The Pharmacist Activist

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Editorial

Accreditation of Community Pharmacies Can Have Important Benefits – But the Program Must Have Credibility and Value for the Participants!

During the last several months two documents containing proposed accreditation standards for community pharmacies have been published with a request for public comment. The Center for Pharmacy Practice Accreditation (CPPA), a joint initiative by the American Pharmacists Association (APhA) and the National Association of Boards of Pharmacy (NABP), has developed "Draft Standards for Community Pharmacy Practice Accreditation," and invited public comment during the period June 30 – August 15, 2012. URAC, formerly known as the Utilization Review Accreditation Commission, has developed "Community Pharmacy Accreditation Proposed Standards," and invited public comment during the period July 6 – August 17, 2012.

The participation of a community pharmacy in an accreditation program would be voluntary.

Initial questions

With these announcements of accreditation programs, some questions come quickly to mind, including the following:

What is the intent of community pharmacy accreditation?

The materials provided by CPPA include frequently asked questions in which this is the first question that is addressed, in part, by the following response:

> The program "…will be focused on accrediting community pharmacy practices to recognize quality, enhance patient safety and provide a mechanism for excellence-committed pharmacy practices to distinguish themselves.
>
> A community pharmacy practice accreditation program may provide the means:
> - to ensure measurable, safe and effective patient care is being provided.
> - to empower pharmacists to practice at a higher level.
> - for a critical mass of pharmacy practices to achieve the JCPP 2015 Vision for Pharmacy Practice.
> - for pharmacy practice networks to recognize and provide consistent care to patients."

These are laudable goals, as is the JCPP 2015 Vision for Pharmacy Practice. Attainment of these goals will be of great benefit for individual patients, society, community pharmacists, and the profession of pharmacy. However, success in attaining these goals is dependent on the extent to which the accreditation program is recognized by community pharmacists as having value, the effectiveness with which the program is developed and implemented, and the credibility of the program both within and outside of the profession.

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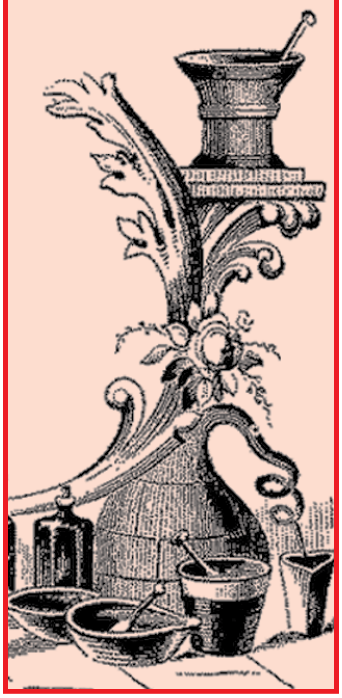

Are two community pharmacy accreditation programs necessary?

In a word, my response is an emphatic "No!" The most likely outcomes of having two programs are competition, confusion, and lack of credibility.

Who are the organizations and individuals who have proposed the accreditation programs?

URAC describes itself as a health care accreditation, education, and measurement organization with programs across the health care continuum. A pharmacist serves as a senior manager of product development and a pharmacist serves as chairman of the advisory group for the accreditation program. CPPA is a partnership between APhA and NABP, two long-established organizations within the profession.

I consider it very important that pharmacy accreditation programs, whether they be for community pharmacies, colleges of pharmacy, or other pharmacy initiatives, be developed and administered within the profession of pharmacy. Accordingly, it is my strong opinion that it is the CPPA initiative that should be supported by the profession of pharmacy. Not only is a second program, whether developed by URAC or another organization, not necessary, but it creates the potential for compromised validity and credibility for both programs. (In the interest of full disclosure, I am the Honorary President of APhA for the 2012-13 year but I was not a participant in the planning or decisions regarding the accreditation program.)

The pharmacists who have participated in the early phases of the accreditation initiatives include leaders from many areas of pharmacy practice. However, it is noteworthy how few of them own a pharmacy or otherwise practice in a community pharmacy on a full-time basis (nor do I as an individual offering opinions regarding this issue). The National Community Pharmacists Association (NCPA) is conspicuous by its absence as a partner in this accreditation initiative, a situation that is probably due to divided opinion among community pharmacists as to whether accreditation of their pharmacies will be of benefit.

In my opinion, the active support and participation of a large number of owners of independent pharmacies are essential if the community pharmacy accreditation program is to have validity and credibility.

Why is the comment period so brief and so lacking in opportunity for open discussions?

The scheduling of the comment period in both programs for such a short period of time (approximately 6 weeks) in the middle of summer is a mistake. I can only assume that this is a consequence of the competition between the two programs, and it represents an early indicator of the importance of not having more than one program. It is my impression that a large majority of community pharmacists and many leaders within the profession have not even seen the proposed standards and are not aware of the invitation to comment.

During the comment period identified, there was only one meeting held by a national pharmacy organization (American Association of Colleges of Pharmacy). A session was held to consider the proposed accreditation standards and the discussion was productive. However, the attendance was low because this was not a topic of high interest or priority for most of those at the meeting, and the session was held from 6:45 – 7:45 am. Open forums to discuss this topic should be held at meetings of organizations at which large numbers of community pharmacists will be in attendance. At the very least, such a forum should be included as part of NCPA's annual meeting in October.

Eligibility for accreditation

Although the proposed standards for accreditation of community pharmacies are specific and comprehensive, some important basic questions exist regarding the eligibility of a pharmacy to be considered for accreditation. I am assuming that a mail-order pharmacy would not be eligible for several reasons. First, it is not *community*-based but at a *remote* site. Secondly, the lack of personal face-to-face communication of pharmacists and patients precludes the provision of patient services that are inherent in certain of the practice standards. It is my understanding that URAC already has accreditation programs for mail-order pharmacies, suggesting that it makes a distinction between mail-order and community pharmacies.

Should a community pharmacy that sells tobacco products and/or alcoholic beverages be eligible for accreditation? My response is an emphatic "No!" A pharmacy that sells these products increases health risks for its patients in a manner that contradicts the intent of the proposed accreditation standards. The accreditation of such pharmacies would seriously compromise the credibility of the accreditation program. The response to one of the frequently asked questions in the materials provided for the CPPA program addresses the distinction between licensure and accreditation as follows:

> "Licensure ensures minimal practice standards, while accreditation distinguishes a commitment to enhanced safety and improved quality of care delivered within the practice."

Accreditation suggests, if not requires, a commitment to the highest standard of safety for the patients served. The

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New Drug Review

Spinosad
(Natroba – ParaPRO)

Pediculicide

New Drug Comparison Rating (NDCR) = 4

(significant advantages) in a scale of 1 to 5 with 5 being the highest rating

Indication:
Topical treatment of head lice infestation in patients 4 years of age and older.

Comparable drug:
Permethrin (e.g., Nix).

Advantages:
- More effective in comparative studies (may be effective in patients with head lice infestation that is resistant to permethrin and pyrethrins);
- A second treatment is less likely to be needed.

Disadvantages:
- Effectiveness and safety are not established in children less than 4 years of age (whereas permethrin is indicated in children 2 months of age and older);
- Labeled indications are more limited (permethrin is also indicated for the treatment of scabies, and pyrethrins with piperonyl butoxide [e.g., RID] is also indicated for pubic lice and body lice infestation);
- Inclusion of benzyl alcohol in formulation is associated with risk if used in young children;
- Requires a prescription (whereas permethrin [when used for head lice] is available without a prescription).

Most important risks/adverse events:
Benzyl alcohol is in formulation and systemic exposure to this agent has been associated with serious reactions ("gasping syndrome") in neonates and low-birth-weight infants (use in patients less than 6 months of age is not recommended because of the potential for increased systemic absorption).

Most common adverse events:
Application site erythema (3%), ocular erythema (2%), application site irritation (1%).

Usual dosage:
Suspension is applied to dry scalp and hair (depending on the length of the hair, up to 120 mL may be needed to adequately cover the scalp and hair); should be left on the hair for 10 minutes and then thoroughly rinsed off with warm water; if live lice are observed 7 days after the first treatment, a second treatment should be applied.

Product:
Topical suspension – 0.9% (should be shaken before use).

Comments:
Spinosad is a pediculicide that is derived from the fermentation of a soil actinomycete bacterium, *Saccharopolyspora spinosa*. It is a mixture of spinosyn A and spinosyn D in a ratio of approximately 5 to 1. Spinosad causes neuronal excitation in insects, and after periods of hyperexcitation, lice become paralyzed and die. The effectiveness of spinosad has been demonstrated in two studies in which it was compared with permethrin (1%). Patients were treated and returned 7 days later for efficacy evaluation. Patients in whom live lice were identified on day 7 received a second treatment. Efficacy was assessed as the proportion of participants who were free of live lice 14 days after the final treatment. Spinosad was effective in 85% and 87% of the patients in studies 1 and 2, respectively, compared with 45% and 43% of the patients treated with permethrin. More of the permethrin-treated patients required two treatments compared with the spinosad-treated patients.

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sale of tobacco products and/or alcoholic beverages must not be considered an acceptable activity for a pharmacy that wishes to have the distinction of being accredited.

At its June meeting, the American Medical Association (AMA) expanded its previous policy opposing the sale of tobacco products in pharmacies by adopting policy that would create a recognition program for pharmacies that voluntarily eliminate the sale of tobacco products. It would be a very unfortunate irony if pharmacy organizations somehow considered the sale of tobacco products to be compatible with accreditation at the same time the AMA is recognizing pharmacies that discontinue such.

Should an individual pharmacy in a large chain be eligible for accreditation if its parent company has policies/positions that increase risk for patients or demean the professional role of pharmacists? For example, should any CVS pharmacy be accredited when CVS/Caremark administers prescription benefit programs that steal patients from local pharmacies and fragment the care of patients, thereby placing them at increased risk of drug-related problems?

For many years, the profession of pharmacy has sought recognition for pharmacists as health care providers. However, in a recent situation, the management of Rite Aid took a position that essentially denied that pharmacists were health care providers. Fortunately, a Superior court judge, based on her determination that pharmacists are health care providers, ruled in favor of the plaintiff and against Rite Aid (Landay v. Rite Aid). To comply with the proposed accreditation standards, pharmacists fulfill responsibilities of a health care provider. Should any Rite Aid pharmacy be eligible for accreditation when its management does not even want its own pharmacists to be recognized as health care providers, and thereby places this recognition in jeopardy for all pharmacists?

Additional issues/recommendations

Numerous other important issues and questions exist, some of which are identified below:

- Pharmacies must be accredited on an individual basis and not via accreditation of a parent organization (e.g., a large chain pharmacy).
- The pharmacist manager of an accredited pharmacy must have the authority to make decisions that pertain to the ability to be in compliance with accreditation standards (e.g., professional services provided, level of professional staffing).
- Many of the accreditation standards require policies, procedures, descriptions, documentation, etc. that will require, particularly for a small pharmacy, an extensive amount of time to develop and implement. Templates and "model" forms/documents should be developed (e.g., by CPPA, APhA, NCPA) to facilitate qualifying for accreditation and easing the administrative burden. The documentation of outcomes is very important but the highest priority must be given to the scope and quality of patient care services.
- Notwithstanding the fact that pharmacy benefit managers (PBMs) do what they want to do and usually get away with it, the PBMs must not be permitted to reduce the size of their pharmacy networks by including only accredited pharmacies when the mail-order pharmacies they own and to which they direct patients do not meet the standards by which community pharmacies will be accredited.
- The financial records of the accreditation program must be transparent.

The accreditation of community pharmacies has exciting potential to be a force for positive change and to accelerate the implementation of programs through which the actions and services of pharmacists enhance drug therapy outcomes for patients. However, it is imperative that the distinction of accreditation and the process through which it is earned are recognized to be of value and credible. This must start with the community pharmacists who are needed to be the participants, and whatever time and actions are necessary to obtain their enthusiastic participation are essential.

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