, in</p>	<p>Clinical Laboratory Improvement Amendments of 1988 (CLIA 88): The College of American Pathologists makes the following recommendations for the minimum requirements for the retention of laboratory records and materials:</p> <p>Donor and Recipient Records: Ten (10) years.</p> <p>Records of Employee Signatures, Initials and Identification Codes: Ten (10) years.</p> <p>Quality Control Records: Ten (10) years.</p>	<p>21 CFR § 610.45: Each donation of human blood or blood components intended for use in preparing a product shall be tested for antibody to HIV by a test approved for use by FDA.</p> <p>MCL § 333.9123(1): A person who procures or collects blood or human tissues, organs, or other specimens for purposes of transplantation, transfusion, introduction, or injection into a human body shall test or provide for the testing of each potential donor or each sample or specimen of blood or tissue, or each organ or other human specimen for the presence in the donor, sample, specimen, or organ of HIV or an</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	accordance with 21 CFR § 606.160(d).	<p>Records of Indefinitely Deferred Donors, Permanently Deferred Donors, or Donors Placed Under Surveillance for the Recipient's Protection: Indefinitely.</p> <p>Specimens From Blood Donor Units and Recipients: Seven (7) days post-transfusion.</p>	<p>antibody to HIV.</p> <p>MCL § 333.11101: An individual shall not donate or sell his/her blood or blood products knowing that (s)he has tested positive for the presence of HIV or an antibody to HIV.</p>
Quality Control/Assurance Activities for Moderate and High Complexity Tests	<p>42 CFR § 493.1721: The laboratory must maintain documentation of all quality assurance activities, including problems identified and corrective actions taken. All quality assurance records must be available to HHS and maintained for a period of two (2) years.</p> <p>42 CFR § 493.1257(b)(3): Cytology. The laboratory must maintain the total number of slides examined by each individual during each twenty-four (24)-hour period. No more than one-hundred (100) sides may be examined in an eight (8)-hour workday.</p> <p>42 CFR § 493.1257(c)(4)(ii). Records must be available to document that each individual's workload unit is reassessed at least every six (6) months and adjusted as necessary.</p> <p>42 CFR § 493.1259(b) and (c).</p>	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	Histopathology. (b) The lab must retain stained slides at least ten (10) years from the date of examination and retain specimen blocks at least two (2) years from the date of examination. (c) The lab must retain remnants of tissue specimens in a manner that assures proper preservation of the tissue specimens until the portions submitted for microscopic exam have been examined and a diagnosis made by an individual qualified under 493.1449(b) or 493.1449 (1)(1).		
Laboratory Procedures	42 CFR § 493.1211(g): The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance. These records must be retained for two (2) years after a procedure has been discontinued.	Not found.	None.
Laboratory Test Report, Errors	42 CFR § 493.1219(d)(3): When errors in the reported patient test results are detected, the laboratory must retain exact duplicates of the original report and corrected report for two (2) years.	Not found.	Exact duplicate defined in 42 CFR § 493.1109.
Laboratory Test Requisitions	42 CFR § 493.1105: The laboratory must maintain the written authorization for testing or documentation of efforts made to obtain a written authorization. Records of test requisitions or test authorizations must be retained for at least two (2) years and must be available to the laboratory at the time of testing and HHS upon request.	Not found.	None.

EMPLOYEE HEALTH

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Employee Exposure	<p>29 CFR § 1910.1020(d)(1)(ii): Employee exposure records must be retained for at least thirty (30) years, subject to exceptions noted in regulation (see comments).</p> <p>Mich. Admin. Code R 325.3457: Records concerning employee exposure to toxic substances or harmful physical agents must be maintained for at least thirty (30) years, subject to exceptions noted in regulation (same as 29 CFR § 1910.1020(d)(1)(ii)).</p> <p>See also Mich. Admin. Code R 325.51474(5)(a): (formaldehyde).</p>	Not found.	<p>29 CFR § 1910.1020(d)(1)(ii):</p> <p>Exceptions:</p> <p>(A) Background data to environmental (workplace) monitoring or measuring, such as laboratory reports and worksheets, need only be retained for one (1) year, so 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;</p> <p>(B) Material safety data sheets and chemical inventory 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; and</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
			<p>(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.</p> <p>Mich. Admin. Code R 325.3453(a): “Records” includes paper documents, microfilm, microfiche, x-ray, or automated data processing.</p> <p>Mich. Admin. Code R 325.3459: Form, manner, and process of preserving a record is not mandated as long as record is preserved and retrievable, EXCEPT chest x-ray films shall be preserved in original form.</p> <p>Mich. Admin. Code R 325.3458: Each analysis using exposure or medical records must be preserved and retained for not less than thirty (30) years, except for the transfer or disposal of records pursuant to R. 325.3475.</p>
Employee Medical Record	29 CFR § 1910.1020(d)(1)(i): Employee medical records must be retained for at least the duration of employment plus thirty (30)	Not found	29 CFR § 1910.1020(d)(1)(i): Exceptions: The following types of records need not be retained for

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>years, subject to exceptions noted in regulation (see comments).</p> <p>Mich. Admin. Code R 325.3456: Employee medical records must be maintained for the duration of employment plus thirty (30) years, subject to exceptions noted in regulation (same as 29 CFR 1910.1020(d)(1)(i))</p> <p>See also, Mich. Admin. Code R325.51474(5)(b): (formaldehyde).</p>		<p>any specified period:</p> <p>(A) Health insurance claims records maintained separately from employer's medical program and its records;</p> <p>(B) First aid records (not including medical histories) of one-time treatment and subsequent observation [...] if made on-site by a non-physician and if maintained separately from the employer's medical program and its records; and</p> <p>(C) Medical records of employees who have worked less than one year for the employer need not be retained beyond the term of employment if records are provided to employee upon termination.</p>
Employee Occupational Illnesses and Injuries (Log & Summary)	<p>29 CFR 1904.33(a): The OSHA 300 Work-Related Injuries and Illness log, privacy case list (if one exists), annual summary and the OSHA 301 Incident Report forms must be maintained for five (5) years following the end of the calendar year that these records cover.</p> <p>Mich. Admin. Code R 408.22133: The</p>	Not found	<p>See also recording criteria for:</p> <p>29 CFR § 1904.4; R 408.22112: general</p> <p>29 CFR § 1904.8; R 408.22113: needlestick and sharps injuries</p> <p>29 CFR § 1904.9; R 408.22114:</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>MIOSHA 300 Log of Work Related Injuries and Illnesses, the privacy case list (if one exists), 300-A Annual Summary of Work Related Injuries and Illnesses, and the MIOSHA 301 Injury and Illness Incident Report forms (related to occupational injuries and illnesses as defined under 408.22107) must be retained for five (5) years following the end of the calendar year that these records cover.</p>		<p>medical removal</p> <p>29 CFR § 1904.10; R 408.22115: occupational hearing loss</p> <p>29 CFR § 1904.11; R 408.22117: work-related tuberculosis</p>
<p>Occupational Noise Exposure</p>	<p>29 CFR §1910.95(m)(3): (i) Noise exposure measurement records must be maintained for two (2) years.</p> <p>(ii) Audiometric test records must be retained for duration of the affected employee's employment.</p> <p>Mich. Admin. Code R 325.60126(1): Employer shall retain records required in R 325.60125 for at least the following periods: (a) Noise exposure measurement records for two (2) years; and (b) Audiometric test records for the duration of the affected employee's employment.</p>	<p>Not found</p>	<p>Mich. Admin. Code R 325.60125: Employer shall maintain accurate records of:</p> <ul style="list-style-type: none"> • All employee exposure measurements (required by R 325.60108 to 325.60111); • Employee audiograms (obtained pursuant to provisions of R 325.60112 to R 325.60114); and • Measurements of the background sound pressure levels in audiometric test rooms (required by R 325.60119(5)). <p>Mich. Admin. Code R325.60126(2): Records required by R 325.60125 must be provided on request to the employee or former employee or representative, and MIOSHA officials.</p> <p>Mich. Admin. Code R</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
			<p>325.60126(3): If employer ceases doing business, records must be transferred to and maintained by the successor employer for the remainder of the period or other specified periods.</p> <p>See also 29 CFR 1904.10 and R 408.22115: Recording criteria for occupational hearing loss.</p>
Radiation Exposure for Portable X-Ray Services – Monitoring	42 CFR 486.108(j): Exposure to radiation of each person operating portable x-ray equipment is evaluated at least monthly. Records of each person’s exposure must be maintained by supplier of portable x-ray services. No retention period is specified.	Not found.	None
Fixed Radiographic Installations	<p>Mich. Admin. Code - Personnel exposure: Records shall be kept on permanent available file at the facility where exposure occurs, as required by:</p> <p>(1) R 325.5317 for therapeutic machines operated above 85 KVP;</p> <p>(2) R 325.5333 for fixed radiographic installations;</p> <p>(3) R 325.5348 for fixed fluoroscopic installations (x-ray equipment); and</p> <p>(4) R325.5366 for medical extremity x-ray installations.</p>	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Respirators, Employee Exposure	<p>29 CFR § 1910.134(h)(3):</p> <p>(i)(B): Respirators for emergency use must be inspected at least monthly and in accordance with the manufacturer's recommendations, and must be checked for proper function before and after each use.</p> <p>(iv) Employers must:</p> <p>(A) Certify the respirators by documenting the date the inspection was performed, the name (or signature) of the person who made the inspection, the findings, required remedial action, and a serial number or other means of identifying the inspected respirator; and</p> <p>(B) Provide this information on a tag or label that is attached to the storage compartment for the respirator, is kept with the respirator, or is included in inspection reports. The information shall be maintained until replaced following a subsequent certification. No retention period is specified.</p> <p>29 CFR § 1910.134(c): Employer must develop and implement a written respiratory protection program, and update it as necessary, with required work-specific procedures and elements for required respirator. No retention period is specified.</p>	Not found.	Mich. Admin. Code R 325.60052 adopts federal standards at 29 CFR 1910.134, by reference.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>29 CFR § 1910.134(m): Employer must establish and retain written information regarding medical evaluations, fit testing, and the respirator program.</p> <p>(1) Medical evaluations must be retained and made available in accordance with 29 CFR § 1910.1020.</p> <p>(2)(i) The employer shall establish a record of the qualitative and quantitative fit tests administered to an employee.</p> <p>(2)(ii) Fit test records shall be retained for respirator users until the next fit test is administered.</p> <p>(3) A written copy of the current respirator program shall be retained by the employer.</p> <p>(4) Written materials required to be retained shall be made available upon request to affected employees and to the Assistant Secretary or designee for examination and copying. No retention period is specified.</p> <p>See also 29 CFR § 1910.134(e)-(g):</p> <p>(e) Medical evaluations;</p> <p>(f) Fit testing; and</p> <p>(g) Use of respirators</p>		
X-ray Technicians for	42 CFR 486.104(c): Employee records must	Not found.	42 CFR 486.104(a),(b): Specifies

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Portable X-Ray Services – Training	<p>be retained showing that each person is qualified for position by training and experience and receives adequate health supervision. Not retention period is specified.</p> <p>Mich. Admin. Code R 325.5396: Training on use of hand-held portable dental x-ray systems is required and records must be maintained for examination by the Department. No retention period is specified.</p>		<p>qualifications of technologists and topics of instruction which must be covered in orientation program by supplier of portable X-ray services.</p>

EQUIPMENT AND SUPPLY MANAGEMENT

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Exposure Records	<p>10 CFR § 34.83: Each license must maintain the following exposure records:</p> <p>(a) Direct dosimeter readings and yearly operability checks required by 10 CFR § 34.47 (b) and (c) for three (3) years after the record is made.</p> <p>(b) Records of alarm ratemeter calibrations for three (3) years after the record is made.</p> <p>(c) Personnel dosimeter results received from the accredited NVLAP processor until the Nuclear Regulatory Commission terminates the license.</p> <p>(d) Records of estimates of exposures as a result of: off-scale personal direct reading dosimeters, or lost or damaged personnel dosimeters, until the Commission terminates the license.</p>	Not found.	None.
Industrial Radiography – Training and Certification	10 CFR § 34.79: Each licensee must maintain records of training and certification for three (3) years after the record is made.	Not found.	<p>10 CFR § 34.79: The following shall be maintained for three (3) years:</p> <p>(a) Records of training of each radiographer and each radiographer's assistant. The records must include radiographer certification documents and</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
			<p>verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations; and</p> <p>(b) Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and his/her assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliances observed by the RSO.</p>
Inspection and Maintenance of Radiographic Exposure Devices, Storage Containers, and Source Change	<p>10 CFR § 34.31 (b)(1): The licensee must conduct a program for inspection and maintenance at intervals not to exceed three (3) months or before the first use thereafter.</p> <p>10 CFR § 34.73(a): The licensee must retain records of equipment problems found in daily checks and quarterly inspections of radiographic exposure devices, transport and storage containers, associated</p>	<p>Not found.</p>	<p>10 CFR § 34.73(b): The record must include the date of check or inspection, name of inspector, equipment involved, and any problems found, and what repair and/or maintenance, if any, was done.</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	equipment, source changers, and survey instruments for three (3) years after it is made.		
Sealed Sources – Inventory Receipts and Transfers; Leak Testing	<p>10 CFR § 34.69(a): Each licensee must retain records of the quarterly inventory of sealed sources and of devices containing depleted uranium (DU) as required by § 34.29 for three (3) years from the date of inventory.</p> <p>10 CFR § 34.29(a): Each licensee must conduct a quarterly physical inventory to account for all sealed sources and for devices containing DU received and possessed under this license.</p> <p>10 CFR § 34.67: Each licensee must retain records of leak test results for devices containing DU for three (3) years after the record is made or until the source in storage is removed.</p>	Not found.	None.
Medical Device Tracking Records	21 CFR § 821.60: The records must be retained for the useful life of device being tracked.	Not found.	21 CFR § 821.60: 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.
Investigator – in Clinical	21 CFR § 812.140(d): An investigator or	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Devices	sponsor must maintain records for two (2) years after the latter of the following two (2) 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 pre-market approval application or a notice of completion of product development.		
Radiation Survey Instruments	10 CFR § 34.65: Each licensee must maintain records of calibrations of radiation survey instruments required under 10 CFR § 34.25 for three (3) years after it is made.	Not found.	None.
Radioisotopes – Receipt, Transfer, Use, Storage, Delivery and Disposal	<p>10 CFR § 30.51(a)(1): The licensee must retain record of receipt of byproduct material as long as material is possessed for three (3) years following transfer or disposal of material.</p> <p>10 CFR § 30.51(a)(2): The licensee who transferred the byproduct material must retain each record of transfer for three (3) years after transfer unless a specific requirement in another part of the regulations in this chapter dictates otherwise.</p> <p>10 CFR § 30.51(a)(3): The licensee who disposed the material must retain each record of disposal of byproduct material until the Commission terminates each license that authorizes disposal of the material.</p>	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	10 CFR § 30.51(b): If retention period is not otherwise specified, the record must be retained until the Commission terminates each license that authorizes the activity that is subject to the recordkeeping requirement.		
Utilization Logs for Sealed Source	10 CFR § 34.71(b): Each licensee must maintain utilization logs for three (3) years after the log is made.	Not found.	None.
X-ray Equipment for Portable X-ray Services – Inspection	42 CFR § 486.110: The supplier of the x-ray services must retain records of current inspections of all x-ray equipment and shielding. Inspection must be done at least every two (2) years by a radiation health specialist who is on the staff of or approved by an appropriate State or local government agency. The supplier maintains records of current inspections which include the extent to which equipment and shielding are in compliance with the safety standards outlined in § 486.108. No retention period is specified.	Not found.	None.

HIPAA PRIVACY REQUIREMENTS

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Consent Forms	<p>45 CFR § 164.508: Subject to limited exceptions, privacy regulations require covered entities and business associates to obtain an individual's consent prior to using or disclosing protected health information.</p> <p>45 CFR § 164.530(j): A covered entity and a business associate must retain the documentation required by paragraph (j) of this section for six years from the date of its creation or the date when it last was in effect, whichever is later.</p>	Not found.	<p>45 CFR § 164.104: Certain entities called "covered entities" and "business associates" must comply with privacy regulations adopted pursuant to the Health Insurance Portability and Accountability Act ("HIPAA"). Covered entities generally include health plans, health care clearinghouses and health care providers who transmit health information in electronic form. The privacy regulations set forth certain record retention requirements.</p> <p>45 CFR § 160.103: Protected health information means individually identifiable health information that is transmitted or maintained in any form or medium.</p>
Authorizations	<p>45 CFR § 164.508: Subject to limited exceptions, covered entities and business associates may not use or disclose protected health information without an authorization.</p> <p>45 CFR § 164.530(j): Authorizations must be retained for six years from the date of its creation or the date when it last was in effect, whichever is later.</p>	Not found.	None.
Notice of Privacy Practices	45 CFR § 164.520(a): Covered entities and	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>business associates generally must provide individuals with adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and the individual's rights and the covered entity's legal duties with respect to protected health information.</p> <p>45 CFR § 164.530(j): These notices must be retained for at least 6 years from the date the notice was created or the date when it was last in effect, whichever is later.</p>		
Policies and Procedures	<p>45 CFR § 164.530(i)(1): Covered entities and business associates must implement policies and procedures with respect to protected health information that are designed to comply with the privacy regulations.</p> <p>45 CFR § 164.530(j): These policies and procedures must be retained for at least 6 years from their date of creation or the date they are last in effect, whichever is later.</p>	Not Found.	None.

MANAGED CARE ORGANIZATIONS

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
HMOs and Alternative Health Care Delivery and Financing Systems	Not found.	Not found.	<p>NOTE: Section 417 applies only to 1876 Cost Plans. Medicare Advantage and Prescription Drug Plans are subject to Sections 422 and 423.</p> <p>42 CFR § 417.142(b)(2)(iv): HMO must provide access to CMS and the Comptroller General or any of their duly authorized representatives for the purpose of audits, examination or evaluation to any books documents, papers and records of the entity relating to its operation as an HMO, and to any facilities that it operates.</p> <p>42 CFR § 422.504(e)(1)(iv); 42 CFR 423.505(e)(1)(iv): HHS has right to evaluate, through inspection, audit, or other means enrollment and disenrollment records for the current contract period and ten (10) prior periods.</p> <p>422.504(e)(4); 423.405(e)(4): HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through ten (10) years from the</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
			end of the final contract period or completion of audit, whichever is later unless an exception applies, in which case CMS may extend the retention period.
Medicare Cost Plans	<p>42 CFR § 417.416(e)(2): An HMO or CMP must maintain a health (including medical) record keeping system through which information pertinent to the health care of its Medicare enrollees is accumulated and readily available to appropriate professionals.</p> <p>42 CFR § 417.480: A reasonable cost contract must provide that an HMO or CMP agrees to maintain certain books, records, documents and other evidence of accounting procedures and practices, including medical and financial information.</p> <p>42 CFR § 417.481: A risk contract must provide that an HMO or CMP agrees to maintain and make available to CMS upon request, books, records, documents, and other evidence of accounting procedures and practices, including at least any records or financial information filed with other Federal agencies or State authorities.</p> <p>42 CFR § 417.482(d): The contract must provide that the HMO or CMP agrees to</p>	Not found.	<p>Medicare Managed Care Manual, Chapter 2, Section 60.8: It is appropriate to allow for storage on microfilm, as long as microfilm versions of enrollment forms and disenrollment requests showing the signature and the date are available to reviewers. Similarly, other technologies that would allow the reviewer to access signed forms and other enrollment requests may also be allowed, such as optically scanned forms stored on disk.</p> <p>MCL § 500.3547: (2) The Commissioner (a) shall have access to all information of the HMO relating to the delivery of health services, including, but not limited to, books, papers, computer databases, and documents, in a manner that preserves the confidentiality of the health records of individual enrollees.</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>allow HHS to evaluate, through inspection or other means, the enrollment and disenrollment records for the current contract period and three (3) prior periods, when there is reasonable evidence of some need for that inspection.</p> <p>42 CFR § 417.482(f): The contract must provide that the HMO or CMP gives HHS the right to inspect, evaluate and audit records regarding services furnished to Medicare enrollees for three (3) years from date of final settlement for any contract period, subject to certain exceptions.</p>		<p>MCL § 500.3548: An HMO shall keep all of its books, records, and files at or under the control of its principle place of doing business in this state, and shall keep a record of all of its securities, notes, mortgages, or other evidences of indebtedness representing investment of funds at its principle place of doing business in this state in the same manner as provided for in section 5256.</p>
<p>Medicare Advantage Organizations and Prescription Drug Plans</p>	<p>42 CFR § 422.60(c)(2): The organization must file and retain election forms for the period specified in the CMS instructions.</p> <p>Medicare Managed Care Manual, Chapter 2, Section 60.9: The MA Organization must retain enrollment and disenrollment records for the current contract period and ten (10) prior periods.</p> <p>42 CFR § 422.504(d): The MA organization agrees to maintain for ten (10) years books, records, documents, and other evidence of accounting procedures and practices.</p> <p>Medicare Managed Care Manual, Chapter 11, Section 110.4.3: The MA Organization</p>	<p>Not found.</p>	<p>None.</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>must maintain books, records, documents, and other evidence of accounting procedures and practices for ten (10) years from the end date of an MA contract or the completion date of an audit, whichever is later.</p> <p>42 CFR § 423.505(d): The Part D plan sponsor agrees to maintain, for ten (10) years, books, records, documents, and other evidence of accounting procedures and practices.</p>		
Medicaid Plans	<p>42 USC § 1396(a)(27): A State plan for medical assistance must provide for agreements with every person or institution providing services under the State plan under which such person or institution agrees (A) to keep such records as are necessary fully to disclose the extent of the services provided to individuals receiving assistance under the State plan, and (B) to furnish the State agency or the Secretary with such information, regarding any payments claimed by such person or institution for providing services under the State plan, as the State agency or the Secretary may from time to time request.</p> <p>42 CFR § 434.6(a)(7): Medicaid Contract must require that contractor maintain an appropriate record system for services to enrolled recipients.</p>	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>State Medicaid Manual (CMS Pub. 45-2) 2080.13: Contractor must maintain appropriate record system for services to enrolled recipient. The record system must provide data in an accurate and current form useful to Federal and State program agencies monitoring and managing the program, as well as data useful for monitoring program performance in quality and accessibility and completion of services.</p> <p>State Medicaid Manual (CMS Pub. 45-2) 2080.14: Records should be retained in accordance with 45 CFR Part 74, Appendix G, Paragraph 14.h. General record retention requirement is three (3) years after final payment is made and all pending matters are closed, plus an additional period if an audit, litigation, or other legal action involving the records is started before or during the original three (3)-year period.</p> <p>State Medicaid Manual (CMS Pub. 45-2) 2080.16: HMOs and CMPs must maintain records in a manner as to assure that all monies collected from third-party resources may be identified on behalf of medical assistance recipients. No time frame is specified.</p>		
HMO (general rules – MI)	MCL § 500.3528: An HMO shall: (a)	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>establish written policies and procedures for credentialing verification of all health professionals with whom the HMO contracts and shall apply these standards consistently; and (e) retain all records and documents relating to a health professional's credentialing verification process for at least two (2) years.</p> <p>1988 Mich. Admin. Code R 325.6801(1): An HMO must maintain a clinical patient record in accordance with accepted professional standards and practices.</p> <p>1988 Mich. Admin. Code R 325.6805(1): An HMO must maintain a unit clinical record with certain required identifying and medical information.</p> <p>1988 Mich. Admin. Code R 325.6810(2): Inactive records must be safely stored and preserved electronically or as an original record or microfilm. The HMO must adopt a policy concerning the length of time and provisions for retention of inactive clinical records, which must include a contingency plan for retention of existing records in the event of cessation of operations. No retention period is specified.</p> <p>Mich. Admin. Code R 325.6365: An HMO must (1) establish an internal enrollee</p>		

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p data-bbox="506 272 1073 488">grievance procedure for approval by the insurance bureau; and (2) retain copies of all complaints and responses at its principle office for inspection by the Department for two (2) years following the year the complaint was filed.</p> <p data-bbox="506 529 1073 1143">Mich. Admin. Code R 500.668(1): Each insurer must retain a file of all printed, published, or prepared advertisements of its individual policies and typical printed, published, or prepared advertisements of its blanket, franchise, and group policies and certificates disseminated in this state, with a notation attached to each advertisement indicating the manner and the extent of distribution and the form number of any policy advertised. This must be maintained in the file for a period from the previous regular report on examination through the next report on examination. Following the completion of a regular report on examination, noncurrent advertising material may be removed from the file.</p>		

MEDICAL WASTE

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Hazardous Waste	<p>MCL 324.11138(1)(a)-(h): A generator of hazardous waste must: compile and maintain information and records regarding the quantities of hazardous waste generated, characteristics and composition of the hazardous waste and the disposition of hazardous waste; provide the information on the manifest as required under section 11135(1) to each person transporting, treating, storing, or disposing of hazardous waste; keep all records readily available for review and inspection by the department, the department of state police, a peace officer, or a representative of the United states environmental protection agency; and compile and submit a periodic report of hazardous waste generated, stored, transferred, treated, disposed of, or transported for treatment, storage, or disposal as required by the department.</p> <p>All records must be kept for three (3) years. This period is automatically extended during the course of any unresolved enforcement action regarding the regulated activity or as required by the department.</p> <p>2008 Mich. Admin. Code R 299.9307(1)-(5): A generator of hazardous waste shall: keep records of test results, waste analyses,</p>	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>or other determinations for at least three (3) years from the date that the waste was last sent to on-site or off-site treatment, storage or disposal; keep a copy of each manifest signed pursuant to R 299.9304(2) for three (3) years or until receipt of a signed copy from the designated facility which received the waste, which signed copy must be kept for at least three (3) years from the date the waste was accepted by the initial transporter; keep a copy of the data submitted under R 299.9308(1), exception report or other report required by the director, or his/her designee, for at least three (3) years from the due date of the report; and keep the documentation required pursuant to R 299.9503(1)(i)(ix) for at least three (3) years from the date that the waste was treated.</p> <p>A generator who generates more than 100 kilograms but less than 1,000 kilograms of hazardous waste in a calendar month is exempt from this requirement.</p> <p>Retention periods are automatically extended during course of any unresolved enforcement action regarding the regulated activity or as requested by the director.</p> <p>Mich. Admin. Code R 299.9609: An owner or operator of a hazardous waste treatment,</p>		

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>storage or disposal facility shall keep an operating record at his/her facility or in an alternative location approved by the director or the director's designee, including information required by federal regulation, construction permits or operating licenses, until closure of the facility. Retention periods are automatically extended during the course of any unresolved enforcement action regarding the facility or as requested by the director.</p>		
Medical Waste	<p>MCL 333.13813(1): Each medical waste producing facility must file a registration form with the department and must have a written medical waste management plan on the premises within ninety (90) days after registration. No retention period is specified. See also MCL 333.13817.</p> <p>MCL 333.13813(3): Certificates of registration are valid for three (3) years from date of issuance. No retention period specified.</p> <p>Mich. Admin. Code R 325.1544: Medical waste producing facilities shall perform certain tests of their decontamination or sanitization equipment and must retain the testing data and results from the most recent test performed for inspection by the department.</p>	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>Mich. Admin. Code R 325.1547(4)-(5): A facility that produces medical waste shall create and retain a record of training for employees who handle medical waste. The training records must include the employee's name, job classification and dates of training. The training records shall be retained for at least three (3) years.</p>		

MENTAL HEALTH SERVICES

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Clinical Information	<p>42 CFR § 412.27(c): Psychiatric units must maintain medical records that permit determination of degree and intensity of treatment provided to individuals who are furnished services in the unit, the development of assessment/diagnostics of patient's condition, psychiatric evaluation, treatment plan, progress notes, and discharge plan and summary. No retention period is specified.</p> <p>42 CFR § 482.60(c): Psychiatric hospital must maintain clinical records on all patients, including records sufficient to permit CMS to determine degree and intensity of treatment furnished to Medicare beneficiaries. No retention period is specified.</p> <p>42 CFR § 482.61: Psychiatric hospital clinical records must include the items described in this section, especially determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution. No retention period is specified.</p> <p>42 CFR § 482.24(b)(1): Hospital medical records must be retained in their original or legally reproduced form for a period of at</p>	<p>American Health Information Management Association, Recommended Standards for Retention:</p> <p>Patient health records (adults): Ten (10) years after most recent encounter.</p> <p>Patient health records (minors): Age of majority plus statute of limitations.</p> <p>Community Health Accreditation Program (CHAP), C25C: Records of adult patients must be retained for at least five years from the date of service and patient records for minors must be retained for seven years beyond the age of majority.</p> <p>Community Health Accreditation Program (CHAP), C27C: The records of occupationally exposed patients must be kept for thirty (30) years.</p>	<p>Mich. Admin. Code R 330.1276: Covers detailed contents records to be maintained by a licensee and made available for examination by the department, including records relating to employees, personnel, patients.</p> <p>Mich. Admin. Code R 330.1276(3): Covers contents of medical records of patients.</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>least 5 years.</p> <p>MCL § 330.1141: A licensee under the Mental Health Code must maintain a record for each patient. The record must contain at a minimum a written assessment and individual plan of services for the patient, a statement of the purpose of hospitalization or treatment, a description of any tests and examinations performed, and a description of any observations made and treatments provided. No retention period is specified.</p> <p>MCL § 330.1746: A complete record must be kept current for each recipient of mental health services. The record must at least include information pertinent to the services provided to the recipient, pertinent to the legal status of the recipient, required by this chapter or other provision of law, and required by rules or policies. This material shall remain confidential as accorded by section 748. No retention period is specified.</p> <p>Mich. Admin. Code R 330.1276: A licensed mental health hospital or unit must maintain confidential, current and accurate records of a multitude of sorts describe by this rule, and make them available for examination by the Department. No retention period is specified.</p>		

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Corporate and Administrative Records	Mich. Admin. Code R 330.1276: A licensed mental health hospital or unit must maintain records and make them available for examination by the Department. No retention period is specified.	Not found.	<p>Mich. Admin. Code R 330.1276(1): Covers contents of records on various matters, including employee mental health, inspections by fire marshal, execution of fire and disaster plan drills, health inspections, and reports of the joint commission on accreditation of hospitals.</p> <p>Mich. Admin. Code R 330.1276(2): Covers contents of administrative records, discharges, transfers and death, personnel matters, notification of responsible persons in the event of a significant change in the physical or mental condition of a patient, unusual deaths of patients, unusual behavior of patients, incidents regarding patients, and accidents or injuries.</p>
Recipient Rights – Advisory Board	MCL § 330.1758(b): Subject to certain exceptions, each licensed hospital under the Mental Health Code shall appoint a recipient rights advisory committee, which must maintain a current list of the names of members and a separate list of the categories represented by each member (primary consumer, family of primary consumer, or public member), to be made available to individuals upon request.	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Recipient Rights – Compliance	MCL § 330.1755(5)(d): The office of recipient rights of a licensed hospital under the Mental Health Code shall maintain a log of apparent and suspected rights violations within the community mental health services program system or the licensed hospital system, including a mechanism for logging in all complaints and a mechanism for secure storage of all investigative documents and evidence.	Not found.	None.
Recipient Rights – Violations and Remedial Action	MCL § 330.1780: Remedial action regarding substantiated violation of mental health recipient rights shall be documented and made part of the record maintained by the office of recipient rights of a licensed mental health hospital.	Not found.	None.

HOSPITAL & NON-HOSPITAL PROVIDERS

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Hospital Records (Inpatient and Outpatient)	<p>42 CFR § 482.24(b)(1): The hospital must maintain a medical record for each inpatient and outpatient for a period of at least five (5) years.</p> <p>42 CFR § 482.26(d)(2): The hospital must maintain the following radiologic service records for at least five (5) years: (i) copies of reports and printouts; and (ii): films, scans and other image records.</p> <p>42 CFR § 485.638(c): The Critical Access Hospitals must maintain records for at least six (6) years from the date of last entry and longer if required by State statute or if the records may be needed in any pending proceeding.</p> <p>42 CFR 482.24(b)(1): The Acute Care Hospitals must maintain medical records in their original or legally reproduced form for a period of five (5) years.</p> <p>42 CFR § 482.60(c): Psychiatric hospital must maintain clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in § 482.62. No retention period is specified.</p>	<p>Joint Commission RC.01.05.01: The hospital must retain its medical records. The retention time of the original or legally produced medical record is determined by its use and hospital policy, in accordance with law and regulation.</p> <p>American Health Information Management Association (AHIMA):</p> <p>The AHIMA recommends maintaining patient health and medical records for adults for ten (10) years after the most recent encounter.</p> <p>The AHIMA recommends maintaining patient health and medical records for minors until the age of majority plus statute of limitations.</p>	<p>42 CFR § 485.638: All records must document the following:</p> <p>(i) Identification and social data, consent forms, medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;</p> <p>(ii) Reports of physical examinations, diagnostic and laboratory test results;</p> <p>(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications and other pertinent information; and</p> <p>(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.</p> <p>42 CFR 482.24(c)(2): All records must document the following:</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
			<p>(i) Evidence of a physical examination, including a medical history, performed no more than thirty (30) days before or twenty-four (24) hours after admission or registration, but prior to surgery or a procedure require anesthesia services;</p> <p>(ii) Admitting diagnosis;</p> <p>(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient;</p> <p>(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia;</p> <p>(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent;</p> <p>(vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
			<p>laboratory reports, and vital signs and other information necessary to monitor the patient's condition;</p> <p>(vii) Discharge summary with outcome of hospitalization, disposition of case and provisions for follow-up care; and</p> <p>(viii) Final diagnosis with completion of medical records within thirty (30) days following discharge.</p>
Hospital Transfer Records	42 CFR § 489.20(r): Hospitals (both the transferring and receiving hospitals) must maintain medical and other records related to individuals transferred to or from the hospital for a period of five (5) years from the date of transfer.	Not found.	<p>42 CFR § 489.20(r): The hospital must document the following:</p> <p>(1) The list of on-call physicians who can provide care to the patient;</p> <p>(2) Log of each individual coming to the emergency department, whether (s)he refused treatment and whether (s)he was transferred, admitted and treated, stabilized and transferred, or discharged.</p>
Hospital (Radiology)	42 CFR § 482.26(d)(2): The hospital must maintain records of radiologic services for at least five (5) years.	Not found.	<p>42 CFR 482.26(d)(1): The hospital must document the following:</p> <p>(i) Copies of reports and printouts; and.</p> <p>(ii) Films, scans, and other image</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
			records as appropriate.
Hospital (Nuclear Medicine)	42 CFR § 482.53(d)(1): The hospital must maintain copies of nuclear medicine reports for at least five (5) years.	Not found.	42 CFR § 482.53(d): The hospital must maintain signed and dated reports of radiology services and nuclear medicine interpretations, consultations, and procedures and records for the receipt and disposition of radiopharmaceuticals for at least five (5) years.
All Health Providers/Suppliers Covered Entities (Entities governed by HIPAA)	<p>45 CFR § 164.530(j)(2): Entities governed by Health Insurance Portability and Accountability Act must maintain documentation for six (6) years from the date of its creation or the date when it last was in effect, whichever is later.</p> <p>45 CFR § 164.500: Health care clearinghouse</p> <p>45 CFR § 164.506: Uses and disclosures to carry out treatment, payment or health care operations</p> <p>45 CFR § 164.508: Use and disclosure for which an authorization is required</p> <p>45 CFR § 164.514: Other requirements relating to uses and disclosure of PHI</p>	Not found.	<p>45 CFR § 164.530: The entity must retain the following documentation:</p> <p>(i) Policies and Procedures implemented;</p> <p>(ii) Documents related to disclosure of PHI, subject to certain exceptions;</p> <p>(iii) Amendments to PHI;</p> <p>(iv) Requests for accounting of disclosures;</p> <p>(v) Requests for additional protections or confidential communications;</p> <p>(vi) Complaints about practices;.</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
			<p>(vii) Record of workforce training on privacy and security policies and procedures;</p> <p>(viii) Business Associate Agreements;</p> <p>(ix) Notices of Privacy practices; and</p> <p>(x) Details of unauthorized disclosure and measures to prevent such disclosure in future.</p>
Medical Records After Patient's Death	45 CFR § 164.502(g)(4): Entities governed by Health Insurance Portability and Accountability Act must comply with the requirements of HIPAA with respect to the PHI of a deceased individual for a period of fifty (50) years following the death of an individual.	Not Found.	None.
Ambulatory Health Care Facility	<p>42 CFR § 416.47: Ambulatory surgical centers must maintain complete, comprehensive, and accurate medical records. It also must develop and maintain a system for proper collection, storage, and use of medical records. No retention period is specified.</p> <p>2001 Mich. Admin. Code R 325.3835: The facility shall maintain a record of the educational training and experience</p>	Joint Commission RC.01.05.01: The hospital must retain its medical records. The retention time of the original or legally produced medical record is determined by its use and hospital policy, in accordance with law and regulation.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	background of each person granted privileges to perform surgery in a facility. No retention period is specified.		
Comprehensive Outpatient Rehabilitation Facility	42 CFR § 485.60(c): Facility must retain clinical record information for five (5) years after patient is discharged.	Not found.	42 CFR § 485.60(c): Provisions must be made for maintenance of such records in the event facility is no longer able to treat patients.
Dental Facility	MCL § 333.16644(2): A dentist must make a record of all dental treatment which has been performed upon a patient, and must retain that treatment record for a period of not less than ten (10) years after the performance of the last service upon the patient. Mich. Admin. Code R 338.11120(3): A dentist must maintain all dental treatment records for not less than ten (10_ years from date of last treatment provided.	Not found.	Mich. Admin. Code R 338.11120(2): All dental treatment records must document: (a) Dental procedures performed upon the patient; (b) Date of procedure; (c) Identity of the dentist or dental auxiliary performing each procedure; (d) The date, dosage, and amount of any medication or drug prescribed, dispensed, or administered; and (e) Radiographs.
End State Renal Disease Facility	42 CFR § 405.2139(e): Medical records must be retained for time specified in State retention statute or statute of limitations or, in the absence of such State law, five (5) years from discharge; or, in the case of a minor, three (3) years after the patient becomes of age under State law, whichever is longest.	Not found.	Applies to hospital-based as well as freestanding facilities.
Federally Qualified Health Centers	42 CFR § 491.10(c): Patient records must be retained for at least six (6) years from date of last entry, or longer if required by	Not found.	42 CFR § 491.10(a)(3): The record must document:

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	state statute.		<p>(i) Identification and social data, consent forms (evidence), medical history, assessment of health status and health care needs of patient, brief summary of the episode, disposition and instructions to the patient;</p> <p>(ii) Reports of physical examinations, diagnostic and laboratory test results & pertinent information;</p> <p>(iii) All physician's orders, reports of treatments and medications, & other pertinent information necessary to monitor the patient's progress; and</p> <p>(iv) Signatures of the physician or other health care professional;</p> <p>The clinic or center must maintain the confidentiality of record information and provide safeguards against loss, destruction or unauthorized use. The clinic must also maintain written policies and procedures which govern the use and removal of records & the conditions for release of information.</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Home Health Agency	42 CFR § 484.48(a): Retain clinical records for five (5) years after the month the cost report to which the records apply is filed with the intermediary, unless State law stipulates a longer period of time.	Not found.	None.
Hospice	<p>42 CFR § 418.104(d): Hospice must establish and maintain a clinical record for each hospice patient. It must be retained for six (6) years after the death or discharge of the patient, unless State law stipulates a longer period of time.</p> <p>Mich. Admin. Code R 325.13109(1)(t)(v): Records must be retained for not less than five (5) years after death or discharge, or in the case of a minor, three (3) years after the individual come of age under State law, whichever is longer.</p> <p>Mich. Admin Code R 325.13104(3): A hospice shall maintain and make available upon request, written complaints filed under its complaint procedure and all complaint investigation reports delivered to each complaint for three (3) years.</p>	Joint Commission RC.01.01.01: The organization must maintain complete and accurate medical records for each individual patient.	42 CFR 418.104(d): If the hospice discontinues operation, hospice policies must provide for retention and storage of clinical records.
Long Term Care Facility	42 CFR § 483.75(l)(2)(i)-(iii): The facility must maintain clinical records on each resident for: (i) The period of time required by State law; or (ii) Five (5) years from the date of discharge (if there are no State law requirements); or	Joint Commission RC.01.05.01: The organization must retain its medical records. The retention time of medical record information is determined by law and regulation and by its use for resident care, legal, research or	42 CFR § 483.75(l)(5): Clinical records must contain: (i) Sufficient information to identify the resident; (ii) A record of the resident's assessment; (iii) The plan of care and services

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>(iii) For a minor, three (3) years after a minor resident reaches legal age under State law.</p> <p>Mich. Admin Code R 325.21102(6): Retain clinical records for 6 years after discharge or 3 years after individual comes of age if a minor, whichever is longer.</p> <p>Mich. Admin. Code R 325.20113(3): A nursing home shall maintain for three (3) years written complaints filed under its complaint procedure and all complaint investigation reports delivered to each complainant, and such records shall be available to the department upon request.</p> <p>MCL § 333.21782: The licensee shall retain for public inspection: (a) a complete copy of each inspection report of the nursing home received from the department during the past five (5) years; (b) a copy of each notice of a hearing or order pertaining to the nursing home issued by the department or a court for not less than three (3) years after its date of issue or not less than three (3) years after the date of the resolution of the subject matter of the notice or order, whichever is later.</p>	<p>educational purposes.</p> <p>American Health Information Management Association (AHIMA): The AHIMA recommends retaining financial records for Medicare residents for five (5) years after the month the cost report was filed. The AHIMA also recommends permanently retaining a master patient index and admission discharge register and retaining a disease index for ten (10) years.</p>	<p>provided;</p> <p>(iv) The results of any pre-admission screening conducted by the State; and</p> <p>(v) Progress notes.</p> <p>42 CFR § 483.75(l)(1): Records must be kept in accordance with accepted professional standards and practices that are:</p> <p>(i) Complete.</p> <p>(ii) Accurately documented.</p> <p>(iii) Readily accessible.</p> <p>(iv) Systematically organized.</p>
Medical Control for Emergency Medical Services	Mich. Admin. Code R 325.23705: A medical control board shall designate a single facility which shall be responsible for	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	maintaining records of all telecommunications activities in support of medical control of limited and advanced mobile emergency care services within the jurisdiction of the medical control authority. These records should be maintained for not less than sixty (60) days.		
Outpatient Physical Therapy or Speech Pathology Services	<p>42 CFR § 485.721(d): Any clinics, rehabilitation agencies and public health agencies as providers of outpatient physical therapy and speech pathology services must retain patient records for not less than:</p> <p>(1) The period determined by the respective State statute, or the statute of limitations in the State; or</p> <p>(2) in the absence of State statutes:</p> <ul style="list-style-type: none"> (i) Five (5) years after discharge, or (ii) If the case of a minor, three (3) years after the patient becomes of age under State law or five (5) years after the date of discharge, whichever is longer. <p>42 CFR § 486.161(d) specifies the same requirements for independent physical therapists.</p>	Not found.	None.
Clinical Records (Comprehensive Outpatient Rehabilitation Facilities)	42 CFR § 485.60(c): The facility must retain clinical record information for five (5) years after patient discharge and must make provision for the maintenance of such records in the event that it is no longer able to treat patients.	Not found.	42 CFR § 485.60(a): Clinical record must contain sufficient information to identify the patient and to justify the diagnosis and treatment. Documentation on each patient must be consolidated into

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
			<p>one (1) clinical record that must contain:</p> <p>(1) The initial and subsequent reassessments of the patient's needs;</p> <p>(2) Current treatment plan;</p> <p>(3) Identification data and consent/authorization forms;</p> <p>(4) Pertinent medical history, past and present;</p> <p>(5) A report of pertinent physical examinations if any;</p> <p>(6) Progress notes or documentation that reflect patient reaction to treatment, tests or injury, or the need to change the established plan of treatment; and</p> <p>(7) Upon discharge, a discharge summary including patient status relative to goal achievement, prognosis and future treatment considerations.</p>
Portable X-ray Services	42 CFR § 486.106(c): All portable X-ray services performed for Medicare beneficiaries must be maintained for a period of at least two (2) years, or for the	Not found.	Applies to hospital-based as well as freestanding facilities.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	period of time required by State law for such records (as distinguished from requirements as to the radiograph itself), whichever is longer.		
Rural Health Clinics	42 CFR § 491.10(c): The clinic or center must maintain patient records for at least six (6) years from date of last entry, or longer if required by State statute.	Not found.	<p>42 CFR § 491.10(a)(3): The record includes:</p> <p>(i) Identification and social data, evidence of consent forms, medical history, assessment of health status and health care needs of patient, and brief summary of the episode, disposition, and instructions to the patient;</p> <p>(ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;</p> <p>(iii) All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress; and</p> <p>(iv) Signatures of the physician or other health care professional.</p> <p>(b): The clinic or center must maintain the confidentiality of record information and provide</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
			safeguards against loss, destruction or unauthorized use. The clinic must also maintain written policies and procedures which govern the use and removal of records & the conditions for release of information.
Substance Abuse/Chemical Dependency Facility	Mich. Admin. Code R 325.14419(1): A client record must be maintained by a program for a period of three (3) years after services are terminated.	Not found.	Stringent limitations upon release of these records may apply. See 42 CFR § 52.1 et seq. Applies to hospital-based as well as freestanding facilities.

PHARMACY/DRUG CONTROL

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Controlled Substances – Acquisition, Dispensing	<p>MCL 333.7303a(3): Licensed prescriber who dispenses controlled substances must maintain the following records separately from the other prescription records:</p> <p>(a) All invoices and other acquisition records for each controlled substance acquired by the prescriber for not less than five (5) years after the date the prescriber acquires the controlled substance.</p> <p>(b) A log of all controlled substances dispensed by the prescriber for not less than five (5) years after the date the controlled substance is dispensed.</p> <p>(c) Records of all other dispositions of controlled substances under the licensee's control for not less than five (5) years after the date of the disposition.</p> <p>Mich. Admin. Code R 338.3153(8): Complete controlled substance records must be maintained or controlled by the licensee for two (2) years, except for controlled substance prescriptions, which must be maintained for five (5) years from the last date of dispensing.</p> <p>21 CFR § 1306.22(f)(3): A hard copy</p>	<p>Not found.</p>	<p>Mich. Admin. Code R 338.3153(2): A licensee must maintain acquisition records as follows:</p> <p>(a) Invoices and other acquisition records of all controlled substances listed in schedules 1 and 2 of R 338.3111 to R 338.3119a must be maintained in a separate file;</p> <p>(b) Invoices and other acquisition records of all controlled substances listed in schedules 3, 4 and 5 of R 338.3120 to R 338.3126 must be maintained in a separate file or in such form so that the information is readily retrievable from the ordinary acquisition records maintained by the dispenser.</p> <p>21 CFR 1306.22(f)(5): The pharmacy must have an auxiliary system during system down times, to document refills of Schedule III and IV controlled substance prescription orders.</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>printout of a controlled substance prescription order refill data must be maintained by the pharmacy for two (2) years from the dispensing date.</p> <p>21 CFR § 1306.27(a)(4)-(5): The retail pharmacy transmitting the prescription information must maintain the original prescription for two (2) years from date the prescription was last fill, and keep a record of receipt of the filled prescription, including date of receipt, method of delivery, and name of employee accepting delivery.</p> <p>21 CFR § 1306.27(b)(1)-(3): The central fill pharmacy receiving the transmitted prescription must keep a copy or electronic record of the prescription, a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, the dates of filling/refilling, the date of delivery, and the method of delivery. No retention period is specified.</p> <p>21 CFR 1305.17(c): DEA Forms 222 must be maintained separately from all other records of the registrant and retained for two (2) years.</p>		
Controlled Substances – Dispensing Without	21 CFR 1306.26: A Schedule II, III, IV, and V controlled substance which is not a	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Prescription	<p>prescription drug may be dispensed by a pharmacist without a prescription at retail.</p> <p>21 CFR 1306.26(e): A bound record book for dispensing controlled substances under this section must be maintained by pharmacies in accordance with 21 CFR 1304.04 and retained for two (2) years after date of last inventory or records.</p> <p>Mich. Admin. Code R 338.3167(3): The pharmacist must maintain a record of the dispensing of controlled substances listed in Schedule 5. The record must be immediately retrievable and may be maintained in the same manner as required for Schedule 5 prescription medicine. See (3)(a)-(f) for list of required information.</p>		
Controlled Substances – Inventories, Records	<p>21 CFR 1304.04: The DEA registrant must retain and make available inventories and records of controlled substances for at least two (2) years from date of inventories or records.</p> <p>MCL 333.7321: Persons licensed to manufacture, distribute, prescribe or dispense controlled substances must keep records and maintain inventories in conformance with the record-keeping and inventory requirements as required by federal law. Licensee must annually inventory and report to the administrator all</p>	Not found.	21 CFR 1304.03: Describes records DEA registrant is required to keep of Schedule II-V controlled substances being prescribed, dispensed or used in research.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	Schedule II to V controlled substances in his possession.		
Controlled Substances – Medical Institution Records	<p>Mich. Admin. Code R 338.3153a(3): Original orders for controlled substances must be retained for five (5) years from the date of patient.</p> <p>Mich. Admin. Code R 338.3154(14): Medication records and documents required must be maintained or controlled by the pharmacy responsible for the device for two (2) years.</p>		Mich. Admin. Code R 338.3154(2): Medication records for a Schedule II-V controlled substances, listed in R 338.3116-338.3125, must include number of doses purchased, dispensed and administered, number of doses dispensed but not administered, annual physical inventory and status of any discrepancies between inventory and dispensing/acquisition records.
Controlled Substances – Order Form	<p>21 CFR § 1305.13(a): A purchaser must retain Copy 1 and Copy 2 of the DEA Form 222 to the supplier and retain Copy 3 in the purchaser's files.</p> <p>21 CFR § 1305.13(e): The purchaser must record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.</p>	Not found.	21 CFR § 1305.17(c): DEA Forms 222 must be maintained separately from all other records of the registrant and be retained for two (2) years.
Controlled Substances – Order Form Preservation	<p>21 CFR § 1305.17(a): The purchaser must retain Copy 3 of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.</p> <p>21 CFR § 1305.17(b): The supplier must</p>	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	retain Copy 1 of each DEA Form 222 that it has filled.		
Controlled Substances – Power of Attorney to Sign Order Forms	21 CFR § 1305.05(a): A registrant may authorize one or more individuals to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual. The power of attorney is to be filed with executed Forms 222 and retained for the same period as any order form.	Not found.	None.
Controlled Substances – Prescriptions	21 CFR § 1306.14(d): All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of § 1304.04(h).	Not found.	None.
Controlled Substances – Prescription Information Transfer	21 CFR § 1306.25(a) and (c): The transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. Both original and transferred prescriptions must be retained for two (2) years from the date of last refill.	Not found.	None.
Controlled Substances – Prescription Refills	21 CFR § 1306.22: Pharmacy records of refills of prescriptions for Schedule III and IV may be maintained manually or by an automated data processing system. Printout, or bound log book in lieu of printout, reviewed and signed by pharmacist(s), must be retained for two (2) years after date of dispensing.	Not found.	None.
Controlled Substances –	21 CFR 1304.24: Each person registered or	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Use in Maintenance Treatment or Detox	<p>authorized to detoxify/maintain controlled substance users in a narcotic treatment program must maintain records for each narcotic controlled substance in a dispensing log at the narcotic treatment program site in accordance with 21 CFR 1304.22. No retention period is specified.</p> <p>21 CFR 13404.04(f): Narcotic treatment programs must keep inventories and records of Schedule I and II drugs separate from those for Schedules III, IV and V drugs.</p>		
Drug Dispensing – Automated Devices	Mich. Admin. Code R 338.489(5)(b): If any medication or device is dispensed from an automated device, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility shall be maintained by the pharmacy for review by an agent of the board. No retention period is specified.	Not found.	<p>See also, Mich. Admin. Code R 338.3154(6): Medication records in medical institutions.</p> <p>See Mich. Admin Code R 338.489(5)(b)(i)-(v) for a list of documentation required.</p>
Hospice Emergency Drug Box	Mich. Admin. Code R 338.500(10): The pharmacy establishing a medication box exchange program for hospice emergency care services in patients' homes must retain a permanent record of drug box exchanges on a drug box exchange log.	Not found.	Mich. Admin. Code R 338.500(10)(a)-(g): Identifies mandatory contents of record.
Nuclear Medicines	42 CFR 482.53(d)(3): The hospital must maintain records of the receipt and disposition of radiopharmaceuticals. No retention period is specified.	Not found.	None.
Prescription Drug Receipts	Mich. Admin. Code R 338.479a(4): A pharmacist must retain a copy of the receipt	Not found.	Mich. Admin. Code R 338.479a(1): Describes mandatory

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	for ninety (90) days.		contents of the receipt. Mich. Admin. Code R 338.480a: Does not apply to inpatient medical institution service.
Prescription Information in Patient Charts	MCL 333.17745(3): A dispensing prescriber must retain complete information (drug names, dosages and quantities) for not less than five (5) years after the information is entered in the patient's chart or clinical record.	Not found.	None.
Prescription Records	MCL 333.17752(1): A prescription, or equivalent record of the prescription, must be retained by licensee or dispensing provider for at least five (5) years. Mich. Admin. Code R 480a(3)(a): Prescription records must be kept for five (5) years.	Not found.	See Mich. Admin. Code R. 338.480a for list of information prescription records must obtain. Does not apply to inpatient services.
Prescription Refill Records	Mich. Admin. Code R 338.480a(3)(a): Pharmacy shall maintain records in written form. Original and refill prescription information must appear on a single document. Pharmacy must retain records for at least five (5) years. Mich. Admin. Code R 338.480a(4)(b): Pharmacy may maintain records in automated data processing system. Entries must be made when prescription is first filled and when refilled. Pharmacy must retain records for at least five (5) years.	None.	Mich. Admin. Code R 338.480a: Does not apply to inpatient medical institution service. Mich. Admin. Code R 338.480a(3)(b): Identifies information required to be maintained.

PHYSICAL PLANT

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Alarm System, Entrance Control Checks at Permanent Radiographic Installations	10 CFR § 34.75: Each licensee must retain records of alarm system and entrance control device tests required under 10 CFR § 34.33 for three (3) years after the record is made.	Not found.	None.
Radiographic exposure devices	<p>10 CFR § 34.73: Each licensee must maintain records specified at §34.31 of equipment problems found in daily checks and quarterly inspections of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments for three (3) years after record is made.</p> <p>10 CFR § 34.85: Each licensee must maintain a record of each exposure device survey conducted before the device is placed in storage as specified in § 34.49(c), if that survey is the last one performed in the workday. Each record must be maintained for three (3) years after it is made.</p>	Not found.	
Industrial Radiography Licenses	10 CFR § 34.61: Each licensee must maintain a copy of its license, license conditions, documents incorporated by reference, and amendments to each of these items until it is superseded by new documents approved by the Commission, or until the Commission terminates the license.	Not found.	

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>10 CFR § 34.79: Each licensee must maintain training and inspection of job performance records for three (3) years after the record is made.</p> <p>10 CFR § 34.81: Each licensee must retain a copy of operating and emergency procedures until the Commission terminates the license. The superseded version must be retained for three (3) years after changes are made.</p> <p>10 CFR § 34.83: Records of personnel monitoring procedures (exposure records) must be retained for three (3) years.</p>		
Environmental Audit Reports	MCL § 324.14802(1): The owner or operator of a facility, or an employee or agent of the owner or operator on behalf of the owner or operator may conduct an environmental audit and may create an environmental audit report at any time. No retention period is specified.	Not found.	None.
PCB Transformer	40 CFR § 761.30(a)(1)(xii): Records of inspection and maintenance history must be retained for at least three (3) years after disposal of PCB transformers.	Not found.	None.
Permits Relating to Discharges, Emissions, etc.	Not found.	Not found.	Permits issued by regulatory agencies generally contain monitoring, testing, and inspection requirements. The specific record-keeping requirements are usually contained within the permit itself.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
			Generally, they require retention of records for at least two (2) years.
Underground Storage Tanks	<p>Mich. Admin. Code R 29.2127(a): All written performance claims pertaining to any release detection system used and the manner in which the claims have been justified or tested by the equipment manufacturer or installer must be maintained for five (5) years from the date of installation or for another reasonable period of time determined by the department.</p> <p>Mich. Admin. Code R 29.2127(b): The results of any sampling, testing, or monitoring shall be maintained for not less than two (2) years or for another reasonable period of time determined by the department.</p> <p>Mich. Admin. Code R 29.2127(b): The results of tank and piping tightness testing conducted in accordance with sections 280.43(c) and 280.44(b) shall be retained for not less than five (5) years.</p> <p>Mich. Admin Code R 29.2127(c) Written documentation of all calibration, maintenance, and repair of release detection equipment permanently located on-site shall be maintained for not less than two (2) years after the servicing work is completed or for</p>	Not found.	<p>40 CFR §280.45: Upon purchase or acquisition of an existing UST system and upon request by the department, the owners and operators of the system shall provide the department with the following documents:</p> <p>(a) Written performance claims pertaining to any release detection system used and the manner in which these claims have been justified or tested by the equipment manufacturer or installer must be maintained for five (5) years from the date of installation, or for another reasonable time determined by the implementing agency, from the date of installation;</p> <p>(b) The results of any sampling, testing, or monitoring must be maintained for at least one (1) year, or for another reasonable time determined by the implementing agency, except that the results of tank tightness testing conducted in accordance with § 280.43(c) must be retained until</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>another reasonable time period determined by the department.</p> <p>Mich. Admin. Code R 29.2127(c) Any schedules of required calibration and maintenance provided by the release detection equipment manufacturer shall be retained for five (5) years from the date of installation.</p> <p>Mich. Admin. Code R 29.2159: Te results of site assessment must be maintained for three (3) years after completion of closure or change in service.</p>		<p>the next test is conducted;</p> <p>(c) Written documentation of all calibration, maintenance, and repair of release detection equipment permanently located on-site must be maintained for at least one (1) year after the servicing work is completed or for another reasonable time determined by the implementing agency. Any schedules of required calibration and maintenance provided by the release detection equipment manufacturer must be retained for five (5) years from the date of installation. If the records are unavailable, the owner/operator shall conduct tightness testing as provided in section 280.44(b).</p>

REIMBURSEMENT

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Medicare Part A – Cost Reports	<p>42 CFR § 413.20 and 42 CFR § 413.24: Record Keeping Requirements for Cost reports:</p> <p>42 CFR §§ 420.300-304 (Medicare Access Clause): For contracts between the entity filing a cost report and a subcontractor where cost over a 12-month period exceeds \$10,000, Medicare requires access to books, documents, and records necessary to verify the nature and extent of costs of services furnished by the contract.</p>	Not found.	<p>18 USC § 3282: Five (5)-year statute of limitations for criminal fraud actions.</p> <p>31 USC § 3731(b) (False Claim Act): A civil fraud action may not be brought:</p> <p>(1) More than six (6) years after the date of the violation; or</p> <p>(2) More than three (3) years after the date when facts material to the right of action are known or reasonably should have been known by the official charged with responsibility to act in the circumstances, but in no event more than ten (10) years after the date on which the violation is committed, whichever occurs last.</p>
Medicare Part B – Claims	<p>Medicare Manual Chapter 24 20.1.1(A)(8):</p> <p>Microform Claims Records: If a corresponding master microfilm record made, intermediaries and carriers must retain for three (3) years after the close of the calendar year in which paid. If a corresponding master microform record has not been made and verified, they must retain</p>	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	for six (6) years and three (3) months. Microform Records: Intermediaries and carriers must retain for six (6) years and three (3) months following the close of the calendar year in which paid.		
Medicare Audit and Review Records	17 CFR §210.2-06(a): Accountant must retain for seven (7) years after concluding an audit or review of financial statements.	Not found.	None.
Civil Rights Compliance – DHHS Funding Recipients	45 CFR § 80.6: Each recipient of Medicare or Medicaid funding must retain such records of compliance with Title VI nondiscrimination requirements as directed by DHHS Office for Civil Rights.	Not found.	Retention period is at discretion of Office for Civil Rights.
Handicapper Rights Compliance – DHHS Funding Recipients	45 CFR § 84.6(c)(2): Each recipient of Medicare and Medicaid funding with fifteen (15) or more employees must for three (3) years maintain on file, make available for public inspection, and provide to the Director upon request: (i) a list of interested individuals consulted; (ii) a description of areas examined and any problems identified; and (iii) a description of any modifications made and of any remedial actions taken.	Not found.	See also 45 CFR § 84.11.
Medicare Part D – Prescription Drug Benefit	42 CFR §423.505(d): The Part D plan sponsor agrees to maintain, for ten (10) years the following: books, records, documents, and other evidence of accounting procedures and practices.	Not found.	None.
MA Organization	42 CFR 422.504(d): The MA organization's contract with CMS must contain a provision	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	that the MA organization agrees to maintain for ten (10) years the following: books, records, documents and other evidence of accounting procedures and practices.		
Medicaid Drug Rebate Program	69 Fed. Reg. 68815 (November 26, 2004): pharmaceutical manufacturers are required to retain records related to rebates paid to states under the Medicaid rebate program for a period of ten (10) years. The records that must be retained include written and electronic data reported to CMS, as well as any other materials from which the calculations of the average manufacturer price and best price are derived, including a record of any assumptions made in the calculations. A manufacturer must retain data beyond the ten-year period if the manufacturer is aware that the records are subject to an unresolved audit or government investigation.	Not found.	None.
Michigan Medicaid	MCL §400.111b(6) and (8): Medicaid providers must maintain records substantiating the medical necessity, appropriateness, and quality of services rendered for which a Medicaid claim is made for a period of seven (7) years.	Not found.	None.
CONS – EDI Enrollment and EDI Claim Record Retention	In order for an entity to become an EDI trading partner, an EDI enrollment form must be completed, approved, and on file with a Medicare contractor. Contractors are required to retain all EDI enrollment forms according to the same CMS Records	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>Schedule retention requirements that apply to the CMS-855 Medicare Enrollment Application. The CMS Records Retention Schedule for Provider Records can be found at the following URL: http://www.cms.hhs.gov/manuals/downloads/pim83c10.pdf in Section 17.3.</p> <p>Once a trading partner has been tested and approved for electronic submission of claims, they can begin submitting electronic claims to Medicare. Contractors are required to retain electronically filed claims under the same CMS Records Retention Schedule retention requirements that apply to hardcopy claim. The CMS Records Retention Schedule for Medicare Records can be found at the following URL: http://www.cms.hhs.gov/manuals/downloads/ge101c07.pdf in section 30.30.</p>		

RESEARCH INFORMATION

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Bioequivalence Testing	21 CFR § 320.36(a): Records must be retained for two (2) years after expiration date of the batch tested and submitted to FDA on request.	Not found.	None.
Institutional Review Board	21 CFR § 56.115(b): Records must be retained for at least 3 years after completion of research and must be accessible for inspection and copying by the FDA at reasonable times and in a reasonable manner.	Not found.	21 CFR § 56.115(a)(1)-(7): IRB records include copies of research proposals reviewed, minutes of IRB meetings, records of continuing review activities, correspondence between IRB and investigators, list of IRB members, written procedures for IRB, and statements of new findings.
Intraocular Lens Investigation Reports, Records, Inspections	21 CFR § 812.140 (d): An investigator or sponsor shall maintain the required records during the investigation and for a period of two (2) years after the latter of the following: 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 or a notice of completion of a product development protocol.	Not found.	None.
Investigational New Drug Applications – Investigator Records	21 CFR § 312.62(c): An investigator must retain records required to be maintained under this part for a period of two (2) years following the date a marketing application is approved for the drug for the indication for which it is being investigated. If no	Not found.	Investigators are required to keep records of the dispositions of the drug, including dates, quantity, and use by subject. Investigators are required to prepare and maintain adequate and accurate

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	application is to be filed or if application is not approved for that indication, until two (2) years after the investigation is discontinued and FDA is notified.		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.
Nonclinical Laboratory Study Results (Intended to Support Applications to the FDA for Research or Marketing Permits)	<p>21 CFR § 58.195(b): Documentation records, raw data and specimens pertaining to a nonclinical laboratory study and required to be made by this part must be retained in the archive(s) for whichever of the following three (3) periods is shortest:</p> <p>(1) Two (2) years after the date on which an application for a research or marketing permit is approved by the FDA;</p> <p>(2) Five (5) years after the date on which the results of the nonclinical laboratory study are submitted to the FDA in support of an application for a research or marketing permit;</p> <p>(3) In other situations (e.g., no application submitted), at least two (2) years after the study is completed, terminated or discontinued.</p> <p>21 CFR § 58.195(c): Wet specimens, samples of test or control articles, and specially prepared material, must be retained only as long as the quality of preparation affords evaluation. In no case shall retention be required for longer</p>	Not found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	periods than those set forth in paragraphs (a) and (b) of this section.		
Records of Adverse Drug Reactions	21 CFR § 482.24(c) (2)(iv): Complications, hospital acquired infections and unfavorable reactions to drugs and anesthesia must be documented in a general medical record and retained for five (5) years.	Not found.	None.

MISCELLANEOUS RECORDS

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Abortions and Related Medical Services Documentation	42 CFR §36.56; 42 CFR §50.309: Maintained for three (3) years.	Not Found.	None.
Department of Veterans Affairs – Diagnostic and Operation Index File	Records Control Schedule (RCS) 10-1, General and Administrative Records (2011): Destroy monthly listing after receipt of consolidated biannual listing. Destroy consolidated biannual listing or prior equivalent twenty (20) years after date of report.	Not Found.	This applies to mechanically prepared listings of coded diagnostic and operative data of discharged patients and manually prepared diagnostic and operative indices and locally approved special inpatient diagnostic and operative indexes.
Department of Veterans Affairs – Disposition Data Files (PTF)	Records Control Schedule (RCS) 10-1, General and Administrative Records (2011): Destroy after one (1) year and after a PTF master record has been created at the data processing center.	Not Found.	This applies to mechanically prepared listings (code sheets) of discharged patients' records.
Department of Veterans Affairs – Gains and Losses File	Records Control Schedule (RCS) 10-1, General and Administrative Records (2011): Destroy master set after one (1) year. Destroy all other copies after purpose has been served.	Not Found.	This applies to daily patient gains and losses sheets.
Department of Veterans Affairs – Medical Records Folder File or CHR (Consolidated Health Record)	Records Control Schedule (RCS) 10-1, Section XLIII – Health Information Management Service (HIMS) (2011): Retain in VA health facility until three (3) years after last episode of care, and then convert to inactive medical records. The inactive medical records then must be	Not Found.	This applies to professional, administrative, medical records or consolidated health records relating to ambulatory care, hospital, nursing home, domiciliary, or other outpatient records.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>retired annually to the records storage facility. If they are not recalled by the accessioning facility for reactivation, they must be destroyed by witness disposal seventy-two (72) years after retirement or seventy-five (75) years after the last episode of care.</p> <p>Any perpetual medical records must be retired to a records storage facility for storage. They must be retained for the remainder of their respective retention period, then destroyed at the facility if not recalled along with their inactive medical record counterparts. If recalled, the inactive medical record counterparts, must be recalled also so that the records can be converted into a Medical Records Folder File. If the records are recalled, the retention period begins anew.</p>		
Department of Veterans Affairs – Patient Locator File	<p>Records Control Schedule (RCS) 10-1, General and Administrative Records (2011): Retain in medical facility seventy-five (75) years after the last episode of care. If the information is entered into electronic media, the hardcopy files may be destroyed after the information has been verified or when no longer needed to support the purpose for which the file was created. The electronic information will be retained until expiration of the authorized retention requirement for the hardcopy records.</p>	<p>Not Found.</p>	<p>This applies to any locator records containing basic identification data for each patient. It includes information such as patients, name, social security number, home address, treatment status, medical records folder file location, and other identification data.</p>

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
Department of Veterans Affairs – Tumor Registry File Index Card and Folder File	Records Control Schedule (RCS) 10-1, General and Administrative Records (2011): Destroy seventy-five (75) years after date of last activity.	Not Found.	This applies to patients treated for tumor.
Drug and Alcohol Violation Disclosures	20 USC § 1232g - Family Educational Rights and Privacy Act: Education records are those records that are directly related to a student and maintained by an education agency or institution or by a party acting for the agency or institution. Disclosure of education records is addressed. Record retention periods are not specified.	Not Found.	None.
Hearing Aid Devices, Dispensers	21 CFR § 801.421(d): The dispenser shall retain for three (3) years after the dispensing of a hearing aid a copy of any written statement from a physician or any written statement waiving medical evaluation.	Not Found.	Group auditory trainers are exempt from this requirement.
Institutional Review Board (IRB) for Clinical Devices	21 CFR § 812.140(d): An investigator or sponsor shall maintain the records during the investigation and for a period of two (2) years after the latter of the following two (2) 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 or a notice of completion of a product development protocol.	Not Found.	None.
IRB or Institutions That Review a Clinical Investigation Documentation	21 CFR § 56.115(b); 38 CFR § 16.115(b): The IRB shall prepare and maintain documentation of IRB activities for three (3) years after completion of research.	Not Found.	None.
Investigator – Investigators	21 CFR § 312.62(c): An investigator must	Not Found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
of New Drugs and Antibiotic Drugs for Investigational Use	maintain records of the disposition of the drug for two (2) years following the date a marketing application is approved for the drug for the indication for which it is being investigated. If no application is to be filed or if the application is not approved for such indication, until two (2) years after the investigation is discontinued and the FDA is notified.		
Mammography – Screening and/or Diagnostic Mammography Services	21 CFR §900.12(c)(4)(i): Each facility that performs mammograms shall maintain films and reports in a permanent medical record of the patient for a period of not less than five (5) years, or not less than ten (10) years, if no additional mammograms of the patient are performed at the facility, or longer if mandated by State or local law.	Not Found.	None.
Medical Device Tracking	31 CFR §821.60: Persons required to maintain records must maintain such records for the useful life of each tracked device manufactured or distributed. The useful life of a device is the time a device is in use or in distribution for use.	Not Found.	None.
Vaccine	42 CFR §300aa-25: Retention periods are not specified. However, each healthcare provider who administers a vaccine set forth in the Vaccine Injury Table (42 CFR §100.3) to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon	Not Found.	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	request) with respect to each such vaccine the date of administration of the vaccine, the vaccine manufacturer and lot number of the vaccine, the name and address and, if appropriate, the title of the healthcare provider administering vaccine, and any other identifying information on the vaccine required pursuant to regulation promulgated by the Secretary.		
Mammography Assurance/Quality Control Records	21 CFR § 900.12(d)(2): Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection employee qualifications to meet assigned quality assurance tasks are properly maintained and updated. The quality control records shall be kept for each test specified in paragraphs (e) and (f) of this section until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two (2) additional times at the required frequency, whichever is longer.	Not Found.	
X-Ray Films	Public Act 481 of 2006: Medical records and x-ray films must be kept and retained	American Health Information Management Association	None.

Type of Record	Legal Requirements	Accreditation/Professional Association Guidelines	Comments
	<p>for a minimum of seven (7) years from the date of service to which the record pertains, unless a longer retention period is required by Federal or State law or regulation.</p> <p>42 CFR 900.12(c)(4)(i): Mammography films and reports must be retained for not less than five (5) years (must be retained for at least seven (7) years in Michigan) or not less than ten (10) years if no additional mammograms of the patient are performed at the facility, or a longer period of mandated by State or local law.</p>	<p>(AHIMA): The AHIMA recommends retaining diagnostic images (such as x-ray film) for:</p> <p>(a) Five (5) years for adults; and</p> <p>(b) Five (5) years after the age of majority for minors.</p>	