



PCAB STANDARDS WITH COMPLIANCE INDICATORS

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Standard 1.00 Regulatory Compliance

Standard 1.10 Facility

The pharmacy is licensed or registered with relevant state and Federal regulatory authorities to operate a pharmacy and if applicable, dispense controlled substances.

Compliance Indicators

- A. The pharmacy lists the state(s) in which it is licensed or registered to operate a pharmacy, including all licenses or registration numbers.
- B. If the pharmacy dispenses controlled substances, it provides documentation that it is registered with the Drug Enforcement Administration (DEA).
- C. If the pharmacy ships or intends to ship medications to residents of states that do not require non-resident pharmacy licensure during the period of accreditation, the names of those states are to be listed.
- D. The pharmacy demonstrates that its employees have access to pharmacy rules and regulations of all states where pharmacy services are being provided.
- E. If the pharmacy has a pending regulatory action, it notifies PCAB within thirty (30) days.

Standard 1.20 Personnel

All personnel including pharmacists, technicians, students, temporary personnel, and those affiliated through contractual or other arrangements who are engaged in compounding and dispensing in the pharmacy are licensed, registered, certified, or otherwise credentialed, if applicable, by the states in which they practice, by an appropriate licensing agency, certifying agency, school of pharmacy, or other body.

Compliance Indicators

- A. The pharmacy provides documentation that all pharmacists, technicians, students, temporary personnel, and those affiliated through contractual or other arrangements who are engaged in compounding and dispensing in the pharmacy are licensed, registered, certified, or otherwise credentialed, if applicable, by the states in which they practice, by an appropriate licensing agency, certifying agency, school of pharmacy, or other body.
- B. The pharmacy provides evidence that its Standard Operating Procedures (SOPs) address the process for verifying the credentials of new independent contractors/employees.

Standard 1.30 External Standards

The pharmacy compounds according to standards of practice adopted by its state board of pharmacy and/or national practices and standards adopted by non-governmental standard setting organizations.

Compliance Indicators

- A. The pharmacy demonstrates that its SOPs provide that the compounding is performed in accordance with state and/or national practice standards.
- B. The pharmacy demonstrates that it has access to all current and applicable standards of the United States Pharmacopeial Convention (USP).

Standard 1.40 Standard Operating Procedures

The pharmacy develops, maintains, follows, and periodically updates written Standard Operating Procedures (SOPs) which addresses all aspects of the compounding operation.

Compliance Indicators

- A. The pharmacy provides a copy of its SOPs manual with a table of contents.
- B. The pharmacy demonstrates that the SOPs are readily available to and accessible by all relevant compounding personnel.
- C. The SOPs contain a “policy on policies” which may include:
 - 1. Identification of the individual(s) in the organization that have authority to approve SOPs and subsequent edits to SOPs;
 - 2. Outlining the process by which SOPs are approved;
 - 3. Recording the date new polices are implemented;
 - 4. Establishing and maintaining an indexing system to facilitate reference and retrieval of SOPs by staff;
 - 5. Document the review, revision, and archiving of existing SOPs.

Standard 2.00 Personnel

Standard 2.10 General

Supervision and level of personnel is sufficient to assure the safety and integrity of compounding. All personnel affiliated with compounding in the pharmacy are competent to perform their assigned duties.

Compliance Indicators

- A. The pharmacy provides a written description of the responsibilities and functions of all compounding personnel.
- B. The pharmacy has SOPs for orienting and training new compounding personnel, including temporary and contracted employees.
- C. The pharmacy has SOPs for educating, training, and assessing the competencies of all compounding personnel on an ongoing basis, including documentation that compounding personnel is trained on SOPs.
- D. The pharmacy demonstrates that it continually assesses its staffing needs relevant to all elements of the compounding and dispensing process including environmental and equipment maintenance.

Standard 2.20 Pharmacist in Charge

There is a pharmacist in charge of the compounding activities who establishes the scope of compounding practice for relevant staff based on the education, training, and demonstrated competence. The pharmacist in charge supervises all compounding personnel, assures that compounded preparations meet SOPs, and maintains compliance with state and Federal regulations and PCAB standards.

Compliance Indicators

- A. The pharmacy provides documentation that the pharmacist in charge has the education, training, and experience consistent with the responsibilities and the scope of compounding practice performed in the pharmacy.
- B. The pharmacy demonstrates that the pharmacist in charge has sufficient authority to carry out these responsibilities.
- C. The pharmacist in charge demonstrates an awareness of these responsibilities under applicable state and/or Federal law, compounding practice within the pharmacy, and current USP standards related to non-sterile and, if applicable, sterile compounding.
- D. The pharmacist in charge demonstrates an adequate knowledge of all operations of the pharmacy relating to good compounding practices as identified in the SOPs.

Standard 2.30 Staff Pharmacists

There are staff pharmacists to assure that compounded preparations are prepared, packaged, labeled, stored, and dispensed according to SOPs of the pharmacy. Staff pharmacists are responsible for patient counseling and/or patient care services required by applicable state law or practice standards.

Compliance Indicators

- A. The pharmacy provides documentation that staff pharmacists are competent, as defined in the SOPs, to assure the quality of preparations compounded, packaged, labeled, stored, and dispensed in the pharmacy.
- B. Staff pharmacists demonstrate adequate knowledge of operations of the pharmacy related to the scope of compounding and dispensing in which they participate or supervise.
- C. Staff pharmacists demonstrate their education and training in good compounding practices.
- D. Staff pharmacists demonstrate that they are knowledgeable about current USP standards related to non-sterile compounding.
- E. Staff pharmacists demonstrate that they are knowledgeable about current USP standards related to sterile compounding, if applicable.
- F. Staff pharmacists demonstrate knowledge of dispensing requirements and procedures used in the pharmacy.
- G. Staff pharmacists are responsible for verifying that SOPs are being followed for preparing compounded preparations.
- H. Staff pharmacists are responsible for direct supervision of all compounding personnel.

Standard 3.00 Facilities and Equipment

Standard 3.10 General

The pharmacy has facilities and equipment sufficient for the safe and accurate compounding of preparations.

Compliance Indicators

- A. The pharmacy demonstrates that the size, type, and quality of facilities and equipment in the pharmacy is adequate to safely and accurately compound preparations in the amount and type relative to the nature of compounding that is performed in the pharmacy. This should include procedures for the control and containment of powders during compounding.
- B. The pharmacy has SOPs for each piece of equipment used in the compounding process that addresses cleaning, maintaining, calibrating and verification according to compendial standards or manufacturers' standards. At a minimum, the SOPs include documentation that equipment is regularly cleaned, maintained, calibrated and verified according to compendial standards or manufacturers' standards.
- C. If the pharmacy handles hazardous materials, it demonstrates that its SOPs are adequate to protect personnel based on volume and scope of compounding performed.

Standard 3.11 References

The pharmacy maintains reference materials that are current and relevant to the compounding performed in the pharmacy and in accordance with state regulations. Reference materials are readily accessible to personnel responsible for compounding of preparations.

Compliance Indicators

- A. The pharmacy has access to references that meets state laws in which the pharmacy is licensed or registered and includes all current and applicable USP standards.
- B. The references are available and accessible to all compounding personnel.
- C. The pharmacy demonstrates that the reference materials are current and relevant to the type of compounding performed in the pharmacy.
- D. The pharmacy demonstrates that compounding personnel are trained in the use of reference material and that compounding personnel use reference material in compounding practice.

Standard 3.20 Non-Sterile Compounding

The pharmacy that compounds non-sterile preparations maintains facilities that provide for minimization of interruptions, avoidance of contamination, and reduction of the potential for contamination of the compounded preparation.

Compliance Indicators

- A. The pharmacy has a dedicated, exclusive area for general, non-sterile compounding that meets current USP <795> standards.
- B. The pharmacy demonstrates that it organizes work flow to minimize interruption of compounding staff during the compounding process. Traffic from employees not involved with compounding is minimized.
- C. The pharmacy demonstrates that it maintains facilities and procedures adequate to avoid cross contamination and contamination by dust and other particulates in the compounding area.
- D. The pharmacy demonstrates that any equipment and surfaces involved in the compounding process is appropriately cleaned and/or sanitized before and after compounding activity as appropriate to prevent contamination.
- E. The pharmacy has SOPs for cleaning and maintaining equipment and for the establishment of cleaning and maintenance schedules.

Standard 3.30 Sterile Compounding

The pharmacy that compounds sterile preparations maintains facilities that provide for minimization of interruption, avoidance of contaminations, and an exclusive area for compounding of sterile preparations.

Compliance Indicators

- A. The pharmacy has an area for aseptic compounding of sterile preparations that meets current USP <797> standards.
- B. The pharmacy demonstrates that it organizes work flow to minimize interruption of compounding staff during the compounding process. Traffic from employees not involved with compounding is minimized.
- C. The pharmacy demonstrates that it maintains facilities and procedures adequate to avoid cross contamination and contamination by dust and other particulates in the compounding area.
- D. The pharmacy demonstrates that any equipment and surfaces involved in the compounding process is appropriately cleaned and/or sanitized before and after compounding activity as appropriate to prevent contamination.
- E. The pharmacy has SOPs for cleaning and maintaining equipment and for the establishment of cleaning and maintenance schedules.
- F. The pharmacy documents that it performs periodic environmental tests of the aseptic environment according to current USP <797> standards.
- G. The pharmacy documents that it monitors and tests sterile compounded preparations for sterility, bacterial endotoxins, pyrogenicity, and strength of ingredients potency according to current USP <797> standards.

Standard 4.00 Chemicals, Components, and Completed Compounded Preparations

Standard 4.10 General

The pharmacy maintains standard operating procedures related to the acquisition, storage, usage and proper destruction of drug substances and drug products, which are used as components in the compounding of preparations. Drug substances and products used to compound meet official compendial standards, if any, including current USP-NF standards, and are accompanied by certificate of analysis, which documents the strength, quality, purity and integrity of the drug substance.

Compliance Indicators

- A. The pharmacy has SOPs governing the acquisition of all chemicals, drug products, and components from reliable sources.
- B. The SOPs provide that certificates of analysis be retained electronically or in hard copy by the pharmacy for a period of not less than two years.
- C. The SOPs provide that certificates of analysis be reviewed by properly trained personnel prior to the release drug substances of chemicals for use in compounding.
- D. The pharmacy documents that it uses appropriate suppliers as the source of all bulk chemical ingredients, inactive ingredients or excipients, and other components used in compounding. The pharmacy obtains the following information from appropriate suppliers:
 - 1. FDA registered and inspected, if applicable;
 - 2. Documentation indicating compliance with FDA current Good Manufacturing Practices
 - 3. Proof of licensure in good standing with applicable state and/or Federal regulatory bodies.
 - 4. Ability to provide ready access to Certificates of Analysis (CofA) and Material Safety Data Sheets (MSDS) with all bulk chemicals.
- E. The pharmacy demonstrates that the SOPs address criteria for identifying and using suppliers for devices, containers, and closures used in compounding including complying with any applicable compendial standards, if applicable.
- F. The SOPs address contingency plans should an active pharmaceutical ingredient, inactive ingredient, excipient, or other component used in compounding become unavailable from any supplier meeting the above criteria. The SOPs set forth an adequate mechanism directing the pharmacist in charge to employ professional judgment in receiving, storing, and using such components from another quality source.
- G. The pharmacy documents that it uses high quality active pharmaceutical ingredients (APIs) for use in compounding that:
 - 1. Meets current USP/NF grade substances. If not available, then the use of other high-quality sources, such as:
 - i. Analytical reagent (AR),
 - ii. Certified American Chemical Society (ACS), or

- iii. Food Chemicals Codex (FCC) grade, are permitted as sources of active ingredients when appropriate.
 - iv. Dietary and nutritional supplements that are “Generally Recognized As Safe”
 - 2. Meets other compendial standards, or
 - 3. Are components of products that have been approved by FDA or grandfathered under the Food, Drug & Cosmetic Act of 1938 (FDCA).
- H. The pharmacy complies with the FDA’s “List of Drug Products That Have Been Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness,” subject to the exceptions provided in such list. Written SOPs exist to safeguard against the use of such components in compounded preparations for human patients.
- I. The pharmacy demonstrates that it has a designated area for the receiving and inspection of chemicals, devices, containers, closures, and other components or supplies used in the compounding operation.
- J. The pharmacy has SOPs that assure Material Safety Data Sheets (MSDS) are properly maintained and readily retrievable.
- K. The pharmacy has SOPs that outline the criteria for acceptance or refusal of components.
- L. The pharmacy demonstrates that upon receipt of a chemical or drug substance, it is quarantined until the Certificate of Analysis (CofA) information is verified by properly trained compounding personnel and the MSDS information is assessed for review, as necessary.

Standard 4.20 Handling, Storage, and Disposal

The pharmacy safely handles, stores, and disposes of all chemicals, drug products and components according to compendial and other applicable requirements. Appropriate storage of chemicals, components, and completed compounded preparations shall be designed to maintain their strength, quality, purity, integrity, and where applicable, sterility.

Compliance Indicators

- A. The pharmacy has SOPs assuring that chemicals, components and completed compounded preparations are maintained within appropriate standards, as established by the current USP, including:
 - 1. Acceptable storage temperature ranges and temperature monitoring and documentation procedures,
 - 2. Contingency plans if conditions fall outside of acceptable ranges,
 - 3. Guidelines to be followed to determine if a component has been compromised and when it should be destroyed,
 - 4. Procedure for handling and storing hazardous and potent chemicals,
 - 5. Individuals responsible for making decisions regarding compromised components,
 - 6. Quarantine specifications, including expired and recall storage,
 - 7. Disposal or return of expired components and completed compounded preparations,

8. Storage and disposal of drug substances and drug products used as components in the compounding of preparations.
 - B. Storage containers include labels that include all relevant information, including but not limited to drug name, strength, lot number, date received, etc.
 - C. The pharmacy conducts periodic inspections to assure that expired components and completed compounded preparations do not remain in stock.
 - D. Storage of chemicals to be utilized for high-risk sterile compounding are stored in a separate area according to current USP <797> standards.

Standard 5.00 Compounding Records

Standard 5.00 Formulation Record and Compounding Record

The pharmacy uses a Formulation Record (FR) that assures the strength, quality, purity, integrity, and where applicable, sterility of the compounded preparation. The pharmacy uses a Compounding Record (CR) for assuring that the procedures employed to prepare compounded preparations are consistent and reproducible. Compounding activities and processes shall be subject to verification of preparations for strength, quality, purity, integrity, and where applicable, sterility that meet or exceed compendial standards.

Compliance Indicators

- A. The pharmacy demonstrates that the SOPs provide for verification of strength, quality, purity, integrity, and, where applicable sterility for all compounded preparations.
- B. The pharmacy documents that, when available, it incorporates into its FR those formulations and formulation procedures developed, tested, and verified by non-governmental standard setting organizations including, but not limited to the United States Pharmacopeial Convention:
 - 1. The pharmacy documents that it maintains a FR for each compounded preparations.
 - 2. The pharmacy identifies which compounding personnel may enter new FR and edit existing FR.
- C. The pharmacy provides documentation of a FR that maintains the following information on preparations that it compounds:
 - 1. Name, strength, and dosage form of the compounded preparation;
 - 2. Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients;
 - 3. Description of all components and ingredients, and their quantities;
 - 4. Compatibility and stability information, including references when available;
 - 5. Equipment used to prepare the compounded preparation, when appropriate;
 - 6. Mixing instructions that include, at a minimum: order of mixing, mixing temperatures or other environmental controls, duration of mixing, and other factors pertinent to the replication of the compounded preparation;
 - 7. Assigned beyond-use date of the compounded preparation;
 - 8. Container used in dispensing;
 - 9. Packaging and storage requirements;
 - 10. Quality control procedures; and
 - 11. References used in the development of the FR, if applicable.
- D. The pharmacy provides documentation of a Compounding Record (CR) that maintains the following information on components of preparations that it compounds to verify accurate compounding in accordance with the FR:
 - 1. Name and strength of the compounded preparation;
 - 2. FR reference for the preparation;

3. Sources, lot numbers, quantities, and expiration dates of components and ingredients;
4. Total quantity compounded and actual net measurements;
5. Name of the personnel involved in the compounding process and the name of the pharmacist who approved the compounded preparation;
6. Date of preparation;
7. Assigned internal identification number or prescription number;
8. Equipment used;
9. Assigned beyond-use date of the compounded preparation; and
10. Results of quality control procedures (e.g. weight range of filled capsules, pH of aqueous liquids, etc.).

Standard 6.00 Beyond-Use Dating, Potency, and Sterility

Standard 6.10 Beyond-Use Date

The pharmacy determines and assigns beyond-use dates to all its compounded preparations.

Compliance Indicators

- A. The pharmacy demonstrates that the SOPs provide for the determination and assignment of beyond-use dating for all of its compounded preparations.
- B. The pharmacy demonstrates by inspection the use of beyond-use dates on compounded preparations.
- C. The pharmacy documents the rationale and sources used to establish beyond-use dates which exceed current USP standards.
- D. The pharmacy documents how it communicates beyond-use dating information to compounding personnel and the patient and/or caregiver.
- E. The pharmacy provides rationale for beyond-use dating which exceeds current USP standards arrived at based on the pharmacist's professional judgment.

Standard 6.20 Potency

Compounded preparations meet established and/or compendial requirements of strength, quality, purity, potency and stability throughout the period for intended use when stored as labeled.

Compliance Indicators

- A. The pharmacy's SOPs satisfy current USP standards regarding potency and microbiological integrity of compounded preparations.
- B. The pharmacy provides documentation that it complies with all applicable state and Federal regulations regarding strength, quality, purity, potency and stability throughout the period for intended use of compounded preparations.

Standard 6.30 Sterility

Compounded preparations adhere to established and/or compendial requirements of sterility and bacterial endotoxin limits, throughout the period for intended use when stored as labeled.

Compliance Indicators

- A. The pharmacy's SOPs satisfy current USP standards regarding sterility and bacterial endotoxicity of compounded sterile preparations.
- B. The pharmacy provides documentation that it complies with all applicable current USP standards, state and/or Federal regulations regarding sterility and bacterial endotoxin limits of compounded sterile preparations.

Standard 7.00 Completed Compounded Preparations

Standard 7.10 Packaging, Labeling, and Delivery for Administration and Dispensing

The pharmacy adheres to state, Federal, and compendial requirements related to packaging, labeling, dispensing, and delivery for administration of compounded preparations.

Compliance Indicators

- A. The pharmacy demonstrates that it complies with applicable state, Federal, and compendial dispensing requirements related to the packaging, labeling, dispensing, and delivery for patient administration of the preparations that it compounds.
- B. The pharmacy demonstrates and documents that:
 - 1. Compounded preparations comply with compendial standards regarding packaging, labeling and dispensing, when applicable,
 - 2. Compounded preparations are packaged and labeled for the safety of the patient,
 - 3. Compliance with HIPAA and state confidentiality laws and regulations, if applicable,
 - 4. Procedures for packaging and shipping compounded preparations are verified periodically to assure the integrity of compounded preparations throughout the shipping process,
 - 5. Packaging and shipment of hazardous substances protect shipping personnel and end users.

Standard 7.20 Internal and External Recalls

The pharmacy has procedures for the appropriate and timely recall of dispensed compounded preparations where subsequent testing or other information demonstrates that the compounded preparation does not meet its declared strength, quality, purity, and, where appropriate, sterility and bacterial endotoxin limit..

Compliance Indicators:

- A. The pharmacy demonstrates in the SOPs a recall procedure which consists of:
 - 1. A procedure to determine the distribution of any compounded product, the date, quantity of distribution, quantity, dosage, and to identify patients receiving compounded preparations in a manner sufficient to allow the recall to be timely and effective based on severity,
 - 2. A method of timely informing prescribers, patients and/or caregivers concerning recalls based on severity,
 - 3. The necessary information to identify patients affected by a recall is readily retrievable.
- B. The pharmacy documents the implementation of a recall, including procedures concerning the disposition and reconciliation of the recalled preparation.

Standard 7.30 Labeling

The pharmacy labels completed compounded preparations according to the PCAB Labeling Guidelines.

Compliance Indicators

PCAB Labeling Guidelines

- A. The primary label of each compounded medication prepared in response to a prescription for a specific patient from a licensed prescriber includes a statement notifying the patient that the medication has been compounded. If space limitations or clinical reasons preclude inclusion on the primary label, the information may be affixed through auxiliary labeling.¹ For all such prescriptions, the statement is prominently displayed in the medication labeling.

“This medicine was specially compounded in our pharmacy for you at the direction of your prescriber.”²

- B. The following items of information, or a reasonable alternative, is included on all compounded prescription labels:³

- (1) Patient's name, and/or species, if applicable;*
- (2) Prescriber's name;*
- (3) Name, address, phone number of the pharmacy preparing the medicine;*
- (4) Prescription number;*
- (5) The medication's established or distinct common name;*
- (6) Strength;*
- (7) Statement of quantity;*
- (8) Directions for use;*
- (9) Date prescription filled;*
- (10) Beyond-use date*
- (11) Storage instructions; and*
- (12) All state labeling requirements.*

- C. The following information, or a reasonable alternative, is included with all compounded medication:

1 For example, when there is concern that a label applied directly to the primary container may affect the quality of the compounded medication. In such cases, the pharmacist may decide, in the pharmacist's professional judgment, that the label and statement be applied in another manner, such as to exterior packaging

2 Alternate language providing a clear designation that the medication has been compounded may be used, where, in the pharmacist's professional judgment, the welfare of the patient requires and the information is adequately and prominently communicated.

3 Label must be in conformity with applicable state, Federal, and compendial regulations and standards. Alternative placement may be acceptable if determined necessary because of space requirement or, in the pharmacist's professional judgment for the needs of the patient.

This medicine was compounded specifically for you in our pharmacy to fill the prescription your prescriber wrote for you. It was specially made to meet your individual needs. For this reason, no standardized information or literature is available with your prescription. If you have not done so, please discuss this medicine with your pharmacist or prescriber to assure that you understand (1) why you have been prescribed a compounded medicine, (2) how to properly take this medicine, and (3) the interactions, if any, this medicine may have with any other medicines you are taking.

Compounding is a long-standing pharmacy practice that allows prescribers to treat their patients' individual needs without being restricted only to off-the-shelf medicines or devices. This medicine was prepared in our compounding pharmacy to meet the specifications ordered by your prescriber.

1. Call your pharmacist or prescriber if:

- ◆ You experience any side effects.*
- ◆ You are taking additional medicines that may interact with this compounded medicine.*
- ◆ You have allergies or other medical conditions that should be noted.*

2. Call our pharmacists if:

- ◆ Information on the label is not clear to you.*
- ◆ You have any concerns regarding precautions, ingredients, or proper storage.*

Our pharmacists are available to address any additional questions or concerns.

- D. The following language is included on the primary label of each package compounded for use in the practitioner's office. If space limitations or clinical reasons⁴ preclude inclusion on primary labeling, the information may be affixed through auxiliary labeling. In either case, the statement is prominently displayed in the medication labeling.

"This medicine was compounded in our pharmacy for use by a licensed practitioner only. This compounded preparation may not be resold."

⁴ For example, when there is concern that a label applied directly to the primary container may affect the quality of the compounded medication. In such cases, the label and statement should instead be applied to exterior packaging.

Standard 8.00 Prescriber Communication and Patient Education

Standard 8.10 Prescriber Communication

The pharmacy communicates with prescribers about preparations that are compounded for their patients.

Compliance Indicators:

- A. The pharmacy has SOPs which address:
 - 1. A method to assure that, if it is not unmistakably evident or not indicated on the original prescription or order that the medication is to be compounded, it is confirmed with the prescriber that the preparation will be compounded,
 - 2. A method to disclose to prescribers all ingredients and methods of compounding as may be necessary in the event of an adverse event or possible untoward reaction.
- B. The pharmacy demonstrates that such communications with prescribers occur regularly.

Standard 8.20 Patient Education

A pharmacy complies with state and Federal patient education and counseling requirements.

Compliance Indicators

- A. The pharmacy's SOPs include a responsibility to provide education and counseling to patients and/or caregivers,
- B. The pharmacy demonstrates that it offers and provides to patients and/or caregivers education and consultation.
- C. The pharmacy has suitable written materials to provide the patient or caregiver with information on the appropriate use of compounded preparations, if applicable.
- D. The pharmacy demonstrates that prospective drug reviews are conducted prior to dispensing compounded preparations.

Standard 9.00 Total Quality Management

Standard 9.00 Total Quality Management

The pharmacy has in place and adheres to a plan for total quality management that is designed to assure, verify, and improve the quality of its compounded preparations and related services.

Standard 9.10 Quality Assurance (QA) Activities

The pharmacy has in place and adheres to a written quality assurance plan that, at a minimum on an annual basis, verifies, monitors, and reviews the adequacy of the compounding process. Quality assurance activities assure that compounded preparations meet criteria for identity, strength, quality, purity, and, where appropriate, sterility and bacterial endotoxin limit.

Compliance Indicators

(NOTE: Documentation of adherence to PCAB Standards 1 through 8 will provide evidence of a quality assurance plan)

- A. The pharmacy provides evidence of investigation(s), if any, regarding the appearance of deviation or actual deviation for standardized compounding procedures, and how these deviations were investigated, evaluated, corrected, and documented, including deviations discovered prior to the dispensing of the compounded preparation.
- B. The quality assurance plan provides that any compounded product that fails to meet quality standards, specifications, or other relevant quality control criteria will be rejected.

Standard 9.20 Quality Control (QC) Activities

The pharmacy has in place and adheres to a written quality control plan.

Compliance Indicators

- A. The pharmacy maintains SOPs related to its QC activities and has designated personnel responsible for QC activities.
- B. The pharmacy demonstrates that its QC plan references how compounded preparations meet current USP standards for strength, quality, purity, integrity, and where applicable, sterility and bacterial endotoxin limit.

Standard 9.30 Quality Related Events (QREs)

The pharmacy has in place and adheres to written SOPs for documenting and handling QREs.

Compliance Indicators

- A. The pharmacy's SOPs address the investigation, documentation, and resolution of QREs, and steps to avoid similar QREs.
- B. The pharmacy demonstrates that these SOPs are being followed.

- C. When appropriate or required by law or regulation, QREs are reported to appropriate agencies.
- D. Pharmacies are encouraged to report adverse drug events (ADE) to FDA's Medwatch system or a patient safety-organization (PSO) as defined by the Patient Safety and Quality Improvement Act of 2005.

Standard 9.40 Quality Improvement (QI) Activities

The pharmacy has in place and adheres to a quality improvement plan that is designed to

- *objectively and systematically collect data about the operations of the compounding process;*
- *evaluate this data and its effect on patient care;*
- *propose and select resolutions to identified problems;*
- *and collect data on whether the selected resolution(s) has/have the intended effect.*

Quality improvements are incorporated into SOPs, employees are trained in their use, and improvements are communicated to patients and prescribers, where appropriate.

The pharmacy uses data and findings from its QA, QC, and QRE monitoring and reporting to identify quality improvement priorities.

Compliance Indicators

- A. The pharmacy maintains SOPs related to its QI activities.
- B. The pharmacy demonstrates that its QI activities includes the collection of QA, QC, QRE and other data to identify priorities for improvement.
- C. The pharmacy provides examples of communicating QI activities to patients and prescribers, when appropriate and applicable.

Appendix

Definitions

Balance, Analytical

An electronic Class A balance with a readability of 0.1mg or lower.

Balance, Electronic

An electronic instrument utilized for weighing components used in the compounding process.

Beyond-Use-Date

The date after which a compounded preparation is not to be used and is determined from the date the preparation is compounded.

CCP - Completed Compounded Preparation

A preparation made by the compounder pursuant to a valid prescription order, that is in its finished state, and which is ready to be dispensed to a patient or prescriber.

Compendial Standards

Standards contained in the *United States Pharmacopeia–National Formulary (USP–NF)* or other official compendium as defined in the Federal Food Drug and Cosmetic Act.

Compliance Indicator

A guide to the interpretation of a standard to be used by surveyors, pharmacy owners and staff to determine how a standard should be applied. Compliance indicators are not “laws” or strict rules, they are guidelines. The failure to adhere to one indicator does not mean the pharmacy failed the standard to which it is applied. Likewise, meeting all indicators may not necessarily mean the standard has been “passed”.

Component

Any ingredient intended for use in the compounding of a completed compounded preparation (CCP).

Compounding Personnel

Any person involved with the compounding of a CCP (completed compounded preparation).

Compounding

Traditional pharmacy practice which includes the preparation, mixing, assembling, packaging, or labeling of a completed compounded preparation

(CCP) or administration device by compounding personnel

- (i) as the result of a practitioner's prescription order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice,
- (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis, and shall not be dispensed for resale by a third party,
- (iii) preparation of drugs or devices in anticipation of prescription orders to be received by the compounding pharmacist based on routine, regularly observed prescribing patterns,
- (iv) preparation of CCPs (completed compounded preparation) for practitioner administration, pursuant to state and federal regulations,
- (v) preparation of Non-Legend CCPs (completed compounded preparation), pursuant to state requirements, and (vii) preparing CCPs (completed compounded preparation) for both human and non-food producing animal patients.

Compounding Scope of Practice

Nonsterile Basic

Nonsterile Basic – compounding which involves the preparation of a formulation containing two or more nonsterile commercially available products employing basic pharmacy training skill sets, as well as, defined policy, procedures and processes necessary to assure quality and consistency of the completed compounded preparation.

Nonsterile Complex

Nonsterile Complex - compounding which involves the art and science of preparing a formulation using bulk drug substances, drug products, and/or other excipients. These formulations require complex procedures or calculations in their preparation and include formulations that incorporate the use of potent or hazardous pharmaceutical ingredients.

Sterile, Low and Medium

Sterile, Low and Medium - compounding which involves the preparation of Compounded Sterile Preparations (CSPs) in closed-system steps or procedures using a few basic aseptic manipulations, as well as those Compounded Sterile Preparations (CSPs) prepared via complex or numerous aseptic manipulations for administration to one patient on multiple occasions or to multiple patients.

Sterile, High

Sterile, High – compounding which involves the preparation of sterile preparations from non-sterile ingredients or with a nonsterile device.

Compounding Pharmacy

A pharmacy with staff skilled in the art and preparation of customized medications to meet specific patient and/or practitioner needs.

Critical Process

A process that is essential to assure the quality of the compounded preparation. (Examples would include properly weighing or measuring the components, etc.)

Discussion

A narrative guide to the standard. It may be a window on the intent of the standard and/or a suggestion to the pharmacy of ways to go beyond the standard itself to serve its patients in additional ways. Often it is just a discussion of the general area covered by the standard. They are designed as an aid to the pharmacy in understanding the area covered by the standard.

Equipment

Any tool, device, container, structure or machine, movable or immovable, used in the preparation, measurement, storage or dispensing of a CCP (completed compounded preparation).

Error (or Err)

A quality related event (QRE) that reaches the patient and is no longer in the pharmacy's control. It is a failure of quality.

Near-Miss

A quality related event (QRE) that does not reach the patient. It represents a success story for the QI activities (See PCAB Standard 9.50) in that even though a mistake may have occurred, the mistake was caught before it reached the patient. The system worked.

Non-Legend CCP (completed compounded preparation)

A CCP (completed compounded preparation), labeled, handled and prepared in accordance with all applicable state and federal laws, that does not require a prescription order to sell to the consumer, and which is not for resale.

Orientation Program

Program, described in the pharmacy's written policy and procedure manual, designed to familiarize compounding laboratory staff with the operations of the pharmacy compounding lab.

Pharmacist in Charge

A pharmacist currently licensed by the board who accepts responsibility for the operation of the pharmacy in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs, and who is personally in full and actual charge of such pharmacy and personnel. The term "pharmacist-in-charge" will also be defined by individual state pharmacy practice acts and regulations pursuant to these acts.

Pharmacy

Premises, laboratory, area or other place:

1. Where drugs are offered for sale and the profession of pharmacy is practiced and where prescriptions are compounded and dispensed; or
2. Which has displayed upon it or within it the words "pharmacist," "pharmaceutical chemist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "drug sundries" or any of these words or combinations of these words or words of similar import either in English or any sign containing any of these words; or
3. Where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" may be exhibited.

Purified Water

Water purified by distillation, reverse osmosis, deionization, ion exchange, filtration, or other suitable purification procedure.

Practitioner Administered Compounds (PAC)

A CCP (completed compounded preparation) prepared as the result of a prescription order, or initiative based on the triad relationship in the course of professional practice, by a licensed practitioner for administration by a practitioner for diagnostic or therapeutic purposes.

Prescription Order or Initiative

An order to be filled by a pharmacist for prescription medication issued and signed by a practitioner in the authorized course of professional practice

An order transmitted to a pharmacist through word of mouth, note, telephone or other means of communication directed by such practitioner.

Quality Assurance*

The planned and systematic activities implemented in a quality system so that quality requirements for the pharmacy's compounded preparations services are fulfilled.

Examples of quality assurance activities processes in the pharmacy setting include training staff to assure proper operation of equipment, developing master formulation records to assure standardized compounds, and using and verifying compounding process records prior to dispensing to assure that each batch is made correctly and consistently.

Quality Control*

The observation techniques and activities used to fulfill requirements of quality.

Examples of quality control in the pharmacy include the sampling of sterile preparations for sterility and bacterial endotoxin limits, and the outside laboratory testing of compounded preparations to verify strength, purity, and other parameters.

Quality Improvement*

An ongoing effort to improve compounded preparations, services, or processes.

These efforts can seek incremental improvement over time or breakthrough improvement all at once.

Examples of quality improvement activities in the pharmacy include identifying the cause of failure when a compounded preparation fails a quality control test, developing and implementing methods to prevent the failure, and continued testing to verify whether the improvements eliminate the problem.

* NOTE: The definitions for Quality Assurance, Quality Control, and Quality Improvement were developed based on information from the American Society for Quality – www.asq.org

Quality Related Event (QRE)

Any event occurring in at any point in the prescription process over which the pharmacy could exercise some level of control. A quality related event may be an error or a near-miss. A QRE may be made at any level, including the prescriber, nurse or a member of the pharmacy staff. They are generally preventable adverse medical events.

Reconstitution

For purposes of these guidelines, the term compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by a product's manufacturer.

Triad Relationship

Practitioner, patient, and pharmacist relationship in the delivery of *healthcare*.

Training Program

Process that assures that a staff member has demonstrated competency before being assigned to that task.

USP <795>

Chapter <795> Pharmaceutical Compounding-Nonsterile of the United States Pharmacopeia. It is the general non –sterile compounding standards chapter of the USP and can be found in the USP Pharmacists' Pharmacopeia.

USP <797>

Chapter <797> Pharmaceutical Compounding-Sterile of the United States Pharmacopeia. It is the general sterile compounding standards chapter of the USP and can be found in the USP Pharmacists' Pharmacopeia.

Utensils

Simple instruments utilized in the compounding process.