Secundum Artem

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Current & Practical Compounding Information for the Pharmacist

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The ACHC-PCAB Pharmacy Accreditation Program

Goal: To provide information on the importance and procedures for obtaining pharmacy accreditation.

Objectives: After reading and studying the article, the reader will be able to:

1. Discuss the history and formation of PCAB and its new relationship with ACHC.
2. Discuss the procedures involved in obtaining ACHC-PCAB accreditation.
3. Apply the standards to the current practice at the facility and determine where additional effort needs to be expended.
4. Determine the advantages of becoming accredited for both patient safety and quality business practices.

INTRODUCTION

Accreditation demonstrates a pharmacy's commitment to quality through compliance with national standards and industry best practices. It plays a significant role in fostering public confidence in the healthcare organizations, enhancing organizational effectiveness, and improving patient care. It also provides the basis on which referral sources and payers can be assured that accredited organizations have complied with a common set of requirements and standards.

Beginning July 1, 2014, the Pharmacy Compounding Accreditation Board, or PCAB, became a service of the Accreditation Commission for Health Care (ACHC). The value of the PCAB brand is well-recognized and ACHC will maintain a separate and distinct PCAB accreditation program.

ACHC is an independent, private, not-for-profit corporation that was established in 1986. The organization has a board of commissioners composed of healthcare professionals and consumers. ACHC surveyors are licensed pharmacists that draw upon their relevant experience to provide a comprehensive assessment of an organization/facility as well as to provide helpful, consultative advice. It accredits pharmacies that dispense medications pursuant to a prescription order for an individually-identified patient for (1) Infusion Pharmacy, (2) Ambulatory Infusion Center, (3) Specialty Pharmacy, (4) Infusion Nursing, (5) Community Retail Pharmacy, (6) Long Term Care Pharmacy, and (7) PCAB Pharmacy Compounding Accreditation (Nonsterile and Sterile). ACHC accredits over 12,000 healthcare sites providing services in a number of different areas as just listed.

Other accrediting agencies include CHAP (Community Health Accreditation Partner) and the Joint Commission, formerly JCAHO (Joint Commission on Accreditation of Healthcare Organizations).

BACKGROUND, HISTORY AND DEVELOPMENT

In 2003, there was a meeting between representatives from the Food and Drug Administration and the U.S. Pharmacopeia about the status of pharmacy compounding. The meeting occurred a few months after the U.S. Supreme Court ruled a portion of Section 503a of the Food and Drug Administration Act of 1997 (FDAMA97) unconstitutional and non-severable, resulting in a loss of the "protection" or "safe harbor" where pharmacy was positioned between 1997 and 2002.

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The purpose of the meeting was to discuss different approaches to enhance the quality of pharmaceutical compounding to minimize the chances of occasional errors that have occurred resulting in harm, and even death, to some patients. Even though the rate of these occurrences is extremely small, they had received a lot of press coverage and needed to be addressed.

The discussion at that meeting resulted in two considerations. First, the establishment of an accrediting body that would inspect and "accredit" compounding pharmacies that meet standards for pharmaceutical compounding and the implementation of a certification program for compounding pharmacists to ensure an acceptable level of training in pharmaceutical compounding.

A number of pharmacy organizations, including the American College of Apothecaries, American Pharmacists Association, International Academy of Compounding Pharmacists, National Association of Boards of Pharmacy, National Community Pharmacists Association, National Alliance of State Pharmacy Associations, National Home Infusion Association, and the United States Pharmacopeia comprise the Pharmacy Compounding Accreditation Board (PCAB), joined together to form the Pharmacy Compounding Accreditation Board (PCAB).

> PCAB appointed a 12-member PCAB Standards Task Force with the following charge:
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> "The charge of the Standards Task Force is the development of a quality compounding standards document. This document will be used as a foundation for the development of an accreditation program for compounding pharmacies".

PCAB was very instrumental in assuring the quality standards of the accredited facilities where compounding occurs. At that time the American Society of Health-Systems Pharmacists decided not to participate since their member hospitals were subject to JCAHO accreditation standards; JCAHO eventually implemented the USP compounding standards into their surveys.

In accreditation, an organization's performance is constantly compared with that of other similar facilities and is challenged to comply with standards. Accreditation by an external standard-setting body officially sanctions a business and differentiates it from competitors. Failing to understand, control and standardize key processes endangers a successful practice of compounding. Compounding is one of the practices where every single step that can be taken to avoid errors must be taken. Quality-control practices must be identified that should be standardized for incorporation into the manual process to ensure the correct preparation of compounded sterile preparations.

STANDARDS AND ACCREDITATION

It seems that everywhere we turn today there are standards that one is expected to meet. General standards might include one's "standard of living" and legal standards might include those governing your practice of pharmacy. Just where does accreditation fit in? What is the difference between standards, legal standards and accreditation?

A "standard" may be something that is established by authority, custom or general consent as a model or example; it can be something set up and established by authority such as a rule for the measure of quantity, weight, extent, value or quality.

A "legal standard" may be one that is constituted or affords a standard for comparison or judgment; or having qualities or attributes required by law or established by custom.

"Accreditation" involves putting something into a reputable category; to give official authorization to or approval of; to provide with credentials; or to vouch for as in conformity with a standard.

As one can see from the definitions, standards and accreditation are no more powerful than the agency, institution or organization providing them. For example, a "standard" that is established by authority, custom or general consent may be very lax or very stringent; the same can go for a "legal standard" and for "accreditation". So one has to look behind the standard or accreditation and see "from whence it comes". Let's look at legal standards and accreditation in more detail.

A legal standard is one that can be enforced by an enforcement agency, either local, state or federal. In pharmacy, we have legally enforceable standards that are enforced by the state boards of pharmacy and the FDA. Where do those come from? The state boards of pharmacy enforce laws and regulations enacted by the individual state legislatures and/or state boards of pharmacy. The FDA enforces laws enacted by Congress, regulations they develop and standards developed by the U.S. Pharmacopeia. We are generally pretty clear on these.

How about "accreditation" though? The value of accreditation is dependent upon the accreditation standards and their application. If the standards are set high, the "accreditation" is very valuable and something worthy of achievement and respect. If the standards are set low or not enforced, then the "accreditation" is of little use and, in fact, may be dangerous. The ACHC-PCAB has established excellent standards for compounding pharmacy and if utilized, will contribute to patient safety and quality compounding.

Accreditation generally requires that a pharmacy have programs for both quality assurance (QA) and continuous quality improvement (CQI). QA is the process of making sure that all compounds are made to consistently high standards. CQI involves periodic examination of pharmacy activities, Standard Operating Procedures (SOPs), goals, QA data, adverse events, and performance to identify best practices and target areas in need of improvement; it involves the implementation of corrective actions or policy changes as needed.

For QA, if a pharmacy is complying with the required standards and documenting compliance, it should not be difficult to demonstrate that the pharmacy has a QA program. There should also be an adverse event documentation program (compounding error, dispensing error, labeling error and employee injury).

CQI is a mechanism for the examination of pharmacy activities, SOPs, goals, QA data, adverse events, and performance to identify best practices and target areas in need of improvement, as well as implementing corrective actions or policy changes as needed.

POLICIES OF THE ACHC-PCAB

The policies of ACHC-PCAB were revised on 11/25/2014 and consist of the following sections: (1) Introduction, (2) Requirements, (3) Principles Governing the Accreditation Survey, (4) Accreditation Process before the Survey, (5) Accreditation Survey Process, (6) Accreditation Process Post Survey, (7) Disciplinary Actions as a Result of Survey Findings, (8) Notification of Changes, (9) Public Information, and (10) Nonconformance Policy. Sections 2 through 6 contain the substance of the process and should be thoroughly reviewed by all those involved in preparation for the accreditation process.

Accreditation by ACHC-PCAB can be for either Nonsterile Compounding, Sterile Compounding, or both.

STANDARDS FOR ACCREDITATION

The former PCAB standards (Prior to July 1, 2014) have been slightly modified with some new requirements and the revised ACHC-PCAB standards became effective July 1, 2014. These are briefly outlined on the following pages.

Categories/Number and Descriptions of Standards

TCRX1-A	Facility Licensure; Rules and Regulations
TCRX1-B	USP Standards
TCRX1-C	Negative Outcome Notification
TCRX2-A	Complaint Reporting
TCRX3-A	Training and Competency - Nonsterile Compounding
TCRX3-B	Training and Competency - Sterile Compounding
TCRX3-C	Training and Competency - Compounding Equipment
TCRX3-D	Training and Competency - Patient Equipment
TCRX3-E	Training and Competency - Hazardous Drugs
TCRX3-F	Training and Competency - New Procedures
TCRX3-G	Personnel Licensure
TCRX3-H	Training and Competency - Pharmacist
TCRX3-I	Technician Supervision
TCRX3-J	After-Hours Supervision
TCRX3-K	Reference Materials
TCRX4-A	OBRA Compliance
TCRX4-B	Shipment Timeliness Quality Control
TCRX5-A	PI Program - General
TCRX5-B	PI Program - Coordinator
TCRX5-C	PI Program - Personnel Involvement
TCRX5-D	PI Program - PI Activities
TCRX5-E	PI Program - Occurrence Handling
TCRX5-F	PI Program - Infection Control
TCRX5-G	PI Program - Finished Product Quality Control
TCRX5-H	PI Program - Monitoring of Nonsterile Process
TCRX5-I	PI Program - Monitoring of Sterile Process
TCRX5-J	PI Program - Complaint Monitoring
TCRX5-K	PI Program - Plans of Correction
TCRX5-L	PI Program - Annual Report
TCRX6-A	Infection Control Monitoring
TCRX6-B	Product Recall
TCRX6-C	Component and Product Storage
TCRX6-D	Shipment Container Quality Control
TCRX6-E	Compounding Equipment Care
TCRX6-F	Ingredient Selection
TCRX6-G	Master Formulation Record
TCRX6-H	Compounding Record

TCRX6-I	Nonsterile Compounding Process and USP 795
TCRX6-J	Nonsterile Compounding of Hazardous Drugs
TCRX6-K	Nonsterile Compounding Facilities
TCRX6-L	Sterile Compounding Process and USP 797
TCRX6-M	Sterile Compounding Facility and Risk Levels
TCRX6-N	Sterile Compounding of Hazardous Drugs
TCRX6-O	Sterile Compounding Environment Maintenance
TCRX6-P	Nonsterile Beyond-Use Dates
TCRX6-Q	Sterile Beyond-Use Dates
TCRX6-R	Sterilization and Testing
TCRX6-S	Sterile Drug Storage by Patient
TCRX6-T	Investigational Drugs
TCRX6-U	Labeling
TCRX7-A	Nonsterile Ongoing Compliance Program
TCRX7-B	Sterile Ongoing Compliance Program

PROCEDURE FOR APPLYING FOR ACCREDITATION

The first step in the accreditation procedure is to go to the ACHC-PCAB website and create a Customer Central Account at:

www.achc.org/programs/pharmacy/pharmacy-accreditation-process

This is the site with the necessary tools. Once registered, you will have the ability to select ACHC standards, complete an online application and access all of ACHC's accreditation resources. You will also receive a personal Account Advisor to serve as a consistent point of contact throughout the process.

Early on, it is important to review the standards to see for what you will be held accountable. You need to assign an Internal Coordinator within your staff to be responsible for the overall and detailed processes. Also, it is important to confirm that the services listed in any marketing materials are actually being offered.

PREPARATION

Preparation for accreditation is not a one-person job, because it is granted to an "organization", not to an "individual". Therefore, obtaining accreditation requires the participation of everyone in the organization. The staff will be involved in the preparation, educational activities and the survey process. The following are "general steps" that are involved:

1. Gather information and find out what is required.
2. Make the decision and commitment.
3. Obtain and implement a thorough set of SOPs.

   (Whatever is contained in each SOP must be practiced and documented in the pharmacy; each SOP must be modified to fit the pharmacy. Implement each item one at a time and confirm that all appropriate personnel are knowledgeable and proficient in the item. It is best not to wait until all procedures are complete before implementation but to do it gradually and one at a time.)
4. Apply for accreditation.
5. Do a preparatory "dry run" for the survey. (Have question-and-answer sessions based on the standards. Observe the compounding techniques of the staff and ask them to explain and show the documentation for what they are doing. Invite a colleague that is accredited to observe and comment if possible.)

6. Prepare everyone for the actual survey.

   A. Thoroughly clean and organize the pharmacy to promote a positive impression for the surveyor.

   B. Review your "Ready for Pick Up" or "Ready for Delivery" Prescriptions. Check labels.

   C. Confirm all documentation on compounding is in place.

   D. Confirm patient consulting and patient counseling log are current.

   E. Confirm that refrigerators and freezers are clean and at the proper temperature and all the documented readings are current.

   F. Inspect all safety equipment (Eyewash stations, spill kits, safety glasses, gloves, spill containment procedures, etc.)

   G. Assess the safety and quality of hazardous material storage (Acids/bases, poisons) and confirm MSDS are available and staff are knowledgeable about their use.

   H. Double-check all logs.

7. Work "with" the surveyor while onsite and respond politely and completely.

8. Wait…for the results.

SUMMARY

Pharmaceutical compounding has made tremendous advances in the past few years. It is projected to continue to grow and improve in quality and in its standards for this vitally important activity of pharmacy for quality patient care. It is wise to begin to adopt ACHC-PCAB standards whether you apply for accreditation now or later. Accreditation demonstrates to physicians and patients that the pharmacy meets a high standard, and accreditation by ACHC/PCAB is that proof of quality.