AGENDA

Florida Board of Pharmacy
Legislative Committee Meeting
October 3, 2017 – 10:15 a.m.

Rosen Plaza Hotel * 9700 International Drive * Orlando, FL 32819 * (407)996-9700

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
Irene Lake, Program Operations Administrator
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.

I. Presentation on “Pathways to Pharmacist Prescriptive Authority”

II. Discussion on Prescriptive Authority
1. NABP Task force
      i. Review state laws and regulations on pharmacists prescriptive authority
      ii. Review Relevant model state pharmacy act and model rules of the NABP language
      iii. Propose key messages that should be conveyed to boards of pharmacy, key stakeholders, and the public.
   b. Executive Committee Review of Recommendations
      i. More emphasis on prescriptive authority was needed rather than on collaborative practice.
   c. Recommendation:
      i. NABP to 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
2. APHA Article
   b. Hormonal contraceptives – now available in Oregon, California, New Mexico, Hawaii
3. New Mexico – 16.19.26
   b. http://164.64.110.239/nmac/parts/title16/16.019.0026.htm
c. Rules written to allow Vaccines, Tobacco Cessation, TB Testing, Naloxone, Hormonal Contraception, to be dispensed or administered given via prescriptive authority

4. NASPA article
   a. [Link](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.

III. 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, and 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. Remote Dispensing site pharmacies are excluded from this regulation.

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 Health 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.

IV. Emergency Management

1. Basis: During Hurricane Irma, concerns regarding necessity to utilize Mobile Pharmacy Units for both damaged locations as well as locations of high need (i.e. shelters or where no pharmacies are currently open). In addition, ability of Florida permit holders to utilize non-Florida licensed personnel during emergency situations.
   i. Discuss Role of DOH and BOP during emergency situations
   ii. Legislative Obstacles to emergency care/Access

2. We would recommend this authority to be provided to the governor at the outset of the issuance of the emergency orders so that organizations can deploy proper resources and make necessary plans to ensure the both manpower and materials are where they need to be when the time comes.

3. Potential Statutes to amend: 252.36 Emergency management powers of the governor

4. Attorney question: Does 252.926 permit non-Florida licensed personnel to provide services during emergency situations?
   i. 252.926 License and permits.—Whenever any person holds a license, certificate, or other permit issued by any state party to the compact evidencing the meeting of qualifications for professional, mechanical, or other skills, and when such assistance is requested by the receiving party state, such person shall be deemed licensed, certified, or permitted by the state requesting assistance to render aid involving such skill to meet a declared emergency or disaster situation, subject to such limitations and conditions as the governor of the requesting state may prescribe by executive order or otherwise.
Agenda

1. Describe the differences between collaborative practice, standing orders, and state wide protocols.

2. Discuss how these three mechanisms have facilitated patient access to medications and services including pharmacist prescribing.

3. Describe the work of the State Wide Protocol Workgroup and the set of policy recommendations they provided.
COLLABORATIVE PRACTICE AGREEMENTS (CPAs)

• Create a **formal practice relationship** between pharmacists and other health care practitioners, whereby the pharmacist assumes **responsibility for specific patient care functions** that are otherwise beyond their typical “scope of practice,” but aligned with their education and training.
  • can include initiation and modification of drug therapy
  • extent of the services authorized under the CPA depends on the state’s statutory and regulatory provisions for CP authority

• State laws and regulations authorizing CPAs are highly variable.
  A. Only specific practitioners able to participate
  B. Restriction on services that may be provided
  C. Extensive logistical barriers that limit the utility of such agreements
Continuum of Pharmacist Prescriptive Authority

Collaborative Prescribing

- **Patient-Specific CPA**
  - Requires a partnering prescriber
  - Voluntarily negotiated
  - Applies to individual patients
    - Require patients listed in agreement
    - Limited to patient panel of collaborating prescriber
    - Limited to post-diagnostic care
  - Multi vs. single prescriber
  - Used for chronic disease management

- **Population-Specific CPA**
  - Requires a partnering prescriber
  - Voluntarily negotiated
  - Applies to patient populations
    - Naturally inclusive of patient-specific
  - Promotes consistency in service provided within the pharmacy
  - Used for **acute** OR chronic disease management **OR** preventive care/public health

Autonomous Prescribing

- **Statewide Protocol**
- **Unrestricted (Category-Specific)**

Most Restrictive

Least Restrictive

Support for Broad Collaborative Authority

Policy Considerations from the National Governors Association (01/2015)

- Enact broad collaborative practice provisions that allow for specific provider functions to be determined at the provider level rather than set in state statute or through regulation.
- Evaluate practice setting and drug therapy restrictions to determine whether pharmacists and providers face disincentives that unnecessarily discourage collaborative arrangements.
- Examine whether CPAs unnecessarily dictate disease or patient specificity.

Continuum of Pharmacist Prescriptive Authority

Differentiating the Terminology

- **Standing orders** - usually prescribe the actions to be taken in caring for patients related to *specific conditions or procedures*. Typically physician’s order that can be carried out by other health care workers when predetermined conditions have been met.

- **Protocols** - sets of *predetermined criteria* that define appropriate interventions and describe situations in which the health care professional (pharmacist) makes *judgments* relative to a *course of action* for effective *management of common patient problems*.

- **Statewide protocols** - similar to CPAs in that a statewide protocol enhances a pharmacist’s ability to perform patient care services, within *defined parameters*, to improve public health.
Statewide Protocol Further Defined

• The term **statewide protocol** refers to a framework that specifies the conditions under which pharmacists are authorized to prescribe a specified medication or category of medications when providing a clinical service.
• Statewide protocols are **issued by an empowered state body** pursuant to relevant state laws and regulations.
• Each protocol specifies the **required training or qualifications** for pharmacist participation and the **procedures that must be followed**.
• Generally, statewide protocols **address public health problems** and are used for patient care needs that do not require a diagnosis or for which a documented diagnosis is known or readily obtainable.

Opioid Crisis – A Catalyst for Change

**Widening the net of naloxone prescribers**

• Initially - Harm reduction organizations partner with friendly doctors.
• Doctors not always available when participants want naloxone; organizations not always able to legally distribute naloxone to clients who need it.
• Locales eliminate this barrier by using a “standing order” model.
• States begin issuing statewide standing orders for naloxone. [NC 2012]
• PA - Statewide standing order model allows for pharmacists in the state to dispense naloxone under Physician General Rachel Levine’s standing order. It has increased the availability and accessibility of naloxone by allowing anyone to walk into their local pharmacy and buy the medication.
Naloxone Access in Community Pharmacies

Based on data collected by NASPA (updated June 2017)

Continuum of Pharmacist Prescriptive Authority

Collaborative Prescribing

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<tr>
<th>Level</th>
<th>CPA Type</th>
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<tr>
<td>Most Restrictive</td>
<td>Patient-Specific CPA</td>
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Autonomous Prescribing

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<tr>
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Statewide Protocols (SWPs)

Adopt evidence-based guidelines with the goal of improving patient care and clinical outcomes.

- Any pharmacist who meets the qualifications specified in the protocol can implement it into practice without requiring an individual prescriber such as a physician.

- The necessary skills to provide such services are often those a pharmacist already attained as part of the education provided during pharmacy school.

- Prescribe medications for conditions or tests that are simple to diagnose or require no diagnosis (typically preventive care.)

- Protocols have been implemented for hormonal contraceptives, travel medications, smoking cessation products, and tuberculosis testing, among others. Recently AZ enacted SWP allowing RPhs to prescribe Fluoride.
33+ SWP Applications

Statewide Protocol vs. Statewide Standing Order
Autonomous Prescribing

Statewide Protocol

- Does not require a partnering prescriber
- Issued by an authorized body of the state (e.g. take it or leave it)
- Apply to patient populations
- Promotes consistency in service provided across state
- Currently used for preventive care/public health

Unrestricted (Category-Specific)

- Does not require a partnering prescriber
- No restriction on authority (except for clinical guidelines)
- No explicit restriction on patient populations
- Promotes consistency in service provided across the state
- Currently used for preventive care/public health

Prescribing Under a Statewide Protocol* or Unrestricted (Category-Specific) Authority

Based on data collected by NASPA (updated August 2016)

*Includes statewide standing orders
Leading up to the workgroup

Pharmacist Collaborative Practice Agreements: Key Elements for Legislative and Regulatory Authority (NASPA Workgroup, July 2015)

NABP Task Force on Pharmacist Prescriptive Authority (September, 2015)

NASPA/NABP Convened Meeting on Statewide Protocols for Pharmacist Prescribing (March, 2016)

NASPA/NABP Convened Stakeholders Meeting: SWPs for Pharmacist Prescribing

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<tr>
<th>Name</th>
<th>Title</th>
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<tbody>
<tr>
<td>Alex Adams</td>
<td>Executive Director</td>
<td>Idaho State Board of Pharmacy</td>
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<td>Joe Bryant</td>
<td>CDR, U.S. Public Health Service</td>
<td>United State Public Health Services</td>
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<tr>
<td>Phil Burgess</td>
<td>Board Member</td>
<td>Community Pharmacy Foundation</td>
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<tr>
<td>Anne Burns</td>
<td>Vice President, Professional Affairs</td>
<td>American Pharmacists Association</td>
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<tr>
<td>Carmen Catizone</td>
<td>Executive Director</td>
<td>National Association of Boards of Pharmacy</td>
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<tr>
<td>Chris Decker</td>
<td>Executive Vice President &amp; CEO</td>
<td>Pharmacy Society of Wisconsin</td>
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<tr>
<td>Chris Jones</td>
<td>Lead Health Scientist</td>
<td>Centers for Disease Control and Prevention</td>
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<tr>
<td>Fiona Karbowicz</td>
<td>Pharmacist Consultant</td>
<td>Oregon State Board of Pharmacy</td>
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<td>Anne Marie Kondic</td>
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<tr>
<td>Eileen Lewalski</td>
<td>Professional Affairs Senior Manager</td>
<td>National Association of Boards of Pharmacy</td>
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<tr>
<td>Dan Luce</td>
<td>National Director, Pharmacy Affairs</td>
<td>Walgreens Boots Alliance</td>
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<tr>
<td>Ed McGinley</td>
<td>President</td>
<td>National Association of Boards of Pharmacy</td>
</tr>
<tr>
<td>Ribita Merai</td>
<td>Health Scientist</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>Lisa Kroon</td>
<td>Professor and Chair</td>
<td>University of California, San Francisco</td>
</tr>
<tr>
<td>Sonia Pandit</td>
<td>Senior Policy Analyst</td>
<td>National Governors Association</td>
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<tr>
<td>Jon Roth</td>
<td>Chief Executive Officer</td>
<td>California Pharmacists Association</td>
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<tr>
<td>David Searle</td>
<td>Director, Pharmacy Development</td>
<td>Pfizer, Inc</td>
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<tr>
<td>Rebecca Sneed</td>
<td>Executive Vice President &amp; CEO</td>
<td>National Alliance of State Pharmacy Associations</td>
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<tr>
<td>Krystalyn Weaver</td>
<td>VP, Policy &amp; Operations</td>
<td>National Alliance of State Pharmacy Associations</td>
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Different SWP Approaches Considered

Focus of the meeting was on states that recently attained authority to issue statewide protocol for products other than immunizations and naloxone.

• CA - conditions and product classes include hormonal contraceptives, nicotine replacement therapy, immunizations, and travel medications. A protocol must be approved first by the state pharmacy board and then by the state medical board.

• OR - pharmacist authorized to prescribe and dispense hormonal contraceptives. A second SWP bill authorized the Oregon Health Authority to develop protocols that would then be adopted by the Board of Pharmacy.

• ID - the definition of the practice of pharmacy includes an exclusive list of pharmaceuticals that pharmacists may prescribe. Unlike the typical statewide protocol, this authority is not tied to a specific protocol or parameters which the pharmacist must follow but rather relies on the pharmacists’ clinical judgment with respect to clinical guidelines. This construct can be described as “unrestricted, category-specific prescriptive authority.”

Result: Need for National Recommendations

1. Statewide Protocol Policy Elements and Model Language

Phase 1: Develop a consensus-based document outlining the model elements of state policies for statewide protocol authority. The report will include a delineation between collaborative practice agreements and statewide protocols and clearly articulate that the elements can be adapted to fit the definitions and construct of individual states’ laws and regulations. *This work is to be done by a group of stakeholders through a consensus-based process.*

Phase 2: Develop model legislative and/or regulatory language based on the consensus based elements developed in Phase 1. *This work is to be done by content experts as part of a working group, informed by the guiding principles of the consensus document.*
Result: Need for National Recommendations

2. Model Statewide Protocols Development

Phase 1: Develop a template for the elements that should be included in a statewide protocol for pharmacist prescriptive authority.

Phase 2: Develop examples of specific statewide protocols (e.g., hormonal contraceptives, smoking cessation medications, vaccines, etc.) that can be implemented by state policy makers with the authority to issue statewide protocols for pharmacist prescribing. This work is to be done by content experts as part of a working group, informed by the guiding principles of the consensus document. The working group will review and leverage existing protocols when available.

Meeting participants agreed that SWPs present a unique opportunity for pharmacists to address public health needs. They encouraged pharmacy stakeholders and public health advocates to work together to increase state policy makers’ awareness of SWPs as a policy option, to facilitate standardization in the legislative authority and statewide protocols used, and to pursue the above recommendations to achieve this goal.

Statewide Protocol Workgroup

Convened by:

• National Alliance of State Pharmacy Associations and

• National Association of Boards of Pharmacy

Initial Call: August 30, 2016

Assignment: Achieve Phase 1 Recommendations
Statewide Protocols Workgroup

- Modified Delphi method used by workgroup to reach consensus on each of the elements discussed

1. Level-setting conference call (August 30, 2016)
2. Distribution of survey with 3 weeks to complete
3. Collect and compile survey results
4. Call to discuss differences of opinions
5. Repeated 2-4 until consensus was reached

Decision-Making Criteria for Workgroup:

- Is this policy what is best for patients and patient care?
- Does this policy facilitate patient access to needed services?
- Is this policy aligned with pharmacists’ current (or feasibly attainable) education and training?
- Does this policy create an unnecessary barrier for implementation?
- Does this policy create an unnecessary barrier for pharmacists that is not imposed on other health professionals?

Workgroup Recommendations

Statewide Protocol vs. Statewide Standing Order

The workgroup recommended that **statewide protocols** are preferable over statewide standing orders and other approaches to make certain products or categories of products available from pharmacists.
The workgroup recommended that the initial authorizing legislation for pharmacist statewide protocols should be general and allow for the specific medications and/or categories of medications to be determined in the regulatory process.

By what state body will protocols be issued?

- Board of Pharmacy
- State Health Department
- Board of Medicine
- Joint Regulation

The workgroup recommended that the state board of pharmacy be the state body primarily responsible for issuing pharmacist statewide protocols. Additionally, the state department of health should be authorized to issue pharmacist statewide protocols for public health needs.
The workgroup recommended that state laws and regulations governing pharmacist statewide protocols be silent with regards to delegation to non-pharmacist staff. The workgroup recommended that state laws and regulations be silent with regards to practice settings where pharmacist statewide protocols could be implemented.

Components of protocols

- The medications or categories of medications included in the protocol.
- Pharmacist training or qualifications required for the pharmacist to use the statewide protocol. (Training/qualifications vary based on the clinical application of the protocol and could include primary training and/or continuing education. Some may be as simple as a state pharmacy license or education that may have been obtained in the pharmacy curriculum.)
- Procedures:
  - Patient inclusion criteria.
  - Requirements for documentation and maintenance of records.
  - Communication requirements (such as notification to the primary care provider).
- The workgroup recommended that product selection decisions, within protocols for categories of medications, should be left to the pharmacist based on their application of clinical judgement to available evidenced based guidelines.
What’s next?

Statewide Protocol Workgroup report is available at
https://naspa.us/resource/swp/

CMS Endorsement of Pharmacist Prescribing

State flexibilities in expanding the ability of pharmacists to prescribe...for certain medications may be effective at helping to address [public health] issues by improving access to care.
| Bill       | Progress          | Summary                                                                 | Comments                                                                 | Sub Category          | SWP/SWGO/ERP Prescribing | General Authority | Tobacco Cessation | Emergency Refills | Roundup Receipts | Contraceptives | TB Tests | Immunizations | Naloxone |
|-----------|-------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|-----------------------|--------------------------|---------------------|------------------|-------------------|------------------|-----------------|----------|----------|------------|----------|
| Arizona HB 1299 | Approved Effective 9/1/2017 | Pharmacists: scope of practice.  
RPh prescribing for emergency refills; tobacco cessation products (nicotine replacement products only), oral | Statewide Protocols  
RPh Prescribing | x x x | Statewide Protocols  
RPh Prescribing |
| Idaho HB 883 | Approved Effective 7/1/2017 | Amends and adds to existing law to provide that prescribing tuberculosis purified protein  
Pharmacist prescribing, administering and interpreting of TB tests | Statewide Protocols  
RPh Prescribing | x | Statewide Protocols  
RPh Prescribing |
| Idaho HB 894 | Approved Effective 7/1/2017 | Amends and adds to existing law to provide that prescribing tobacco cessation products is  
Pharmacist prescribing tobacco cessation products, including Chantix and Zyban | Statewide Protocols  
RPh Prescribing | x | Statewide Protocols  
RPh Prescribing |
| Idaho HB 1381 | Approved Effective 7/1/2017 | Amends existing law to provide that pharmacists may mail certain prescriptions as  
Allows board of pharmacy to issue statewide protocols for pharmacist prescribing | Statewide Protocols  
RPh Prescribing | x | Statewide Protocols  
RPh Prescribing |
| Indiana HB 1540 | Approved Effective 7/1/2017 | Allows the state health commissioner or a designated public health authority who is a  
adds to the list of immunizations that a pharmacist may  
administer pursuant to a protocol. Allows for CPAs with | Immunization  
Statewide | x | Immunization  
Statewide |
Allows for pharmacists to “order and dispense” OTC nicotine replacement products. | Statewide Protocols  
RPh Prescribing | x | Statewide Protocols  
RPh Prescribing |
| Maryland HB 787 SB 421 | Approved Effective 7/12/2017 | For the purpose of authorizing a pharmacist who meets the requirements of certain  
“prescribe and dispense” birth control | Statewide Protocols  
RPh Prescribing | x | Statewide Protocols  
RPh Prescribing |
| New Hampshire HB 264 (SR 32) | Approved Effective 7/25/2017 | New Title establishing a commission to study  
allowing pharmacists to prescribe or make | Creates a study regarding pharmacists prescribing birth control. | Statewide Protocols  
**Study** | x | Statewide Protocols  
**Study** |
| New Jersey AS 295 SB 1334 (S 163) | Approved Effective 6/9/2017 | This bill would expand public access to opioid antitoxins, such as naloxone hydrochloride, by  
Statewide standing order for naloxone | Statewide Protocols  
SWGO | x | Statewide Protocols  
SWGO |
| Oregon HR 2397 | Approved Effective 6/9/2017 | Limits term of committee members to two years. Directs State Board of Pharmacy to  
Creates an advisory committee that may create a  
formulary of drugs that pharmacists may prescribe and | Statewide Protocols  
RPh Prescribing | x | Statewide Protocols  
RPh Prescribing |
| Virginia HB 2793 | Approved Effective 7/1/2017 | Provides that a pharmacist may dispense naloxone in the absence of a patient specific  
Codifies the naloxone standing order issued in 2016 | Statewide Protocols  
SWGO | x | Statewide Protocols  
SWGO |

Pathways to Pharmacist Prescriptive Authority

Thank You! !

American Association of Colleges of Pharmacy (AACP)

National Association of Boards of Pharmacy (NABP)