Report of the Task Force on Pharmacy Licensure Standards

Members Present:

Joanne Trifone (MA), *chair;* Gayle Cotchen (PA); Mark Hardy (ND); Virginia "Giny" Herold (CA); Donna Horn (MA); Doug Lang (MO); Stephanie McAntee (WY); Michael Podgurski (PA); Ken Saunders (NE); Cody Wiberg (MN).

Others Present:

William Cover, *Executive Committee liaison*; Carmen Catizone, Josh Bolin, Melissa Madigan, Eileen Lewalski, Heather McComas, Denise Frank, Lisa Huxhold, Cameron Orr, *NABP staff*.

Introduction:

The Task Force on Pharmacy Licensure Standards met October 14-15, 2013, at NABP Headquarters. This task force was established in response to the Executive Committee's recommendation to explore the possibility of creating a standardized inspection form to assist states with the inspection of resident and nonresident pharmacies.

Review of the Task Force Charge:

Task force members reviewed their charge and accepted it as follows:

1. Review existing state pharmacy inspection forms.
2. Compile requirements that are consistent across the states with the possible purpose of structuring a uniform inspection form that may assist states with the inspection of resident and non-resident pharmacies.
3. Review relevant language from the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* and recommend amendments, if necessary, to address pharmacy licensure standards.

Recommendation 1: NABP Should Create a Uniform Pharmacy Inspection Form by Modifying the Iowa Nonresident Pharmacy Inspection Program Document and Encourage State Boards of Pharmacy to Adopt the Standardized Form

The task force recommends that NABP develop a standardized pharmacy inspection form that can be used by both NABP inspectors and by the state boards of pharmacy. The task force concurs that NABP's current draft inspection form should be used as a basis for developing the standardized form and that the existing document should be restructured and modified to maximize its applicability and utility. The task force furthermore recommends that NABP encourage all state boards of pharmacy to adopt the standardized inspection form for use in all pharmacy inspections to promote consistent, uniform inspection quality and content across states.

Background:

Task force members agreed that there is a clear call for uniformity in pharmacy inspections and that a standardized pharmacy inspection form would support a consistent inspection process and protect the public health. The New England Compounding Center tragedy has increased scrutiny of pharmacy practice and underscored the need for the boards of pharmacy to ensure that all pharmacies serving a state's patients are in compliance with applicable laws and regulations. Additionally, the task force's review of existing state pharmacy inspection forms highlighted the current diversity in pharmacy inspection protocols across states.

Beyond the need for standardization and consistency in inspections, the task force recognized that a uniform inspection form would have broad utility and multiple applications. The document could be used by NABP inspectors in various programs, including the existing inspection partnership programs in Iowa and New Jersey, as well as the newly launched Verified Pharmacy Program™. A standardized form would also offer numerous advantages to state boards of pharmacy. Adoption of a standardized inspection form by all boards of pharmacy would ensure consistency in pharmacy inspections across states and, as such, allow boards to rely on one another's inspections in evaluating licensure applications for nonresident pharmacies.

NABP staff summarized the Association's qualifications for developing a standardized inspection form, including the staff and expertise associated with NABP's numerous accreditation programs. Additionally, through its partnership with the Iowa Board of Pharmacy to inspect nonresident compounding pharmacies, NABP has already developed a document that can serve as a prototype for developing a standardized inspection form. The task force concurred that NABP has the expertise and resources to support this initiative.

After reaching an early consensus that NABP should develop a standardized pharmacy inspection form, the task force reviewed and discussed in detail NABP's current inspection form that was being used to conduct the Iowa Nonresident Pharmacy Inspection Program. Task force members suggested numerous adjustments to the prototype form to maximize its utility and clarity and ensure ease of use for inspectors. The task force also recommended changes based on their review of existing state pharmacy inspection forms. ~~NABP staff has incorporated the task force's recommended modifications, and the revised form is included in this report (see **Appendix A**).~~ Major changes suggested by the task force included:

- Moving pharmacy demographic information, facility category, and patient care services to the beginning of the form to allow for quick identification of facility type
- Revising terminology and language throughout the form to be consistent with the *Model Act*
- Defining and clarifying unfamiliar terms, as needed
- Adding an assessment of a pharmacy's physical facility, to include physical security (particularly for controlled substances), equipment, sanitation, and any unique physical features (e.g., drive-thru window)
- Inserting questions related to pharmacy practice, including method of prescription transmission, labeling requirements, policies and procedures for inventory control, drug substitution, and unique practice characteristics (e.g., delivery services or provision of investigational drugs)

- Adding questions regarding pharmacy personnel, to include employee background checks, scope of training, and staffing formulas

The task force concurred that NABP should encourage all state boards of pharmacy to adopt a~~the~~ standardized inspection form. Universal use of a~~the~~ standardized form will ensure high-quality pharmacy inspections across states and allow boards of pharmacy to rely upon inspections performed by other entities. The task force noted that although a~~the~~ standardized form would create a set of core inspection standards across states, this would not infringe upon the boards' decision-making authority. A~~T~~he standardized form would simply serve as a means to collect inspection data and record observations. Task force members stressed that all determinations regarding a pharmacy's compliance with state laws and regulations would remain with the respective board of pharmacy.

Recommendation 2: NABP Should Convene Workgroups to Develop Supplementary Standardized Inspection Forms for Specific Facility Categories

The task force recommends that NABP convene workgroups to develop supplementary inspection modules to address the specialized inspection needs of particular facility categories.

Background:

The standardized inspection form developed by the task force represents a general inspection document that can be used as the first step in assessing any pharmacy facility type. To gather data specific to certain facility types and/or specialized services, the task force recommended that several supplemental inspection modules be developed to support additional types of inspections. The task force suggested that NABP convene workgroups composed of members with expertise in specific practice settings to develop these supplemental inspection forms.

The task force discussed various possible supplemental inspection forms and the relative priority for creating these additional modules. The task force ranked the priority for creating these specialized forms as follows: (1) Sterile compounding, (2) Nuclear pharmacy, (3) Mail order, (4) Hospital/Institutional, and (5) Central fill/central services. After completion of these additional inspection modules, the need for additional forms will be assessed.

Recommendation 3: NABP Should Develop a Process for Regularly Reviewing and Updating the Standardized Inspection Form

The task force recommends that a process be developed and implemented to regularly update and review the standardized inspection form to ensure that it reflects current pharmacy practice standards.

Background:

The task force stressed the importance of regularly reviewing and updating the standardized inspection form to ensure that it reflects any changes to practice standards and meets the needs of its users. Task force members agreed that the form should be revised following the release of new or updated standards from the US Pharmacopeial Convention. The task force suggested that NABP implement a routine review schedule to ensure that the form is current with all practice standards and meets the needs of pharmacy inspectors.

Recommendation 4: NABP Should Allow the Uniform Pharmacy Inspection Form to Be Publicly Available

The task force recommends that the uniform pharmacy inspection form be publicly available so that it may be used not only for inspections but also as a pharmacy self-assessment tool.

Background:

The task force noted that not all states currently allow open access to their pharmacy inspection forms. Task force members discussed the advantages of allowing the standardized inspection form to be publicly available, which include use of the form for self-inspections and allowing pharmacies to review the assessment criteria and address any deficiencies in advance. The task force agreed that the standardized inspection form should be an open-access document and that NABP should work with the boards of pharmacy to obtain consensus on making the form publicly available.

Recommendation 5: NABP Should Train Pharmacy Inspectors to Perform Due Diligence Prior to Conducting Inspections

The task force recommends that NABP train pharmacy inspectors to perform due diligence prior to site visits to ensure adequate preparation and determine particular areas of focus for the inspection.

Background:

The task force discussed the importance of advance preparation and data collection for inspections. Along with the obvious gains in efficiency from such preparation, this due diligence may suggest particular areas of concern or inquiry for the inspection. In particular, the task force suggested that inspectors obtain background checks for pharmacy personnel, check licensure status of all employees with the state board of pharmacy, and review NABP Clearinghouse information for facility personnel prior to the inspection date to identify any potential problem areas in advance of the site visit.

Recommendation 6: NABP Should Support the Practice of Unannounced Pharmacy Inspections

The task force recommends that NABP support the practice of unannounced pharmacy inspections to ensure that inspectors are observing the routine operations of the facility.

Background:

The task force discussed the advantages and disadvantages of unannounced inspections. Task force members noted that inspections scheduled by appointment may allow unscrupulous facilities to hide deficiencies or misrepresent their normal practice operations. However, others voiced concern about the potentially disruptive effect of unannounced inspections and the accompanying negative impact on patient safety. The task force acknowledged these points but noted that these issues could be addressed through inspector training. Specifically, inspectors should be trained to display a collaborative (vs. adversarial) demeanor during facility visits, to strive for minimal inconvenience and disruption to pharmacy operations, and to encourage the pharmacist-in-charge to request additional staff assistance if needed during the inspection. The task force agreed that reinforcement of these concepts during inspector training will ensure that patient safety is maintained during unannounced inspections.

Although inspections should be unannounced, the task force noted that inspectors performing nonresident pharmacy inspections should notify the facility's state board of pharmacy prior to the inspection as a professional courtesy. This would also allow a representative from the facility's state board of pharmacy to accompany the inspector on the site visit, if desired.

Recommendation 7: NABP Should Encourage the Sharing of Inspection Reports With Inspected Facilities, State Boards of Pharmacy, and the NABP Clearinghouse

The task force recommends that NABP encourage the release of pharmacy inspection reports to all inspected facilities. Additionally, the task force recommends that inspection reports be made available to state boards of pharmacy and posted in the NABP Clearinghouse to facilitate the evaluation of nonresident pharmacy licensure applications.

Background:

The task force discussed the current variation among states in the release of inspection reports. Some states allow inspectors to leave a copy of the completed inspection form with the pharmacy following an inspection, while others only supply the pharmacy with a list of deficiencies at a later date. Policies regarding the release of inspection reports to other state boards of pharmacy also vary from state to state.

Task force members agreed that inspected pharmacies should receive a copy of the inspection results, whether the inspector provides a copy of the completed inspection form and discusses the findings with the pharmacist-in-charge at the conclusion of the inspection or a report is sent to the facility at a later date. Provision of the inspection report to the pharmacy allows personnel to review the results and correct any deficiencies.

The task force agreed that inspection results should also be released to other state boards of pharmacy and the NABP Clearinghouse. This will allow the boards to use the results to evaluate applicants for nonresident pharmacy licensure. Allowing access to inspection reports across states will eliminate duplication in inspection efforts and reduce the costs associated with inspections. As noted previously, utilization of a standardized inspection form will ensure uniformity and consistency in inspection processes and allow the boards to rely upon inspections performed by other entities.

To facilitate the release of inspection reports, the task force recommended that NABP work with the state boards of pharmacy to reach agreement on this issue. NABP staff indicated that a memorandum of understanding to facilitate the sharing of inspection data across states is currently under development.

Recommendation 8: NABP Should Amend the *Model Act*

The task force recommends that the *Model Act* be revised to update and clarify language related to pharmacy licensure standards and pharmacy inspections. The task force also supports updating the *Model Act* to expressly delineate a board of pharmacy's authority to license and regulate pharmacies inside and outside of the state. The revisions recommended by the task force are denoted by underlines and ~~strikethroughs~~.

Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

…

Article II

Board of Pharmacy

…

Section 213. Powers and Responsibilities.

(a) The Board of Pharmacy shall be responsible for the control and regulation of the Practice of Pharmacy in this State including, but not limited to, the following:

(1) the licensing by examination or by license transfer of applicants who are qualified to engage in the Practice of Pharmacy under the provisions of this Act;

(2) the renewal of licenses to engage in the Practice of Pharmacy;

(3) the establishment and enforcement of compliance with professional standards and rules of conduct of Pharmacists engaged in the Practice of Pharmacy;

(4) the determination and issuance of standards for recognition and approval of degree programs of schools and colleges of Pharmacy whose graduates shall be eligible for licensure in this State, and the specification and enforcement of requirements for practical training, including Pharmacy practice experience;

(5) the enforcement of those provisions of this Act relating to the conduct or competence of Pharmacists practicing in this State; the Revocation, Summary Suspension, Suspension, Probation, Censure, or Reprimand of, or the issuance of Warnings or the assessment of Fines/Civil Penalties or Costs/Administrative Costs against licenses to engage in the Practice of Pharmacy; and the issuance of Cease and Desist orders against any Person or entity;

(6) the licensure and regulation of the training, qualifications, and employment of Pharmacy Interns and Pharmacy Technicians;

(7) the collection of professional demographic data;

(8) the right to seize any such Drugs and Devices found by the Board to constitute an imminent danger to the public health and welfare;

(9) establishing minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for the storage, Compounding and/or Dispensing of such Drugs or Devices, ~~and~~ for the monitoring of Drug therapy, and for the Manufacture and Distribution of Drugs and Devices;

(10) establishing minimum standards for the purity and quality of such Drugs, Devices, and other materials within the Practice of Pharmacy;

(11) the issuance and renewal of licenses for pharmacies located within this State, or outside this State if providing services to patients within this State, that Compound or Dispense Drugs or Devices or provide Pharmacist Care.

(12~~1~~) the issuance and renewal of licenses of all Persons engaged in the Manufacture and Distribution of Drugs and Devices located within this State, or outside this State if providing services within this State;

(13~~2~~) inspection at all reasonable hours of the facility and appropriate records of any licensed Person or licensed facility and any Person or facility seeking licensure for the purpose of determining if any provisions of the laws governing licensure,

the legal Distribution of Drugs or Devices, or the Practice of Pharmacy are being violated, including the inspection of Protected Health Information. The Board of Pharmacy, its officers, inspectors, and representatives shall cooperate with all agencies charged with the enforcement of the laws of the United States, of this State, and of all other states relating to Drugs, Devices, and the Practice of Pharmacy;

(14~~3~~) establishing minimum standards for maintaining the integrity and confidentiality of prescription information and other patient health care information; and

(15~~4~~) the approval of Pharmacy practice initiatives that improve the quality of or access to Pharmacist Care, but which fall outside the scope of present regulations. This subsection shall not be construed to expand the definition of the Practice of Pharmacy as defined in this Act.

…

Section 213(a). Comment.

The "Practice of Pharmacy in this State" includes shipping Drugs into this State from another jurisdiction.

Article V

Licensing of Facilities

…

Section 502. Application.

(a) The Board shall specify by rule the licensure procedures to be followed, including but not limited to, specification of forms for use in applying for such licensure and times, places, and applicable fees.

(b) Applicants for licensure to Distribute, Wholesale Distribute, Manufacture, sell, purchase, transfer, and/or produce Drugs or Devices, and applicants for licensure as a Pharmacy Benefits Manager, shall file with the Board of Pharmacy a verified application containing such information as the Board requires of the applicant relative to the qualifications for a license.

(c) Licenses issued by the Board pursuant to this Act shall not be transferable or assignable.

(d) The Board shall specify by rule minimum standards for responsibility of any Person, Pharmacy, or Pharmacy Benefits Manager that has employees or personnel engaged in the Practice of Pharmacy, or Manufacture, Distribution, Wholesale Distribution, production, sale, or use of Drugs or Devices in the conduct of their business. If the licensed Person is a Pharmacy located in this state, that portion of the facility to which such license applies shall be operated only under the direct supervision of a Pharmacist licensed to practice in this State.

…

Section 503. Notifications.

(a) All licensed Persons shall report to the Board of Pharmacy the occurrence of any of the following:
- (1) permanent closing;
- (2) change of ownership, management, location, or Pharmacist-in-Charge of a Pharmacy;
- (3) any theft or loss of Drugs or Devices;
- (4) any conviction of any employee of any State or Federal Drug laws;
- (5) any criminal conviction or pleas of guilty or nolo contendere of all licensed or registered personnel;
- (6) disasters, accidents, or any theft, destruction, or loss of records required to be maintained by State or Federal law;
- (7) occurrences of Significant Quality Related Events ~~Adverse Drug Reactions as defined by Rules of the Board~~;
- (8) illegal use or disclosure of Protected Health Information; ~~or~~
- (9) any and all other matters and occurrences as the Board may require by rule~~.~~; or
- (10) report of any inspection conducted by any State or Federal regulatory agency or authorized agent thereof.

…

Model Rules for the Practice of Pharmacy

Introductory Comment

The Board finds that in the interest of protecting the public health and welfare, in order to ensure optimum effect of Drug therapy, and to maximize the quality of Pharmacist Care, the following rules are essential.

Section 1. Facility.

(a) To obtain a license for a Pharmacy, an applicant shall:
- (1) have submitted an application in the form prescribed by the Board of Pharmacy;
- (2) have attained the age of majority;
- (3) be of good moral character; and
- (4) have paid the fees specified by the Board of Pharmacy for the issuance of the license.

(b) The facility owner, if an individual, shall have undergone a state and federal fingerprint-based criminal background check as specified by Board rule;

(c) The facility shall have undergone a Pharmacy inspection by the Board or authorized agent thereof; and

(d) Minimum requirements for a Pharmacy:
- (1) Each Pharmacy shall be of sufficient size, as determined by the Board, to allow for the safe and proper storage of Prescription Drugs and for the safe and proper Compounding and/or preparation of Prescription Drug Orders.
- (2) Each Pharmacy shall maintain an area designated for the provision of Patient Counseling services. This area shall be designed to provide a reasonable expectation of privacy of Protected Health Information.
- (3) Each Pharmacy shall have ready access to references applicable to the services provided, to include at least one current reference in each of the following categories:
  - (i) State and Federal Drug laws relating to the Practice of Pharmacy and the legal Distribution of Drugs and any rules or regulations adopted pursuant thereto;
  - (ii) pharmacology;

(iii) dosage and toxicology;
(iv) general.

(4) Each Pharmacy shall maintain patient-oriented reference material for guidance in proper Drug usage.

(5) Each Person involved in the development, maintenance, or use of a Drug formulary shall maintain a currently accepted reference containing guidelines for a sound Drug formulary system.

(6) All areas where Drugs and Devices are stored shall be dry, well lighted, well ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the Drugs prior to their Dispensing as stipulated by the United States Pharmacopeia–National Formulary (USP-NF) and/or the Manufacturer's or Distributor's Product Labeling unless otherwise indicated by the Board.

(7) Each Pharmacy shall have access to a sink with hot and cold running water that is convenient to the Compounding area for the purpose of hand scrubs prior to Compounding.

(8) Security.
(i) Each Pharmacist, while on duty, shall be responsible for the security of the Pharmacy, including provisions for effective control against theft or diversion of Drugs and/or Devices.
(ii) The Pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time when the Pharmacist is not present. Such barrier shall be approved by the Board of Pharmacy before being put into use. In the event of separation of employment of an employee due to any confirmed Drug-related reason, including diversion, or other acts involving dishonesty, suitable action shall be taken to ensure the security of the pharmacy.
(iii) Prescription and other patient health care information shall be maintained in a manner that protects the integrity and confidentiality of such information as provided by the rules of the Board.

(9) Equipment/Supplies.
The Pharmacy shall carry and utilize the equipment and supplies necessary to conduct a Pharmacy in a manner that is in the best interest of the patients served and to comply with all State and Federal laws.

(10) The Pharmacy shall provide a means for patients to prevent disclosure of Confidential Information or personally identifiable information that was obtained or collected by the Pharmacist or Pharmacy incidental to the Delivery of Pharmacist Care other than as authorized by law or rules of the Board.

(11) The Pharmacy, if conducting business over the Internet, shall be accredited by a program approved by the Board.

…

Comments

Section 1(a)(3). Comment.

Boards may wish to give examples in each of these categories of reference texts.

Section 1(da)(4). Comment.

Patient-oriented reference material can include publications such as Facts and Comparisons' Patient Drug Facts, or the United States Pharmacopoeia Dispensing Information (USPDI).

…

Background:

The task force reviewed sections of the *Model Act* pertinent to pharmacy licensure and inspections. The task force concurred that the *Model Act* should be amended to clarify language regarding pharmacy licensure and inspections, as well as to expressly state the boards' authority to license resident and nonresident pharmacies.

In addition to these specific language changes, the task force recommended that the *Model Act* be reorganized to create standalone sections on various topics (wholesale distributors, etc.). Task force members also suggested that a hyperlinking system be developed to easily connect *Model Act* text with associated comments. NABP staff concurred that these were desirable changes and will try to incorporate these recommendations in future versions of the document.

Appendix A

NABP Uniform Inspection Form