Pharmacy Compounding Accreditation Board:

Process, Standards, and Areas of Focus

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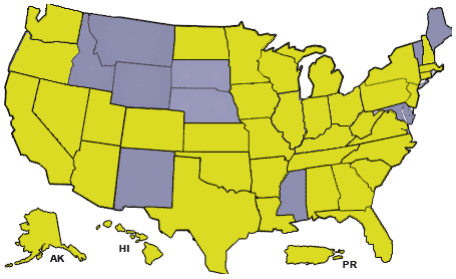
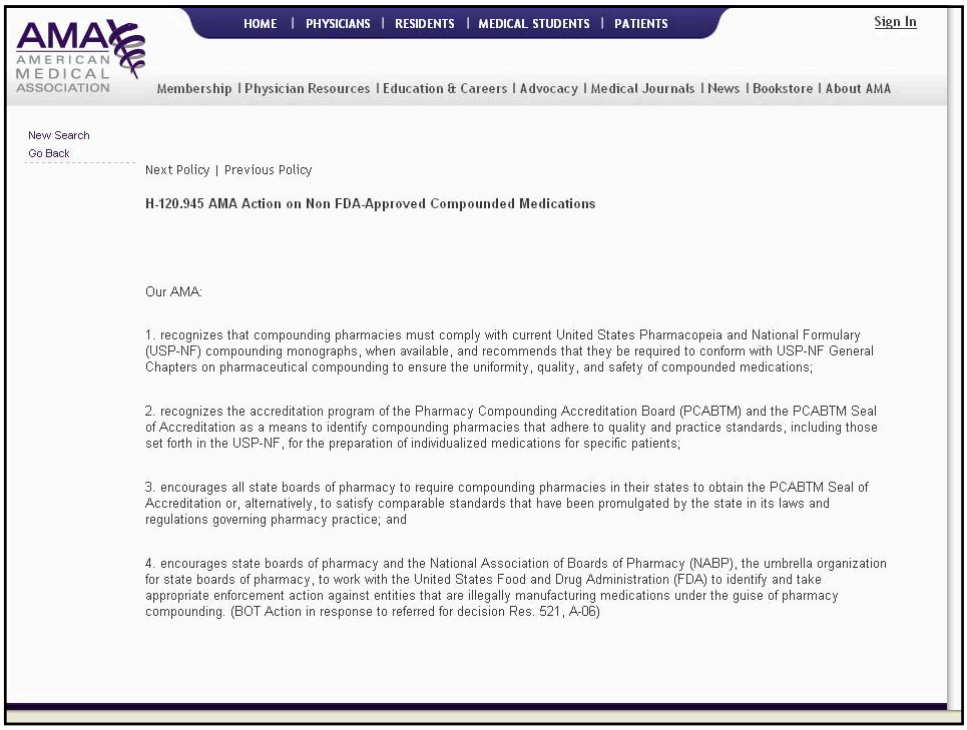
Numbers

- Click on the map of the United States on www.pcab.org for a current list of PCAB Accredited pharmacies





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H-120.945 AMA Action on Non FDA-Approved Compounded Medications

Our AMA:

1. recognizes that compounding pharmacies must comply with current United States Pharmacopeia and National Formulary (USP-NF) compounding monographs, when available, and recommends that they be required to conform with USP-NF General Chapters on pharmaceutical compounding to ensure the uniformity, quality, and safety of compounded medications;

2. recognizes the accreditation program of the Pharmacy Compounding Accreditation Board (PCABTM) and the PCABTM Seal of Accreditation as a means to identify compounding pharmacies that adhere to quality and practice standards, including those set forth in the USP-NF, for the preparation of individualized medications for specific patients;

3. encourages all state boards of pharmacy to require compounding pharmacies in their states to obtain the PCABTM Seal of Accreditation or, alternatively, to satisfy comparable standards that have been promulgated by the state in its laws and regulations governing pharmacy practice; and

4. encourages state boards of pharmacy and the National Association of Boards of Pharmacy (NABP), the umbrella organization for state boards of pharmacy, to work with the United States Food and Drug Administration (FDA) to identify and take appropriate enforcement action against entities that are illegally manufacturing medications under the guise of pharmacy compounding. (BOT Action in response to referred for decision Res. 521, A-06)

W I I F M

WHAT'S IN IT FOR ME...

- Up to 15% credit from Pharmacists Mutual
- Business generation
  - VA Hospitals require PCAB Accreditation for contracts for non-sterile compounds
  - AAEP 2010 will only allow PCAB-Accredited pharmacies to exhibit
- Marketing kit created by national PR firm
- More efficient operation (e.g. fewer throw-aways)

PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

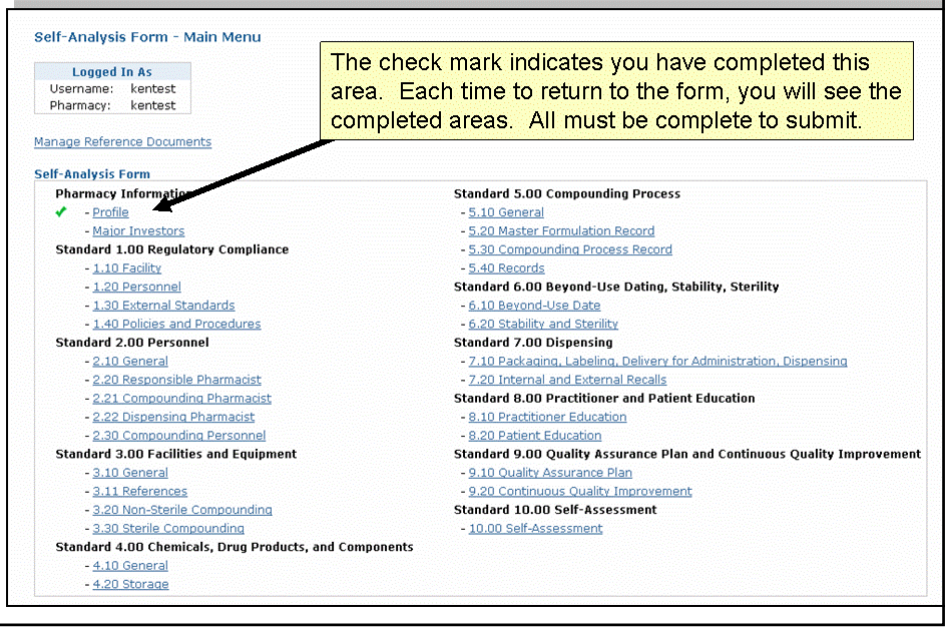
Steps in PCAB Accreditation Process

- Application
- Pre-survey review
- On-site survey
- Post-survey review
- *Accreditation Committee*
  - Currently being formed & implemented

Create user account

- Click on “Apply to PCAB”
- Submit demographic information
- Receive periodic updates from PCAB
- *FREE*
- First step in accreditation process

Submitting your self – analysis form and documentation proof



What is reviewed during this process?

- Policy and procedures
- Pharmacy Website
- Licensure of pharmacy and personnel
- Personnel file of compounding personnel
- Chemical files (MSDS sheets, C of A)
- Master formulation worksheets (BUDs)
- Labeling and patient education
- QA data and CQI process (e.g. testing)

PCAB Principles

- Triad relationship
- Commercially-available products
- Prescriber and patient awareness compounded product is being used
- Anticipatory compounding
- Advertising
- Office Use

Common areas of non-compliance

- Incomplete personnel records
  - Examples: No job descriptions; no record of training or assessment (initial or ongoing)
- Facilities and equipment
  - Examples: Lack engineering controls for powder containment; incomplete calibration logs; lack of temperature/humidity logs
- Chemicals
  - Example: Lack of ready access to MSDS

Common areas of non-compliance

- Beyond use dating (BUD)
  - Example: Extending BUDs beyond USP guidelines without proper documentation or testing
- Recall procedure
  - Example: Lack of internal and/or external recall procedure; No patient phone calls fo severe recalls

Common areas of non-compliance

Quality Assurance (QA) and Continuous Quality Improvement (CQI)

- Not to be confused with Quality Control (QC)

- QA: process insures that compounds are made to consistently high standards
- CQI: periodic examination of P&Ps, QA data, adverse events, etc. to improve targeted areas
  - Includes implementation of corrective actions or policy changes where needed)

Documentation

- Personnel file containing training record, future training schedule, and competency assessment
- Prescription logs from the past 60 days
- Master Formula Worksheet for top ten (10) compounds
- Compounding Process Records for top ten (10) compounds
- Example of documentation for any BUDs which exceed USP guidelines
- MSDS sheets and C of A for top ten (10) chemicals used
- Record of cleaning equipment and compounding areas
- QA records indicating testing program for strength, quality, and purity; and endotoxicity and sterility, if applicable

Example of onsite procedure

Look at 10-20 Rxs that are already prepared (e.g. will call bin)

- pull original Rx
- ask for Master Formulation Record
- look at labeling and patient education
- ask about recalls and have staff demonstrate process
- ask about BUDs and any accompanying documentation
- if shipping – review shipping process and follow-up post delivery
- appropriate storage if in Fridge & how does it get to patient (verification)
- QA checks (QC; particulates; etc)

Tips from PCAB Surveyors

- Find a qualified person and put them in charge of the operation with authority to implement changes.
- ****Read**** the standards and compliance indicators before starting the process and perhaps work on the hardest ones first (PCAB Standards 2 and 9)

Tips from PCAB Surveyors

- Develop a "policy on policies".
- Identify critical processes and develop SOPs for these.
- Document all staff training programs and processes. Initiate, plan, and make time for regular staff meetings.
- Identify and delegate staff members who have talent in writing SOPs and training employees. Make sure that appropriate time is given to accomplish the tasks. *Set realistic goals and deadlines.*

Tips from PCAB Surveyors

Select 2 days per week to conduct a review of all completed prescriptions for compliance with:

1. PCAB principles (commercially available, triad relationship, office use, etc.)
2. Regulatory compliance: (state laws, Federal laws, shipping out of state, etc.)
3. PCAB Labeling Guidelines
4. Track documentation from Rx to patient
5. OBRA issues (prospective DUR, retrospective review DUR, etc.)

Tips from PCAB Surveyors

- PCAB Standard 9 requires a Quality Assurance Plan and a Quality Improvement Program. These are two different requirements.
- PCAB standards 1-8 are essentially an outline of a quality assurance/quality control program. If you meet those standards, your pharmacy will have a quality assurance program.

Tips from PCAB Surveyors

- CQI implies that you actively measure something before you improve it, and actively measure after you make improvements to quantify the results.
- Part of your PCAB preparation will probably include working on improving compliance with one or more PCAB standards.
- Since you are going to be doing this anyway, if you measure and document your progress, you can use some of the PCAB preparation work as a CQI Project.

Example

- As a part of your preparation review, you note that your pharmacy does not give written handout information for “Compound A”. This needs to be improved for PCAB.
- Prior to your survey, a review is again conducted, and it is found that now 95% of patients receive a written handout.
- Over 3 months, pharmacy students are assigned to find and/or write patient handouts for your 30 most compounded medications.

Example continued…

- Your pharmacy has now met the requirements of PCAB Standard 8.20 related to written patient materials.
- Additionally, because the process of meeting this requirement and the outcome was documented as a quality improvement need, it can also be used as evidence of having a quality improvement program, a requirement of standard 9.

Tips from PCAB Surveyors

- Develop SOPs for critical equipment.
- Identify and document QREs (Quality Related Events)
- If compounding sterile preparations, review USP<797> and develop the plan to follow the guidelines completely.
- Begin thinking in terms of Quality Assurance, Quality Control and Continuous Quality Improvement from start to finish.

Tips from PCAB Surveyors

- Have a valid recall system in place and be able to demonstrate how it works.
- Wear appropriate attire for non-sterile as well as sterile compounding.
- Be sure the compounding lab is clean (e.g. no dust on top of refrigerator, etc.).
- Implement engineering controls to appropriately contain powders.

Tips from PCAB Surveyors

- Prevent cross contamination by covering open powders and liquids.
- Balances should record weights by electronic, paper or double check by personnel.
- New formulas should be checked by pharmacists.
- If pharmacist-owner also works as compounding pharmacist, documentation of initial and ongoing training and any quality activities should be provided.

Tips from PCAB Surveyors

- Written SOPs should match actual practice. Only utilize pre-prepared SOPs as a guide. Allow compounding staff to develop/edit SOPs and have management verify.
- Use a trackable testing system. Many of the labs now offer this service to be able to pull up a graph of your last 10 tests that can be sorted by active, date, staff member, etc.

Tips from PCAB Surveyors

- Meticulously review a broad sample of items on your "Ready for Pick Up" shelf. If anything is missing, incorrect, or unclear, chances are a PCAB standard is not being met.
- Examples include, auxiliary labels, written patient handouts, appropriate BUDs, etc.

Tips from PCAB Surveyors

- To insure compliance with written SOPs, distribute 10 SOPs to key staff and have them review for appropriateness and compliance.

BOTTOM LINE: Assess and document quality in all aspects of pharmacy compounding as part of daily routine.

Questions:

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