



Pharmacy Compounding Accreditation Board PCAB™

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.

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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](#)

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.

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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

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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.

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- 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

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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™.

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

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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™, 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™ Rules and Terms;
2. Any documentation submitted to PCAB™ on behalf of Pharmacy, including the initial or any renewal application for PCAB™ 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

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- c. Engages in any conduct that is a violation of state or federal law, that is not in compliance with the PCAB™ Rules and Terms, or that is found by PCAB™ to be detrimental to the public health or welfare or the reputation of any other Accredited Pharmacy or PCAB™.
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™ 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™ Seal of Accreditation, or fails to timely remove the PCAB™ Seal of Accreditation when directed by PCAB™ or as set forth herein or in the Policy;
7. The Pharmacy fails to timely pay required fees;
8. The Pharmacy prevents PCAB™ from performing a Review or Survey, e.g., by refusing to provide sufficient access to Pharmacy records, facilities, or employees; or
9. PCAB™ 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™ if it is found by PCAB™ 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™ Seal of Accreditation from all displayed locations within five (5) business days of the date of the notice.
2. If PCAB™ reasonably believes that grounds for suspension exist due to activity described in Section K, subsections 4, 5, 6, 7, 8, or 9, PCAB™ 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™ 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.

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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 or may be obtained by contacting PCAB™.

Policy for 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 PCAB™ accredited. Accredited Pharmacies may not display the “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 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 Seal of Accreditation in connection with any Pharmacy operation.
- Each use of the PCAB™ Seal of Accreditation must include the trademark symbol.
- PCAB™ will provide the artwork for the Seal of Accreditation. No user may remove or alter any element of the 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 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 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 Seal of Accreditation on any Web site also must comply with the following.

- The preferred way to display the 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 Seal of Accreditation shall not be posted on a secure Web page.
- The Seal of Accreditation must always contain an active link to the PCAB™ site, www.pcab.org, when used on a Web page. Each use of the PCAB™ Seal of Accreditation must be accompanied by a notice “Click to Verify Accreditation Status of [pharmacy name],” with a link to the PCAB™ verification site.
- The Web page title and other trademarks and logos must appear at least as prominently as the Seal of Accreditation. No user may combine the Seal of Accreditation with any other object, logo, word, icon, graphic, photo, slogan, number, or other design element.
- The Seal of Accreditation must be displayed in its original color version and original size.
- The Seal of Accreditation must appear by itself, with a minimum spacing of 15 pixels between each side of the Seal of Accreditation and other graphic or textual elements on the page.
- No user may display the 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.

Revised 12/13/05

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

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(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.

Revised 12/13/2005

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

PCAB™ Rules & Terms
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- 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.

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