Pathways to Pharmacist Prescriptive Authority

District 1 and 2 Meeting
Groton, CT
September 16, 2017

Presented by: Ed McGinley

Learning Objectives

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.
Attendance Code

To obtain CPE credit for this activity, you are required to actively participate in this session. The attendance code is needed to access the evaluation and CPE form for this activity. Your CPE must be filed by **October 31, 2017** in order to receive credit.

Disclosures

*Neither Krystalyn Weaver nor I have actual or potential conflict of interest; a vested interest in or affiliation with any corporate organization offering any type of financial support or grant monies for this meeting, or this continuing education activity.*
Collaborative Practice Agreements (CPAs) are

A. An informal delegation of authority from a pharmacist to a pharmacy technician
B. A formal relationship where a physician delegates authority to a pharmacist under negotiated conditions
C. An informal collaboration between a physician and a pharmacist
D. An agreement between a patient and pharmacist to conduct patient visits regularly

Self Assessment Questions

• How many states currently have a Collaborative Practice Agreement of some kind in place?

A. 36
B. 25
C. 48
D. 19
Self Assessment Questions

Which of the following are the most restrictive model of pharmacist prescribing?
A. Statewide protocol
B. Category Specific Authority
C. Patient-Specific Collaborative Practice Agreement
D. Population-Specific Collaborative Practice Agreement

Self Assessment Questions

Standing Orders (SOs) are the most prevalent mechanism for access to Naloxone
A. True
B. False

Statewide Standing Orders (SWSOs) differ from (SOs)
A. True
B. False
Self Assessment Questions

The following are all examples of existing statewide protocols, except:

A. immunizations
B. smoking cessation products
C. flu treatments
D. contraceptives

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
COLLABORATIVE PRACTICE AGREEMENTS (CPAs)

• 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
- Population-Specific CPA

Autonomous Prescribing
- Statewide Protocol
- Unrestricted (Category-Specific)

Most Restrictive
Least Restrictive

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

States with CPA laws
- 48
- 4 Limited to inpatient settings
- 36 Allows initiation of medications in outpatient settings
- 19 Patient-specific
  - 17 Population-specific
  - 9 Prevent initiation of medications
  - 8 Limited to one prescriber
  - 11 Allow multiple prescribers

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.

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**Naloxone Access in Community Pharmacies**

Based on data collected by NASPA (updated June 2017)

| Statewide Protocol/Pharmacist Prescribing | 10 |
| Statewide Standing Order | 11 |
| Dispense without a prescription | 5 |
| Standing Order | 22 |
| None | 2 |
Continuum of Pharmacist Prescriptive Authority

**Collaborative Prescribing**
- Patient-Specific CPA
- Population-Specific CPA

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


Statewide Protocols 101

- Statewide authority
- Allows pharmacists to prescribe
- Address public health goals
- Do not require differential diagnosing
- New Mexico, 2004
- California, 2013
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.

SWP Applications

33+

Naloxone (11)  Immunizations (17)
General Authority (3)  Smoking Cessation (2)
TB Testing (1)  Contraceptives (2)
Fluoride (1)  Epinephrine (1)
Limited Formulary (1)
## Statewide Protocol vs. Statewide Standing Order

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<th>Unrestricted (Category-Specific)</th>
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## 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

*Includes statewide standing orders

Based on data collected by NASPA (updated August 2016)

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

Leading up to the workgroup

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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<thead>
<tr>
<th>Name</th>
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<td>Alex Adams</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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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

SWP Workgroup Participants

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<td>Lynette Bradley-Baker</td>
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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.