AGENDA

Florida Board of Pharmacy
Legislative Committee Meeting
August 15, 2017 – 9:00 a.m.

(immediately following the Controlled Substance Standards Committee meeting)

Embassy Suites Fort Lauderdale * 1100 SE 17th Street
Fort Lauderdale, FL 33316 * (954)315-1326

Committee Members:
Jeenu Philip, BPharm – Chair
Goar Alvarez, PharmD
David Bisallion
Debra Glass, BPharm
Michele Weizer, PharmD

Board Staff
C. Erica White, MBA, JD - Executive Director
Savada Knight, Regulatory Supervisor
Jessica Hollingsworth – Gov. Analyst II

Board Counsel:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Note: Participants in this public meeting should be aware that these proceedings are being recorded.

1. **Pharmacist Prescribing – 465.186** (page 2)
2. **Legal presumption and validity of a prescription written by an ARNP and PA** (page 5)
3. **Discussion on RPh prescriptive authority vs. collaborative practice agreements vs. statewide protocols** (page 6)
4. **Amendment to 465.189 – To permit pharmacists to provide treatment of influenza** (page 8)
5. **Supervision of Pharmacy Technicians and the definition of Direct supervision** (page 9)
6. **Telepharmacy** (page 10)
7. **Reference Material:**
   - NABP Taskforce report - https://nabp.pharmacy/wp content/uploads/2016/07/Report_TaskForce_PharmacistPrescriptiveAuthority_Final.pdf
   - Legislation/Processes in other states that we can model
8. **Old Business/New Business**
9. **Public Comment**
10. **Adjourn**

I. Pharmacist Prescribing - Potential Amendments to 465.186

1. Basis: To better align pharmacists knowledge, skills and abilities with direct application of these to assist patients, increase access to low cost healthcare, reduce overall healthcare costs and reducing barriers to healthcare. The current statute has not changed in over 20 years and is well overdue for change considering the number of pharmacists that have advanced pharmacy degrees, extensive clinical experience and additional certifications.
2. Suggestion #1:

465.186 Pharmacist's order for medicinal drugs; dispensing procedure; development of formulary.—
(1) There is hereby created a committee composed of two members of the Board of Medicine licensed under chapter 458 chosen by said board, one member of the Board of Osteopathic Medicine licensed under chapter 459 chosen by said board, three members of the Board of Pharmacy licensed under this chapter and chosen by said board, and one additional person with a background in health care or pharmacology chosen by the committee. The committee shall establish a formulary of medicinal drug products and dispensing procedures which shall be used by a pharmacist when ordering and dispensing such drug products to the public. Dispensing procedures may include matters related to reception of patient, description of his or her condition, patient interview, patient physician referral, product selection, and dispensing and use limitations. In developing the formulary of medicinal drug products, the committee may include products falling within the following categories:
(a) Any medicinal drug of single or multiple active ingredients in any strengths when such active ingredients have been approved individually or in combination for over-the-counter sale by the United States Food and Drug Administration.
(b) Any medicinal drug recommended by the United States Food and Drug Administration Advisory Panel for transfer to over-the-counter status pending approval by the United States Food and Drug Administration.
(c) Any medicinal drug containing any antihistamine or decongestant as a single active ingredient or in combination.
(d) Any medicinal drug containing fluoride in any strength.
(e) Any medicinal drug containing lindane in any strength.
(f) Any over-the-counter proprietary drug under federal law that has been approved for reimbursement by the Florida Medicaid Program.
(g) Any topical anti-infectives excluding eye and ear topical anti-infectives.
However, any drug which is sold as an over-the-counter proprietary drug under federal law shall not be included in the formulary or otherwise affected by this section.
(2) The Board of Pharmacy, the Board of Medicine, and the Board of Osteopathic Medicine shall adopt by rule a formulary of medicinal drugs and dispensing procedures as established by the committee. A pharmacist may order and dispense a product from the formulary pursuant to the established dispensing procedure, as adopted by the boards, for each drug in conjunction with its inclusion in the formulary. Any drug product ordered by a pharmacist shall be selected and dispensed only by the pharmacist so ordering, and said order shall not be refilled, nor shall another medicinal drug be ordered for the same condition unless such act is consistent with dispensing procedures established by the committee. Appropriate referral to another health care provider is indicated under such circumstances. On each occasion of such dispensing, the pharmacist shall create and maintain a prescription record in the form required by law.
(3) The board of pharmacy shall adopt rules for certain drugs, drug categories or devices. Such drugs and devices shall be prescribed in accordance with the product's federal food and drug administration-approved labeling. Drugs, drug categories or devices authorized by the board under this section shall be limited to conditions that:
(i) Do not require a new diagnosis;
(ii) Are minor and generally self-limiting;
(iii) Have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988;
(iv) In the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such cases, only sufficient quantity may be provided until the patient is able to be seen by another provider.
(v) The drug is not a controlled drug, compounded drug or biological product.

(~~3~~ **4**) Affixed to the container containing a medicinal drug dispensed pursuant to this section shall be a label bearing the following information:

(a) The name of the pharmacist ordering the medication.

(b) The name and address of the pharmacy from which the medication was dispensed.

(c) The date of dispensing.

(d) The order number or other identification adequate to readily identify the order.

(e) The name of the patient for whom the medicinal drug was ordered.

(f) The directions for use of the medicinal drug ordered.

(g) A clear, concise statement that the order may not be refilled.

(**4** ~~5~~) Any pharmacist performing the services authorized by this section shall be eligible for reimbursement by third party prescription programs when so provided by contract or when otherwise provided by such program.

(~~5~~ **6**) Any person ordering or dispensing medicinal drugs in violation of this section shall be guilty of a misdemeanor of the first degree, and such violation shall be punishable as provided in s. 775.082 or s. 775.083.

3. Suggestion #2:

465.186 Pharmacist's order for medicinal drugs; dispensing procedure; development of formulary.—

(1) There is hereby created a committee composed of two members of the Board of Medicine licensed under chapter 458 chosen by said board, one member of the Board of Osteopathic Medicine licensed under chapter 459 chosen by said board, three members of the Board of Pharmacy licensed under this chapter and chosen by said board, and one additional person with a background in health care or pharmacology chosen by the committee. The committee shall establish a formulary of medicinal drug products and dispensing procedures which shall be used by a pharmacist when ordering and dispensing such drug products to the public. Dispensing procedures may include matters related to reception of patient, description of his or her condition, patient interview, patient physician referral, product selection, and dispensing and use limitations. In developing the formulary of medicinal drug products **and devices**, the committee may include products falling within the following categories:

(a) Any medicinal drug of single or multiple active ingredients in any strengths when such active ingredients have been approved individually or in combination for over-the-counter sale by the United States Food and Drug Administration.

(b) Any medicinal drug recommended by the United States Food and Drug Administration Advisory Panel for transfer to over-the-counter status pending approval by the United States Food and Drug Administration.

(c) Any medicinal drug containing any antihistamine or decongestant as a single active ingredient or in combination.

(d) Any medicinal drug containing fluoride in any strength.

(e) Any medicinal drug containing lindane in any strength.

(f) Any over-the-counter proprietary drug under federal law that has been approved for reimbursement by the Florida Medicaid Program.

(g) Any topical anti-infectives excluding eye and ear topical anti-infectives.

(h) Any medicinal drug for the treatment of minor conditions

(i) Any medical device

(j) Any medicinal drug that is based on a CLIA-Waived test

(k) Any medicinal drug to treat for clinical gaps in care

(l) Any medicinal drug for the purpose of travel

However, any drug which is sold as an over-the-counter proprietary drug under federal law shall not be included in the formulary or otherwise affected by this section.

(2) The Board of Pharmacy, the Board of Medicine, and the Board of Osteopathic Medicine shall adopt by rule a formulary of medicinal drugs and dispensing procedures as established by the committee. A pharmacist may order and dispense a product from the formulary pursuant to the established dispensing procedure, as adopted by the boards, for

each drug in conjunction with its inclusion in the formulary. Any drug product ordered by a pharmacist shall be selected and dispensed only by the pharmacist so ordering, and said order shall not be refilled, nor shall another medicinal drug be ordered for the same condition unless such act is consistent with dispensing procedures established by the committee. Appropriate referral to another health care provider is indicated under such circumstances. On each occasion of such dispensing, the pharmacist shall create and maintain a prescription record in the form required by law. **For all drugs or devices prescribed and dispensed listed in 1(h) to 1(l), the pharmacy must notify the primary care phycisian(if applicable) by any means.**

(3) Affixed to the container containing a medicinal drug dispensed pursuant to this section shall be a label bearing the following information:

(a) The name of the pharmacist ordering the medication.

(b) The name and address of the pharmacy from which the medication was dispensed.

(c) The date of dispensing.

(d) The order number or other identification adequate to readily identify the order.

(e) The name of the patient for whom the medicinal drug was ordered.

(f) The directions for use of the medicinal drug ordered.

(g) A clear, concise statement that the order may not be refilled.

(4) Any pharmacist performing the services authorized by this section shall be eligible for reimbursement by third party prescription programs when so provided by contract or when otherwise provided by such program.

(5) Any person ordering or dispensing medicinal drugs in violation of this section shall be guilty of a misdemeanor of the first degree, and such violation shall be punishable as provided in s. 775.082 or s. 775.083.

II. Legal presumption and validity of a prescription written by an ARNP and PA. :

1. Due to changes in prescriptive authority for both PA's & ARNP's which now allows for the writing of controlled substances, this statute needs revision to permit pharmacists the proper authority to dispense controlled substance prescriptions with a presumption of receiving legal prescriptions. The basis for this presumption is that they do not have access to review ARNP & PA protocols prior to dispensing. Pharmacists would still be required to validate prescriptions pursuant to 64B16-27.831.
2. Suggestion #1: Amendment to 456.0392

456.0392 Prescription labeling**: Legal presumption and validity of a prescription written by an ARNP and PA**

(1) A prescription written by a practitioner who is authorized under the laws of this state to write prescriptions for drugs that are ~~**not**~~ listed as controlled substances in chapter 893 ~~**but who is not eligible for a federal Drug Enforcement Administration number**~~ shall include that practitioner's name**,** ~~**and**~~ professional license number **and federal Drug Enforcement number**. The pharmacist or dispensing practitioner must include the practitioner's name on the container of the drug that is dispensed. A pharmacist shall be permitted, upon verification by the prescriber, to document any information required by this section.

(2) A prescription for a **medicinal** drug ~~**that is not listed as a controlled substance in chapter 893**~~ which is written by an advanced registered nurse practitioner certified under s. 464.012 is presumed, subject to rebuttal, to be ~~**valid**~~ **legal** and within the parameters of the prescriptive authority delegated by a practitioner licensed under chapter 458, chapter 459, or chapter 466.

(3) A prescription for a **medicinal** drug ~~**that is not listed as a controlled substance in chapter 893**~~ which is written by a physician assistant licensed under chapter 458 or chapter 459 is presumed, subject to rebuttal, to be ~~**valid**~~ **legal** and within the parameters of the prescriptive authority delegated by the physician assistant's supervising physician.

III. Discussion on RPh prescriptive authority vs. collaborative practice agreements vs. statewide protocols

1. NABP Task force
    a. https://nabp.pharmacy/wp-content/uploads/2016/07/Report_TaskForce_PharmacistPrescriptiveAuthority_Final.pdf
2. APHA Article
    a. http://www.pharmacist.com/states-give-pharmacists-more-prescriptive-authority
3. New Mexico – 16.19.26
    a. http://www.rld.state.nm.us/boards/pharmacy_rules_and_laws.aspx
    b. http://164.64.110.239/nmac/parts/title16/16.019.0026.htm
4. NASPA article
    a. https://naspa.us/2017/06/pharmacists-authorized-to-prescribe-tobacco-cessation-therapy-in-more-states/
5. Examples: Wisconsin:
    a. 450.033 **Services delegated by physician.**
        1. A pharmacist may perform any patient care service delegated to the pharmacist by a physician, as defined in s. 448.01 (5)
    b. Potential amendment based on WI language. Amend 465.003 (13) Definitions: Practice of the profession of pharmacy
        i. "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services. **A pharmacist may perform any patient care service delegated to the pharmacist by a physician, as defined in Chapter 458.305(4) or 459.003(4).** For purposes of this subsection, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s. 465.189.

6. Amendment to 465 –creation of a new statute [e.g. 465.011 Collaborative Practice Agreements]
    a. Basis: In alignment with creating "Team-Based Care" models, CPA's create a formalized method to create a relationship between pharmacists and healthcare practitioners. CPA's permit a pharmacist to practice

pharmacy that is closer aligned to their education and training and practitioners to leverage the expertise of pharmacists to serve patients and provide a higher standard of care.

b. Recommended provisions that should be included in **465.011 Collaborative Practice Agreements**:

i. **A pharmacist may collaborate with and perform any patient care service delegated to the pharmacist by a practitioner with prescriptive authority, as defined in Chapter 458, chapter 459, Chapter 461, 464 or Chapter 466.**

ii. **A collaborative practice agreement may be written between single or multiple pharmacists and single or multiple prescribers.**

iii. **Collaborative practice agreements may apply to single patients, multiple patients or patient populations as specified in the agreements.**

iv. **A pharmacist may initiate and modify drug therapy as authorized under a Collaborative Practice Agreement by a practitioner.**

v. **All prescriptions drugs, including controlled substances as defined in Chapter 893, may be included in Collaborative Practice Agreements.**

vi. **Collaborative Practice Agreements shall be maintained by the pharmacist and collaborating practitioner(s) and be available upon request or inspection**.

IV. Amendment to 465.189 – To permit pharmacists to provide treatment of influenza; mirrored after language in 2017 SB1180:

(3) A pharmacist certified under subsection (7) may, within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459, perform the following services related to the treatment of influenza:
(a) Order and evaluate laboratory and clinical tests; and
(b) Administer, modify, and discontinue medications

(5)~~(4)~~ A pharmacist administering vaccines **or treating influenza** under this section shall maintain and make available patient records using the same standards for confidentiality and maintenance of such records as those that are imposed on health care practitioners under s. 456.057. These records shall be maintained for a minimum of 5 years.

(8) ~~(7)~~The written protocol between the pharmacist and supervising physician under this section must include particular terms and conditions imposed by the supervising physician upon the pharmacist relating to the administration of vaccines **or the treatment of influenza** by the pharmacist pursuant to this section. The written protocol for the **administration of vaccines** shall include, at a minimum, specific categories and conditions among patients for whom the supervising physician authorizes the pharmacist to administer such vaccines. The terms, scope, and conditions set forth in the written protocol between the pharmacist and the supervising physician must be appropriate to the pharmacist's training and certification for administering such vaccines **or the treatment of influenza**. Pharmacists who have been delegated the authority to administer vaccines under this section by the supervising physician under the protocol shall provide evidence of current certification by the Board of Pharmacy to the supervising physician. A supervising physician shall review the administration of such vaccines **or the treatment of influenza** by the pharmacist pursuant to the written protocol between them, and this review shall take place as outlined in the written protocol. The process and schedule for the review shall be outlined in the written protocol between the pharmacist and the supervising physician.

(9)~~(8)~~ The pharmacist shall submit to the Board of Pharmacy a copy of his or her protocol or written agreement to administer vaccines **or** engage in **the treatment of influenza** under this section.

V. Definition of Direct supervision

1. Recommended Suggestion? Amend 465.003 to require the BOP to define Direct and Indirect Supervision.
2. Locations of direct supervision in 465
3. 465.014 (1) Pharmacy technician
    i. All such delegated acts must be performed under the direct supervision of a licensed pharmacist who is responsible for all such acts performed by persons under his or her supervision.
4. 465.015(1)(b), 465.015(2)(b) Violations and Penalties
    i. 1(b) In which a person not licensed as a pharmacist in this state or not registered as an intern in this state or in which an intern who is not acting under the direct and immediate personal supervision of a licensed pharmacist fills, compounds, or dispenses any prescription or dispenses medicinal drugs.
    ii. 2(b) To fill, compound, or dispense prescriptions or to dispense medicinal drugs if such person does not hold an active license as a pharmacist in this state, is not registered as an intern in this state, or is an intern not acting under the direct and immediate personal supervision of a licensed pharmacist.
5. 465.016 (1(c), Disciplinary actions
    i. (c) Permitting any person not licensed as a pharmacist in this state or not registered as an intern in this state, or permitting a registered intern who is not acting under the direct and immediate personal supervision of a licensed pharmacist, to fill, compound, or dispense any prescriptions in a pharmacy owned and operated by such pharmacist or in a pharmacy where such pharmacist is employed or on duty.
6. 465.0266 Common database
    i. Any pharmacist dispensing a prescription has at all times the right and obligation to exercise his or her independent professional judgment. Notwithstanding other provisions in this section, no pharmacist licensed in this state participating in the dispensing of a prescription pursuant to this section shall be responsible for the acts and omissions of another person participating in the dispensing process provided such person is not under the direct supervision and control of the pharmacist licensed in this state.
7. Recommended revision to 465.014(1):
    i. All such delegated acts must be performed under the direct **or indirect supervision as defined by the board** of a licensed pharmacist who is responsible for all such acts performed by persons under his or her supervision.

VI. Telepharmacy

1. Basis: There are currently many locations in Florida that would be considered medically underserved with health professional shortages. Telepharmacy is seen as a way to improve access to pharmacy and healthcare services by leveraging technology to allow the practice of pharmacy to occur without a pharmacist required to be "on-site".
2. Amendment to the definition of pharmacy in 465.003

(11)(a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, a~~nd an~~ Internet pharmacy, **and a Remote dispensing site pharmacy.**

(1)-(5), unchanged

(6)The term "Remote dispensing site pharmacy" includes locations staffed by registered pharmacy technicians and supervised by an off-site pharmacist through electronic supervision.

~~**(11)(b) The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.**~~

3. Amendment to 465.021

465.021 Remote Dispensing Site Pharmacy Permits.-

(1)Any person desiring a permit to operate a remote dispensing site pharmacy shall apply to the department. If the board certifies that the application complies with applicable law, the department shall issue the permit. No permit shall be issued unless a duly licensed and qualified pharmacist is designated as being the prescription department manager. Notwithstanding s. 465.003(11)(b), a pharmacist may supervise the activities of the pharmacy remotely. A remote dispensing site pharmacy may store, hold, and dispense all medicinal drugs including those listed under s. 893.03. A prescription department manager or a consultant pharmacist of a pharmacy may also serve as the prescription department manager of one or more remote dispensing site pharmacies, if both pharmacies are under common control. The permittee shall notify the department within 10 days of any change of the prescription department manager. A remote dispensing site pharmacy license may be issued to a location that does not have adequate access to dispensing or pharmaceutical care services. The Board shall adopt rules to determine locations eligible for a remote dispensing site pharmacy permit which at a minimum must include medically underserved areas and populations and health professional shortage areas as determined by the Department of Health and Human Services Heath Resources and Services Administration.

(2) Each pharmacy operating as a remote site dispensing pharmacy pursuant to this chapter must maintain a policy and procedures manual, which shall be made available to the board or its agent upon request. The policy and procedures manual shall include the following information:

(a) A description of how the pharmacy will comply with federal and state laws, rules, and regulations.

(b) The procedure for supervising the remote site dispensing pharmacy and counseling the patient.

(c) The procedure for reviewing the drug inventory and drug records maintained by the pharmacy.

(d) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information.

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.

…

Model Rules for the Practice of Pharmacy

…

Section 5. Pharmacist Care

…

(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.

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 26 PHARMACIST PRESCRIPTIVE AUTHORITY

16.19.26.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy, Albuquerque, NM.
[16.19.26.1 NMAC - N, 12-15-02; A, 03-07-11]

16.19.26.2 SCOPE: All pharmacists that intend to exercise the authority to prescribe dangerous drugs based on written protocols approved by the board.
[16.19.26.2 NMAC - N, 12-15-02]

16.19.26.3 STATUTORY AUTHORITY: Section 61-11-6.A(1) NMSA 1978 authorizes the board of Pharmacy to adopt, regularly review and revise rules and regulations necessary to carry out the provisions of the Pharmacy Act. Section 61-11-6.A(7) gives the board authority to enforce the provisions of all laws of the state pertaining to the distribution of drugs. Under the Pharmacist Prescriptive Authority Act, Sections 61-11B-1 to 61-11B-3 NMSA 1978, the board is required to establish regulations governing certification as a pharmacist clinician. Section 61-11-6.A(19) authorizes the board to adopt rules and protocols for the prescribing of dangerous drug therapy.
[16.19.26.3 NMAC - N, 12-15-02]

16.19.26.4 DURATION: Permanent.
[16.19.26.4 NMAC - N, 12-15-02]

16.19.26.5 EFFECTIVE DATE: 12-15-02, unless a later date is cited at the end of a section.
[16.19.26.5 NMAC - N, 12-15-02]

16.19.26.6 OBJECTIVE: The objective of Part 26 of Chapter 19 is to protect the health and safety of New Mexico citizens by regulating the prescriptive authority of pharmacists.
[16.19.26.6 NMAC - N, 12-15-02]

16.19.26.7 DEFINITIONS:

A. "Antigen" means a substance recognized by the body as being foreign; it results in the production of specific antibodies directed against it.

B. "Antibody" means a protein in the blood that is produced in response to stimulation by a specific antigen.

C. "Immunization" means the act of inducing antibody formation, thus leading to immunity.

D. "Vaccine" means a specially prepared antigen, which upon administration to a person, will result in immunity.

E. "Vaccination" means the administration of any antigen in order to induce immunity; is not synonymous with immunization since vaccination does not imply success.

F. "Written protocol" means a physician's order, standing delegation order, or other order or protocol as defined by rule of the New Mexico board of pharmacy.

G. "Emergency contraception drug therapy" means the use of a drug to prevent pregnancy after intercourse.

H. "Tobacco cessation drug therapy" means the use of therapies, which may include drugs to assist in quitting any form of tobacco use.

I. "Hormonal contraception drug therapy" means the use of hormonal therapies to prevent pregnancy.
[16.19.26.7 NMAC - N, 12-15-02; A, 07-15-04; A, 06-09-17]

16.19.26.8 REFERRAL: Any pharmacist not certified to provide a prescriptive authority service is required to refer patients to a pharmacist or other provider who provides such a service.
[16.19.26.8 NMAC - N, 12-15-02; 16.19.26.8 NMAC - N, 07-15-04]

16.19.26.9 VACCINES:

A. Protocol:

(1) Prescriptive authority for vaccines shall be exercised solely in accordance with the written protocol for vaccine prescriptive authority approved by the board.

(2) Any pharmacist exercising prescriptive authority for vaccines must maintain a current copy of the protocol for vaccine prescriptive authority approved by the board.

B. Education and training:

(1) The pharmacist must successfully complete a course of training, accredited by the accreditation council for pharmacy education (ACPE), provided by: a) the centers for disease control and prevention (CDC); or b) a similar health authority or professional body approved by the board.

(2) Training must include study materials, hands-on training and techniques for administering vaccines, comply with current CDC guidelines, and provide instruction and experiential training in the following content areas:

(a) mechanisms of action for vaccines, contraindication, drug interaction, and monitoring after vaccine administration;

(b) standards for pediatric, adolescent, and adult immunization practices;

(c) basic immunology and vaccine protection;

(d) vaccine-preventable diseases;

(e) recommended pediatric, adolescent, and adult immunization schedule;

(f) vaccine storage management;

(g) biohazard waste disposal and sterile techniques;

(h) informed consent;

(i) physiology and techniques for vaccine administration;

(j) pre and post-vaccine assessment and counseling;

(k) immunization record management;

(l) management of adverse events, including identification, appropriate response, documentation and reporting;

(m) reimbursement procedures and vaccine coverage by federal, state and local entities.

(3) Continuing education: Any pharmacist exercising prescriptive authority for vaccines shall complete a minimum of 0.2 CEU of live ACPE approved vaccine related continuing education every two years. Such continuing education shall be in addition to requirements in 16.19.4.10 NMAC.

(4) Basic life support/cardiopulmonary resuscitation (BLS/CPR): Any pharmacist exercising prescriptive authority for vaccines shall complete and have current live BLS/CPR certification.

C. Authorized drugs:

(1) Prescriptive authority shall be limited to those drugs and vaccines delineated in the written protocol for vaccine prescriptive authority approved by the board, and;

(2) Other vaccines as determined by the CDC, the advisory committee on immunization practices (ACIP) or New Mexico department of health that may be required to protect the public health and safety

D. Records:

(1) The prescribing pharmacist must generate a written or electronic prescription for any dangerous drug authorized.

(2) Informed consent must be documented in accordance with the written protocol for vaccine prescriptive authority approved by the board and a record of such consent maintained in the pharmacy for a period of at least three years.

E. Notification: Upon signed consent of the patient or guardian the pharmacist shall:

(1) notify the New Mexico department of health immunization program and the patient's designated physician or primary care provider and;

(2) update the New Mexico department of health immunization program's electronic database (NMSIIS) of any vaccine administered.

[16.19.26.9 NMAC - N, 12-15-02; 16.19.26.9 NMAC - Rn, 16.19.26.8 NMAC & A, 07-15-04; A, 01-31-07; A, 09-06-15]

16.19.26.10 EMERGENCY CONTRACEPTION DRUG THERAPY:

A. Protocol:

(1) Prescriptive authority for emergency contraception drug therapy shall be exercised solely in accordance with the written protocol for emergency contraception drug therapy approved by the board.

(2) Any pharmacist exercising prescriptive authority for emergency contraception drug therapy must maintain a current copy of the written protocol for emergency contraception drug therapy approved by the board.

B. Education and training:

(1) The pharmacist must successfully complete a course of training, accredited by the accreditation council for pharmacy education (ACPE), in the subject area of emergency contraception drug therapy provided by: a) the department of health; or b) planned parenthood or c) a similar health authority or professional body approved by the board.

(2) Training must include study materials and instruction in the following content areas:

(a) mechanisms of action, contraindication, drug interaction, and monitoring of emergency contraception drug therapy;

(b) current standards for prescribing emergency contraception drug therapy;

(c) identifying indications for the use of emergency contraception drug therapy;

(d) interviewing patient to establish need for emergency contraception drug therapy;

(e) counseling patient regarding the safety, efficacy and potential adverse effects of drug products for emergency contraception;

(f) evaluating patient's medical profile for drug interaction;

(g) referring patient follow-up care with primary healthcare provider;

(h) informed consent;

(i) record management;

(j) management of adverse events, including identification, appropriate response, documentation and reporting.

(3) Continuing education: Any pharmacist exercising prescriptive authority for emergency contraception drug therapy shall complete a minimum of 0.2 CEU of ACPE approved emergency contraception drug therapy related continuing education every two years.

Such continuing education shall be in addition to requirements in 16.19.4.10 NMAC.

C. Authorized drugs:

(1) Prescriptive authority shall be limited to emergency contraception drug therapy and shall exclude any device intended to prevent pregnancy after intercourse.

(2) Prescriptive authority for emergency contraception drug therapy shall be limited to those drugs delineated in the written protocol for emergency contraception drug therapy approved by the board.

D. Records:

(1) The prescribing pharmacist must generate a written or electronic prescription for any dangerous drug authorized.

(2) Informed consent must be documented in accordance with the approved protocol for emergency contraception drug therapy and a record of such consent maintained in the pharmacy for a period of at least three years.

E. Notification: Upon signed consent of the patient or guardian, the pharmacist shall notify the patient's designated physician or primary care provider of emergency contraception drug therapy prescribed.

[16.19.26.10 NMAC - N, 12-15-02; 16.19.26.10 NMAC - Rn, 16.19.26.9 NMAC & A, 07-15-04; A, 09-06-15]

16.19.26.11 TOBACCO CESSATION DRUG THERAPY:

A. Protocol:

(1) Prescriptive authority for tobacco cessation drug therapy shall be exercised solely in accordance with the written protocol for tobacco cessation drug therapy approved by the board.

(2) Any pharmacist exercising prescriptive authority for tobacco cessation drug therapy must maintain a current copy of the written protocol for tobacco cessation drug therapy approved by the board.

B. Education and training:

(1) The pharmacist must successfully complete a course of training, accredited by the accreditation council for pharmacy education (ACPE), in the subject area of tobacco cessation drug therapy provided by: a) the department of health; or b) health and human services or c) a similar health authority or professional body approved by the board.

(2) Training must include study materials and instruction in the following content areas:

(a) mechanisms of action for contraindications, drug interactions, and monitoring cessation;

(b) current standards for prescribing tobacco cessation drug therapy;

(c) identifying indications for the use of tobacco cessation drug therapy;

(d) interviewing patient to establish need for tobacco cessation drug therapy;

(e) counseling patient regarding the safety, efficacy and potential adverse effects of drug products for tobacco cessation;

(f) evaluating patient's medical profile for drug interaction;

(g) referring patient follow-up care with primary healthcare provider;

(h) informed consent;

(i) record management;

(j) management of adverse events, including identification, appropriate response, documentation and reporting;

(k) reimbursement procedures and tobacco cessation drug therapy and education coverage by federal, state and local entities.

(3) Continuing education: Any pharmacist exercising prescriptive authority for tobacco cessation drug therapy shall complete a minimum of 0.2 CEU of ACPE approved tobacco cessation drug therapy related continuing education every two years. Such continuing education shall be in addition to requirements in 16.19.4.10 NMAC.

C. Authorized drugs:

(1) Prescriptive authority shall be limited to tobacco cessation drug therapy including prescription and non-prescription therapies.

(2) Prescriptive authority for tobacco cessation drug therapy shall be limited to those drugs delineated in the written protocol approved by the board.

D. Records:

(1) The prescribing pharmacist must generate a written or electronic prescription for any dangerous drug authorized.

(2) Informed consent must be documented in accordance with the approved protocol for tobacco cessation drug therapy and a record of such consent maintained in the pharmacy for a period of at least three years.

E. Notification: Upon signed consent of the patient, the pharmacist shall notify the patient's designated physician or primary care provider of tobacco cessation drug therapy prescribed.

[16.19.26.11 NMAC - N, 07-15-04; A, 09-06-15]

16.19.26.12 TB TESTING:

A. Protocol:

(1) Prescriptive authority for Tuberculosis (TB) testing shall be exercised solely in accordance with the written protocol for TB testing drug therapy approved by the board.

(2) Any pharmacist exercising prescriptive authority for TB testing must maintain a current copy of the written protocol for TB testing approved by the board.

B. Education and training:

(1) The pharmacist must successfully complete training as specified by the New Mexico department of health tuberculosis department.

(2) Continuing education: Any pharmacist exercising prescriptive authority for TB testing shall complete continuing education as specified by the centers for disease control.

C. Authorized drugs:

(1) TB skin antigen serum(s).

(2) Prescriptive authority for TB testing shall be limited to those drugs delineated in the written protocol approved by the board.

D. Records:

(1) The prescribing pharmacist must generate a written or electronic prescription for any TB test administered.

(2) Informed consent must be documented in accordance with the approved protocol for TB testing and a record of such consent maintained in the pharmacy for a period of at least three years.

E. Notification: Upon signed consent of the patient, the pharmacist shall notify the patient's designated physician or primary care provider and the department of health of any positive TB test.

[16.19.26.12 NMAC - N, 03-07-11; A, 09-06-15]

16.19.26.13 NALOXONE FOR OPIOID OVERDOSE:

A. Protocol:

(1) Prescriptive authority for naloxone drug therapy shall be exercised solely in accordance with the written protocol for naloxone drug therapy approved by the board.

(2) Any pharmacist exercising prescriptive authority for naloxone drug therapy must maintain a current copy of the written protocol for naloxone drug therapy approved by the board.

B. Education and training:

(1) The pharmacist must successfully complete a course of training, accredited by the accreditation council for pharmacy education (ACPE), in the subject area of naloxone for opioid overdose drug therapy provided by:

(a) the New Mexico pharmacists association; or

(b) a similar health authority or professional body approved by the board.

(2) Training must include study materials and instruction in the following content areas:

(a) mechanisms of action;

(b) contraindications;

(c) identifying indications for the use of naloxone drug therapy;

(d) patient screening criteria;

(e) counseling and training patient and care-giver regarding the safety, efficacy and potential adverse effects of naloxone;

(f) evaluating patient's medical profile for drug interactions;

(g) referring patient for follow-up care with primary healthcare provider;

(h) informed consent;

(i) record management;

(j) management of adverse events.

(3) Continuing education: Any pharmacist exercising prescriptive authority for naloxone drug therapy shall complete a minimum of 0.2 CEU of live ACPE approved naloxone drug therapy related continuing education every two years. Such continuing education shall be in addition to requirements in 16.19.4.10 NMAC.

C. Authorized drug(s):

(1) Prescriptive authority shall be limited to naloxone and shall include any device(s) approved for the administration of naloxone.

(2) Prescriptive authority for naloxone drug therapy shall be limited to naloxone as delineated in the written protocol for naloxone drug therapy approved by the board.

D. Records:

(1) The prescribing pharmacist must generate a written or electronic prescription for any naloxone dispensed.

(2) Informed consent must be documented in accordance with the approved protocol for naloxone drug therapy and a record of such consent maintained in the pharmacy for a period of at least three years.

E. Notification: Upon signed consent of the patient, the pharmacist shall notify the patient's designated physician or primary care provider within 15 days of naloxone dispensing.

[16.19.26.13 NMAC - N, 03-14-14]

16.19.26.14 HORMONAL CONTRACEPTION DRUG THERAPY:

A. Protocol:

(1) Prescriptive authority for hormonal contraception drug therapy shall be exercised solely in accordance with the written protocol for hormonal contraception drug therapy approved by the board.

(2) Any pharmacist exercising prescriptive authority for hormonal contraception drug therapy must maintain a current copy of the written protocol for hormonal contraception drug therapy approved by the board.

B. Education and training:

(1) The pharmacist must successfully complete a course of training, accredited by the accreditation council for pharmacy education (ACPE), in the subject of hormonal contraception drug therapy provided by:

(a) the New Mexico pharmacists association or;

(b) a similar health authority or professional body approved by the board.

(2) Training must include study materials and instruction in the following content areas:

(a) mechanisms of action, contraindication, drug interaction and monitoring of hormonal contraception drug therapy;

(b) current standards for prescribing hormonal contraception drug therapy;

(c) identifying indications for use of hormonal contraception drug therapy;

(d) interviewing patient to establish need for hormonal contraception drug therapy;

(e) counseling patient regarding the safety, efficacy and potential adverse effects of drug products for hormonal contraception;

(f) evaluating patient's medical profile for drug interaction;

(g) referring patient follow-up care with primary healthcare provider;

(h) informed consent;

(i) management of adverse events, including identification, appropriate response, documentation and reporting.

(3) Continuing education: any pharmacist exercising prescriptive authority for emergency contraception drug therapy shall complete a minimum of 0.2 CEU of live ACPE approved hormonal contraception drug therapy related continuing education every two years. Such continuing education shall be in addition to requirements in 16.19.4.10 NMAC.

C. Authorized drugs:

(1) Prescriptive authority shall be limited to hormonal contraception drug therapy and shall exclude and device intended to prevent pregnancy after intercourse.

(2) Prescriptive authority for hormonal contraception drug therapy shall be limited to those drugs delineated in the written protocol for hormonal contraception drug therapy approved by the board.

D. Records:

(1) The prescribing pharmacist must generate a written or electronic prescription for any dangerous drug authorized.

(2) Informed consent must be documented in accordance with the approved protocol for hormonal contraception drug therapy and a record of such consent maintained in the pharmacy for a period of at least three years.

E. Notification: Upon signed consent of the patient or guardian, the pharmacist shall notify the patient's designated physician or primary care provider of hormonal contraception drug therapy prescribed.

[16.19.26.14 NMAC - N, 06-09-17]

HISTORY OF 16.19.26 NMAC: [RESERVED]

News

Pharmacists Authorized to Prescribe Tobacco Cessation Therapy in More States

Posted on June 23, 2017

More and more states are looking to pharmacists to provide tobacco cessation therapy to patients, whether through a statewide protocol or state regulations. Here's a summary of which states now (or will soon) allow pharmacists to prescribe tobacco cessation medications:

New Mexico

New Mexico has had statewide protocols for some time – per the 2001 legislation that allowed for pharmacist prescribing. Their statewide protocols include smoking cessation, immunizations, naloxone, TB testing, and just recently, hormonal contraceptives. New Mexico laws allow for statewide protocols to be issued through a regulatory process – in this case a collaborative one between the boards of pharmacy, nursing, and medicine. Their protocol for tobacco cessation includes all "FDA approved products for tobacco cessation," including nicotine replacement products, Chantix® and Zyban®.

New Mexico's Protocol

California

Pursuant to a bill passed in 2013, all licensed pharmacists in California may "furnish" prescription nicotine replacement products and devices for smoking cessation pursuant to the pharmacist following the statewide protocol and other regulations, which includes at least 2 hours of continuing education in smoking cessation.

California's Regulations

Idaho

Legislation passed this year in Idaho giving pharmacists the authority to prescribe smoking cessation medications. This authority is included directly in the definition of the practice of pharmacy and includes "any tobacco cessation product approved by the federal food and drug administration." This means medications beyond nicotine replacement products, like Chantix® and Zyban® can be prescribed by pharmacists.

Idaho's Bill

Arizona

Legislation passed in 2017 in Arizona to authorize licensed pharmacists, who have completed a training course, to prescribe and administer oral fluoride varnish or tobacco cessation medications (limited to nicotine replacement products) pursuant to rules adopted by the Board of Pharmacy.

Arizona's Bill

Maine

Also in 2017, Maine passed legislation that adds the "ordering and dispensing of over-the-counter nicotine replacement products" to the definition of the practice of pharmacy.

Maine's Bill

Colorado

After the passage of a bill in 2016 allowing for statewide protocols to be developed through the regulatory process, the Colorado boards of pharmacy, medicine and nursing have collaborated to develop protocols to allow Colorado pharmacists to prescribe hormonal contraceptives and soon also tobacco cessation products. The tobacco cessation protocol has been developed and includes nicotine replacement therapy, Zyban®, Chantix®, and combination therapies. According to the board of pharmacy website (linked below), more information is under development regarding this authority.

Colorado's Protocol

More Information on Tobacco Cessation and Statewide Protocols

Statewide Protocols

- For more information on statewide protocols, be sure to check out the report recently released by NASPA and the National Association of Boards of Pharmacy, Pharmacist Statewide Protocols: Key Elements for Legislative and Regulatory Authority.

Pharmacists and Smoking Cessation

- Pharmacists: Help Your Patients Quit Smoking – CDC resource with links for pharmacists to engage in a key role in the fight against tobacco use. This resource provides links to several handouts, fact sheets, free continuing education, and videos to aid pharmacists in helping their patients quit smoking.

Support for Pharmacists' Role in Tobacco Cessation

- Access to Tobacco Cessation Medication Through Pharmacists – this guide was developed by the Tobacco Control Network, an organization comprised of the tobacco control program managers and staff from each state and territorial health agency in the U.S. The guide highlights the role pharmacists can play in tobacco cessation. Of note, it was published before authority for pharmacist prescribing of tobacco cessation products was finalized

in 2017 for Arizona, Colorado, Idaho, and Maine.
- CMCS Bulletin on the Value of Pharmacist Prescribing – issued by the Center for Medicaid and Chip Services, this informational bulletin highlights the opportunity for pharmacists to help address public health needs– including pharmacist prescribing of tobacco cessation products.

Related

Read about states authorizing pharmacist-prescribed contraceptives here.

Categories: State Associations Tagged: pharmacist prescribing, smoking cessation, statewide protocol, statewide protocols, tobacco cessation

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Member Spotlight

Being a NASPA member helps me to envision the future of pharmacy by interacting with state, national and even international leaders in the profession. This contact allows me to help pharmacists in Kansas ready themselves for inevitable changes in the way they practice pharmacy.

Aaron Dunkel

Kansas Pharmacists Association

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States give pharmacists more prescriptive authority

July 14, 2015 **Share This Page**

Oregon is the latest to pass legislation allowing pharmacists to prescribe hormonal contraceptives

Oregon now joins California as the only other state that allows women to purchase hormonal contraceptives at a pharmacy without a doctor's prescription.

On July 6, Oregon Gov. Kate Brown signed HB 2879, legislation that gives pharmacists prescribing authority for some hormonal contraceptives after a woman completes a self-administered risk-screening test.

"It makes no sense that men should have unrestricted access to contraceptives, while women must first get a prescription from their physician," said Oregon Rep. Knute Buehler, an orthopedic surgeon who introduced HB 2879. "As a doctor, I believe birth control should be as easy and accessible as possible. If a woman wants to purchase birth control at her local pharmacy, she should be able to do that without having to schedule an appointment with a doctor."

California passed a similar law, SB 493, in 2013. The legislation allows pharmacists to initiate prescriptions for hormonal contraceptives and also gives them authority to prescribe other types of medications, such as nicotine replacement therapy. The protocols and state regulations for SB 493 are now entering the final stage. Jon Roth, CAE, CEO of the California Pharmacists Association, told ***Pharmacy Today*** in a June interview that by next quarter, pharmacists will be implementing SB 493.

Interpreting Oregon's new law

Oregon's law specifically states that pharmacists can prescribe hormonal contraceptives based on guidelines developed, and that they will need to be trained first to carry out this new duty.

"We're hopefully going to have the training program up and online by the beginning of November," said Lorinda Anderson, PharmD, BCPS, Pharmacy Instructor at Oregon State University, who is working with the Oregon Board of Pharmacy to put the training program together.

If all goes according to plan, Oregon pharmacists will be able to exercise their new prescribing authority beginning in January 2016.

The Oregon Health Authority and Oregon State Board of Pharmacy are responsible for structuring rules to ensure safe prescribing by pharmacists, creating a self-screening test for contraindications, and notifying the patient's primary care provider, according to Buehler's office. Contraceptives under the new law would still be covered by insurance.

However, Oregon pharmacists will be limited to prescribing oral and transdermal hormonal contraceptives. Gary DeLander, BSPharm, PhD, Oregon State Pharmacy Association President, said the association had hoped to include vaginal rings but was unsuccessful. He said the group may pursue the addition following successful implementation of the current statute.

Pushing greater access to contraceptives

In June, Brown signed another bill, which complements HB 2879, allowing women to pick up a 12-month supply of oral contraceptives in a single visit. Pharmacists could eventually be involved in initiating prescriptions under this law, according to Anderson. The law will also take effect next year.

The idea to improve contraceptive access has also gained traction on the federal level. Sens Cory Gardner (R-Colorado) and Patty Murray (D-Washington) have both introduced bills that would increase access to hormonal contraceptives.

However, what makes the bills in California and Oregon attractive is that a pharmacist has permission to prescribe following a protocol rather than merely making hormonal contraceptives OTC. This keeps professional oversight intact while also improving access.

California legislation SB 493 allows pharmacists to do more than initiate prescriptions for hormonal contraceptives. It also enables pharmacists to provide nicotine replacement therapy to patients, prescribe medications for travel abroad, and order tests to monitor and manage the efficacy and toxicity of drug therapies for patients with diabetes, hypertension, and other conditions.

“There is growing recognition across the U.S. that pharmacists are a perfect resource to enhance access to public health services due to their expertise in medications and wellness and their exceptional accessibility,” said Krystalyn Weaver, Director of Policy and State Relations for the National Alliance of State Pharmacy Associations.

She said they are seeing more and more states implementing policies giving pharmacists prescriptive authority for certain products important to public health, such as naloxone, smoking cessation products, hormonal contraceptives, and travel medications.

Oregon’s newly enacted provider status law also authorizes the Oregon Health Authority to work with the state Board of Pharmacy to establish statewide protocols, primarily for postdiagnostic clinical services such as smoking cessation and travel medicine.

Other states, including New Mexico and Idaho, also have statewide protocols giving pharmacists prescriptive authority for certain products.

Weaver said looking to pharmacists to provide a variety of health and wellness services is a perfect solution to improve health.

Loren Bonner, MA, Reporter

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