PHARMACIST STATEWIDE PROTOCOLS: KEY ELEMENTS FOR LEGISLATIVE AND REGULATORY AUTHORITY

A REPORT OF THE STATEWIDE PROTOCOL WORKGROUP
CONVENED BY THE NATIONAL ALLIANCE OF STATE PHARMACY ASSOCIATIONS
AND THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

March 2017

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BACKGROUND ON STATEWIDE PROTOCOLS

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.[1] Statewide protocols are issued by an authorized state body pursuant to relevant state laws and regulations. Each protocol specifies the qualifications required for pharmacists to implement the protocol and the procedure(s) that must be followed. Generally, statewide protocols address identified public health problems and are used for patient care needs that do not require a new diagnosis or for which a documented diagnosis is known or readily available.

Statewide protocols are sometimes compared to or equated with collaborative practice agreements, which allow pharmacists and prescribers to enter an agreement that authorizes the pharmacist to initiate, modify, or discontinue drug therapy for patients or patient populations defined in the agreement. However, the substantive difference is that statewide protocols are issued by an authorized state regulatory body, whereas collaborative practice agreements are developed and implemented between individual or groups of prescribers and pharmacists. Additionally, because statewide protocols allow all licensed pharmacists in the state who meet the qualifications specified in the protocol to implement it into practice, it allows for broader applicability in care delivery across the state and may more effectively address significant public health needs.

Because statewide protocols facilitate pharmacists' ability to perform patient care services, within defined parameters, they can be used by states to address significant public health needs. For example, existing statewide protocols promote access to important vaccines, naloxone for opioid overdose, hormonal contraceptives, travel medications, and tobacco cessation medications, among others.

RELATED APPROACHES

Currently, states have a wide range of policies that utilize the expertise and accessibility of pharmacists to increase access to medications important for public health. In addition to statewide protocols that are consistent with the above definition, variations such as statewide standing orders, statewide collaborative practice agreements, and allowances for a specified medication to be "dispensed without a prescription" are in place.

Statewide standing orders and/or statewide collaborative practice agreements are issued by a specific prescriber (e.g., in Pennsylvania, the statewide standing order for naloxone is issued by the Physician General) for use by all pharmacists in the state. These are distinct from more traditional collaborative practice agreements and standing orders since a pharmacist does not need to identify an individual collaborating prescriber. When a medication is dispensed under these authorities, the person who issued the agreement or standing order is commonly indicated on prescriptions as the prescriber, even

[1] Note that existing state law varies regarding the terminology used to describe this activity. Currently, there are states that also use the terms furnish or initiate, rather than prescribe, to describe the act of making the medication available to an appropriate patient.

though a pharmacist assesses patients to determine if it is clinically appropriate for them to receive the medication.

Additionally, there are a limited number of examples where state laws or regulations authorize a medication to be “dispensed without a prescription.” This approach is uncommon and can cause barriers including issues with insurance coverage.

PROJECT OVERVIEW

An increasing number of states are considering the implementation of policies related to statewide protocols and statewide standing orders. The lack of contemporary and available resources for policy makers, state boards of pharmacy, or state pharmacy associations on this topic, prompted the National Alliance of State Pharmacy Associations and the National Association of Boards of Pharmacy to collaborate in this project to meet this need.

Initially, a meeting of stakeholders was convened in March 2016 to examine the issue and make recommendations for resource needs and the process for development. In addition to general support for the concept, meeting participants developed the following recommendations for next steps:

Summary Recommendations for Next Steps

In order to increase awareness and to assist states in implementing new policy, the following recommendations were developed by meeting participants:

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.*

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.) to serve as templates 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.*

Overall, meeting participants agreed that statewide protocols 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 statewide protocols 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.

In response to the stakeholders' recommendations, NASPA and NABP convened the Statewide Protocol Workgroup to achieve the phase 1 recommendations. The workgroup was charged with the development of model elements of state policies for statewide protocol authority and a template for the elements that should be included in a statewide protocol. Using a modified Delphi-method (see Appendix B), the Statewide Protocol Workgroup conducted this work with the following key questions in mind:

- 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?

The following is a report of the workgroup's recommendations.

WORKGROUP RECOMMENDATIONS

GENERAL APPROACH

The workgroup first broadly considered which of the existing approaches—statewide protocols, statewide standing orders, or authority to "dispense without a prescription"—is best for ensuring patient access, through pharmacists, to public health services.

> **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 recommendation was supported by the possibility that a prescriber who issues a statewide standing order, or statewide collaborative practice agreement, may change positions and thus cause a need for more frequent changes to the policy than if a protocol is issued by an empowered state body. There was also concern expressed with the liability that may fall upon the single prescriber who issues a statewide standing order or statewide collaborative practice agreement, which may serve as a deterrent to uptake.

SPECIFICITY OF AUTHORITY

To date, statewide protocol authority has been introduced in state legislatures using one of two types of legislation. The first type describes the specific medication or category of medications for which a specified state body is authorized to issue a statewide protocol. Examples of the first, more specific, type of legislation have been passed in states such as California, North Dakota, and Vermont. The second type of legislation authorizes the state body to issue protocols to address public health needs. Examples of the second, more general, type of legislation have been passed in Colorado, Idaho, New Mexico, and Oregon.

> **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.**

The workgroup discussed that by allowing for more flexibility at the legislative level, the state body issuing protocols could be more responsive to the public health needs of the state.

AUTHORIZED STATE BODY

Current state laws and regulations are highly variable regarding which state body is authorized to issue statewide protocols for pharmacists. In some states, it is just one state body, such as the Board of Pharmacy or the State Health Department. In other states, several bodies must approve the protocol. In Colorado, protocols need to be approved by the Colorado Medical Board, Colorado Board of Nursing, and the State Board of Pharmacy. In Oregon, the protocol is to be developed by the Oregon Health Authority and adopted by rule by the Board of Pharmacy. Currently, no states thus far have been identified that issue protocols solely from a body other than the board of pharmacy or the health department.

> **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.**

During discussion, it was recognized that input from a variety of stakeholders is valuable during the statewide protocol development process. However, it was also emphasized that state laws requiring approval of protocols by multiple boards or agencies could create significant delays in the implementation of a protocol—thus delaying patient access. However, it was acknowledged that input from a variety of stakeholders is valuable and input should be sought during the development process. The board of pharmacy was felt to have the optimal understanding of pharmacy practice and pharmacists' education and training. Thus the board of pharmacy is in best position to appropriately

issue protocols. By also empowering the state department of health, it would enable those public health professionals to respond to urgent public health needs.

NON-PHARMACIST STAFF ROLE

No state currently (explicitly) allows for services authorized under a statewide protocol to be delegated to another individual. One state, Connecticut, included language in their provisions which specifies that the pharmacists' authority to prescribe naloxone could not be delegated.

> **The workgroup recommended that state laws and regulations governing pharmacist statewide protocols be silent with regards to delegation to non-pharmacist staff.**

It was discussed that the duties of pharmacy staff members and the specific authorities that may be delegated to them are included in other areas of the law. It was acknowledged that there may be administrative roles associated with statewide protocols that pharmacy technicians can fulfill, such as filing appropriate paperwork. The importance of engaging supervised student pharmacists in all areas of pharmacy practice was also supported by the workgroup.

PRACTICE SETTING

One state, Maryland, explicitly allows for their authority (in this case a statewide standing order for naloxone) to be used at mail order pharmacies. This includes the ability for mail order pharmacies in other states providing naloxone for Maryland residents; provided the pharmacy employs a Maryland licensed pharmacist and ensures compliance with all laws and regulations in the pharmacy's resident state. All other states are silent on practice setting within their statewide protocol authority (note that there may be restrictions on pharmacy practice generally in other areas of the law).

> **The workgroup recommended that state laws and regulations be silent with regards to the practice settings where pharmacist statewide protocols could be implemented.**

During discussion, it was noted that there should not be restrictions on practice setting in the laws and regulations authorizing statewide protocols. Instead, any pharmacy practice setting where it is clinically appropriate for a statewide protocol to be implemented, should be able to do so.

COMPONENTS OF THE PROTOCOL

Participants reviewed the components of statewide protocols currently in place, which are inconsistent and variable in the degree of specificity included. The following recommendation was developed to serve as a guide during the protocol development phase. Consistent with the above recommendation that the initial authorizing legislation should not be specific to a medication or medication class, it is not recommended that these elements be included in legislation authorizing statewide protocols generally. Instead, these components should be included in regulation or guidance from the board of pharmacy.

> **The workgroup recommended that the following core components be included in the design of pharmacist statewide protocols:**
>
> - **The medications or categories of medications included in the protocol.**
> - **Training or qualifications required for licensed pharmacists to implement the statewide protocol. (Training/qualifications vary based on the clinical application of the protocol and could include further training, such as continuing education, in addition to educational experiences obtained through pharmacy school curricula).**
> - **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 that apply to categories of medications, should be left to the pharmacist based on their application of clinical judgement and/or available evidenced based guidelines.

ENSURING IMPLEMENTATION AND PATIENT ACCESS

It was acknowledged that payment and insurance coverage for the products and services provided by a pharmacist pursuant to a statewide protocol are critical for ensuring adequate patient access and impact on public health needs. Insurance policies should allow these products and services provided by pharmacists to be covered in the same manner as they are when provided by other health care professionals. Policy makers should consider whether state laws or regulations need to be modified to ensure that payment and insurance coverage are available and equitable for the products and services rendered by a pharmacist under a statewide protocol.

The key to ensuring insurance coverage of a prescription medication is the generation of a prescription order. State laws and regulations regarding the creation of a prescription order are variable. These provisions should be examined to ensure that a valid prescription order is generated and subsequently submitted to and covered by an insurance provider pursuant to a statewide protocol. Policy makers, including boards of pharmacy, should consider if guidance is needed to assist clinicians in understanding how to implement statewide protocols, particularly around the pharmacist being listed as the prescriber on the prescription generated under a statewide protocol.

APPENDIX A: WORKGROUP PARTICIPANTS

The individuals listed below were invited to participate in the Statewide Protocol Workgroup based on their experience with statewide protocols, their participation in the initial stakeholder meeting on statewide protocols, or their knowledge and expertise in state pharmacy and health policy.

Participants were asked to provide their own professional perspectives on the topic under consideration. Participants from the national pharmacy associations were not acting in an official capacity on behalf of their organizations but rather as individuals whose experiences with their various memberships provide them with an informed perspective.

Name	Organization/State
Alex Adams	Idaho State Board of Pharmacy
Jason Ausili	National Association of Chain Drug Stores
Lynette Bradley-Baker	American Association of Colleges of Pharmacy
CDR Joe Bryant	United States Public Health Service
Phil Burgess	Community Pharmacy Foundation
Anne Burns	American Pharmacists Association
Kelly Fine	Arizona Pharmacists Association
Kate Gainer	Iowa Pharmacy Association
Ronna Hauser	National Community Pharmacists Association
Lisa Kroon	University of California San Francisco
Danielle Laurent	Pharmacy Society of Wisconsin
Dan Luce	Walgreens Boots Alliance
Christina Martin	American Society of Health-System Pharmacists
Ed McGinley	National Association of Boards of Pharmacy
Dianne Miller	Michigan Pharmacists Association
Mary Jo Carden	Academy of Managed Care Pharmacy
Jon Roth	California Pharmacists Association
David Searle	Pfizer, Inc
Pete Vlasses	Accreditation Council for Pharmacy Education
Marc Watt	Oregon State Board of Pharmacy
Edwin Webb	American College of Clinical Pharmacy

APPENDIX B: MODIFIED DELPHI METHOD

The goal of the workgroup was to reach consensus on each of the elements discussed. To do this, a modified Delphi-method was used.[2] A survey was sent to all participants to collect their initial thoughts on each of the elements identified in currently existing statewide protocol laws and/or regulations. Participants were given the current variations of each element as a multiple-choice selection with the opportunity to answer in free form text if the desired option was not listed. After completion of the survey, the workgroup discussed all questions where consensus was not already reached via conference call. The conference call discussions were structured to have a defined period for discussion, followed by a summary of the current options being discussed, and a roll call vote by each of the participants. The item was included on the next survey if consensus was not reached on the conference call. This process was repeated a total of three times before the group reached consensus on all items being considered. See below for a diagram of the process used.

[2] Hsu C, Sandford B. 2007. The Delphi Technique: Making Sense of Consensus. PARE. [accessed January 26, 2017] 12(10). http://pareonline.net/getvn.asp?v=12&n=10.

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NASPA and NABP would like to thank Pfizer for their sponsorship which helped to make this work possible.