



## Pharmacy Compounding Accreditation Board

c/o Executive Offices  
2215 Constitution Avenue, NW  
Washington, D.C. 20037  
866.377.5104  
www.pcab.org

Executive Director  
Joe Cabaleiro, R.Ph.  
866.377.5104 ext. 804

### Board of Directors & Founders

American College of Apothecaries  
•  
American Pharmacists Association  
•  
International Academy of  
Compounding Pharmacists  
•  
National Association of Boards of  
Pharmacy  
•  
National Community Pharmacists  
Association  
•  
National Council of State Pharmacy  
Association Executives  
•  
National Home Infusion Association  
•  
United States Pharmacopeia

# PCAB<sup>®</sup> Accreditation Manual

Pharmacy Compounding Accreditation Board (PCAB<sup>®</sup>) is a not for profit corporation established to recognize those compounding pharmacies that meet the highest standards of quality and assist all compounding pharmacies to attain those standard.

## Table of Contents and Index

<b>5</b>	<b>PCAB® Principles of Compounding</b>
<b>6</b>	<b>Standard 1.00 Regulatory Compliance</b>
6	Standard 1.10 Facility Compliance Indicators
6	Standard 1.20 Personnel Compliance Indicators
7	Standard 1.30 External Standards Compliance Indicators
7	Standard 1.40 Standard Operating Procedures Compliance Indicators
<b>8</b>	<b>Standard 2.00 Personnel</b>
8	Standard 2.10 General Compliance Indicators
8	Standard 2.20 Pharmacist in Charge Compliance Indicators
9	Standard 2.30 Staff Pharmacists Compliance Indicators
<b>10</b>	<b>Standard 3.00 Facilities and Equipment</b>
10	Standard 3.10 General Compliance Indicators
10	Standard 3.11 References Compliance Indicators
11	Standard 3.20 Non-Sterile Compounding Compliance Indicators
11	Standard 3.30 Sterile Compounding Compliance Indicators
<b>12</b>	<b>Standard 4.00 Chemicals, Components, and Completed Compounded Preparations</b>
12	Standard 4.10 General Compliance Indicators
13	Standard 4.20 Handling, Storage, and Disposal Compliance Indicators
<b>15</b>	<b>Standard 5.00 Compounding Records</b>
15	Standard 5.00 Formulation Record and Compounding Record Compliance Indicators
<b>17</b>	<b>Standard 6.00 Beyond-Use Dating, Potency, and Sterility</b>
17	Standard 6.10 Beyond-Use Date Compliance Indicators

## Table of Contents and Index

17	Standard 6.20 Potency Compliance Indicators
17	Standard 6.30 Sterility Compliance Indicators
<b>18</b>	<b>Standard 7.00 Completed Compounded Preparations</b>
18	Standard 7.10 Packaging, Labeling, and Delivery for Administration and Dispensing Compliance Indicators
18	Standard 7.20 Internal and External Recalls Compliance Indicators
19	Standard 7.30 Labeling Compliance Indicators
<b>21</b>	<b>Standard 8.00 Prescriber Communication and Patient Education</b>
21	Standard 8.10 Prescriber Communication Compliance Indicators
21	Standard 8.20 Patient Education Compliance Indicators
<b>22</b>	<b>Standard 9.00 Total Quality Management</b>
22	Standard 9.10 Quality Assurance (QA) Activities Compliance Indicators
22	Standard 9.20 Quality Control (QC) Activities Compliance Indicators
22	Standard 9.30 Quality Related Events (QREs) Compliance Indicators
23	Standard 9.40 Quality Improvement (QI) Activities Compliance Indicators
<b>24</b>	<b>Appendix</b> Definitions
<b>30</b>	<b>Rules &amp; Terms for Obtaining and Maintaining PCAB® Accreditation</b>
30	A. Incorporation by Reference. PCAB® Standards for Compounding Pharmacy PCAB® Principles of Compounding Policy for Using and Displaying the PCAB® Seal of Accreditation PCAB® Fees & Costs Schedule PCAB® Procedure for Appeal PCAB® Policy on Revocation, Suspension, or Probation of a License
30	B. Definitions & Terms.
31	C. Application for Accreditation.
31	D. Verification.

## Table of Contents and Index

33	E. Change of Control/Termination of Pharmacy Practice
33	F. Compounding Scope of Practice and Changes in Scope of Practice.
34	G. Modification of Standards; Compliance Indicators.
34	H. License to Use PCAB® Seal of Accreditation.
36	I. Use of PCAB® Seal of Accreditation.
36	J. Right of Publicity by PCAB®.
37	K. Grounds for Denial or Suspension of Accreditation.
37	L. Suspension of Accreditation.
38	M. Appeal from Suspension or Denial.
38	N. Termination by Accredited Pharmacy.
38	O. Pharmacy Representations and Warranties.
39	P. Warranty Disclaimer/Indemnifications.
39	Q. Consequential Damages Waiver, Limitation of Liability.
39	R. Notices/Modification.
40	S. Severability.
40	T. Waiver.
40	U. Governing Law.
40	Items Incorporated by Reference.
	PCAB® Standards and Principles of Compounding
	Policy for Using and Displaying the PCAB® Seal of Accreditation
	Display
	Internet Display
	PCAB® Fees & Costs Schedule
	Annual Fees
	Surveyor expense
	Compliance Fees
	PCAB® Procedure for Appeal
	PCAB® Policy on Revocation, Suspension, or Probation of a License
<b>46</b>	<b>PCAB® Guidance to Pharmacies Regarding Hazardous and Potent Substances and Primary Engineering Controls</b>
<b>49</b>	<b>PCAB® Guidance to Pharmacies Regarding Maintenance and Calibration Logs</b>

# PCAB<sup>®</sup> Principles of Compounding

As of August 25, 2011, PCAB is in the process of reviewing and revising the PCAB Principles of Compounding. PCAB will announce any changes or revisions as soon as the process is complete.

# PCAB® STANDARDS WITH COMPLIANCE INDICATORS

## 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 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 policies 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.<sup>1</sup> 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.”<sup>2</sup>*

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

- (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 reasons<sup>4</sup> 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."*

---

<sup>4</sup> 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**

*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](http://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.

## **Rules & Terms for Obtaining and Maintaining PCAB® Accreditation**

The Pharmacy Compounding Accreditation Board [PCAB®] was formed to provide quality standards for compounding pharmacy through a voluntary accreditation program. PCAB® assesses those pharmacies that voluntarily apply, and awards the PCAB® Seal of Accreditation to those pharmacies that accept the PCAB® requirements, meet the criteria, and comply with the Rules and Terms of the PCAB® program, including adherence to PCAB® Standards. The PCAB® Seal of Accreditation provides evidence of adherence to quality standards and to principles of the profession of pharmacy compounding.

Below are the Rules and Terms that a Pharmacy must accept and abide by in order to obtain and maintain the PCAB® Seal of Accreditation. As part of these Rules and Terms, a Pharmacy must pledge adherence to the PCAB® Principles of Compounding. Pharmacists are among the most trusted professionals for a reason. PCAB® urges all Pharmacy applicants and all Accredited Pharmacies not just to agree, but to read and study; post for all to see; and take the Principles of Compounding seriously. As part of its commitment to ethical pharmacy practices, PCAB® has adopted the Code of Ethics of the American Pharmacists Association (APhA). As with all standards, rules, terms, and principles, these Rules and Terms will change, grow and evolve with time and experience. Each Accredited Pharmacy is expected to stay current with these Rules and Terms, including the Standards for Compounding Pharmacy and Principles of Compounding incorporated herein.

**Please read and study these PCAB® Rules and Terms carefully before agreeing to them.**

### **A. Incorporation by Reference.**

The following items are incorporated by reference and made a part hereof.

1. PCAB® Standards for Compounding Pharmacy
2. PCAB® Principles of Compounding
3. Policy for Using and Displaying the PCAB® Seal of Accreditation
4. PCAB® Fees & Costs Schedule
5. PCAB® Procedure for Appeal
6. PCAB® Policy on Revocation, Suspension, or Probation of a License

### **B. Definitions & Terms.**

1. “Accredited Pharmacy” is a Pharmacy that has been determined by PCAB® to meet all PCAB® Standards, has agreed to these Rules and Terms, and has been awarded a license to use the PCAB® Seal of Accreditation.
2. “Annual Fee(s)” means the amount payable by Pharmacy as provided in the PCAB® Fees & Costs Schedule in each year.
3. “Compliance Fee(s)” means fees that may be charged in addition to the Annual Fee and surveyor expenses if a second or subsequent Review and Survey is needed for a Pharmacy in any three-year period.

4. "Compliance Indicator(s)" means informational items in the PCAB® Standards designed to assist surveyors in the conduct of Reviews and Surveys, and to assist Pharmacies and staff in meeting PCAB® Standards and maintaining compliance.
5. "PCAB® Standards" are the PCAB® Standards for Compounding Pharmacy, which are the principal requirements for PCAB® accreditation.
6. "Pharmacy" is a licensed pharmacy that has applied for or has been awarded PCAB® accreditation and whose authorized representative has agreed, on behalf of the pharmacy and its owners, to adhere to applicable state and federal law, and all requirements set forth in these Rules and Terms. Pharmacy includes Accredited Pharmacy.
7. "Review" means a review of documentation, including but not limited to the Pharmacy's policies and procedures, to determine compliance with PCAB® Rules and Terms.
8. "Seal of Accreditation" means any statement, sign, attestation, indication or suggestion of any type, without limitation, that a Pharmacy is, was or may in the future be an Accredited Pharmacy. No reference to the PCAB® Seal of Accreditation may be made without the express written consent of PCAB®.
9. "Survey" means a review of documentation and an onsite, in-Pharmacy survey to determine compliance with PCAB® Rules and Terms.

#### **C. Application for Accreditation**

1. To be considered for PCAB® accreditation, Pharmacy must submit the following to PCAB®:
  - a. Completed application, in a form acceptable to PCAB®;
  - b. Affidavit executed by Pharmacy attesting to its compliance with these Rules and Terms; and
  - c. Annual Fee, determined in accordance with the PCAB® Fees & Costs Schedule.
2. PCAB® will conduct a Review and Survey, as described in section D, Verification, below.
3. Pharmacy will be notified of decision. A Pharmacy that is denied accreditation shall be permitted to appeal the decision as described in section M, below.
4. On an annual basis, an Accredited Pharmacy shall execute a renewal application in a form approved by PCAB® and submit it along with the Annual Fee at least 30 days prior to the anniversary of the date of original application. Such annual renewal application shall include an PCAB® Rules & Terms affidavit executed by Accredited Pharmacy attesting to its continued compliance with these Rules and Terms.
5. A Pharmacy agrees to notify PCAB® in writing within thirty (30) days of any change in any information provided to PCAB®.

#### **D. Verification.**

1. PCAB® may itself, or through an independent third party designated by PCAB®, conduct a Review and/or Survey of Pharmacy's compliance with PCAB® Rules and Terms on PCAB®'s own initiative, upon request by Pharmacy (through an initial application or renewal application), in response to complaints from third parties, in the event of a change in the compounding products or services provided by Pharmacy, or otherwise as provided in these Rules and Terms.

2. PCAB® shall provide Pharmacy reasonable notice of its intent to conduct a Review and/or Survey.
3. Every three years after initial accreditation, PCAB® shall perform a Review and Survey.
4. PCAB® may perform a Review and/or Survey of any Accredited Pharmacy at any time, to verify licensure and compliance with the PCAB® Rules and Terms.
5. PCAB® may at any time collect and test compounded products of any Pharmacy. Any such testing shall be conducted at the expense of PCAB®. Such tests may be with or without notice and with or without cause. Results of all such tests shall be provided to the Accredited Pharmacy.
6. Pharmacy agrees to cooperate with PCAB® in the conduct of all Reviews and Surveys for compliance with PCAB® Rules and Terms.
  - a. Pharmacy agrees to provide PCAB® sufficient access to Pharmacy premises and staff and to Pharmacy records for all Reviews and Surveys deemed by PCAB® to be necessary to ensure that Pharmacy is in compliance with all PCAB® Rules and Terms.
  - b. For all Reviews and Surveys, Pharmacy agrees to permit and facilitate interviews with employees, staff and others that PCAB® may determine may have information useful to evaluate Pharmacy's compliance with the PCAB® Rules and Terms. PCAB® and surveyors will schedule such interviews with reasonable notice to the Pharmacy, at reasonable times and for a reasonable duration.
7. Fees and Costs.
  - a. Pharmacy shall pay fees and costs as detailed in the PCAB® Fees & Costs Schedule.
  - b. PCAB® may require payment of Annual Fees, any required Compliance Fee, and estimated surveyor expenses in advance of any Review and/or Survey.
  - c. Failure to remit any payments due may result in the suspension and/or termination of Pharmacy's eligibility to apply for or maintain accreditation, the suspension and/or termination of any license to use or display the Seal of Accreditation, and/or the cancellation of any Review or Survey which may have been scheduled.
8. Confidentiality
  - a. All Information submitted to PCAB® and all Survey and Review findings shall be kept confidential, except:
    - i. To the extent that information provided to or obtained by PCAB® is in the public domain;
    - ii. To the extent that disclosure is required by law or necessary to comply with any properly executed court order or subpoena, or otherwise is legally mandated;
    - iii. For enforcement of or claims regarding PCAB®'s license and service agreements; and
    - iv. As otherwise provided in the PCAB® Rules and Terms.
  - b. This confidentiality provision shall not in any manner preclude the termination of the use of the Seal of Accreditation if the Accredited Pharmacy is found to not be in compliance with the PCAB® Rules and Terms.



- c. PCAB® reserves the right to share with any appropriate regulatory agency or board and with the public, if deemed by PCAB® in its sole discretion to be necessary or instructional for the health of patients, information pertaining to the termination, suspension or disqualification of a Pharmacy from the PCAB® program.
- d. PCAB reserves the right to notify all appropriate regulatory or law enforcement authorities when PCAB, its employees, or agents believe in good faith that the pharmacy, the corporation, the owners, the corporate staff, and/or the pharmacy staff are engaging in conduct that violates state or federal law.

#### **E. Change of Control/Termination of Pharmacy Practice**

1. If Pharmacy undergoes a significant change in ownership or control (defined as a change of 20% or more of Pharmacy's ownership), Pharmacy must provide written notification to PCAB® within ten (10) days. Pharmacy may be required to submit a new PCAB® application and a Compliance Fee, and may be subject to a Review and/or Survey, in order to continue to qualify as an Accredited Pharmacy following such change in ownership or control.
2. Pharmacy agrees to notify PCAB® in writing within ten (10) days of cessation of Pharmacy operations. In this notification, Pharmacy shall affirm that all references to the PCAB® program and the PCAB® Seal of Accreditation have been removed from all Pharmacy material.

#### **F. Compounding Scope of Practice and Changes in Scope of Practice.**

1. For purposes of PCAB® Accreditation, Compounding Scope of Practice shall be classified into the following areas, which are defined in greater detail in the appendix attached to the PCAB® Standards:
  - a. Basic non-sterile;
  - b. Complex non-sterile;
  - c. Low and medium sterile; and
  - d. High sterile.
2. Pharmacy must comply with the Standards applicable to its Compounding Scope of Practice.
3. Pharmacy has an obligation to notify and inform PCAB® of its Compounding Scope of Practice.
4. If at any time an Accredited Pharmacy expands its Compounding Scope of Practice, the Accredited Pharmacy shall:
  - a. Meet the Standards applicable to the expanded Compounding Scope of Practice prior to dispensing;
  - b. Notify PCAB® within thirty (30) days of expanding;
  - c. Submit an abbreviated application within sixty (60) days of expanding its Compounding Scope of Practice; and
  - d. Be fully accredited by PCAB® for its entire Compounding Scope of Practice within six (6) months.

#### **G. Modification of Standards; Compliance Indicators.**

1. The PCAB® Standards may be modified by PCAB® at its sole discretion upon thirty (30) days prior notice. In the event of any change, Accredited Pharmacy shall be given a reasonable period of time in which to comply with the revised PCAB® Standards considering the extent and significance of the change. Such reasonable period shall not be longer than one year.
2. PCAB® may publish Compliance Indicators.

#### **H. License to Use PCAB® Seal of Accreditation.**

1. Pharmacy acknowledges PCAB's sole ownership of the PCAB® Seal of Accreditation and all ownership rights thereof, and agrees not to challenge or do any act that would interfere either directly or indirectly with such ownership. Pharmacy will not assert or seek any rights in such Seal other than those granted under these Rules and Terms.
2. PCAB grants each Accredited Pharmacy a nonexclusive and non-transferable license to display the PCAB® Seal of Accreditation in connection with the compounding pharmacy operations of the Accredited Pharmacy.
3. Pharmacy agrees that any grant of such license to an Accredited Pharmacy does not constitute an endorsement by PCAB of any part of the Pharmacy's operations or practice other than compounding and may not be used in any manner to imply or suggest more.
4. Pharmacy shall submit to PCAB in writing any questions regarding the acceptable use of the Seal of Accreditation.
5. Pharmacy may not sublicense, transfer, or assign the PCAB® Seal of Accreditation. An Accredited Pharmacy may provide the Seal of Accreditation to any advertising contractor, including any Web site hosting service, to allow display of the Seal of Accreditation in advertising and on the Accredited Pharmacy Web site as permitted under the limited license hereunder.
6. PCAB reserves the right to suspend all use and display of the PCAB® Seal of Accreditation following notice by an Accredited Pharmacy of a change of ownership, pending submission of a new application, payment of Compliance Fee, and/or completion of a Review and/or Survey, as required by PCAB.
7. Discontinuance of the PCAB Accreditation program shall terminate any license awarded by PCAB.

#### **Using and Displaying the PCAB® Seal of Accreditation**

Except as PCAB may authorize in writing elsewhere, only a PCAB® Accredited Pharmacy may display the PCAB® Seal of Accreditation. Anyone using or displaying the PCAB® Seal of Accreditation shall be bound by these policies.

#### **Display**

Accredited Pharmacies are encouraged to notify patients and prescribers that the Pharmacy is a PCAB Accredited® compounding pharmacy. Accredited Pharmacies may not display the PCAB® Seal of Accreditation in any manner that implies sponsorship or endorsement by PCAB of the Pharmacy's products or services.

Accredited Pharmacies may only display the PCAB® Seal of Accreditation in advertisements, literature, informational pieces, press releases, and Web sites as specified in this Policy, and not in any other manner. No person or entity other than an Accredited Pharmacy may use the PCAB® Seal of Accreditation in connection with any Pharmacy operation. Each use of the PCAB® Seal of Accreditation must include the ® symbol.

Upon request, PCAB can provide the artwork for the PCAB® Seal of Accreditation. No user may remove or alter any element of the PCAB® Seal of Accreditation, including size, proportions, colors, or elements, in any manner or animate, morph, or otherwise distort its perspective or appearance.

These policies do not grant a license or any other right to any other PCAB logo or trademark. By using the PCAB® Seal of Accreditation, each user agrees to be bound to the terms of the *PCAB Rules & Terms for Obtaining and Maintaining PCAB Accreditation*.

PCAB reserves the right, at its sole discretion, to terminate or modify permission to display the PCAB® Seal of Accreditation at any time. PCAB reserves the right to take action against any use that does not conform to these policies, infringes any PCAB intellectual property or other right, or violates other applicable law.

#### Internet Display

In addition to the general requirements applicable for any display of the PCAB® Seal of Accreditation, any display of the PCAB® Seal of Accreditation on any Web site also must comply with the following.

The preferred way to display the PCAB® Seal of Accreditation is on the opening ("home") page of the Web site. A separate dedicated page is an acceptable alternative. Any other posting requires the prior written permission of PCAB. The PCAB® Seal of Accreditation shall not be posted on a secure Web page.

The Web page title and other trademarks and logos must appear at least as prominently as the PCAB® Seal of Accreditation. No user may combine the PCAB® Seal of Accreditation with any other object, logo, word, icon, graphic, photo, slogan, number, or other design element.

The PCAB® Seal of Accreditation must be displayed in its original color version and original size.

The PCAB® Seal of Accreditation must appear by itself, with a minimum spacing of 15 pixels between each side of the PCAB® Seal of Accreditation and other graphic or textual elements on the page.

No user may display the PCAB® Seal of Accreditation on any site that disparages PCAB or its members or programs, infringes on any PCAB intellectual property or other rights, or violates any state, federal, or international law.

Except as PCAB may authorize in writing elsewhere, only a PCAB® Accredited compounding pharmacy may display the PCAB® Seal of Accreditation. Anyone using or displaying the PCAB® Seal of Accreditation shall be bound by these policies.

#### **I. Use of PCAB® Seal of Accreditation**

1. Pharmacy agrees to adhere to the Policy for Using and Displaying the PCAB® Seal of Accreditation.
2. No Pharmacy other than an Accredited Pharmacy may display the PCAB® Seal of Accreditation.
3. The Accredited Pharmacy shall not alter, cause, or authorize the alteration of the Seal of Accreditation in any manner whatsoever.
4. If Accredited Pharmacy uses the PCAB® Seal of Accreditation on a Web site, the Web site must include an active link from the PCAB® Seal of Accreditation to PCAB®'s Web site in a form and manner acceptable to PCAB®, as described in detail in the Policy for Using and Displaying the PCAB® Seal of Accreditation.
5. If Accredited Pharmacy engages another party to provide advertising, printing, marketing, or Web hosting services, Accredited Pharmacy shall be responsible for ensuring that such party displays and uses the Seal of Accreditation solely as permitted under these Rules and Terms.

#### **J. Right of Publicity by PCAB®**

Accredited Pharmacy grants PCAB® a non-exclusive, royalty-free license to use and distribute information about Accredited Pharmacy in any list of Accredited Pharmacy locations, on any and all PCAB® Web sites, in PCAB® Program brochures, and in other PCAB® publications. Such information may include, but is not limited to:

1. Accredited Pharmacy name, address, phone number, FAX number, and E-mail address;
2. Accredited Pharmacy Web site address, including link(s);
3. Name of pharmacist-in-charge;
4. Compounding Scope of Practice verified;
5. Date Accredited Pharmacy was accredited;
6. Date of next scheduled annual renewal, Review and/or Survey;
7. List of states and state pharmacy license numbers in which the Accredited Pharmacy is authorized to practice pharmacy and licensure disciplinary information about the Accredited Pharmacy, if any;
8. Toll-free phone number and/or Web site address by which patients may report business-related complaints to or regarding the Accredited Pharmacy;
9. Toll-free phone number and/or Web site address by which patients may report medication and/or device problems to or regarding the Accredited Pharmacy; and
10. The name, address, phone number, FAX number, E-mail address, state of incorporation, years in business, name of CEO of any parent or closely related brother/sister or subsidiary organization if PCAB® determines such information is necessary or desirable for the viewer of the information.

#### **K. Grounds for Denial or Suspension of Accreditation.**

Subject to Section L below, PCAB<sup>®</sup>, at its sole discretion, may at any time deny or suspend accreditation if:

1. The Pharmacy, or any of its employees, affiliates, or agents violate any PCAB<sup>®</sup> Rules and Terms;
2. Any documentation submitted to PCAB<sup>®</sup> on behalf of Pharmacy, including the initial or any renewal application for PCAB<sup>®</sup> accreditation or documents submitted in support thereof, is false or inaccurate in any manner;
3. The Pharmacy or any corporate officer, proprietor, partner, or licensed pharmaceutical professional employed by or providing services on behalf of the Pharmacy:
  - a. Is indicted or convicted of any felony or violation of any state or federal drug or pharmacy practice statute, or is under investigation concerning the potential violation of any state or federal drug or pharmacy practice statute;
  - b. Has a final judgment or decree of disciplinary action issued against him/her by a board of pharmacy or governmental authority; or
  - c. Engages in any conduct that is a violation of state or federal law, that is not in compliance with the PCAB<sup>®</sup> Rules and Terms, or that is found by PCAB<sup>®</sup> to be detrimental to the public health or welfare or the reputation of any other Accredited Pharmacy or PCAB<sup>®</sup>.
4. The Pharmacy is disqualified from participation in or is denied accreditation or credentialing by any other accreditation or credentialing entity;
5. The Pharmacy files for or is made an involuntary party to bankruptcy proceedings;
6. The Pharmacy displays the PCAB<sup>®</sup> Seal of Accreditation in any manner or location that is in any way misleading or that contravenes the Policy for Using and Displaying the PCAB<sup>®</sup> Seal of Accreditation, or fails to timely remove the PCAB<sup>®</sup> Seal of Accreditation when directed by PCAB<sup>®</sup> or as set forth herein or in the Policy;
7. The Pharmacy fails to timely pay required fees;
8. The Pharmacy prevents PCAB<sup>®</sup> from performing a Review or Survey, e.g., by refusing to provide sufficient access to Pharmacy records, facilities, or employees; or
9. PCAB<sup>®</sup> fails to timely receive any written notice required by these Rules and Terms.

#### **L. Suspension of Accreditation.**

1. The accreditation of Pharmacy will be immediately suspended upon written notice from PCAB<sup>®</sup> if it is found by PCAB<sup>®</sup> that Accredited Pharmacy has engaged in the activity described in Section K, subsections 1, 2, or 3. Upon immediate suspension, Pharmacy may appeal the suspension as provided in Section M. Immediate suspension will require the Accredited Pharmacy to remove the PCAB<sup>®</sup> Seal of Accreditation from all displayed locations within five (5) business days of the date of the notice.
2. If PCAB<sup>®</sup> reasonably believes that grounds for suspension exist due to activity described in Section K, subsections 4, 5, 6, 7, 8, or 9, PCAB<sup>®</sup> shall notify Accredited Pharmacy in writing of the questions raised, the possible suspension of Pharmacy's status as an Accredited Pharmacy, and the basis thereof.
3. The Accredited Pharmacy may respond to the charge. Any response must be made in writing and received by PCAB<sup>®</sup> within twenty-one (21) days after the date of the notice.

4. After receiving Accredited Pharmacy's written response, PCAB® may investigate the facts relating to the allegations, considering Pharmacy's response. PCAB® shall determine if sufficient grounds exist to suspend Accredited Pharmacy from participation in the PCAB® program.
5. If no response to the allegations is timely received or if PCAB® determines that sufficient grounds exist to support suspension, PCAB® will notify Accredited Pharmacy in writing of the PCAB® decision to suspend Accredited Pharmacy's status as an Accredited Pharmacy. The notice will require the Accredited Pharmacy to remove the PCAB® Seal of Accreditation from all displayed locations within five (5) business days of the date of the notice.
6. PCAB® may redirect the hyperlink of the Seal of Accreditation assigned to the Pharmacy to display a notice that the Accredited Pharmacy has been suspended.

#### **M. Appeal from Suspension or Denial.**

1. A Pharmacy may appeal a suspension or denial of accreditation in accordance with the terms and conditions of the PCAB® Procedure for Appeal.
2. Unless otherwise agreed, if the Pharmacy does not discontinue use and display of the PCAB® Seal of Accreditation within the required time frame, or if PCAB® does not receive a written notice of appeal and fee payment within the time period set forth in the PCAB® Procedure for Appeal, the Pharmacy shall be disqualified from the PCAB® program and any accredited status shall cease, with no further rights of appeal.
3. Pharmacy shall have no further rights to appeal after either the Appellate Commission or the Executive Committee has rendered a decision to disqualify Pharmacy from the PCAB® program.
4. If Pharmacy is disqualified, PCAB® shall not consider any future PCAB® applications from Pharmacy until all findings and bases for the disqualification are remedied and resolved.
5. Pharmacy shall not be entitled to receive a prorated refund of any prepaid Annual Fee upon termination except in the event of the discontinuation of the PCAB® program.

#### **N. Termination by Accredited Pharmacy.**

1. Accredited Pharmacy may terminate its status as an Accredited Pharmacy upon thirty (30) days written notice to PCAB®. No prorated refund of the unused portion of any Annual Fee will be paid to Accredited Pharmacy.
2. Upon termination, all rights and benefits granted to Accredited Pharmacy by PCAB® shall terminate and Accredited Pharmacy shall immediately cease use and display of the PCAB® Seal of Accreditation and shall no longer hold itself out as being PCAB® accredited.

#### **O. Pharmacy Representations and Warranties.**

Pharmacy represents and warrants the following:

1. All of the information in its initial application and any renewal application, and all information submitted in support thereof, is accurate and truthful;
2. The Pharmacy, its owners, proprietors, partners, and members of the Pharmacy staff, except as disclosed in writing to PCAB®:

- a. Are not currently individually and/or collectively under formal investigation, indictment, or prosecution; and
  - b. Have not been convicted or disciplined over the past five (5) years by any governmental entity or self regulatory program in any country, for violation of any governmental statutes, rules, or regulations under or related to the drug laws or criminal laws of any such jurisdiction.
3. In the event that Pharmacy, or any of its owners, proprietors, partners, or members of the Pharmacy staff becomes the subject of such an investigation, indictment, prosecution, conviction, or disciplinary order, Pharmacy will notify PCAB® within thirty (30) days of learning of such investigation, indictment, prosecution, conviction or disciplinary order; and
4. The individual signing the application on behalf of Pharmacy has the authority to bind Pharmacy to these Rules and Terms.

**P. Warranty Disclaimer/Indemnification.**

1. All grants of the right to display the PCAB® Seal of Accreditation and to refer to Pharmacy as PCAB® Accredited are made with no express or implied warranty by PCAB®.
2. Pharmacy agrees to indemnify and hold PCAB® harmless against any claim, loss, lawsuit, damage, or expense, including, without limitation, reasonable attorney's fees, arising out of:
  - a. Any failure on the part of the Pharmacy to comply with any of the PCAB® Rules and Terms;
  - b. Any content contained in any advertisement, publication, Web site, or any other site substantially owned or controlled by Pharmacy including, but not limited to, any claim related to infringement, misappropriation or other violation of a right of another person (including, without limitation, a copyright, right of privacy or publicity, or trade secret claim), or a claim for defamation or obscenity; or
  - c. The sale of any product or service advertised or sold by Pharmacy.

**Q. Consequential Damages Waiver, Limitation of Liability.**

Neither party shall be liable to the other or any third party for any indirect, incidental, or consequential damage or damages from lost profits or lost use. The maximum aggregate liability of PCAB® for all claims arising out of or relating to accreditation and/or PCAB® Rules and Terms, regardless of the form or cause of actions, shall be total fees and expenses paid by Pharmacy under the PCAB® program for the preceding twelve (12) month period.

**R. Notices/Modification.**

All notices required by these Rules and Terms to be provided to PCAB® shall be in writing and sent to:

Pharmacy Compounding Accreditation Board  
2215 Constitution Ave, NW  
Washington, DC 20037

All notices required to be provided to Pharmacy shall be sent to the address indicated in Pharmacy's most recent application or renewal, unless Pharmacy has indicated otherwise in writing.

#### **S. Severability.**

The provisions of all PCAB® Rules and Terms are severable. If any provision is determined by a court of competent jurisdiction or a governmental regulatory entity to be invalid or unenforceable, in whole or in part, that provision shall be construed or limited in such a way as to make it enforceable and consistent with the manifest intentions of the parties. If such construction or limitation is impossible, the unenforceable provision will be stricken, and the remaining provisions will remain valid and enforceable.

#### **T. Waiver.**

The failure of PCAB® to exercise any right or to take any action regarding any of these PCAB® Rules and Terms shall not be deemed to be a waiver of any right to take future action nor be deemed to be a waiver of any subsequent breach.

#### **U. Governing Law.**

PCAB® Rules and Terms shall be governed by and interpreted according to the laws of the District of Columbia. Should any court determine it has jurisdiction, or should any person contend that any court has jurisdiction of any matter regarding the PCAB® program, these PCAB® Rules and Terms shall be governed by and interpreted under Federal law and the laws of the District of Columbia without regard to any conflict of laws provisions.

### **Items Incorporated by Reference**

#### ***PCAB® Standards and Principles of Compounding***

PCAB® Standards and Principles of Compounding are posted on the PCAB® pharmacy information web site at [www.pcab.info](http://www.pcab.info) or may be obtained by contacting PCAB®.

#### ***Policy for Using and Displaying the PCAB® Seal of Accreditation***

Except as PCAB® may authorize elsewhere, only a PCAB® Accredited Pharmacy may display PCAB® Seal of Accreditation. Anyone else using or displaying the PCAB® Seal of Accreditation shall be bound by these policies.

#### **Display**

- Accredited Pharmacies are encouraged to notify patients and prescribers that the Pharmacy is a PCAB Accredited® compounding pharmacy. Accredited Pharmacies may not display the PCAB® Seal of Accreditation in any manner that implies sponsorship or endorsement by PCAB of the Pharmacy's products or services.
- Accredited Pharmacies may only display the PCAB® Seal of Accreditation in advertisements, literature, informational pieces, press releases, and Web sites as specified in this Policy, and not in any other manner. No person or entity other than an Accredited Pharmacy may use the PCAB® Seal of Accreditation in connection with any



Pharmacy operation. Each use of the PCAB® Seal of Accreditation must include the ® symbol.

- Upon request, PCAB can provide the artwork for the PCAB® Seal of Accreditation. No user may remove or alter any element of the PCAB® Seal of Accreditation, including size, proportions, colors, or elements, in any manner or animate, morph, or otherwise distort its perspective or appearance.
- These policies do not grant a license or any other right to any other PCAB logo or trademark.
- By using the PCAB® Seal of Accreditation, each user agrees to be bound to the terms of the *PCAB Rules & Terms for Obtaining and Maintaining PCAB Accreditation*.
- PCAB reserves the right, at its sole discretion, to terminate or modify permission to display the PCAB® Seal of Accreditation at any time. PCAB reserves the right to take action against any use that does not conform to these policies, infringes any PCAB intellectual property or other right, or violates other applicable law.

#### Internet Display

- In addition to the general requirements applicable for any display of the PCAB® Seal of Accreditation, any display of the PCAB® Seal of Accreditation on any Web site also must comply with the following.
- The preferred way to display the PCAB® Seal of Accreditation is on the opening ("home") page of the Web site. A separate dedicated page is an acceptable alternative. Any other posting requires the prior written permission of PCAB. The PCAB® Seal of Accreditation shall not be posted on a secure Web page.
- The Web page title and other trademarks and logos must appear at least as prominently as the PCAB® Seal of Accreditation. No user may combine the PCAB® Seal of Accreditation with any other object, logo, word, icon, graphic, photo, slogan, number, or other design element.
- The PCAB® Seal of Accreditation must be displayed in its original color version and original size.
- The PCAB® Seal of Accreditation must appear by itself, with a minimum spacing of 15 pixels between each side of the PCAB® Seal of Accreditation and other graphic or textual elements on the page.
- No user may display the PCAB® Seal of Accreditation on any site that disparages PCAB or its members or programs, infringes on any PCAB intellectual property or other rights, or violates any state, federal, or international law.
- Except as PCAB may authorize in writing elsewhere, only a PCAB® Accredited compounding pharmacy may display the PCAB® Seal of Accreditation. Anyone using or displaying the PCAB® Seal of Accreditation shall be bound by these policies.

## **PCAB® Fees & Costs Schedule**

### **Annual Fees**

To be considered for and maintain accreditation by PCAB®, a Pharmacy must pay an Annual Fee. The amount of that fee is set by the PCAB® Board of Directors.

As a part of the initial application and each annual renewal application, each Pharmacy must calculate and indicate to PCAB® the fees that apply to it for the year. The fee calculation performed by the Pharmacy is subject to an annual audit.

A Pharmacy's Annual Fee is based on the number of prescription preparations compounded on the average day. The figure is calculated using a five-day week (totaling 262 days per year) and averaged by the year. A Pharmacy can calculate its Annual Fee, and thus the amount it must pay to begin the accreditation process, by dividing the number of prescriptions compounded in the previous 12 months by 262.

The current Annual Fees are:

- **1 to 15 compounded Rx preparations /day = \$1,250.00 / year**
- **16 to 100 compounded Rx preparations/day = \$2,500.00 / year**
- **over 100 compounded Rx preparations/day = \$5,000.00 / year**

In computing the number of prescriptions compounded, the Pharmacy should consider the amount of compounding conducted in the 365 days immediately preceding the calculation (not the calendar year). The calculation should not include non-compounded prescriptions filled. Compounded preparations that generally may be available over-the-counter, as well as compounded herbal preparations, should be included in the calculation only if they are dispensed to a patient pursuant to a prescription written by a licensed prescriber.

The first Annual Fee is due with the submission of the initial application. Thereafter, the Annual Fee is due with each annual renewal application. The fees may be paid by check or credit card. If an application is submitted electronically, a check may be mailed at the time of submission. All fees must be paid in full before work on the application can begin.

### **Surveyor expense**

In addition to the Annual Fee, each Pharmacy must pay the expenses of the surveyor for the on-site or in-pharmacy Survey. These expenses cover travel, either by automobile or air; hotel expenses; meals and such usual and customary expenses a surveyor might incur in the process of assessing a Pharmacy.

At the time that the Survey is scheduled, the Pharmacy must pay an estimated amount to cover the surveyor expenses. Following the Survey, the Pharmacy will be refunded any amount paid that exceeded the surveyor's actual expenses.

PCAB® has contracted with the National Association of Boards of Pharmacy (NABP) to conduct Surveys and Reviews. The number of surveyors to be assigned to each Pharmacy will be determined by NABP in consultation with PCAB®. The number of surveyors will depend on the

volume and complexity of the Pharmacy's compounding business. In general, one or two surveyors will be assigned to each Pharmacy.

### ***Compliance Fees***

In the event that it is necessary to make an additional Survey or Review in a single three-year period, PCAB® may charge Compliance Fees. The amount of these fees will be based upon the reasons and circumstances for the additional Survey or Review. The Pharmacy will be notified of the amount of the Compliance Fee and the due date, and will be given an estimate of any additional surveyor expenses that will be required. Payment for any of these additional Compliance Fees will be due prior to any additional work being done.

### ***PCAB® Procedure for Appeal***

- A. Pharmacy may file a written Notice of Appeal with PCAB® within twenty-one (21) days after the date of the notice of denial or suspension. A \$1,500 payment (the "Costs of Appeal") must be submitted with the Notice of Appeal to be applied to the costs incurred by convening the PCAB® Appellate Commission.
- B. Both parties to the appeal shall have the right to representation by counsel throughout the appeal procedure.
- C. Not more than thirty (30) days after receipt of a Notice of Appeal, the PCAB® Appellate Commission appointed by the Board of Directors shall notify the parties of the members of the Appellate Commission and such other matters as the Commission may determine appropriate.
  - 1. In the event that any person designated as a member of the Appellate Commission shall be disqualified, refuse to serve, or be unable to serve for any reason at any time, an alternate member shall be selected by the remaining members of the Appellate Commission.
  - 2. An individual's service and affiliation with PCAB®, PCAB®'s Executive Committee, or the Appellate Commission shall not be grounds for disqualification as a member of the Appellate Commission on the basis of conflict of interest, bias, or the like.
  - 3. All reasonable expenses incurred by the Appellate Commission, including but not limited to travel expenses (i.e., transportation, accommodations, and meals), shall be paid by the Pharmacy.
  - 4. Failure of Pharmacy to pay the Appellate Commission's reasonable expenses, in full, within seven (7) days of the date of the bill or invoice, shall result in termination of the appeals procedure and disqualification of Pharmacy from the PCAB® program.
- D. As part of the appeal, the Pharmacy may request an audit of its compliance with the PCAB® Rules and Terms. At the time of request, Pharmacy must submit an additional fee ("Audit Fee") of \$1,500 to be applied to the costs of performing the audit, with additional expenses to be billed following the completion of the audit. PCAB® shall conduct the audit. A written report of the audit findings will be provided to the Pharmacy, PCAB®, and the members of the Appellate Commission.
- E. The Appellate Commission shall set a date, time, and place for a hearing on the appeal. Unless otherwise agreed by the parties, the hearing shall be set for not more than sixty (60)

days after the date upon which the Pharmacy was notified of the members of the Appellate Commission, or the date upon which the audit report is provided, whichever is later.

- F. Not less than ten (10) days before the hearing, Pharmacy and PCAB® shall present written statements of their respective positions to the Appellate Commission.
- G. Both parties may present evidence at the hearing.
- H. Closing arguments shall be submitted to the Appellate Commission in writing, and must be filed within fourteen (14) days after the conclusion of the hearing.
- I. Within thirty (30) days after the date upon which closing arguments are due, the Appellate Commission shall render a decision:
  - 1. To disqualify Pharmacy from the PCAB® program;
  - 2. To not disqualify Pharmacy from the PCAB® program; or
  - 3. To remand the matter to PCAB® for a further Survey and reconsideration.
- J. The Appellate Commission shall submit its findings and decision in writing to the Executive Director of PCAB® and the Pharmacy.
- K. Any matter remanded to PCAB® for reconsideration shall be heard and considered by the full Executive Committee of PCAB®.
  - 1. The decision of the Executive Committee shall be final.
  - 2. The Executive Committee shall issue a written report of its findings and decision to PCAB's Executive Director and the Pharmacy.

## ***PCAB® Policy on Revocation, Suspension, or Probation of a License***

### **Non-Discretionary**

It is the policy of the PCAB® Board that accreditation will be routinely and uniformly denied or suspended for pharmacies that meet the following criteria:

#### **Resident State Disciplinary Action:**

Accreditation will be denied or suspended if a pharmacy license is revoked or suspended for any reason by the resident state. Accreditation will be denied or suspended if the pharmacy license is placed on probation (also called “terms and conditions”) by the resident state for any grounds related to compounding pharmacy services, patient or public safety, or controlled substances violations. A pharmacy may reapply for PCAB® accreditation after reinstatement or removal of probationary status of the license, provided it meets PCAB®’s then current standards and conditions for accreditation.

#### **Non-resident State Disciplinary Action:**

Accreditation will be denied or suspended if a pharmacy license is revoked, suspended, or placed on probation by a non-resident state for any grounds related to the safety of compounding pharmacy services or compounded preparations, patient or public safety issues, or significant controlled substances violations. A pharmacy may reapply for PCAB® accreditation after reinstatement of the license, provided it meets PCAB®’s then current standards and conditions for accreditation.

### **Discretionary**

It is the policy of the PCAB® Board that denial or suspension of accreditation will also be seriously considered and a determination made on a case-by-case basis, for any revocation or suspension by a non-resident state for any reason other than grounds administrative in nature, or for any probationary status

## **PCAB® Guidance to Pharmacies Regarding Hazardous and Potent Substances and Primary Engineering Controls**

This document is designed to provide guidance to pharmacies regarding PCAB® requirements for powder and fume containment devices in pharmacies that handle hazardous or potent drugs. Every pharmacy practice is unique and site-specific considerations should be addressed when implementing the suggestions outlined in this guidance document. Please email CONTACT@PCAB®.ORG with any questions and recommended improvements to this guidance document.

### ***Introduction***

PCAB® requirements for protective equipment and procedures for non-sterile compounding are primarily addressed in standard 3.00, Facilities and Equipment.

Standard 3.10 states, “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.”

“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 3.30 states,

“A. The pharmacy has an area for aseptic compounding of sterile preparations that meets current USP <797> standards.”

“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.”

For sterile compounding, PCAB® requires compliance with USP <797> standards that address compounding with hazardous materials. Compliance Indicator F states “If the pharmacy practices aseptic sterile compounding, it has an appropriate area for compounding of aseptic preparations that meets or exceeds USP <797>.”

In order to meet the requirements of the above standards, PCAB® requires pharmacies that handle hazardous substances to have appropriate primary engineering controls (Biological Safety Cabinets-BSCs) designed to protect the operator from exposure to the hazardous substance. This requirement is consistent with NIOSH and OSHA standards and recommendations.

### ***Non-Sterile Compounding***

For non-sterile compounding, a Class I BSC, a device designed to protect personnel and the environment from hazardous and potent drugs is required. Class I BSCs are available in various sizes and configurations from a variety of vendors. These devices are sometimes called vented balance safety enclosures or powder hoods.

In order to meet PCAB®, NIOSH, and OSHA requirements weighing and compounding of hazardous and potent drugs must occur in a type I BSC. Optimally, Class I BSCs should be vented to the outside. However, devices that are designed to recirculate room air are acceptable.

Regardless of whether a pharmacy purchases a class I BSC or designs and constructs a device in-house, PCAB® surveyors will ask for documentation that device meets standards for operator protection.

In addition, there are testing protocols for Class I BSCs that include air flow and filter leakage tests. Devices should be tested upon installation and annually to assure they are working correctly.

### ***Sterile Compounding***

Sterile portions of the sterile compounding process such as weighing must, at a minimum, be performed in equipment meeting the requirements above for nonsterile compounding. The equipment must be situated in an environment meeting USP 797 standards.

Sterile compounding with hazardous or potent drugs must occur in a Class II BSC or compounding aseptic containment isolator (CACI), devices designed to protect personnel and the environment from the hazardous material, and the product from bacterial or particulate contamination.

For pharmacies that compound a significant amount of hazardous substances, the class II BSC must be located in a minimum ISO Class 7 environment that is physically separate from other preparation areas. This environment should have negative pressure relative to the outside environment of not less than 0.01 inches of water.

A CACI must be located in an ISO Class 7 or 8 environment that is physically separate from other preparation areas. This environment should have negative pressure relative to the outside environment of not less than 0.01 inches.

In cases where the pharmacy only prepares a small volume of hazardous drugs, the use of two tiers of containment, for example, a Class II BSC or CACI and the use of closed system transfer devices is acceptable.

ISO environments must be tested every 6 months as required by USP <797>. Protective equipment such as Class I BSCs must be tested upon installation and annually to assure they protect operators as intended.

### ***Storage***

Hazardous drugs should be stored separately from other inventory, preferably within a negative pressure room.

### ***Frequently Asked Questions***

***Our pharmacy rarely works with hazardous substances; do we need primary engineering controls?***

Yes.

***Our pharmacy provides our staff with masks, respirators and other personal protective equipment to work with hazardous drugs, is this Ok?***

Yes...but PCAB<sup>®</sup>, NIOSH and OSHA all recognize that personal protective equipment is not a substitute for primary engineering controls. PPE is an adjunct to primary engineering controls, and should be available in case of spills or accidents. PCAB<sup>®</sup> will not accept personal protective equipment as a substitute for primary engineering controls.

***Our pharmacy designed its own primary engineering control, is this acceptable?***

Yes, provided that the device has passed appropriate testing by a qualified outside testing service.

***Our pharmacy performs serum/saliva/air or other types of testing for hazardous substances and has never had a problem. Are we exempt from the requirements for primary engineering controls?***

No. PCAB<sup>®</sup>, OSHA and NIOSH require primary engineering controls regardless of any other precautions.

### ***Additional Information/Resources***

IACP Hazard Alert: Compounding with Hazardous or Potent Pharmaceuticals.

[www.iacprx.org](http://www.iacprx.org).

NIOSH: Preventing Occupational Exposure to Antineoplastic and Other

Hazardous Drugs in Health Care Settings. [www.cdc.gov/niosh/docs/2004-165/](http://www.cdc.gov/niosh/docs/2004-165/)

OSHA: Controlling Occupational Exposure to Hazardous Drugs.

[www.osha.gov/dts/osta/otm/otm\\_vi/otm\\_vi\\_2.html](http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html)



## PCAB® Guidance to Pharmacies Regarding Maintenance and Calibration Logs

This document is designed to provide guidance to pharmacies regarding PCAB® requirements for record keeping in regards to maintenance and calibration logs.

Various PCAB® Standards require or imply that a pharmacy must maintain maintenance and calibration logs for various pieces of equipment and processes such as cleaning and disinfection.

For example, Standard 3.10 states, “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.”

In order to comply with the above requirements, pharmacies should consider: Do the manufacturer or compendial (USP) standards require any specific documentation of cleaning and use for this equipment?

For example:

- Capsule Machines – At a minimum, should be cleaned between compounding with different API or when a spill or occurs.
- Tube sealer – At a minimum, should be cleaned and disinfected on a regular basis, when visibly dirty or when a spill or accident occurs.
- Balance – At a minimum, should be cleaned and disinfected regularly, calibrated daily, and also cleaned and disinfected when dirty or soiled, or when a spill or accident occurs.
- Hot Plate - At a minimum, should be cleaned and disinfected regularly, and also cleaned and disinfected when dirty or soiled, or when a spill or accident occurs. A pharmacy may choose to calibrate a hot plate, or, it may choose to monitor the temperature of the preparation being heated on the hot plate in lieu of calibration.
- EMP - At a minimum, should be cleaned and disinfected regularly, and also cleaned and disinfected when dirty or soiled, or when a spill or accident occurs.

Written SOPs should govern how the equipment is used, cleaned and maintained. A log may be appropriate for certain equipment, but often, equipment used many times per day in the compounding processes can have the compounding record address cleaning, calibration, other required setup or that maintenance was properly done. For example, the SOP for an ointment mill may specify that the equipment is to be cleaned and sanitized before and after use, and that the compounder who prepared the preparation has confirmed by signing on the compounding record that this task was performed for this preparation.

If, for example, the pharmacy's SOPs require that the ointment mill undergo a more thorough monthly cleaning, this procedure could be documented on a log. The log could be a part of a sheet of tasks that are performed daily, weekly and monthly. This log may be on paper or electronic.

If the pharmacy's SOPs require the pH meter calibration once a day before use, this calibration can be documented on a log that addresses other daily calibration, cleaning or maintenance items. For example, a single daily log can have sections for documenting pH meter calibration, refrigerator, freezer & storeroom temperatures, (Logs should list what the acceptable temperature range is), balance calibrations and daily cleaning and disinfection of countertops.

If the pharmacy's SOPs require the pH meter calibration prior to each use, the pharmacy may choose to include the calibration as part of the procedure documented on the compounding record.

PCAB® also requires a minimum of a 90 day track record of compliance with documentation requirements as specified under the Standards for all pharmacies undergoing initial accreditation. For re-accreditation, PCAB® Surveyors may review records for up to one year prior to the survey date.