Report of the Task Force on Pharmacist Prescriptive Authority

NOTE: The NABP Executive Committee accepted the report and appreciated the research and discussion of the Task Force. However, the Executive Committee concluded that the recommendations do not adequately address the Task Force charge regarding pharmacist prescriptive authority. In response, the Executive Committee will engage in additional research to develop specific recommendations for states to establish and recognize pharmacist prescriptive authority.

Members Present:

Dennis Wiesner (TX), *chair;* Kerstin Arnold (TX); Tom Bender (NJ); Tim Fensky (MA); Cathy Hanna (KY); Virginia "Giny" Herold (CA); Leo Lariviere (RI); Cathy Lew (OR); Mike Podgurski (PA); Joyce Tipton (TX); Cynthia Warriner (VA).

Others Present:

James DeVita, *Executive Committee liaison*; Krystalyn Weaver (NASPA); Robert Braylock, PharmD/MBA candidate (University of Findlay College of Pharmacy), *guests;* Carmen Catizone; Eileen Lewalski; Maureen Schanck; Angie Rutkowski, *NABP staff.*

Introduction:

The Task Force on Pharmacist Prescriptive Authority met September 1-2, 2015, at NABP Headquarters. This task force was established in response to Resolution 111-4-15, Task Force on Pharmacist Prescriptive Authority, which was approved by the NABP membership at the Association's 111th Annual Meeting in May 2015.

Review of the Task Force Charge:

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

1. Review existing state laws and regulations addressing pharmacists' prescriptive authority and relevant NABP *Model Act* language.
2. Recommend revisions, if necessary, to the NABP *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* addressing this issue.
3. Propose key messages that should be conveyed to boards of pharmacy, key stakeholders, and the public about the patient care benefits of granting pharmacists limited prescriptive authority.

Recommendation 1: NABP Should Support Pharmacists Having Limited Ability to Initiate, Modify, and Terminate Drug Therapy.

The task force recommends that NABP support pharmacists having limited ability to initiate, modify, and terminate drug therapy under certain circumstances including, but not limited to collaborative practice agreements and state protocols.

Background:

The task force members discussed how the health care delivery landscape is constantly changing and the fact that we are entering a time when there is an emphasis on expanding accessible, affordable, and quality health care. Members agreed that health care professionals should be encouraged to practice at the highest level possible for their profession as long as proper safeguards are in place; this would include pharmacists who are trained and competent in drug therapy and who are vastly underutilized in most health care delivery systems. Members pointed out that pharmacists, who are the most accessible health care team member, may be the key to reaching patients with health care services that they may not otherwise receive or have difficulty accessing.

The task force discussed how some states like California and Oregon have implemented new laws and updated existing laws and rules to allow for pharmacists to initiate, modify, and terminate drug therapy in limited circumstances, while other states have expanded their collaborative practice guidelines and statewide protocols to allow for pharmacists to be more actively involved in managing drug therapy. Members agreed that, with the projected demand on the current health care delivery model, the need and opportunity for pharmacists' involvement in health care delivery has never been greater.

The task force members were resolute in their belief that today's pharmacists, with more clinical opportunities and training, are needed to provide more for patients while continuing to dispense medication. This is grounded on the knowledge that pharmacists are now impacting more lives and reaching more individuals through such means as community pharmacist immunizations, antimicrobial stewardships, diabetes clinics, and warfarin clinics than would have ever been possible before pharmacists entered the clinical arena. Pharmacists working in the Indian Health Services and the Veterans Health Administration have demonstrated positive impact on patient outcomes for decades and are a valued member of the health care team. These benefits include "improved patient access to physicians, improved continuity of care and more comprehensive medication management," to name a few.[1]

Recommendation 2: NABP Should Amend the Model Act.

The task force recommends that NABP amend the Model Act. The amendments recommended by the task force are denoted by underlines and ~~strikethroughs~~.

National Association of Boards of Pharmacy Model State Pharmacy Act

[1] Ragan, A. Case Study: *The Advancement of Clinical Pharmacist Prescribing Privileges.* Bethesda, MD: American Society of Health-System Pharmacists; n.d.

Article I

Title, Purpose, and Definitions

Section 104. Practice of Pharmacy.

The "Practice of Pharmacy" means the interpretation, evaluation, and implementation of Medical Orders; the accepting, processing, or Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; the provision of Patient Counseling; the provision of those acts or services necessary to provide Pharmacist Care in all areas of patient care, including Primary Care, Medication Therapy Management, Collaborative Pharmacy Practice, the ordering, conducting, and interpretation of appropriate tests, and the recommendation and Administration of immunizations; and other approved patient care services such as the initiation of Drug therapy; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, Repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices, and maintenance of required records. The practice of pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training.

(See comment list.)

Comments

Section 104. Comment.

The definition of the "Practice of Pharmacy" is one of the most important, and perhaps one of the most discussed, clauses in the NABP *Model Act*. The definition is purposely expressed in broad terms to provide substantial latitude to the Board of Pharmacy in the adoption of implementing rules. Additionally, the definition limits certain activities to performance by Pharmacists only, while allowing qualified personnel to assist Pharmacists in practice. That distinction is noted by listing activities that must be performed by the Pharmacist, such as the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders; Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; Patient Counseling; Pharmacist Care; and other tasks that the Pharmacist has responsibility for, such as Compounding and Labeling of Drugs and Devices; the proper and safe storage of Drugs and Devices, and maintenance of proper records. The deliberate distinction between the terms "must perform" and "is responsible for" intends to allow delegation of tasks to Certified Pharmacy Technicians or Pharmacy Technicians.

Pharmacy is a dynamic profession and a broad definition of the practice will permit the Board to make necessary changes from time to time to meet the changing practice. Such changes may be affected by new or amended rules, which would be promulgated pursuant to the requirements of the State Administrative Procedures Act, affording all interested parties an opportunity to review and comment on any proposed rules.

NABP recognizes that protection of the public health should extend across state borders. Accordingly, the NABP *Model Act* incorporates the Practice of Telepharmacy Across State Lines within the scope of the "Practice of Pharmacy."

In the interest of public health and patient access to timely, efficient, and quality care, it is warranted to ensure that the definition of the "Practice of Pharmacy" includes pharmacists with the legislative and regulatory authority to initiate medication therapy based upon the following specific parameters. The development of the parameters should include all stakeholders needed to appropriately define and confine the authority within the pharmacist's education and expertise. (Examples where a pharmacist could potentially initiate medication therapy include public health and preventative medications such as, but not limited to, naloxone, hormonal contraceptives, and travel medications.)
The following factors should be considered in the development of parameters:

1. No diagnosis required or is easily assessed
2. Formulary or protocol (such as regional, Board, or State-established)
3. Communications and feedback is required between pharmacist, patient, and primary care provider where one exists or referral by pharmacist to primary care provider and/ or appropriate practitioner, if necessary.

Section 105. Definitions.

…

(u) "Collaborative Pharmacy Practice" is that Practice of Pharmacy whereby one or more Pharmacists have jointly agreed, on a voluntary basis, to work in conjunction and collaboration with one or more Practitioners ~~under protocol and in collaboration with Practitioner(s)~~ to provide patient care services to achieve optimal medication use and desired patient outcomes.

(v) "Collaborative Pharmacy Practice Agreement" is a written and signed agreement between one or more Pharmacists and one or more Practitioners that provides for Collaborative Pharmacy Practice as defined by law and the Rules of the Board.

…

(b4) "Medical Order" means a lawful order of a Practitioner that may or may not include a Prescription Drug Order.

…

(w4) "Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement" means those duties and limitations of duties placed upon one or more Pharmacists by the collaborating Practitioner or Practitioners, the Board, and applicable law, and includes the limitations implied by the scope of practice of the collaborating Practitioner or Practitioners.

…

(f5) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and Administer Drugs in the course of professional practice.

…

(j5) "Prescription Drug Order" means a lawful order from a Practitioner for a Drug or Device for a specific patient, including orders derived from Collaborative Pharmacy Practice, where a valid Patient-Practitioner relationship exists, that is communicated to a Pharmacist in a licensed Pharmacy.

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Model Rules for the Practice of Pharmacy

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Section 5. Pharmacist Care

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(d) Collaborative Pharmacy Practice

(1) Collaborative Pharmacy Practice Agreement

A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct activities approved by the Practitioner, and as defined by law and by the Rules of the Board. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner's current practice. Patients or caregivers shall be advised of such agreement.

(2) Contents

The Collaborative Pharmacy Practice Agreement shall include:

(i) identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;

(ii) the types of decisions that the Pharmacist is allowed to make. ~~may include:~~

~~(A) a detailed description of the types of diseases, Drugs, or Drug categories involved, and the activities allowed in each case;~~

~~(B) a detailed description of the methods, procedures, decision criteria, and plan the Pharmacist is to follow when conducting allowed activities; and~~

~~(C) a detailed description of the activities the Pharmacist is to follow, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the Practitioner concerning specific decisions made.~~

(iii) a process for generating any necessary medical orders, including prescription orders, required to initiate allowed activities.

(iv) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;

(~~i~~v) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;
(vi) a provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;
(vii) a provision that allows either party to cancel the Agreement by written notification;
(viii) an effective date; ~~and~~
(~~viii~~ix) signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as dates of signing~~.~~; and
(x) a procedure for periodic review and renewal within a time frame that is clinically appropriate.

(3) Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.

(3~~4~~) ~~Initiation of the Collaborative Pharmacy Practice Agreement~~
~~The Collaborative Pharmacy Practice Agreement must be coupled with a medical order from the Practitioner to initiate allowed activities for any particular patient.~~

(4) Documentation of Pharmacist activities
Documentation of allowed activities must be kept as part of the patient's permanent record and be readily available to other health care professionals providing care to that patient and who are authorized to receive~~d~~ it. Documentation of allowed activities shall be considered Protected Health Information.

~~(5) Review~~
~~At a minimum, the written agreement shall be reviewed and renewed and, if necessary, revised every year.~~

Background:

Krystalyn Weaver from National Alliance of State Pharmacy Associations (NASPA) presented to the task force members trends in collaborative practice authority and recommendations from NASPA's Collaborative Practice Workgroup, which included NABP observation. Included in the discussion was the fact that state collaborative practice statute and regulations are highly variable between states. Krystalyn also explained that there is variability in how related terms such as protocol are defined. The NASPA workgroup recommended that the framework for collaborative practice agreements should consider the pharmacist's education and training while keeping patient safety and best interest paramount.

The task force members concluded that NABP should encourage state boards of pharmacy to review current requirements for collaborative practice agreements and revise requirements to remove barriers that may have previously prevented the greater acceptance and wider adoption of collaborative practices between physicians and pharmacists. It was agreed that state collaborative practice laws and rules should be broad in scope to allow varying degrees of collaboration and should not interfere with the extent of collaboration between a pharmacist and other health care providers.

In regard to collaborative practice laws and rules, the task force members stressed that states should not impede, among other things, pharmacists from collaborating with multiple providers, the ability of a pharmacist to initiate drug therapy, the administration and interpretation of tests, the number of patients and disease states that can be treated per collaborative practice agreement, and the types of drugs that a pharmacist can initiate, discontinue or modify within a collaborative practice agreement. As has been demonstrated by pharmacists working in the Indian Health Service and other federal health care systems, the depth and scope of collaborative practice should be determined by the pharmacist and prescriber entering into a collaboration.

Recommendation 3: NABP Should Support Key Messages Pertaining to Pharmacists' Role in Providing Health Care

The task force recommends that NABP support the following key messages pertaining to pharmacists' role in providing health care:

1. Expand pharmacists' role, consistent with their education and training, on health care teams to increase patient access to quality health care.
2. Pharmacists continue efforts to enter into collaborative agreements with practitioners to improve outcomes by increasing patient access to timely and efficient care.
3. States continue to implement and expand collaboratively developed initiatives to provide for limited pharmacists' prescriptive authority through formularies and protocols.
4. Pharmacists gain provider status in support of efforts to improve access to pharmacist care.
5. Educate the public and other stakeholders on the expanding role of pharmacists in health care.

Background:

Members conveyed how pharmacists have long provided the public with advice on over-the-counter (OTC) products as part of their role as medication experts. With the implementation of robotics and technology to assist with the dispensing functions and the public demand for more access to primary care, the pharmacist is well positioned to provide increased patient-centered services and an expanded role in patients' drug therapy. Being that the pharmacist is the most accessible health care provider and hospital emergency departments are often burdened with patients having a noncritical need for drug therapy, the task force recommends that boards of pharmacy and departments of health support pharmacists' initiatives to provide timely drug therapy in circumstances such as preventative medicine where patient access to drug therapy is warranted yet not deemed critical. This is already the case in certain states and counties where regulations have been instituted to allow pharmacists to deliver travel medications, nicotine replacements, hormonal contraceptives, naloxone, Antibiotic therapy for the treatment of Lyme disease, and, if warranted, following a pharmacist administered swab test to detect influenza and streptococcal infections.

The task force agreed that states can assist timely access to drug therapy by approving statewide protocols or state approved formulary whereby a pharmacist can furnish certain drugs to a patient when the pharmacist demonstrates adequate training and or obtains the required certification. The task force also called on support from FDA and other stakeholders for implementation of a third class of drugs beyond OTC and prescription only medication that may offer patients access

to certain medications only after consultation with a pharmacist. Some examples could include methylprednisolone dose pack for poison ivy exposure or other topical agents for dermatitis. Members determined that this third class of drugs would be appropriate for conditions that are either self-diagnosed or easily diagnosed.

In order to facilitate employer support and pharmacists' incentive to provide services beyond their historic role in drug delivery, the task force deemed it imperative that pharmacists gain provider status for reimbursement purposes. Provider status is the vehicle by which clinical pharmacy services will systematically be offered by pharmacists to patients on a consistent basis. Members stressed that by achieving provider status, establishing a payment system for clinical services offered by pharmacists should ensue.

With millions of individuals entering the health care system as a result of the Affordable Care Act, there is a need for increased access to care. Currently there is a lack of primary care physicians (PCPs), which requires the health care industry's attention. According to a report published by the Association of American Medical Colleges, the projected shortage of PCPs by 2025 will range from 12,500 to 31,100.[2] With such a shortage, other members of the health care team, such as pharmacists, must help bridge the gap. While members of the pharmacy profession are aware of the potential role of pharmacists in health care delivery, further education must be provided to the general public and other stakeholders about the benefits of pharmacists' interventions. Informing the public and stakeholders about these potential benefits will lead to an appreciation and utilization of the expertise of pharmacists to help advance health and wellness, improve outcomes, and increase patient safety.

[2] IHS Inc., *The Complexities of Physician Supply and Demand: Projections from 2013 to 2025.* Washington, DC: Association of American Medical Colleges; 2015.