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PHARMACY
COMPOUNDING
ACCREDITATION
BOARD

ACHC ACCREDITATION STANDARDS



PHARMACY

CUSTOMIZED FOR:

PCAB STERILE
COMPOUNDING



PCAB ACCREDITATION PROGRAM FOR COMPOUNDING

Pharmacy Compounding is a process by which a pharmacist prepares drugs by combining, mixing, or altering ingredients into a pharmaceutical preparation. Compounding includes the preparation of drugs in anticipation of receiving prescription drug orders based on routine, regularly observed prescribing patterns.

PCAB Accreditation includes two classes of compounding:

- Non-sterile compounding is the practice of preparing medications as result of a practitioner's patient specific prescription drug order that are designed to be administered by a route of administration that does not require sterility.
- Sterile Pharmacy Compounding is the practice of preparing sterile medications as a result of a practitioner's patient specific prescription drug order through strict procedures to prevent contamination and maintain patient safety.

PCAB Accreditation for Pharmacy Compounding measures a specific set of process standards that concentrate on the quality and consistency of compounded preparations.

Standard TCRX1-A: The organization is an established entity with legal authority to operate and has a physical location with the appropriate licensure, Articles of Incorporation, or other documentation of legal authority.

Interpretation: The organization is an established entity with legal authority to operate, and has the appropriate Articles of Incorporation, or other documentation of legal authority. Legal authority is granted to one individual, members of a Limited Liability Corporation (LLC), a Board of Directors, usually referred to as the governing body, and as allowed in state statutes for the appropriate type and structure of the organization. The entity, individual or organization has a copy of the appropriate documentation or authorization to conduct business.

If state or applicable local law requires a license or permit, the organization posts the current copy in a prominent location in all locations/branches, and/or in accordance with appropriate regulations or laws. The organization will display all licenses and/or permits required in the pharmacy operation in an area of public view:

- Resident state board of pharmacy permit/license
- Non-resident board of pharmacy permit/license as required, if applicable
- Drug Enforcement Administration (DEA) registration
- State controlled substance license, if applicable
- Pharmacists licenses
- Pharmacy technicians licenses/certificates, if applicable
- Biohazard generator permit or appropriate contract as required

The organization is in compliance with all applicable federal, state, and local laws and regulations and has access to the pharmacy rules and regulations of all states where pharmacy services are provided.

Evidence: License and/or Permits

Evidence: Observation

Standard TCRX1-B: The organization has access to relevant United States Pharmacopeia (USP) standards.

Interpretation: The pharmacy has access to current USP standards that are relevant to the scope of compounding performed.

Pharmacies that perform non-sterile compounding have access to relevant and current United States Pharmacopeia standards, including but not limited to USP Chapter <795>.

Pharmacies that perform sterile compounding have access to relevant and current United States Pharmacopeia standards, including but not limited to USP Chapter <797>.

Evidence: Observation



Standard TCRX1-C: The organization informs the accrediting body and other state/federal regulatory agencies, as appropriate, of negative outcomes from review/audits.

Interpretation: Negative outcomes affecting accreditation, licensure, or Medicare/Medicaid certification are reported to ACHC within 30 days of the occurrence. The report includes all actions taken and plans of correction (POCs).

Incidents reported to ACHC include, but are not limited to:

- License suspension
- License probation; conditions/restrictions to license
- Non-compliance with Medicare/Medicaid regulations identified during survey by another regulatory body
- Civil penalties of ten thousand dollars (\$10,000.00) or more
- Revocation of Medicare/Medicaid/third-party provider number

Evidence: Board of Director Meeting Minutes

Evidence: Response to Interviews

Standard TCRX2-A: Written policies and procedures are established and implemented by the organization requiring that the client/patient be informed at the initiation of service on how to report complaints or grievances to the organization and/or ACHC.

Interpretation: The organization investigates and attempts to resolve all client/patient complaints/grievances and documents the results within a described time frame as defined in policies and procedures.

Written policies and procedures include, but are not limited to:

- The appropriate person to be notified of the complaint/grievance
- Time frames for investigation activities, to include after hours
- Reporting of information
- Review and evaluation of the collected information
- Communication with the client/patient
- Documentation of all activities involved with the complaint/grievance, investigation, analysis and resolution

The organization provides all clients/patients with written information that includes a telephone number, contact person, and the organization's process for receiving, investigating and resolving complaints/grievances about its services.

ACHC's telephone number must be provided at the time of initial service. The ACHC phone number requirement is not applicable to organizations if this is their first ACHC survey.

The organization maintains records of complaints/grievances and their outcomes and submits a summary report to the organization's leadership. This information is included in the Performance Improvement (PI) annual report.

Personnel are oriented and familiar with the client/patient complaint/grievance/concern policies and procedures. Personnel assist in implementing the resolution process when needed.

Evidence: Written Policies and Procedures

Evidence: Complaint/Grievance Log

Evidence: Response to Interviews



Standard TCRX3-B: Written policies and procedures are established and implemented requiring all sterile compounding personnel to receive training and/or education and to competently perform the required client/patient service activities prior to being assigned to work independently.

Interpretation: Written policies and procedures define the minimum education and training, licensure, certification, experience, and the minimum competencies required for each service offered, as well as the method for documenting that personnel have received the required training.

The organization designs and implements a competency assessment program based on the service provided. Competency assessment is an ongoing process and focuses on the service being provided. Competency assessments are conducted initially during orientation and annually thereafter except when required more frequently, for example, for sterile compounding personnel per USP Chapter <797>. Verification of skills is specific to the employee's role and job responsibilities.

Policies and procedures are in place for determining that personnel are competent to provide quality service. Competency may be verified through observation, knowledge-based tests, and self-assessment. All competency assessments and training are documented. A self-assessment tool alone is not acceptable. There is a plan in place for addressing performance and education of personnel when they do not meet competency requirements.

Prior to personnel performing sterile compounding, training takes place and competency assessments are performed, which include:

- Didactic training and written testing
- Media-fill testing consistent with the risk level of compounding, in accordance with USP Chapter <797>
- Cleaning and disinfecting procedures
- Hand hygiene and garbing, in accordance with USP Chapter <797>
- Gloved fingertip sampling consistent with the risk level of compounding performed

For personnel who perform sterile compounding, competency assessments are done annually and/or consistent with the risk level of the compounding, which includes:

- Didactic training and written testing
- Media-fill testing consistent with the risk level of compounding, in accordance with USP Chapter <797>
- Cleaning and disinfecting procedures
- Hand hygiene and garbing, in accordance with USP Chapter <797>
- Gloved fingertip sampling consistent with the risk level of compounding performed

Any competency assessment that is not satisfactory requires the individual to be re-trained and the competency assessment repeated. All training and competencies are documented.

Evidence: Written Policies and Procedures

Evidence: Competency Assessment/Initial Training

Evidence: Response to Interviews

Standard TCRX3-C: Pharmacy personnel are trained to operate, clean, maintain, and calibrate compounding equipment.

Interpretation: Personnel responsible for compounding are trained and competent in the use of all equipment as applicable to their job description and/or assigned responsibilities.

Evidence: Training Logs

Standard TCRX3-D: Pharmacy personnel are trained to perform routine cleaning and maintenance of equipment used in the client's/patient's home.

Interpretation: Personnel responsible for delivery, setup, pickup and maintenance of equipment are trained and competent in the use of equipment used in the client's/patient's home.

Evidence: Training Logs/Files

Standard TCRX3-E: Written policies and procedure are established and implemented in regard to personnel who work with hazardous drugs receiving training and demonstrating competency in their storage, handling and disposal.

Interpretation: Personnel who compound with hazardous drugs are trained in the identification, storage, handling and disposal of these drugs. This training includes the use of personal protective equipment (PPE), safety equipment such as eye washes and spill kits, and engineering controls. The competency of personnel who handle hazardous drugs is assessed at least annually. Personnel of reproductive capability confirm in writing that they understand the risk of handling hazardous drugs.

Evidence: Personnel Files/Training Logs

Standard TCRX3-F: Written policies and procedures are established and implemented in regard to personnel being trained and/or demonstrating competence to perform any new tasks/procedures prior to performing those tasks independently. Personnel are not allowed to perform any task for which they were evaluated as unsatisfactory.

Interpretation: Written policies and procedures define the process to ensure that personnel demonstrate competency in any new task before being assigned to perform that task. The organization also has a process to ensure that personnel are proven competent to perform tasks after re-training is provided.

Evidence: Written Policies and Procedures

Evidence: Response to Interviews

Evidence: Observation

Standard TCRX3-G: All pharmacy services are provided by qualified personnel and administered in accordance with the organization's policies and procedures, job descriptions and each state board of pharmacy's rules and regulations where medications are shipped or dispensed.

Interpretation: Pharmacists and pharmacy technicians function in accordance with the organization's policies and procedures and job descriptions, accepted ethical and professional practice standards, and in accordance with all applicable federal, state, and local laws and guidelines set by the state board of pharmacy.

If medications are dispensed in other states, the pharmacy has the appropriate license/permits for those states serviced. Current copies of applicable rules and regulations are available.

Evidence: Personnel Records

Evidence: Observation

Standard TCRX3-H: Written policies and procedures are established and implemented in regard to all pharmacy services being provided under the direction of a Registered Pharmacist who has documented training and competency in the scope of services provided.

Interpretation: All pharmacy services are provided under the direction of a Registered Pharmacist with sufficient education and experience in the scope of services offered.

Written policies and procedures identify the method and frequency for assessing the Pharmacist's competency in order to ensure that services are provided appropriately.

Evidence: Written Policies and Procedures

Evidence: Personnel Files



Standard TCRX3-I: The Registered Pharmacist supervises pharmacy technicians in accordance with the state board of pharmacy rules and regulations.

Interpretation: The pharmacy follows its state board of pharmacy regulations and the organization's policies and procedures that demonstrate that the Registered Pharmacist supervises the services provided by pharmacy technicians.

Evidence: Observation

Standard TCRX3-J: Supervision is available during all hours that service is provided.

Interpretation: Supervision of personnel in the compounding pharmacy is provided 24 hours a day, 7 days a week, as applicable. Supervision is consistent with state laws and regulations.

Evidence: Observation

Evidence: On-Call Schedules

Evidence: Response to Interviews

Standard TCRX3-K: The organization's personnel have access to a reference library and/or internet access that is appropriate to the level of services provided.

Interpretation: Personnel have available a library of reference books, journals, internet access, etc., that is appropriate for the client/patient population served.

Resources include, but are not limited to:

- Professional journals
- General clinical reference
- Drug reference books
- Clinical guidelines
- Current medical dictionary
- Current statutes and rules for any state in which the personnel provide services

Evidence: Observation



Standard TCRX4-A: A Registered Pharmacist reviews all client/patient medications and consults with other health care professionals caring for the client/patient, including the physician, as applicable. All Omnibus Budget Reconciliation Act (OBRA) counseling is completed as specified by law.

Interpretation: The pharmacy obtains the age, gender, allergies, species (for veterinary patients), medical conditions and pertinent information that may affect drug utilization. Prior to dispensing compounded medications a Pharmacist reviews all prescription and non-prescription medications that a client/patient is currently taking.

A medication profile is established at the start of therapy. This profile is updated whenever there are changes in the client's/patient's medication therapy or as designated by the pharmacy policies and procedures.

A Registered Pharmacist is specifically responsible for recognizing the following as they pertain to compounded medications dispensed by the pharmacy:

- Side effects
- Toxic effects
- Allergic reactions
- Desired effects
- Unusual and unexpected effects
- Actual or potential drug interactions
- Appropriateness of the drug for the client's/patient's diagnosis
- Appropriateness of the dose
- Changes in the client's/patient's condition that contraindicate continued use of the drug

The Pharmacist, in conjunction with other health care professionals, is able to anticipate those effects that may rapidly endanger a client's/patient's life or wellbeing and instruct the client/patient in the prescribed regimen.

Evidence: Client/Patient Records

Evidence: Response to Interviews

Evidence: Observation

Standard TCRX4-B: Written policies and procedures are established and implemented which address the timeliness of shipping, shipping errors, turnaround time and lost shipments.

Interpretation: Written policies and procedures include, but are not limited to:

- Timeliness of shipping to ensure the client/patient receives medication prior to the administration date
- Ability to track the preparations after they leave the organization
- Notifying the client/patient if the shipment will be delayed
- Processes in place to ensure the client/patient has a continuous supply of medication if shipment is delayed or lost

Personnel implement the policies and procedures for the process of tracking shipments.

Evidence: Written Policies and Procedures

Evidence: Observation

Standard TCRX5-A: The organization develops, implements, and maintains an effective, on-going, organization wide Performance Improvement (PI) program.

Interpretation: Each organization develops a program that is specific to its needs. The methods used by the organization for reviewing data include, but are not limited to:

- Current documentation (e.g., review of client/patient records, incident reports, and complaints)
- Direct observation
- Interviews with personnel



The data collected by the organization for self-assessment includes, but is not limited to:

- Adverse events
- Client/patient complaints
- Client/patient records
- At least one important aspect related to the service provided
- Ongoing monitoring of processes that involve risks including infections and communicable diseases

Evidence: Written Policies and Procedures/PI Plan



Standard TCRX5-B: The organization ensures the implementation of an organizational wide Performance Improvement (PI) Plan by the designation of a person responsible for coordinating PI activities.

Interpretation: Duties and responsibilities relative to PI coordination include:

- Assisting with the overall development and implementation of the PI Plan
- Assisting in the identification of goals and related client/patient outcomes
- Coordinating, participating in and reporting of activities and outcomes

The individual responsible for coordinating PI activities may be the owner, manager, supervisor or other designated personnel.

Evidence: Job Description

Evidence: Observation

Standard TCRX5-C: There is evidence of personnel involvement in the Performance Improvement (PI) process.

Interpretation: Personnel receive training related to PI activities and their involvement. Training includes, but is not limited to:

- The purpose of PI activities
- Person responsible for coordinating PI activities
- Individual's role in PI
- PI outcomes resulting from previous activities

Personnel are involved in the evaluation process through carrying out PI activities, evaluating findings, recommending action plans, and/or receiving reports of findings.

Evidence: Response to Interviews

Standard TCRX5-D: Each performance improvement (PI) activity or study contains the required items.

Interpretation: Each PI activity/study includes the following items:

- A description of indicator(s) to be monitored/activities to be conducted
- Frequency of activities
- Designation of who is responsible for conducting the activities
- Methods of data collection
- Acceptable limits for findings
- Designation of who will receive the reports
- Plans to re-evaluate if findings fail to meet acceptable limits
- Any other activities required under state or federal laws or regulations

Evidence: Performance Improvement Activities/Studies

Standard TCRX5-E: Written policies and procedures are established and implemented by the organization to identify, monitor, report, investigate and document all adverse events, incidents, accidents, variances, or unusual occurrences that involve clients/patients who receive compounded preparations.

Interpretation: Written policies and procedures describe the process for identifying, reporting, monitoring, investigating and documenting all adverse events, incidents, accidents, variances, or unusual occurrences. Policies and procedures include, but are not limited to:

- Action to notify the supervisor or after hours personnel
- Time frame for verbal and written notification
- Appropriate documentation and routing of information
- Guidelines for notifying the physician, if applicable
- Follow-up reporting to the administration/board/owner



Written policies and procedures identify the person responsible for collecting incident data and monitoring trends, investigating all incidents, taking necessary follow-up actions and completing appropriate documentation.

The organization investigates all adverse events, incidents, accidents, variances or unusual occurrences that involve client/patient services and develops a POC to prevent the same or a similar event from occurring again. Events include, but are not limited to:

- Unexpected death
- A serious injury
- Significant adverse drug reaction, if applicable
- Significant medication error, if applicable
- Other undesirable outcomes as defined by the organization
- Adverse client/patient care outcomes
- Client/patient injury, (witnessed and un-witnessed)

There are written policies and procedures for the organization to comply with the FDA and state boards of pharmacy to facilitate any recall notices submitted by the manufacturer, if applicable.

The organization has developed a standardized form it uses to report adverse events and to document all incidents, accidents, variances, and unusual occurrences. The organization initiates an investigation within 24 hours after becoming aware of an incident resulting in a client's/patient's hospitalization or death. For other occurrences, the organization investigates within 72 hours after being made aware of the incident, accident, variances or unusual occurrences.

This data is included in the PI plan. The organization assesses and utilizes the data to reduce further safety risks.

Evidence: Written Policies and Procedures

Evidence: Incident/Variance Reports

Evidence: Performance Improvement Reports

Standard TCRX5-F: Performance Improvement (PI) activities include an assessment of processes that involve risks, including infections and communicable diseases.

Interpretation: A review of all variances, which includes but is not limited to incidents, accidents and complaints/grievances, is conducted at least quarterly to detect trends and create an action plan to decrease occurrences.

Evidence: Performance Improvement Reports

Evidence: Incident/Variance Reports

Standard TCRX5-G: Written policies and procedures are established and implemented regarding continuous quality control for finished preparations.

Interpretation: The pharmacy establishes an on-going quality control program that defines:

- When to test preparations
- What test(s) should be performed
- Appropriate methods and equipment to use
- How to interpret the test
- Limits of the test
- Specific actions required when a preparation does not meet the test
- How quality control information is used to improve the performance of personnel
- How quality control information is incorporated into the pharmacy's PI Program

Testing every compounded preparation is not required; ACHC encourages organizations to design quality control programs that can be used to verify the quality of compounded preparations and the competency of compounding personnel. For example:



For non-sterile preparations:

- Using the procedure defined in USP Chapter <1163>, each compounder performs weight assessment for each of the following dosage forms they prepare: capsules, tablets, suppositories, inserts and lozenges every six months.
- Each compounder's finished preparation is tested for potency in each of the following dosage forms they prepare: solutions, suspensions, capsules, tablets, suppositories, creams/ointments and lozenges every six months.

For sterile preparations:

- For accuracy and precision testing for automated compounding devices, a periodic assessment of large volume parenterals to verify fill volume is performed.
- For potency testing of finished preparations, each compounder's finished high risk preparation is tested for potency in each of the following dosage forms they prepare:
 - Preparations sterilized by filtration
 - Sterilization
 - Dry heat every six months
- Sterility testing of high risk preparations is performed in accordance with USP Chapter <71>.
- Inspection of low and medium risk preparations is performed for proper labeling, absence of cores/particulates etc.

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Response to Interviews

Standard TCRX5-I: Performance Improvement (PI) activities include ongoing monitoring of at least one important aspect related to the sterile compounding process.

Interpretation: The organization conducts monitoring of at least one important aspect of the sterile compounding process. An important aspect of service reflects a dimension of activity that may be high volume (occurs frequently or affects a large number of clients/patients), high risk (causes a risk of serious consequences if the service is not provided correctly), or problem-prone (has tended to cause problems for personnel or clients/patients in the past).

Examples of activities include but are not limited to:

- Monitoring of the finished compounded preparation by testing that the sterility or potency is performed in accordance with the organization's written policies and procedures
- Tracking and classifying quality-related events to identify opportunities for improvement
- Auditing of compounding and formulation records for accuracy and completeness
- Auditing of personnel records to ensure that sterile compounding training and competency assessments are performed as required

Evidence: Performance Improvement Reports

Standard TCRX5-J: Performance Improvement (PI) activities include the ongoing monitoring of client/patient complaints/grievances.

Interpretation: PI activities include ongoing monitoring of client/patient complaints and the action(s) needed to resolve complaints and improve client/patient service.

Evidence: Performance Improvement Reports

Standard TCRX5-K: There is a written plan of correction (POC) developed in response to any Performance Improvement (PI) findings that do not meet an acceptable threshold.

Interpretation: A written POC is developed in response to any PI activity that does not meet an acceptable threshold. The POC identifies changes in policies and procedures that will improve performance.

Evidence: Written Corrective Action Plans



Standard TCRX5-L: There is an annual Performance Improvement (PI) report written.

Interpretation: There is a comprehensive, written annual report that describes the PI activities, findings and corrective actions that relate to the service provided. In a large multi-service organization, the report may be part of a larger document addressing all of the organization's programs.

While the final report is a single document, improvement activities must be conducted at various times during the year. Data for the annual PI report may be obtained from a variety of sources and methods, such as audit reports, client/patient questionnaires, feedback from referral sources and outside survey reports.

Evidence: Performance Improvement Annual Report



Standard TCRX6-A: Written policies and procedures are established and implemented that address the surveillance, identification, prevention, control and investigation of infectious and communicable diseases and the compliance with regulatory standards.

Interpretation: The organization maintains and documents an effective infection control program that protects clients/patients and personnel by preventing and controlling infections and communicable diseases.

The organization's infection control program must identify risks for the acquisition and transmission of infectious agents. There is a system to communicate with all personnel about infection prevention and control issues including their role in preventing the spread of infections and communicable diseases through daily activities.

Written policies and procedures are established and implemented to include accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions.

Accepted standards of practice for health care providers are typically developed by government agencies, professional organizations and associations.

Written policies and procedures include, but are not limited to:

- General infection control measures appropriate for service provided
- Hand washing
- Use of standard precautions and personal protective equipment (PPE)
- Needle-stick prevention and sharps safety, if applicable
- Appropriate cleaning/disinfecting procedures
- Infection surveillance, monitoring, and reporting of employees and clients/patients
- Disposal and transportation of regulated waste, if applicable
- Employee health conditions limiting their activities
- Assessment and utilization of data obtained about infections and the infection control program
- If the pharmacy compounding activities require the manipulation of a patient's blood-derived or other biological material, the pharmacy is compliant with the OSHA Bloodborne Pathogens Standard.

Written policies and procedures identify the personnel who are responsible for implementing the infection control activities and personnel education.

Evidence: Written Policies and Procedures

Evidence: Observation

Standard TCRX6-B: Written policies and procedures are established and implemented for preparation and/or component recall.

Interpretation: The pharmacy has a mechanism for identifying, in a timely and effective manner, which clients/patients received recalled compounded preparations or their components.

Written policies and procedures include, but are not limited to:

- Identification of clients/patients who received a recalled preparation or component
- Timely and effective notification to affected clients/patients and prescribers
- Tracking of preparations and their components
- External reporting of components and preparation defects
- Safe disposal of recalled medications or preparations

Documentation includes, but is not limited to:

- Records that permit the identification of clients/patients who received a recalled preparation or component
- The manufacturer or source of each ingredient in a preparation and the lot number
- The batch number of the preparation
- Serial numbers used to track equipment
- Records indicating the pharmacy has completed recall(s) in a manner that is consistent with its written policies and procedures, if applicable



Evidence: Written Policies and Procedures
Evidence: Dispensing/Compounding Records
Evidence: Response to Interviews

Standard TCRX6-C: Written policies and procedures are established and implemented relating to the storage of pharmaceuticals, components (including active pharmaceutical ingredients, excipients, ingredients, and devices) and compounded preparations.

Interpretation: Written policies and procedures that are established and implemented that include, but are not limited to:

- Storage of pharmaceuticals, components, and compounded preparations in order to maintain their integrity and security
- Establishing appropriate storage temperatures and other storage conditions for pharmaceuticals, components, and compounded preparations
- Monitoring and documenting that storage area(s), refrigerator, and freezer temperatures maintain the appropriate storage conditions
- Regular inspections to remove, quarantine, and dispose of expired pharmaceuticals, components and compounded preparations
- Defining a quarantine area for pharmaceuticals, components and compounded preparations removed from inventory due to recall, expiration or other reasons
- Contingency plans addressing situations where storage conditions fall outside of established ranges
- Storage and handling of hazardous and potent drugs
- Disposal of pharmaceuticals, components, and compounded preparations
- Labeling of storage containers, including but not limited to name, strength, lot number, transfer date, expiration date and manufacturer or source
- Cleaning and disinfecting of any reusable storage containers

Pharmaceuticals, components and finished compounded preparations are stored in accordance with manufacturer or USP requirements. Storage conditions are monitored wherever these items are stored to ensure that the requirements are met. Pharmaceuticals, components, and finished compounded preparations are stored in the licensed pharmacy, which is accessible only under the supervision of a Registered Pharmacist.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Temperature/Cleaning Logs
Evidence: Response to Interviews

Standard TCRX6-D: The organization uses delivery containers that assure pharmaceuticals are maintained under appropriate conditions of sanitation, light and temperature in the course of deliveries.

Interpretation: The organization ensures that pharmaceuticals are maintained under appropriate conditions of sanitation, light, and temperatures in the course of deliveries. Where appropriate, the organization uses delivery containers such as coolers and ice packs to maintain the storage conditions in accordance with the manufacturer, USP, and/or other applicable requirements.

The organization educates the client/patient on the appropriate conditions for the storage of pharmaceuticals in the home environment. When necessary, the pharmacist intervenes, as indicated, to ensure that appropriate conditions are achieved or maintained.

Shipping methods are tested periodically under the typical conditions the organization's shipments experience (i.e. extreme summer heat and winter cold) to ensure that containers stay within specified temperature requirements.

Evidence: Observation
Evidence: Response to Interviews

Standard TCRX6-E: Written policies and procedures are established and implemented by the Pharmacy relating to the appropriate use, calibration, cleaning and as appropriate, disinfection or sterilization of equipment used for preparing, dispensing, labeling, and shipping of preparations.

Interpretation: The written policies and procedures and the implementation must include, but are not limited to:

- Appropriate use of equipment
- Calibration of machines and equipment that states frequency and findings
- Cleaning schedules for equipment
- Disinfection or sterilization procedures and schedules
- Testing of equipment
- Procedure for the use, calibration, maintenance, and accuracy testing of ACDs (applies to sterile compounding only)

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Manufacturer's Service Manuals/Guidelines

Evidence: Response to Interviews

Standard TCRX6-F: Written policies and procedures are established and implemented for compounding preparations that outline the selection of ingredients and are in compliance with applicable law, regulations and standards of good practice.

Interpretation: Written policies and procedures are established for compounding preparations that outline the selection of ingredients in a manner that is compliant with applicable laws, regulations, and standards of good practice, which include but are not limited to:

- A process for documenting that suppliers for bulk chemicals are FDA registered, licensed in good standing and are able to provide Certificates of Analysis (CofAs) and Safety Data Sheets (SDSs)
- Criteria for acceptance or rejection of components based upon CofA review and other criteria
- A process for incorporating pertinent CofA data into MFRs and for the retention of CoAs
- A process for ensuring that the pharmacy does not compound for human patients with medications included on the FDA's "List of Drug Products That Have Been Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness," or the FDA's "demonstrable difficulties for compounding" list.
- Bulk substances comply with the standards of an applicable USP or National Formulary (NF) monograph, if one exists
- If a monograph does not exist, the drug substance(s) in compounded medications for human patients must be a component of an FDA-approved human drug product
- If a monograph does not exist and the drug substance in compounded medications for human patients is not a component of an FDA-approved human drug product, it must appear on a list of bulk drug substances for use in compounding developed by the FDA
- Official compounded preparations are prepared from ingredients that meet requirements of the compendial monograph for those individual ingredients for which monographs are provided
- For non-sterile preparations, ensuring that components that do not have expiration dates assigned by the supplier are labeled with the date of receipt and are assigned a conservative expiration date based on stability data and not to exceed three years from the date of receipt.
- For sterile preparations, the date of receipt for bulk substances and excipients will be clearly and indelibly marked on each package of ingredient, packages of ingredients that lack a supplier's expiration date cannot be used after one year unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality

Evidence: Written Policies and Procedures

Evidence: Record Reviews

Evidence: Observation

Evidence: Response to Interviews

Standard TCRX6-G: Written policies and procedures are established and implemented that outline the contents of the Master Formulation Record for each compounded preparation.

Interpretation: Written policies and procedures are established and implemented in regard to the use of a formulation record that provides the pharmacy with a consistent source document for preparing each compounded preparation. The process is consistent with applicable laws and regulations.



There is a Master Formulation Record (MFR) for each preparation that includes:

- Name, strength and dosage form
- Ingredients and their quantities
- Pertinent calculations
- Equipment and equipment settings used to produce the preparation
- Mixing and/or other pertinent instructions
- Quality control procedures and expected results
- Compatibility and stability information including references when available
- Beyond use date (BUD) and supporting justification/reference
- Container and packaging used for dispensing
- Packaging and storage requirements
- Labeling information including generic name and quantity/concentration of each active ingredient
- A description of the final preparation

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Response to Interviews

Standard TCRX6-H: Written policies and procedures are established and implemented that outline the contents of the compounding record for each preparation.

Interpretation: Written policies and procedures are established and implemented in regard to the use of a Compounding Record that documents the actual ingredients in a preparation, the person responsible for compounding, and the Pharmacist who approves the finished preparation. The process is consistent with applicable laws and regulations.

There is a Compounding Record for each preparation that includes:

- Formulation record used
- Ingredients and quantity of each, lot, expiration date, manufacturer or source
- Quantity prepared
- Names of the individual(s) making the preparation
- Signature or initials of the supervising Pharmacist responsible for in-process and final checks
- Date of preparation
- Prescription or batch number
- Assigned BUD
- Results of quality control procedures (weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing, as appropriate to each dosage form)

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Response to Interviews

Standard TCRX6-L: Written policies and procedures are established and implemented in regard to compounding sterile preparations in accordance with USP Chapter <797> standards, the art and science of pharmacy, applicable laws and regulations.

Interpretation: Personnel use appropriate techniques to compound preparations. Written policies and procedures are established and implemented to ensure preparations are made in accordance with applicable USP standards, the art and science of pharmacy, and applicable laws and regulations.

Written policies and procedures define how compounding is performed, including but not limited to:

- How critical processes are performed (including but not limited to weighing, measuring, and mixing)
- How dosage forms are prepared according to applicable USP standards, the art and science of pharmacy, and applicable laws and regulations
- Checks and rechecks for each procedure at each stage of the process

- Compounding preparations using the MFR, the Compounding Record, and associated written procedures, documenting any deviation in procedures
- Access to the buffer area is restricted to relevant personnel, and interruptions are minimized
- Introduction of only those medications, supplies, and equipment into the controlled air environments, which are necessary for the current preparation
- The use of carts in controlled air environments
- Proper aseptic technique, including attention to the concept of “first air”
- Cleaning and sanitizing compounding areas and equipment prior to compounding
- Segregating compounding activities to prevent mix-ups among ingredients, containers, labels, in-process materials, and finished preparations
- Performing compounding activities in a manner designed to prevent cross-contamination
- Clean room behaviors, including but not limited to food, gum, drinks, jewelry, rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infection, etc.
- Thoroughly and promptly cleaning the compounding area and all equipment after use
- Avoiding interruption of personnel during the compounding process
- Personal hygiene, hand washing, gowning, and gloving for non-hazardous sterile compounding
- Preparing hazardous drugs, including using appropriate garb and biological safety cabinets (BSCs)
- Preparation of sterile drugs from non-sterile ingredients, if applicable

Personnel are knowledgeable and follow the appropriate steps to ensure that preparations are made in accordance with applicable USP standards, the art and science of pharmacy and applicable laws and regulations.

Evidence: Written Policies and Procedures

Evidence: Observation

Standard TCRX6-M: Non-Hazardous sterile preparations are compounded in an environment that meets requirements for the appropriate risk level as defined by USP Chapter Chapter <797>, state board of pharmacy regulations, and standards of good practice.

Interpretation: The pharmacy has the proper environment(s) for the preparation of compounded sterile preparations (CSPs), which at a minimum, meet the USP Chapter <797>, applicable board of pharmacy requirements and standards of good practice appropriate to the risk level of CSPs it prepares, including but not limited to:

- Low risk preparations: A primary engineering control Compounding aseptic isolator (CAI), Compounding aseptic containment isolator (CACI) or Laminar Flow Workstation (LAFW) located outside of a minimum ISO-7 area
- Low and medium risk preparations: A primary engineering control (CAI, CACI, LAFW) located in an ISO class 7 buffer area with an ISO class 7 or 8 ante-area for buffer areas not physically separated from ante-areas with a minimum airflow of 40 feet per minute that is maintained across the line of demarcation

or

- A CAI or CACI meeting the following requirements:
 - The device provides isolation from the room and maintains ISO class 5 during dynamic operating conditions
 - Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site maintain ISO Class 5 levels during compounding operations
 - Not more than 3520 particles (0.5 µm and larger) per m³ shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer
 - The pharmacy has documentation from the manufacturer that the CAI/CACI will meet the above requirements when located in environments where the background particle counts exceed ISO Class 8
- Low, medium and high risk preparations: A primary engineering control (CAI, CACI, LAFW) located in an ISO class 7 buffer area with an ISO class 7 or 8 ante-area; ante-areas and buffer rooms are physically separated, and maintain a minimum differential positive pressure of 0.02-0.05 inch water column.
- Low, medium and high-risk preparations: A CAI or CACI located in a minimum ISO-8 areas; for high-risk preparations, pre-sterilization procedures are performed in the ISO-8 area.
- The surfaces of ceilings, walls, floors, fixtures, furniture, shelving, counters, and cabinets in the buffer area are impervious, free from cracks and crevices, and non-shedding, and resistant to disinfectants



- Facilities are comfortable and can maintain a temperature of 68 degrees Fahrenheit or cooler
- Buffer areas do not contain sinks or floor drains

Evidence: Observation

Standard TCRX6-N: Written policies and procedures are established and implemented in regard to how hazardous sterile preparations are compounded in an environment that meets requirements for the appropriate risk level as defined by USP Chapter <797>, state board of pharmacy regulations, and standards of good practice.

Interpretation: Written policies and procedures define appropriate garb and personal protective equipment (PPE) (e.g. gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and double gloving with sterile chemo-type gloves) to compound hazardous preparations.

The pharmacy has the proper environment(s) to prepare sterile preparations which, at a minimum, meet the USP Chapter <797>, applicable board of pharmacy requirements and standards of good practice appropriate to the risk level of its CSPs, including but not limited to:

- Pre-sterilization procedures such as weighing, mixing and other manipulations are performed in a minimum Class I BSC.
- Hazardous sterile preparations are compounded in an appropriate primary engineering control such as an ISO Class 5 BSC or CACI.
- The ISO Class 5 or better BSC or CACI is placed in an ISO Class 7 or better area that is physically separated and has not less than 0.01- inch water column negative pressure to the adjacent ISO Class 7 or better anteroom.
- In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., closed system vial transfer device CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable in lieu of a negative pressure room.
- If a CACI meeting USP Chapter <797> requirements is used outside of a buffer area, the room area must maintain at least 0.01 inch water column negative pressure and 12 air changes per hour (ACHs).

Evidence: Written Policies and Procedures

Evidence: Observation

Standard TCRX6-O: Written policies and procedures are established and implemented for cleaning, disinfecting and monitoring the controlled air environment(s).

Interpretation: Cleaning and disinfection procedures follow requirements set forth by USP General Chapter <797> and the individual state boards of pharmacy. Written policies and procedures include, but are not limited to:

- Processes for cleaning/disinfecting work surfaces, equipment, and work areas including frequency, cleaners/disinfectants and documentation/logs
- Processes for certification of primary and secondary engineering controls at a minimum of every six months, and for the review and documentation of the results
- Processes for monitoring and recording pressure differentials between buffer area and ante-area, and between the ante-area and the general environment
- A program for viable air sampling meeting USP Chapter <797> requirements, including use of active air sampling equipment at a minimum of every six months, definition of sampling locations, method of collection, volume of air sampled, activity in the compounding area during sampling, and action levels
- Documentation of viable air sampling results
- Regardless of the colony forming unit (cfu) identified by airborne particle sampling, identification of microorganisms recovered (at least the genus level) and measures to be taken when pathogenic organisms are identified



- Action levels based on cfu counts for microbial contamination and measures to be taken when action levels are met or exceeded
- Requirements for a surface sampling program meeting USP Chapter <797> requirements, which include but are not limited to: definition of sampling locations, method of collection, sampling frequency, and action levels

Action levels based on cfu counts for microbial contamination and measures to be taken when action levels are met or exceeded.

Evidence: Written Policies and Procedures

Evidence: Quality Control Records

Evidence: Observations

Standard TCRX6-Q: Written policies and procedures are established and implemented in regard to assigning each sterile preparation a Beyond Use Date (BUD) to assure that the preparation retains its strength, purity and quality until the labeled BUD date.

Interpretation: Written policies and procedures are established and implemented to ensure that an appropriate BUD is assigned to each sterile preparation, which includes:

- When the pharmacy lacks stability information that is applicable to a specific drug and preparation, BUDs for sterile preparations are assigned using USP Chapter <797> guidelines for each CSP risk level:
 - Low risk preparations: In the absence of passing a sterility test, storage periods before administration cannot exceed 48 hours at controlled room temperature, 14 days at a cold temperature, or 45 days frozen.
 - Medium risk preparations: In the absence of passing a sterility test, storage periods before administration cannot exceed 30 hours at controlled room temperature, 9 days at a cold temperature, or 45 days frozen.
 - High risk preparations: In the absence of passing a sterility test, storage periods before administration cannot exceed 24 hours at controlled room temperature, 3 days at a cold temperature or 45 days frozen.
- When BUDs are assigned that exceed USP Chapter <797> guidelines, the rationale for the BUD assignment is based upon the following in order of priority:
 - Stability information derived from validated testing of the specific preparation, conditions, and container
 - USP/NF Monographs
 - Published stability information for similar compounds and formulations with the specific container and conditions
 - Stability studies published in literature (peer reviewed preferred)
 - Manufacturer (if a manufactured product is involved)
 - Professional judgment
- The rationale/source for the BUD assignment is documented on the MFR
- Compounded preparations are packaged in a manner that maintains their identity, strength, quality and purity until the labeled BUD

Personnel should be aware that potency tests are designed to determine how much of the active drug is in the sample, whereas stability tests are used to determine a BUD for the preparation.

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Response to Interviews

Standard TCRX6-R: Written policies and procedures are established and implemented to assure preparations adhere to requirements for sterility and endotoxin limits.

Interpretation: This standard only applies to pharmacies that:

- Assign BUDs that exceed USP defaults for each risk level
- Prepare high risk compounded sterile products (CSPs)



Written policies and procedures are established and implemented to ensure that preparations adhere to established and/or compendial requirements for sterility requirements and endotoxin limits, which include:

Sterilization by filtration:

- Filters incorporate a 0.2 micron pore membrane that is chemically and physically compatible with the CSP. Filters are approved for human-use applications in sterilizing pharmaceutical fluids.
- Filters are of a size and capacity that permit the entire volume to be filtered without replacement.
- An integrity test (e.g. bubble point test) is performed on each filter after use. The integrity test follows manufacturer's recommendations and is documented on the compounding record.

Sterilization by steam:

- Testing is performed to verify that the mass of containers to be sterilized will be sterile after the selected exposure duration in the particular autoclave.
- Containers are placed to ensure that live steam contacts all ingredients and surfaces to be sterilized.
- Pass solutions are passed through a 1.2 micron or smaller pore size filter into final containers to remove particulates before sterilization.
- The effectiveness of steam sterilization is verified using appropriate biological indicators. The testing and results are documented.

Sterilization by dry heat:

- Dry heat is only used for those materials that cannot be sterilized by steam.
- Containers are placed to ensure circulation of hot air over all ingredients and surfaces to be sterilized.
- Dry heat sterilization is performed in a device designed for sterilization and capable of distributing heated air evenly throughout the chamber with a blower device.
- The effectiveness of dry heat sterilization is verified using appropriate biological indicators. The testing and results are documented.

Sterility testing:

- When BUDs are assigned that exceed USP Chapter <797> defaults for CSPs in the absence of a sterility test, sterility is verified by USP Chapter <71>, equivalent, or superior sterility testing.
- The testing and results are documented.

Endotoxin testing:

- All high-risk level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages or in multiple-dose vials (MDVs) for administration to multiple clients/patients or that are exposed longer than 12 hours at 2° to 8° and longer than six hours at warmer than 8° before they are sterilized are tested to ensure that they do not contain excessive bacterial endotoxins
- The testing results are documented.

Depyrogenation:

- Dry heat depyrogenation or an equivalent, superior depyrogenation method is used to render glassware and other containers and utensils free of pyrogens and viable microorganisms.
- The specific heat depyrogenation cycle and duration for specific load items is included in written documentation.
- The effectiveness of dry heat depyrogenation is verified using endotoxin challenge vials. The vials are tested to verify that the cycle can produce a 3-log reduction in endotoxins.

Evidence: Written Policies and Procedures

Evidence: Observation

Evidence: Response to Interviews

Standard TCRX6-S: The organization ensures that pharmaceuticals are stored under appropriate conditions of sanitation, light and temperature in the client's/patient's home.

Interpretation: Pharmaceuticals dispensed to the client/patient are clearly labeled with the appropriate storage conditions requirements.

The organization educates the client/patient on the appropriate conditions for the storage of pharmaceuticals in the home environment. When necessary, the Pharmacist intervenes, as indicated, to ensure that appropriate conditions are achieved or maintained.



Evidence: Client/Patient Records
 Evidence: Response to Interviews

Standard TCRX6-T: Written policies and procedures are established and implemented for participating in clinical research/experimental therapies and/or administering investigational drugs.

Interpretation: Written policies and procedures include, but are not limited to:

- Informing clients/patients of their responsibilities
- Informing clients/patients of their right to refuse investigational drugs or experimental therapies
- Informing clients/patients of their right to refuse to participate in research and clinical studies
- Notifying clients/patients that they will not be discriminated against for refusal to participate in research and clinical studies
- Stating which personnel can administer investigational medications/treatments
- Describing personnel's role in monitoring a client's/patient's response to investigational medications/treatments
- Identifying the responsibility for obtaining informed consent
- Defining the use of experimental and investigational drugs and other atypical treatments and interventions

Evidence: Written Policies and Procedures
 Evidence: Client/Patient Records

Standard TCRX6-U: Written policies and procedures are established and implemented to assure that compounded preparations are labeled in accordance with applicable laws and regulations, USP standards and standards of good practice.

Interpretation: Compounded preparations are labeled appropriately per state and federal laws and regulations, USP standards and standards of good practice. At a minimum labels for compounded preparations include:

- Name, address, and phone number of the pharmacy
- Date prescription was filled
- Prescription number
- Patient's name and species (if applicable)
- Name and strength(s) of active ingredient(s)
- Quantity or total volume
- Directions for use including the route of administration and rate of administration if applicable
- Prescriber's name
- Beyond Use Date (BUD)
- Storage and handling instructions
- Notification that the preparation is compounded

Evidence: Written Policies and Procedures
 Evidence: Observation



Standard TCRX7-B: Organizations that are PCAB Accredited for Sterile Compounding are required to provide documentation as evidence of continued compliance on an annual basis. This documentation is submitted two months prior to the expiration of the annual PCAB Accreditation. (This is an informational standard only for providers applying for sterile compounding for the first time.)

Interpretation: Organizations submit documentation annually to demonstrate continued compliance with PCAB Accreditation Sterile Compounding requirements.

The following documentation is submitted to ACHC two months prior to the expiration of the organization's PCAB Accreditation. The documentation requirements are:

- A description of any compounding equipment that was added since the last ACHC visit, and evidence of staff training consistent with ACHC **Standard TCRX3-B**
- The total number of pharmacists and pharmacy technicians performing sterile compounding
- Submission of initial (for new hires) and annual competency assessments (for existing personnel) as required under ACHC Standards TCRX3-B and TCRX3-F
- Submission of a summary of all calibration logs and certifications done on the sterile compounding equipment including balance calibrations, consistent with ACHC **Standard TCRX6-E**
- Submission of a sample of 10 Master Formulation Records (MFRs) and Compounding Record(s) for a variety of preparation prepared over the previous 12 months consistent with ACHC **Standard TCRX6-G and TCRX6-H**
- Documentation of compliance with the quality control program defined by ACHC **Standard TCRX5-G including a summary of internal testing results and copies of external potency testing results**
- Submission of POCs as outlined in ACHC **Standard TCRX5-K, including plans for correcting out-of-specification test results as a result of quality control testing performed under ACHC Standard TCRX5-G**
- Summary of records indicating compliance with the requirements of ACHC standard TCRX6-R in regards to sterility and endotoxin testing, including but not limited to: lot or batch number, quantity or volume prepared, units and/or volume tested, results of the test(s) and specific actions taken if the test(s) indicated the potential for microbiological contamination or excessive endotoxins.
- Submission of the annual PI report as outlined in TCRX5-L

Evidence: **(This is an informational standard only for providers applying for sterile compounding for the first time.)**
