

## The cream of the compounding crop

### *Profession has swiftly embraced PCAB*

Now in its third year, the Pharmacy Compounding Accreditation Board (PCAB), has bestowed the prestigious "PCAB Accredited Compounding Pharmacy" designation on 32 pharmacies—an eight-fold increase over 2006. In addition, more than 100 pharmacies have an in-process application. PCAB, which Tom Murry, Executive Director of PCAB, described to *Pharmacy Today* as a "patient safety initiative," was formed to promote profession-driven, high-quality, and safe compounding practices through a voluntary and rigorous accreditation process. PCAB also provides a Web-accessible forum ([www.pcab.info](http://www.pcab.info)) that allows patients and prescribers to identify pharmacies that satisfy accreditation criteria.

Whether a voluntary compounding accreditation program will be sufficient



The APhA-published *Pharmacy Compounding Accreditation: A How-to Manual* serves as a workbook, providing step-by-step instructions, relevant examples, and sample materials designed to acclimate candidates to PCAB's stringent compliance standards. For details on purchasing the manual, visit the Shop APhA section of [www.pharmacist.com](http://www.pharmacist.com) or call 800-878-0729.

to keep FDA from intervening has been a topic of some debate. Murry believes that PCAB continues to be an effective tool to address the agency's concerns, pointing to three important elements: the coalition of eight leading pharmacy organizations, including APhA, USP, and the National Association of Boards of Pharmacy, that developed PCAB's stringent standards; the board's considerable progress in its brief 3-year history; and the creation of marketplace tools to help compounding pharmacies obtain PCAB accreditation.

#### What is PCAB?

The PCAB Board of Directors and the PCAB Standards Committee crafted a definition of compounding, which led to

the adoption of key principles, including the following:

- Compounding is subject to regulation and oversight from the state boards of pharmacy. If allowed by state law, a compounded medication can be dispensed to prescribers for office use, which does not include reselling of compounded medications by prescribers.
- Anticipatory compounding is limited to reasonable quantities, based on routine, consistently observed prescribing patterns.
- Preparation of copies of commercially available drug products is not considered compounding. Compounded medications are *not* considered commercially available products if they result in a marked difference for the patient

between the compounded drug and the comparable commercially available drug product or if the prescriber determines them necessary for the medical best interest of the patient (e.g., removal of a dye because of an allergic reaction).

#### A tool for state boards

In 2006, the American Medical Association (AMA) passed resolution H-120.945, which recognized PCAB's Seal of Accreditation as a means to identify compounding pharmacies that adhere to quality and best-practice standards, including those set forth in the *USP-National Formulary*. AMA also encouraged all state boards of pharmacy to require compounding pharmacies to obtain PCAB accreditation or to satisfy comparable standards.

When asked if he thought a voluntary accreditation program for compounding pharmacies was enough to satisfy FDA, Murry said, "I like it when the marketplace fixes problems instead of the government. That being said, boards of pharmacy are

strapped in many ways. Not just for money, but in terms of staff workload."

Despite these pressures, Murry believes that PCAB and state boards of pharmacy can work together to help resolve the compounding issues in a given state. As a voluntary body, PCAB does not have the power of the state; however, this is not a hindrance because PCAB's purpose is not to regulate. PCAB could play a pivotal role, however, if state boards of pharmacy choose to take the route recently taken in Colorado. Effective in August of this year, Colorado pharmacies that derive more than 10% of sales from compounding must obtain accreditation.

#### Reaching key constituencies

While U.S. demand for customized patient care through pharmacy compounding increases each year, compounded medications are still only estimated to represent 1% to 2% of total annual prescriptions. Because PCAB is unlikely to become a household name, achieving awareness in the segments of health care most affected by compounding is of vital importance. "The main areas of compounding are pain, pediatrics, pets, and postmenopausal women," said Murry. "Having those four constituencies aware that there is an accrediting body for compounding and that there are pharmacies that are and are not accredited is the key goal."

The appearance of marketplace tools such as the recent APhA publication *Pharmacy Compounding Accreditation: A How-to Manual* (see sidebar) provides a signal to Murry that compounding pharmacists have long awaited the arrival of PCAB standards.

"When you have a new organization, sometimes the marketplace isn't ready for it," said Murry. "In the past year and a half, we've seen organizations gearing their member education outreach efforts toward PCAB compliance. The groups who serve the compounding pharmacy industry have responded by creating tools to help pharmacies get PCAB accredited. That is one of the best indicators of just how the idea of accreditation has been received by that segment. I think that's an encouraging sign."

—Joe Sheffer