



Pharmacy Compounding Accreditation Board™

PCAB™ STANDARDS With Compliance Indicators

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Standard 1.00 Regulatory Compliance

Standard 1.10 Facility

A pharmacy must provide documentation to verify that the pharmacy is licensed or registered with appropriate state and federal regulatory authorities, e.g. DEA and state boards of pharmacy. The pharmacy must also provide documentation to demonstrate that the licensure or registration is in good standing with those regulatory authorities.

Compliance Indicators

- A. The pharmacy lists the state(s) in which it is licensed or registered to operate a pharmacy and distribute controlled substances, including the license or registration numbers.
- B. If the pharmacy ships or intends to ship medications to residents of states that do not require non-resident pharmacy licensure during period of accreditation, the names of those states must be listed.
- C. Pharmacy has access to pharmacy rules and regulations of all states in which the pharmacy dispenses medications.
- D. The pharmacy's required state licenses or registrations in its domicile state are current and in good standing.
- E. All of the pharmacy's required state licenses or registrations in all other states are current and in good standing.
- F. The pharmacy's federal controlled substance registration is current and in good standing.
- G. The pharmacy has written policies and procedures outlining how the facilities are designed and maintained to allow compounding in an efficient, effective and safe manner, both for the patient and the employees.

Standard 1.20 Personnel

A pharmacy must provide documentation to verify that all relevant personnel are licensed, registered, and/or certified with appropriate state and/or federal regulatory authorities and/or non-governmental accreditation organizations. Additionally, where applicable, the pharmacy must provide documentation to verify that the licensure or registration of personnel is in good standing with those regulatory authorities or third-party accreditation organizations.



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Compliance Indicators

- A. All personnel, including pharmacists and technicians, volunteers, students, temporary employees and those affiliated through contractual or other arrangement, who are engaging in compounding within this pharmacy are appropriately licensed, registered, or certified and in good standing in the state(s) in which they practice.
- B. The pharmacy verifies the licensure, permit or registration of pharmacists, where applicable, pharmacy technicians and other compounding personnel, such as students and technicians in training.
- C. The pharmacy's policy and procedures address procedures for the verification of licensure of new independent contractors/employees.

Standard 1.30 External Standards

A pharmacy must provide documentation to verify that compounding is performed according to standards of practice adopted by the state board of pharmacy and the practices and standards that are adopted by non-governmental standards setting organizations.

Compliance Indicators

- A. The pharmacy has written policies and procedures that document how the pharmacy's compounding is performed according to state and national practices and standards.
- B. The pharmacy has ready access to applicable USP standards.
- C. The pharmacy complies with applicable USP standards.
- D. Pharmacy personnel can demonstrate ability and knowledge to utilize resources appropriately.

Standard 1.40 Policies and Procedures

A pharmacy must provide documentation of a compounding policy and procedure manual that establishes procurement procedures, methodologies for the formulation and compounding of preparations, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures of the facility. The manual shall also establish the framework for the assurance that the facility, personnel, and operations of the pharmacy comply with applicable state and federal laws and regulations and shall be approved by the pharmacist responsible for the operation of the pharmacy, and where required, by the state board of pharmacy. Provision must be made for the revision of the manual, the method of implementation of those revisions, and the notification to personnel of changes to the manual.



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Compliance Indicators

- A. The written policies and procedures document how they are organized, authorized, reviewed, revised, and retired/archived.
- B. The policies and procedures are
 - 1. readily accessible by the staff.
 - 2. effectively maintained
- C. The policies and procedures contain a “policy on policies” that addresses the following issues:
 - 1. Who in the organization has authority to approve the Policies and Procedures,
 - 2. How Policy and Procedure approval is obtained,
 - 3. How the pharmacy records the date of implementation of new policies,
 - 4. How the pharmacy maintains a trained staff.
 - 5. How the pharmacy establishes an indexing system to facilitate reference and retrieval by staff, and
 - 6. How the pharmacy defines how Policies and Procedures are retired and archived.
- D. The pharmacy has written policies and procedures that document methodologies for maintaining the compounding facilities.
- E. The pharmacy has written policies and procedures that document methodologies for maintaining the compounding equipment, including the cleaning, maintenance and operation.
- F. The pharmacy has written policies and procedures that document procurement procedures.
- G. The pharmacy has written policies and procedures that document methodologies for the formulation and compounding of preparations.
- H. The pharmacy has written policies and procedures that sets forth standard operating procedures of the facility.



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Standard 2.00 Personnel

Standard 2.10 General

A pharmacy must document that all relevant personnel are competent to perform their assigned duties and must establish procedures for assessing that competency on an ongoing basis. Specific duties and responsibilities shall be clearly defined and described. A pharmacy shall retain documentation of current and ongoing education, training, and competency of all personnel involved in the compounding of preparations. Supervision of personnel shall be sufficient to assure preparation integrity and safety.

Compliance Indicators

- A. There are written policies and procedures that outline assigned duties for positions.
- B. There are written policies and procedures that establish job descriptions for positions
- C. There are written policies and procedures that sets forth a new employee (including temporary employees) orientation program.
- D. There are written policies and procedures that outline training and educational guidelines for employees.
- E. There are written policies and procedures that establish a system of documentation of required and additional training and education.
- F. There are written policies and procedures that establish procedures for assessing the competency of all professional, technical and outsourced services staff on an ongoing basis.
- G. The pharmacy has job descriptions for each compounding position.
- H. The pharmacy demonstrates that staff is properly trained to perform their individual tasks and responsibilities.
- I. The pharmacy demonstrates that the staff is competent to perform their individual tasks and responsibilities.
- J. The pharmacy has policies and procedures to assess and determine adequate staff is in place to meet all the requirements and needs to accomplish all elements of the compounding and dispensing process, including environmental and equipment maintenance.



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Standard 2.20 Responsible Pharmacist

A pharmacy must provide documentation of education and training of the pharmacist responsible for the compounding activities. The pharmacist responsible for the compounding activities shall establish the scope of compounding practice of the pharmacy based upon the education and training of the personnel and the facilities and equipment of the pharmacy. The pharmacist responsible for the compounding activities shall be knowledgeable about the compounding processes of the pharmacy and shall be responsible for adherence to regulatory and accreditation standards.

Compliance Indicators

- A. The designated Responsible Pharmacist has been educated and trained in all aspects of compounding consistent with the scope of compounding practiced by the pharmacy.
- B. The designated Responsible Pharmacist demonstrates an awareness of all operations of the pharmacy relating to its scope of compounding.
- C. The designated Responsible Pharmacist demonstrates an awareness of the responsibility of his or her position under the law, within the pharmacy, and as it relates to the pharmacy's practice of compounding, including all state and national laws, regulations, and standards.
- D. The designated Responsible Pharmacist has sufficient authority within the pharmacy structure to carry out his or her responsibilities.
- E. The designated Responsible Pharmacist demonstrates an adequate knowledge of all operations of the pharmacy relating to compounding, including job descriptions and roles of all compounding personnel.

Standard 2.21 Compounding Pharmacist

The compounding pharmacist is responsible for ensuring that the compounded preparation has been prepared, labeled, stored, and properly packaged for dispensing. This shall include ensuring the stability and sterility of the preparation consistent with its preparation, labeling, and intended use. The compounding pharmacist is responsible for the completed compounded preparation, including in-process and end-process preparation verification.

Compliance Indicators

- A. The pharmacy's written policies and procedures outline the duties of the compounding pharmacist as responsible for:
 - 1. Assuring that the compounded preparation has been prepared, labeled, stored, and properly packaged for dispensing.



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2. Assuring that the stability and sterility of the preparation is consistent with its preparation, labeling, and intended use.
 3. the completed compounded preparation, including in-process and end-process preparation verification
 4. direct supervision of all compounding personnel and processes.
- B. Compounding Pharmacist demonstrates an awareness of operations of the pharmacy relating to the scope of compounding, in which they participate and/or supervise.
- C. Compounding Pharmacists know and understand all policies and procedures regarding compounding in the pharmacy.
- D. Compounding Pharmacists have been adequately educated and trained in good compounding practices.
- E. Compounding Pharmacists are familiar with USP standards related to non-sterile compounding.
- F. Compounding Pharmacists are familiar with USP standards related to sterile compounding.
- G. The pharmacy's written policies and procedures outline a method of reasonably assuring that all compounding pharmacists are competent in the art and science of compounding.

Standard 2.22 Dispensing Pharmacist

The dispensing pharmacist, if different than the compounding pharmacist, shall verify that the compounded preparation has been labeled, stored, and properly packaged for dispensing. The dispensing pharmacist shall ensure the stability and sterility of the preparation upon dispensing and through its intended administration, if the preparation remained in the control of the pharmacy consistent with its preparation, labeling, and intended use. The dispensing pharmacist's responsibility for the integrity of the preparation ends with the transfer of control of the preparation to the patient or patient's representative. The dispensing pharmacist is responsible for any patient counseling or patient care services required by applicable state law.

Compliance Indicators

- A. There are written policies and procedures outlining the duties of the dispensing pharmacist as including the responsibility to:
1. verify, to the extent practicable, that the compounded preparation has been labeled, stored, and properly packaged for dispensing.
 2. Assure, to the extent practicable, the stability and sterility of the preparation upon



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dispensing and through its intended administration, if the preparation remained in the control of the pharmacy consistent with its preparation, labeling, and intended use.

3. provide, to the extent practicable, appropriate patient counseling or patient care services.
- B. Dispensing Pharmacists are aware of all dispensing operations of the pharmacy.
- C. Dispensing Pharmacists know and understand pharmacy policies and procedures regarding labeling, storing, dispensing, and delivering compounded preparations.

Standard 2.30 Compounding Personnel

A pharmacy must provide documentation of an education program that demonstrates and verifies that personnel responsible for the compounding of preparations are knowledgeable about the processes and procedures they employ. The pharmacy shall only utilize personnel that have been properly trained and educated, and that have demonstrated minimum competency in these areas. Pharmacies that engage in sterile compounding shall document and verify adequate didactic education and training in aseptic technique by those personnel authorized to assist and prepare sterile compounded preparations.

Compliance Indicators

- A. The pharmacy has written policies and procedures outlining the competency of compounding personnel, including at least documentation of the following:
1. an education program that demonstrates, assesses and verifies that personnel responsible for the compounding of preparations are trained, educated and knowledgeable concerning the processes and procedures they employ.
 2. demonstrated minimum competency concerning the processes and procedures they employ.
 3. Pharmacies that engage in sterile compounding document and verify education and training in aseptic technique by those personnel authorized to assist and prepare compounded sterile preparations.
- B. Pharmacy compounding personnel are trained in their job responsibilities.



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Standard 3.00 Facilities and Equipment

Standard 3.10 General

A pharmacy must document the presence of sufficient facilities and equipment for the safe and accurate compounding of preparations. Equipment must be regularly calibrated, cleaned, maintained, and validated according to the requirements contained in the pharmacy's policy and procedure manual, which, at a minimum, shall meet the manufacturer's standards. Documentation of compliance with applicable facility, equipment, and maintenance standards shall be maintained.

Compliance Indicators

- A. The size, type and quantity of equipment at the pharmacy is adequate to safely and accurately compound prescriptions in the amount and type of compounding performed in the pharmacy.
- B. The equipment is properly calibrated, cleaned, monitored and maintained.
- C. The cleaning and maintenance of equipment is adequately performed and documented.
- D. The written policies and procedures adequately outline appropriate procedures to properly maintain the equipment.
- E. The pharmacy has policies, procedures, and compliance logs that verify the proper maintenance, cleaning, calibration and monitoring of equipment.
- F. The pharmacy has policies and procedures for safe handling and disposal of hazardous materials.

Standard 3.11 References

Reference materials must be current and relevant to the compounding performed at the pharmacy and in accordance with state regulation. Reference materials must be readily accessible to the personnel responsible for the compounding of the preparation.

Compliance Indicators

- A. The pharmacy library of references meets or exceeds state law in all states in which the pharmacy is licensed or registered.
- B. The pharmacy has ready access to adequate reference material which is available to the pharmacists and pharmacy staff for the compounding performed.
- C. The available material is current and in keeping with the type and quantity of compounding performed



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- D. The pharmacy maintains an adequate library.
- E. The pharmacy staff is trained in the use of necessary reference material.
- F. There is evidence that the available reference material is used in the pharmacy compounding practice.

Standard 3.20 Non-Sterile Compounding

A pharmacy preparing non-sterile preparations must design its facilities to provide for: minimization of interruption, avoidance of contamination by dust and other particulates, and reduction of the potential for contamination or adulteration of the compounded preparation.

Compliance Indicators

- A. The pharmacy's process and procedures outline mechanisms adequate for minimizing interruption during compounding.
- B. The pharmacy's process and procedures outline mechanisms adequate for avoiding contamination by dust and other particulates in the compounding area, including policies and procedures outlining how preparations are kept contaminant free.
- C. The pharmacy has procedures adequate for avoiding cross-contamination.
- D. The pharmacy's written policies and procedures outline mechanisms adequate to reduce the potential for contamination or adulteration of the compounded preparation.
- E. Pharmacy has a dedicated, exclusive area for general, non-sterile compounding.
- F. The area for general compounding (non-sterile compounding) meets environmental standards.
- G. The area for general compounding (non-sterile compounding) meets or exceeds USP <795> standards.
- H. The area for general compounding (non-sterile compounding) is designed to minimize traffic from employees not involved in compounding.
- I. Consistent with Standard 9, Quality Assurance, pharmacy has policies and procedures to monitor and test compounded preparations for quality.

Standard 3.30 Sterile Compounding

A pharmacy preparing sterile preparations must design its facilities to provide for: minimization of interruption, avoidance of contamination, and an exclusive area for the compounding of sterile preparations. Policies and procedures shall be established for periodic environmental testing to assure continued adequacy of the aseptic environment.



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Compliance Indicators

- A. The pharmacy's written policies and procedures outline mechanisms adequate for minimizing interruption during compounding.
- B. The pharmacy's written policies and procedures outline mechanisms adequate for avoiding contamination by dust and other particulates in the aseptic compounding area.
- C. The pharmacy's written policies and procedures outline mechanisms adequate to reduce the potential for contamination or adulteration of the compounded preparations.
- D. Pharmacy policies and procedures outline procedures for periodic environmental testing of the aseptic environment.
- E. Pharmacy meets state law requirements as to sterile compounding.
- F. If the pharmacy practices aseptic sterile compounding, it has an appropriate area for compounding of aseptic preparations that meets or exceeds USP <797>.
- G. Consistent with Standard 9, Quality Assurance, pharmacy has policies and procedures to monitor and test, as applicable according to USP <797>, sterile compounded preparations for sterility, pyrogenicity and potency.



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Standard 4.00 Chemicals, Components, and Completed Compounded Preparations

Standard 4.10 General

A pharmacy must provide documentation of the acquisition, storage, and proper destruction of drug substances and drug products used as components in the compounding of preparations. The drug substances and drug products used must be appropriate for the compounding that is performed. The pharmacy shall provide evidence that the drug substances and drug products used to compound meet or exceed any official compendium standards, if any, and at minimum, be accompanied by a certificate of analysis that is retained by the pharmacy. The certificate of analysis must be reviewed prior to approval for use of the drug substance. A certificate of analysis shall be used to document the strength, quality, purity, and integrity of the chemical.

Compliance Indicators

- A. The pharmacy has written policies and procedures for acquiring all chemicals, drug products, and components from reliable sources.
- B. The pharmacy uses appropriate suppliers as the source of all active pharmaceutical ingredients, inactive ingredients or excipients, and other components used in compounding. Appropriate suppliers are:
 - 1. FDA registered and inspected, if applicable
 - 2. Comply with FDA current Good Manufacturing Practices
 - 3. Licensed and in good standing with applicable state and/or federal regulatory boards, and
 - 4. Able to provide ready access to Certificates of Analysis (C of A) and MSDS with all bulk chemicals..
- C. The pharmacy uses appropriate suppliers for devices, containers, and closures used in compounding.
- D. If an active pharmaceutical ingredient, inactive ingredient or excipient, or other component used in compounding is unavailable from any supplier meeting the above criteria, the policies and procedures set forth an adequate mechanism directing the Responsible Pharmacist to employ professional judgment in receiving, storing, and using such components from another high quality source.
- E. The compounding pharmacy will obtain high quality active pharmaceutical ingredients (APIs) for use in compounding. Active pharmaceutical ingredients should



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1. Meet 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.
 2. meet other compendial standards, or
 3. be components of products that have been approved by FDA or grandfathered under the Food, Drug & Cosmetic Act of 1938 (FDCA).
- F. The pharmacy does not compound using components included on FDA's "List of Drug Entities That Have Been Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness," subject to the exceptions provided in such list. Written policies exist to safeguard against the use of such components.
- G. The pharmacy has a designated area for the receiving and inspection of chemicals, devices, containers, closures, and other components or supplies used in the compounding operation.
- H. The policies and procedures include written policies and procedures to assure Material Safety Data Sheets (MSDS) are properly maintained and readily retrievable.
- I. The pharmacy has written policies and procedures that outline the criteria for acceptance or refusal of components.

Standard 4.20 Storage

All chemicals and components must be used and stored according to compendial and other applicable requirements. Storage of chemicals, components, and completed compounded preparations shall be designed to maintain their strength, quality, purity, integrity, and where applicable, sterility. Pharmacies must provide evidence that all relevant Material Safety Data Sheets (MSDS) for chemicals or drug substances present in the pharmacy are properly maintained and readily retrievable.

Compliance Indicators

- A. The pharmacy has written policies and procedures to assure medications and devices are maintained within appropriate temperature, light, and humidity standards, as established by the United States Pharmacopeia.
- B. The pharmacy uses temperature logs or similar forms, electronic or otherwise.
- C. The policies and procedures include acceptable storage temperature ranges and continuous temperature monitoring procedures.



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- D. The policies and procedures include contingency plans if conditions fall outside of acceptable ranges.
- E. The policies and procedures include guidelines to be followed in determining if a component has been compromised and when it should be destroyed.
- F. The policies and procedures identify the individual responsible for making decisions regarding compromised components.
- G. Upon receipt of a component, the component is quarantined until the Certificate of Analysis information is verified by properly trained compounding personnel and the MSDS information is assessed for review, as necessary.
- H. Hazardous and potent pharmaceuticals are identified and handled according to the pharmacy's policy on these chemicals.
- I. Components are stored and rotated so that the oldest stock is used first.
- J. The pharmacy conducts periodic inspections to ensure that expired components and completed compounded preparations do not remain in stock.
- K. The pharmacy policy and procedure manual addresses appropriate disposal or return of expired components and completed compounded preparations.
- L. The compounding pharmacy has an area specifically assigned for storage of components used in the compounding operation.
- M. The pharmacy has an area specifically designated for storage of incoming shipments of components or lab supplies.
- N. The pharmacy has a procedure elaborating quarantine specifications, including expired and recall storage.
- O. For active pharmaceutical ingredient or excipient, the pharmacy has a system to promptly determine necessary storage conditions.
- P. The pharmacy has written policies and procedures for the storage and proper disposal of drug substances and drug products used as components in the compounding of preparations.



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Standard 5.00 Compounding Process

Standard 5.10 General

Compounding processes shall involve the application of standardized formulations and procedures that maintain the strength, quality, purity, integrity, and where applicable, sterility of the compounded preparation appropriate for the compounding that is performed. A pharmacy must establish a mechanism for ensuring that the procedures employed to prepare compounded preparations are consistent and reproducible. Compounding activities shall be subject to process verification for strength, quality, purity, integrity, and where applicable, sterility.

Compliance Indicators

- A. The pharmacy has written policies and procedures that outline the compounding process in a manner designed to produce preparations according to prescriptions presented.
- B. The pharmacy has policies and procedures outlining a mechanism whereby compounded preparations are verified for strength, quality, purity, integrity, and where applicable, sterility.
- C. The pharmacy shall have written policies and procedures that promote and uphold consistency, high quality of the completed compounded preparations, and minimize error throughout the compounding process.
- D. The Compounding Pharmacy must have a written, formal, and working standardized process that is used to conduct all compounding operations.
- E. Properly trained compounding personnel approve or reject all components of completed compounded preparation (CCP).



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Standard 5.20 Master Formulation Record

A pharmacy must provide documentation of standardized formulations and compounding procedures used in the compounding of each preparation. Whenever a non-governmental, authoritative standard-setting organization establishes, tests, and validates a formulation or formulation process, a pharmacy must provide evidence of the incorporation of that formulation or formulation process as a method for preparing the compounded drug preparation and shall incorporate the formulation or formulation process into its Master Formulation Records.

Compliance Indicators

- A. The pharmacy maintains a Master Formulation Record for each compounded preparation.
- B. Pharmacy has policies and procedures outlining how Master Formulation Records are used, maintained, and reviewed.

Standard 5.30 Compounding Process Record

A pharmacy must provide documentation of the use of the actual components, the quantities of each component, the supplier, the lot number of each component, if applicable, the equipment used, the establishment of an internal reference number, and all personnel involved in the compounding of each preparation.

Compliance Indicators

- A. The pharmacy has written policies and procedures outlining a workflow that sets forth how formulations and components are used, and how compounding procedures are recorded for each preparation.
- B. For each preparation a system is established that mandates, where applicable, documentation of the following items:
 - 1. identification of each component
 - 2. quantity of each component used
 - 3. lot number and expiration date of each component used
 - 4. equipment used
 - 5. internal reference number used
 - 6. personnel involved



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Standard 5.40 Records

A pharmacy must prepare, maintain, and retain all records required by its individual state pharmacy regulatory authority and those of any applicable federal regulatory authority. Pharmacies must maintain the documentation for such period as may be required by the relevant authority or until the subsequent accreditation, whichever is longer.

Compliance Indicators

- A. The pharmacy has written policies and procedures that mandate the retention of records per state pharmacy rules and regulations.
- B. Records shall be readily retrievable.



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Standard 6.00 Beyond-Use Dating, Stability, Sterility

Standard 6.10 Beyond-Use Date

A pharmacy must provide documentation of the basis for its determination of the beyond-use date assigned to its compounded preparation. A pharmacy may consider and use authoritative sources for general recommendations on the establishment of its beyond-use date.

Compliance Indicators

- A. The pharmacy has written policies and procedures for determining beyond-use dating.
- B. The pharmacy documents the sources and other evidence used to establish beyond-use dating.
- C. The pharmacy has policies and procedures for adequately communicating beyond-use dating information to compounding personnel and the patient and/or caregiver.

Standard 6.20 Stability and Sterility

A pharmacy must provide documentation that demonstrates that its compounded preparations adhere to compendial requirements of strength, quality, purity, stability, and where required or appropriate, sterility and bacterial endotoxin content, throughout the period of intended use.

Compliance Indicators

- A. The pharmacy's policies and procedures comply with USP <795> standards regarding stability of compounded preparations.
- B. The pharmacy's policies and procedures comply with USP <797> standards regarding stability, sterility, and bacterial endotoxin, where applicable, of compounded preparations.
- C. The pharmacy is in compliance with all applicable state and federal regulations regarding stability, sterility, and bacterial endotoxin, where applicable, of compounded preparations.



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Standard 7.00 Completed Compounded Preparations

Standard 7.10 Packaging, Labeling, Delivery for Administration, Dispensing

A pharmacy must provide documentation of adherence to state board of pharmacy requirements. Pharmacies must provide documentation of the proper patient packaging, labeling, delivery for administration, and dispensing of compounded preparations.

Compliance Indicators

- A. The pharmacy has written policies and procedures that assure the compounded preparations are packaged and labeled for the safety of the patient.
- B. The pharmacy has written policies and procedures detailing the steps in conducting prospective drug reviews and appropriate counseling prior to dispensing of compounded preparations.
- C. The pharmacy policies, procedures and practices will be in compliance with HIPAA and state confidentiality laws and regulations.
- D. The policies and procedures address appropriate packaging of medications for shipment, which is on file and used in shipping.

Standard 7.20 Internal and External Recalls

A pharmacy must have procedures for the appropriate 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 content.

Compliance Indicators:

- A. The pharmacy has policies and procedures outlining a mechanism to identify patients receiving compounded medications sufficient to allow recall to be effective.
- B. The pharmacy has documented procedures for the recall of compounded preparations when necessary.
- C. The pharmacy has written policies and procedures to inform patients or caregivers concerning drug recalls.



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Standard 8.00 Practitioner and Patient Education

Standard 8.10 Practitioner Education

A pharmacy must provide documentation of a process to communicate with practitioners about preparations that are compounded for their patients.

Compliance Indicators:

- A. The pharmacy's policies and procedures contain a method to assure that the prescriber knows which prescriptions are compounded.
- B. The pharmacy's DUR process encourages pharmacy staff to communicate patient risk management questions to prescribers and a mechanism to resolve such questions.
- C. The pharmacy's policies and procedures recognize the physician's role as patient risk assessor.
- D. The pharmacy has a documented procedure 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.

Standard 8.20 Patient Education

A pharmacy must comply with the patient education requirements of the state board of pharmacy. A pharmacy must provide documentation that patients for whom compounded preparations are dispensed or their caregivers have been counseled about the appropriate, safe, and effective use of the compounded preparation.

Compliance Indicators

- A. The pharmacy has evidence of a system for patient education and consultation.
- B. The pharmacy has suitable written materials to provide the patient or caregiver with information on the appropriate, safe, and effective use of compounded preparations.
- C. The pharmacy staff regularly uses such written patient information for the benefit of the patient or caregiver.



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Standard 9.00 Quality Assurance Plan and Continuous Quality Improvement

Standard 9.10 Quality Assurance Plan

A pharmacy must provide documentation of the development of and adherence to a quality assurance plan. The quality assurance plan must include verification, monitoring, and review of the adequacy of the compounding process. The quality assurance plan must include documentation of that review by the assigned personnel to demonstrate the compounded preparation meets the specified criteria of strength, quality, purity, and where appropriate, sterility, and bacterial endotoxin content. Any appearance of deviation or actual deviation from the standardized compounding process shall be documented, evaluated, and corrected, if required, prior to the dispensing of the compounded preparation. An essential element of any quality assurance plan is the verification of the processes and procedures used. The pharmacy must document periodic verification of the processes, procedures, and personnel involved in compounding preparations and activities. A pharmacy must provide evidence of a system for the internal and external reporting of quality-related events and for their prompt resolution.

Compliance Indicators

- A. The pharmacy has a written quality assurance plan
- B. The pharmacy's quality assurance plan is being used on a regular basis.
- C. All quality related events are documented, evaluated, and corrected, if required, prior to the dispensing of the compounded preparation.

Standard 9.20 Continuous Quality Improvement

A pharmacy must have and utilize a continuous quality improvement plan. The plan must be designed to objectively and systematically collect data about the operations of the compounding process, evaluate the data on the quality of the compounding process and its effect on patient care, propose resolutions to identified problems, select an appropriate resolution, incorporate the resolution into the policy and procedure manual, communicate the resolution to appropriate individuals, including patients and practitioners, and collect data on whether the selected resolution has the intended effect.



PCABTM STANDARDS With Compliance Indicators

Compliance Indicators

- A. The pharmacy policies and procedures provide adequate documentation of the Continuous Quality Improvement (CQI) nature of the quality assurance program
- B. The pharmacy has provided evidence of a system for the internal and, as necessary, external reporting of quality-related events and for their prompt resolution.



PCABTM STANDARDS With Compliance Indicators

Standard 10.00 Self-Assessment

A pharmacy must provide a self-assessment of adherence to these standards. The self-assessment shall systematically evaluate the operation of the pharmacy against each criterion and its interpretative advice. The self-assessment must be submitted with the application for accreditation and re-accreditation.

Compliance Indicators

- A. The Pharmacy policy and procedure manual provides a system of Self-Assessment allowing the pharmacy to monitor its continuing adherence to the standards established by the pharmacy and PCABTM.
- B. Pharmacy staff have access to information regarding the standards established by PCABTM



PCAB™ STANDARDS With Compliance Indicators

Appendix

Definitions

From Standards Appendix

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.

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 practitioner.

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 (completed compounded preparation).

Compounder

Any person involved with the preparation, mixing, assembling, packaging, or labeling 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



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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 skillsets, as well as, defined policy, procedures and processes necessary to ensure 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.



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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 ensure 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 CQI program, 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*.



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Pharmacist-in-Charge (PIC)

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 or by reverse osmosis. It contains no added substances.

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.



PCAB™ STANDARDS With Compliance Indicators

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> of the United States Pharmacopeia. It is the general compounding standards chapter of the USP and can be found in the Pharmacists Pharmacopeia.

USP <797>

Chapter <797> of the United States Pharmacopeia. It is the sterile compounding standards chapter of the USP and can be found in the Pharmacists Pharmacopeia.

Utensils

Simple instruments utilized in the compounding process.