

Optimization of Pharmacy Practice: Current status and trends

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Topics

- Collaborative Practice Agreements (CPA's)
- Statewide Protocols
- Administration of medications beyond immunizations
- Update on Pharmacy Provider Status at the Federal and State Level



Learning Objectives

- Discuss key elements of collaborative practice agreement (CPA) legislative and regulatory authority.
- Discuss emerging areas of pharmacists' practice addressing public health needs including statewide protocols.
- Define provider status at the federal and state levels.
- Identify examples of state level successes in the three areas of state level provider status.



About NASPA

The National Alliance of State Pharmacy Associations (NASPA), founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.



Collaborative Practice Agreements



Collaborative Practice Agreements

- Creates formal relationship between pharmacists and physicians or other providers
- Defines certain patient care functions that a pharmacist can autonomously provide under specified situations and conditions
- Many are used to expand the depth and breadth of services the pharmacist can provide to patients and the healthcare team



Components of a CPA Authority

Statute/Regulations

- Define collaborative practice authority and restrictions
- HIGHLY variable

Agreement

- Defined by collaborating practitioners
- Defines the conditions of the relationship, delegation of authority/expansion of scope, defines the parties
- Legal document

Protocol

- Defines the clinical parameters for the provision of care
- Varying degrees of detail
- May or may not be required by state laws/regulations



Existing Landscape

- Collaborative practice authority: 48 states
 - Proposed in AL and in the works in DE
- Pharmacist modification of therapy: 45 states
- Pharmacist initiation of therapy: 39 states
- Allow multiple pharmacists on one agreement: 25 states
- Many other parameters...



Elements Currently in State Law

Services/Authority

- Modify therapy
- Initiate therapy
- Physical assessment
- Order labs
- Interpret labs
- Perform lab tests

Requirements

- Continuing education requirements
- Pharmacist qualifications
- Liability insurance

Restrictions

- Disease state
- Site of practice
- Drug

Who involved

- # of pharmacists
- # of prescribers
- # of patients
- Types of prescribers
- Relationship between patient and prescriber
- Pharmacist to prescriber ratio

Procedural requirements

- Patient involvement
- Agreements approved or reported to whom
- Length of time agreement valid
- Payment provisions
- Documentation
- Physician review



Support for Collaborative Agreements

- Policy Considerations from the National Governors Association
 - 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.



NGA PAPER

The Expanding Role of Pharmacists in a Transformed Health Care System



PHARMACIST COLLABORATIVE PRACTICE
AGREEMENTS:
KEY ELEMENTS FOR LEGISLATIVE AND
REGULATORY AUTHORITY

A REPORT OF THE COLLABORATIVE PRACTICE WORKGROUP
CONVENED BY THE NATIONAL ALLIANCE OF STATE PHARMACY ASSOCIATIONS

July 2015

Collaborative Practice Workgroup

Convened by the National Alliance of State Pharmacy Associations



Workgroup Objective

- Develop a set of elements that are considered to be the best practice for inclusion in collaborative practice provisions
- Developed through a consensus based process by a panel of experts convened by NASPA
- Can then be used as a resource for those advocating for changes to their collaborative practice provisions in their state



Committee Participants

State/National	Organization	Name
National	NACDS	Alex Adams
National	APhA	Anne Burns
National	NCPA	Carolyn Ha
National	ASHP	Douglas Scheckelhoff
National	ACCP	Ed Webb
National	AACP	Lynette Bradley-Baker
National	ACPE	Pete Vlasses
National	NABP	Scotti Russell
National	AMCP	Susan Oh
State	Iowa	Anthony Pudlo
State	South Carolina	Bryan Ziegler
State	Maryland	Christine Lee-Wilson
State	Michigan	Dianne Miller
State	Pennsylvania	Jennifer Bacci
State	Minnesota	Julie Johnson
State	Arizona	Kelly Ridgway
State	Alaska	L. Michelle Vaughn
State	Arizona	Sandra Leal



Process: Developing Recommendations

- Step 1: Examine existing authority
- Step 2: Make recommendations; based on:
 - Is this recommendation in the best interest of the patient receiving care under a collaborative agreement?
 - Is this recommendation aligned with pharmacists' education and training?



Process: Modified Delphi Method

1. Level-setting conference call

2. Distribution of survey with 3 weeks to complete

3. Collect and compile survey results

4. Call to discuss differences of opinions

5. Repeat 2-4 until consensus is reached



Workgroup Recommendations

Participants

- Which providers?
- Which patients?

Authorized services

- What can be done under the agreement?

Requirements and Restrictions

- Logistics
- Education
- Others



Workgroup Recommendations

Included in Laws and Regulations

Framework should be flexible to facilitate innovation in care delivery

Decided by Individual Providers

Safeguards should be established to ensure optimal patient care



Participants

Included in Laws and Regulations

- Any prescriber may collaborate with pharmacists
- Single or multiple pharmacists/prescribers may be parties to one agreement
- Single, multiple and populations of patients can be on one agreement

Decided by Individual Providers

- Specifically list which pharmacists and prescribers are included in agreement
- Identify the pharmacist training or credentials, if any, necessary to provide delineated services
- Identify which specific patients or patient populations are included in agreement



Authorized Services

Included in Laws and Regulations

- Initiation and modification of drug therapy can be authorized in the agreement

Decided by Individual Providers

- Specify which disease states are being managed
- Specify which specific services are included
- Specify if/which protocols or clinical guidelines are to be followed



Requirements & Restrictions

Included in Laws and Regulations

- All medications may be managed under the agreement, including controlled substances
- Agreement should be available, upon request, to the Board of Pharmacy

Decided by Individual Providers

- Specify an appropriate level of patient consent for services
- Specify the timeframe for renewal of agreement
- Specify the documentation processes
- Specify the liability insurance needs, if any
- Identify the continuing education requirements for participation



CPA Applications

- Chronic Disease Management
 - Anticoagulation
 - Cardiovascular disease/hypertension
 - Diabetes
 - Others
- Acute Treatment
 - Strep/Influenza
- Public Health
 - Naloxone
 - Immunizations



Other Approaches to Addressing Public Health Needs



Statewide Protocols

- Used to address public health concerns
- Standard across the state, applies to all pharmacists
- Additional pharmacist education/training could be required
- Allows pharmacist to prescribe for conditions with no diagnosis or that are easily diagnosed
- Protocols can be in law (CA) or delegate authority to state boards (OR)



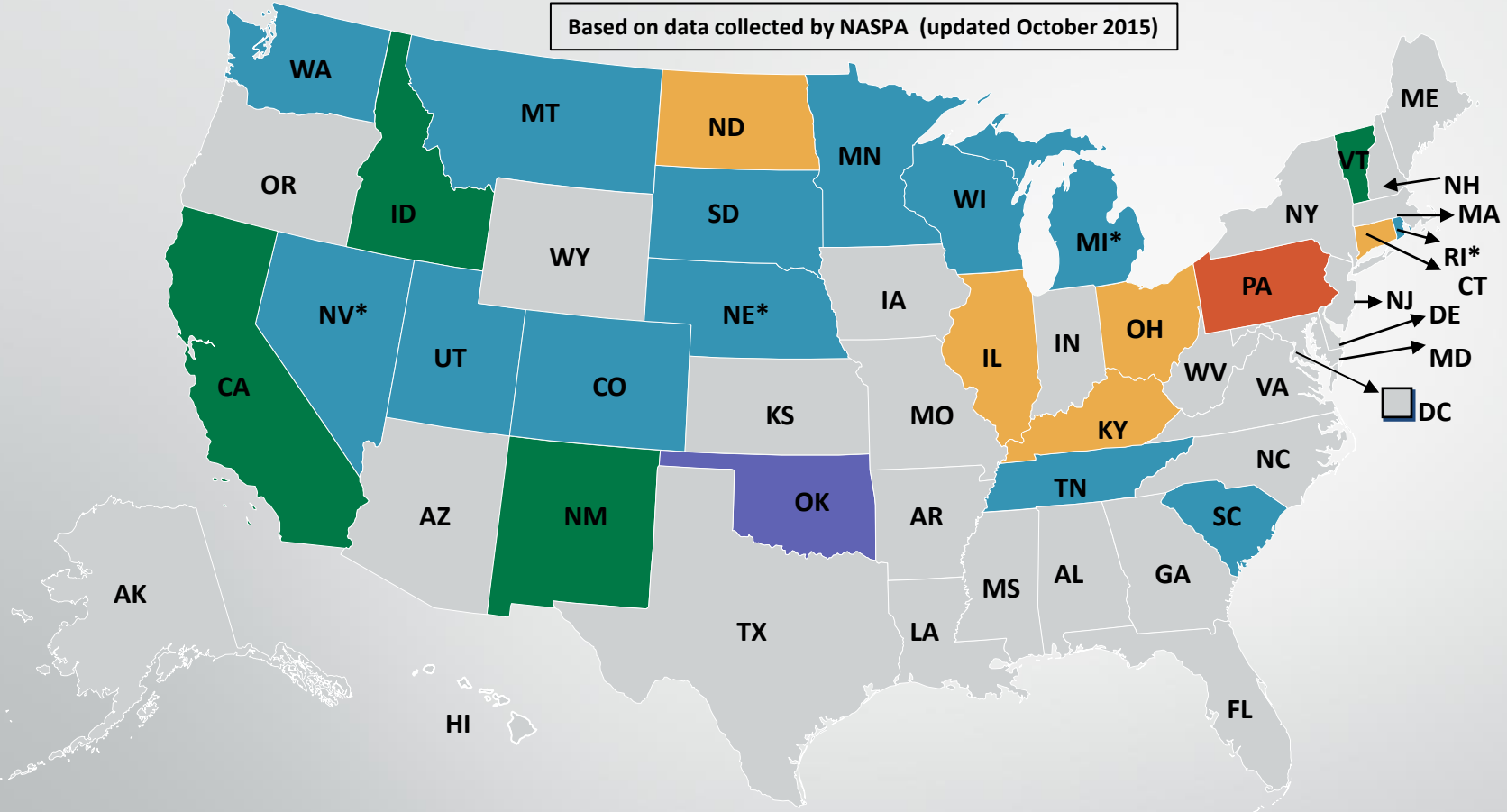
Statewide Protocols

- Naloxone
- Immunizations
- Smoking Cessation
- Hormonal Contraceptives
- Travel Medications
- TB
- Fluoride



Case Study: Naloxone

Based on data collected by NASPA (updated October 2015)



	Statewide naloxone protocol or prescriptive authority for pharmacists
	Broad** collaborative practice provisions
*	Broad collaborative practice provisions but need a separate agreement for each pharmacist
	Pharmacists are authorized to dispense without a prescription
	Statewide protocol or prescriptive authority bill passed in 2015 session
	Statewide standing order issued



**Broad = Allow initiation of therapy, community pharmacists authorized to participate, no drug restrictions (may need to specify within the agreement), laws/regulations silent regarding the relationship between the prescriber and the patient

Administration of Medication

- NABP Model Practice Act Definition
 - Section 104
 - 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;
- 39 states
 - Some restrict to CPA or have other limitations



Administration Examples

- Naloxone
- Long acting antipsychotics
- Long acting birth control injections
- Medications that are typically self-administered to train patients how to administer

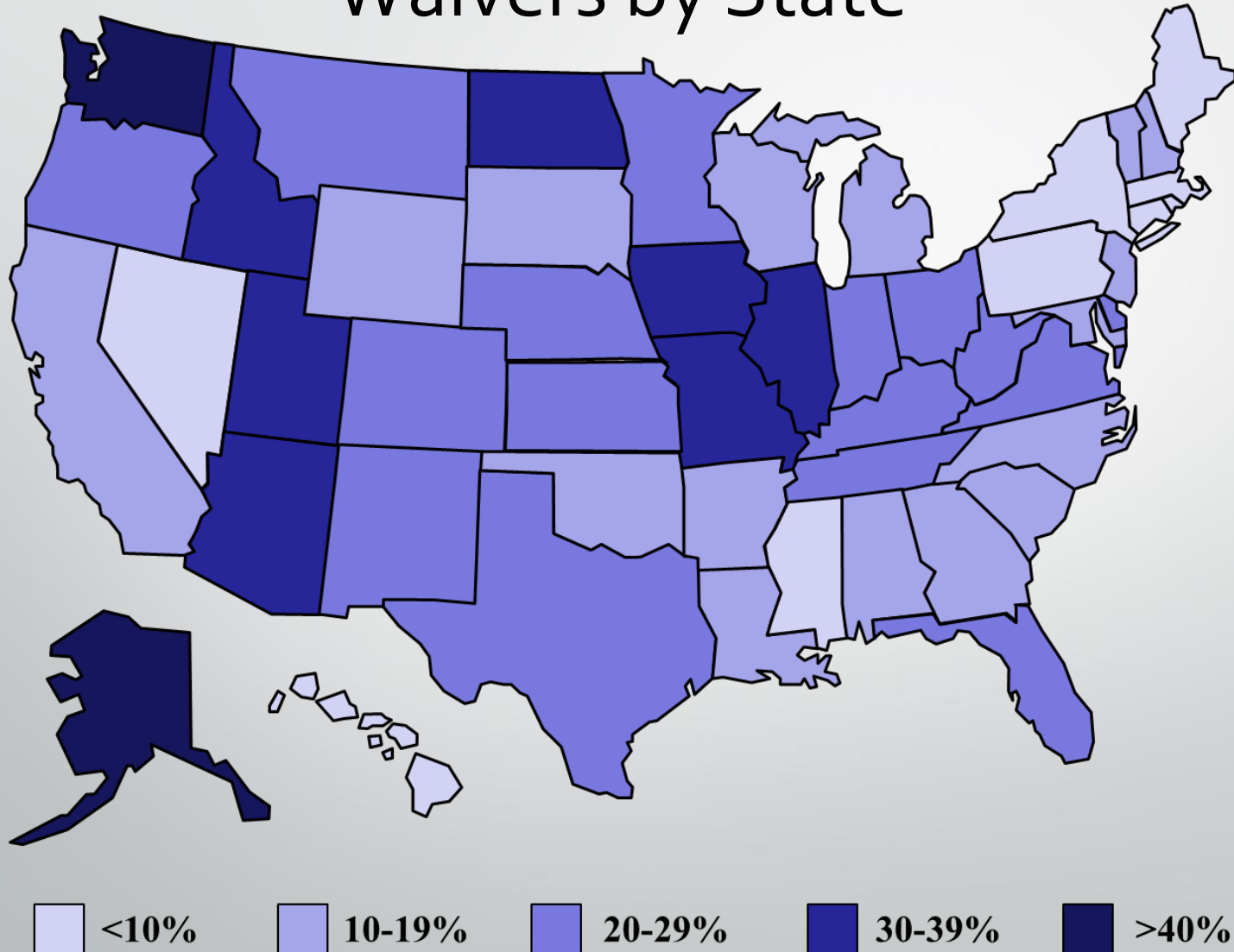


Lab tests

- NABP Model Practice Act Definition
 - Section 104
 - The “Practice of Pharmacy” means thethe ordering, conducting, and interpretation of appropriate tests,
- Order/interpret to optimize drug therapy
- Conduct CLIA-waived tests
 - Federal authority
 - States can establish stricter requirements



Percentage of Pharmacies with CLIA-Waivers by State



Klepser M, Adams AJ, Srnis P, et al. U.S. Community Pharmacies as CLIA-Waived Facilities: Prevalence, Dispersion, and Impact on Patient Access to Diagnostic Testing. *Research in Social & Administrative Pharmacy* (2015), doi: 10.1016/j.sapharm.2015.09.006.

Provider Status



Why Provider Status?



Promote consumer access and coverage for pharmacists' patient care services.

-Tom Menighan



What We Know

When pharmacists are on the team:

- **Patients benefit** —enhanced satisfaction, care, and outcomes
- **Communities benefit** —healthier population, increased access to immunizations
- **The health care system benefits** —quality, access, and costs are improved

Provider status for pharmacists will result in a team-based patient-centered health care system providing improved care and value.



Possible Pathways to Achievement

- Federal Sector
 - Social Security Act (SSA) (Medicare Part B & D, CMMI, ACOs)
 - Sustainable Growth Rate Formula
 - Federal Regulations (CMS, AHRQ, HRSA)
- State Provider Status
 - Medicaid
 - Health Insurance Exchanges, state health plans
 - Build a grassroots support
- Private Payer System
 - ACOs
 - Private or Employer-based Insurers
 - Medical Homes



The Patient Access to Pharmacists' Care Coalition (PAPCC)

- Publically announced early March 2014
- Currently more than 29 organizations and growing
- Representing patients, pharmacists, and pharmacies, as well as other interested stakeholders



www.pharmacistscare.org

Expanding Patient Access to Pharmacists' Services

[Home](#) [Access to Care](#) [The Solution](#) [About PAPCC](#) [FAQs](#) [News & Updates](#) [Contact Us](#)



Patient Access to Pharmacists' Care Coalition



2015 Legislative Activity

- January 28, 2015: House Bill 592 introduced
 - Sponsors: Reps. Brett Guthrie (R-KY), G.K. Butterfield (D-NC), Todd Young (R-IN), and Ron Kind (D-WI)
- January 29, 2015: Senate Bill 314 introduced
 - Sens. Charles Grassley (R-IA), Sherrod Brown (D-OH), Mark Kirk (R-IL) and Bob Casey (D-PA)
- Both titled: The Pharmacy and Medically Underserved Areas Enhancement Act
- Follows 2014's H.R. 4190



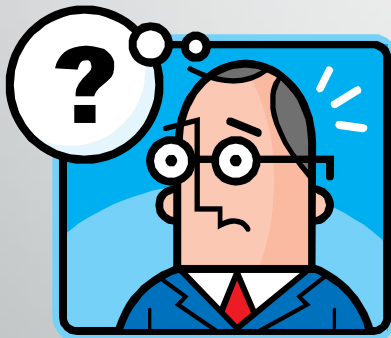
PAPCC – H.R. 592 and S. 314

Scope of Proposal

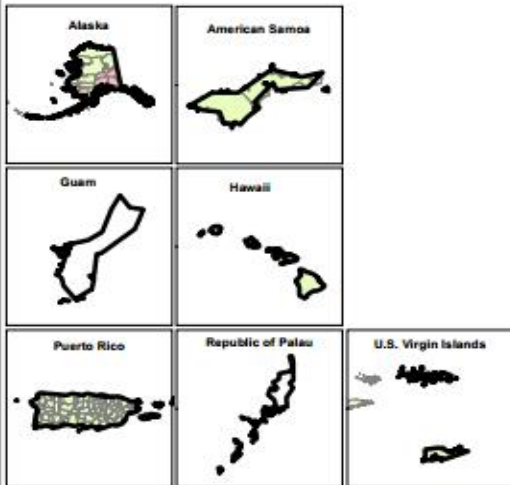
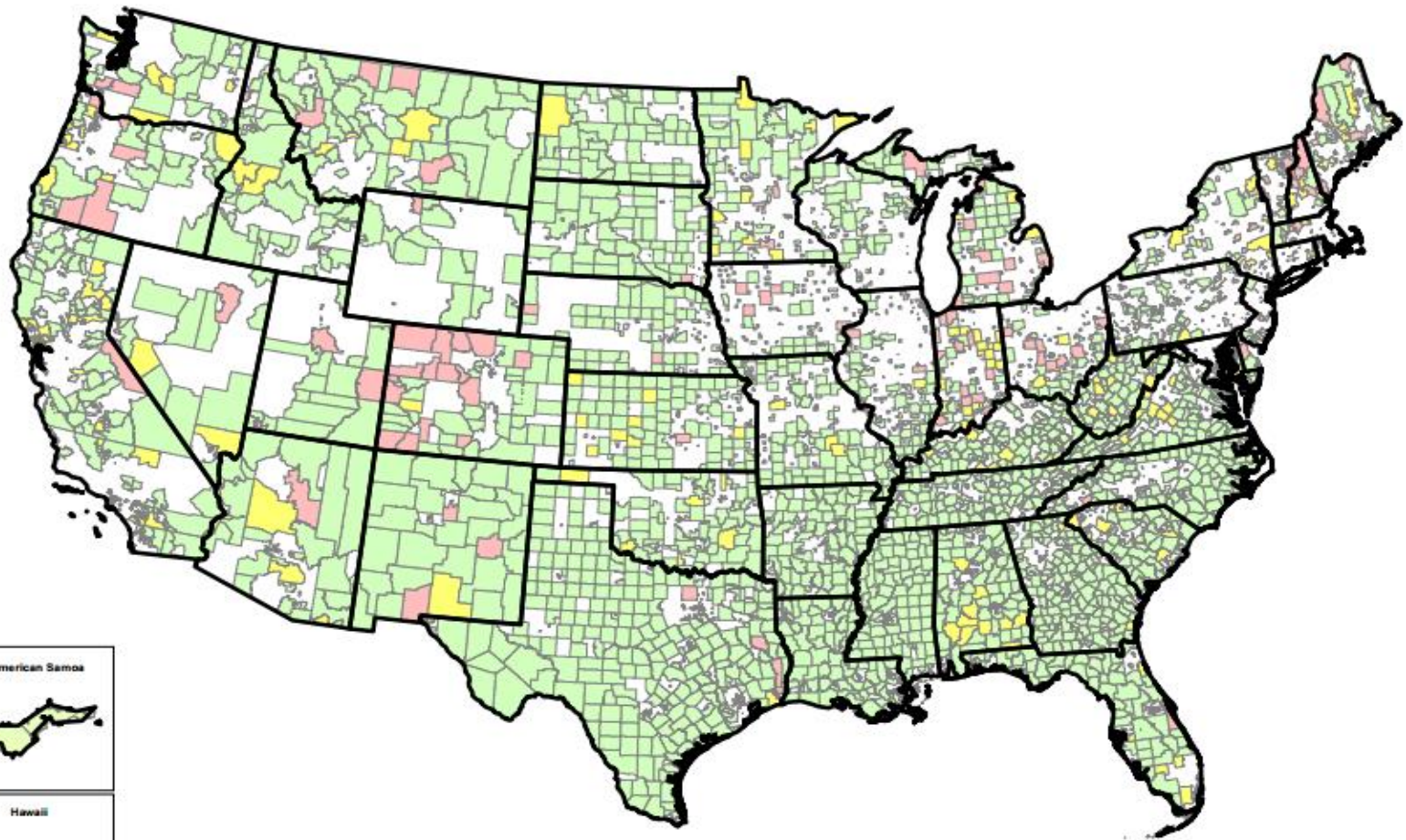
- **Pharmacists** – State-licensed pharmacists with a B.S. Pharm. or Pharm. D. degree who may have additional training and certificates depending on state laws
- **Services** – Services authorized under state pharmacy scope of practice laws
- **Patients** – Services provided in/ for Medically Underserved Areas (MUA), Medically Underserved Populations (MUP), or Health Professional Shortage Areas (HPSA)
- **Reimbursement** – Consistent with Medicare reimbursement for other non-physician practitioners, pharmacist services would typically be reimbursed at 85% of the physician fee schedule



PAPCC - H.R. 592 and S. 314



**Are only a
limited number
of pharmacists
eligible under the
federal bill?**



Feedback from Hill

- Positive feedback overall but cost is important
 - Need to “score” low by Congressional Budget Office (CBO)
 - Pharmacy challenged to be “saver, not coster”
 - Concern by pharmacy that savings, especially those that are long-term, are not considered when scoring
- Hill equates provider status with “fee-for-service”
 - Current focus is on new payment models (e.g. ACOs)
- There is not a good understanding of “Pharmacists’ Services”
 - Will they occur in isolation (i.e. coordination with other providers)



Next Steps

- Developing long-term strategy; this is not a sprint
- Education and Outreach
 - Meet with Federal Agencies (e.g. HHS, FTC) and add provider status messaging in comments to regulations
 - PAPCC continues to educate House and Senate members
 - Work to increase membership
 - Include patient and other health care provider groups

SENATE: 33 COSPONSORS
HOUSE: 239 COSPONSORS

Co-sponsors as of 11/3/15



State vs. Federal Landscape

State

- Designation not usually associated with payment
- Scope of practice defined in state statute
- Incremental changes, year by year
- No one solution fits every state

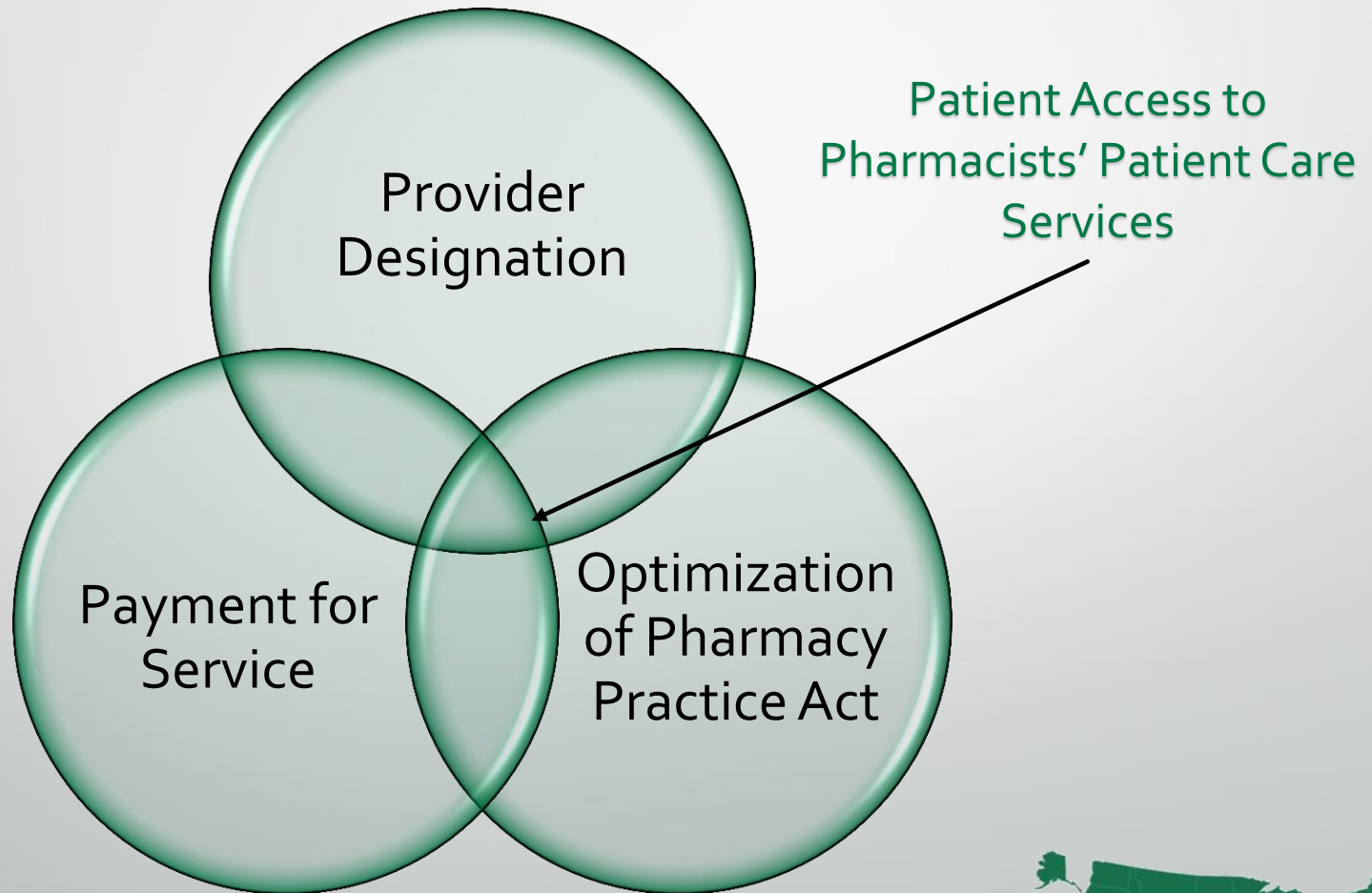
Federal

- Designation in Social Security Act would likely lead to payment for service
- Scope of practice not defined
- All “asks” are a heavy lift, difficult to go back year after year
- Generally unified goal

Common Goal:
Patient Access to Pharmacists' Patient Care
Services



Achieving Patient Access





Provider Designation

Provider vs. Practitioner

Provider

- Definition: a person or thing that provides
- Can include a person or establishment that provides a product such as a prescription. *Pharmacies* and hospitals can be considered providers.
- Some statutory definitions may include a qualifier: *healthcare* provider

Practitioner

- Definition: a person who practices a profession or art
- Can only be a specially trained person. This term may more specifically identify the professional who provides a cognitive service rather than physical product.



Insurance Code vs. Other Areas of State Laws

Insurance Code

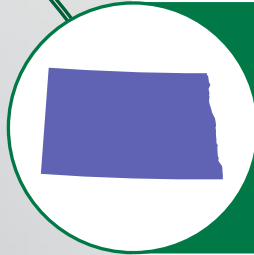
- There is sometimes a list of professionals who are defined as health care providers for the purposes of the provisions in the insurance code
- Challenge: A limited number of patients are covered by insurers who are held to these provisions (non-ERISA exempt plans)

Other Areas of State Laws

- Pharmacy Practice Act
- Business/Professional Code
- Being “on the list” as a provider here may not have much of an impact on payment for services unless areas of the insurance code, Medicaid provisions, or state employee benefit provisions refer back to this language
- Pharmacists can also be separately recognized as providers within Medicaid laws



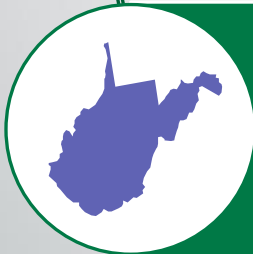
2015 Activity



North Dakota

PASSED!

- SB 2104
- Included in language related to naloxone access
- Re-assertion of pharmacists as providers



West Virginia

PASSED!

- SB 6; HB 2006
- Adds pharmacists to the medical liabilities law
- Re-assertion of pharmacists as providers



Nebraska

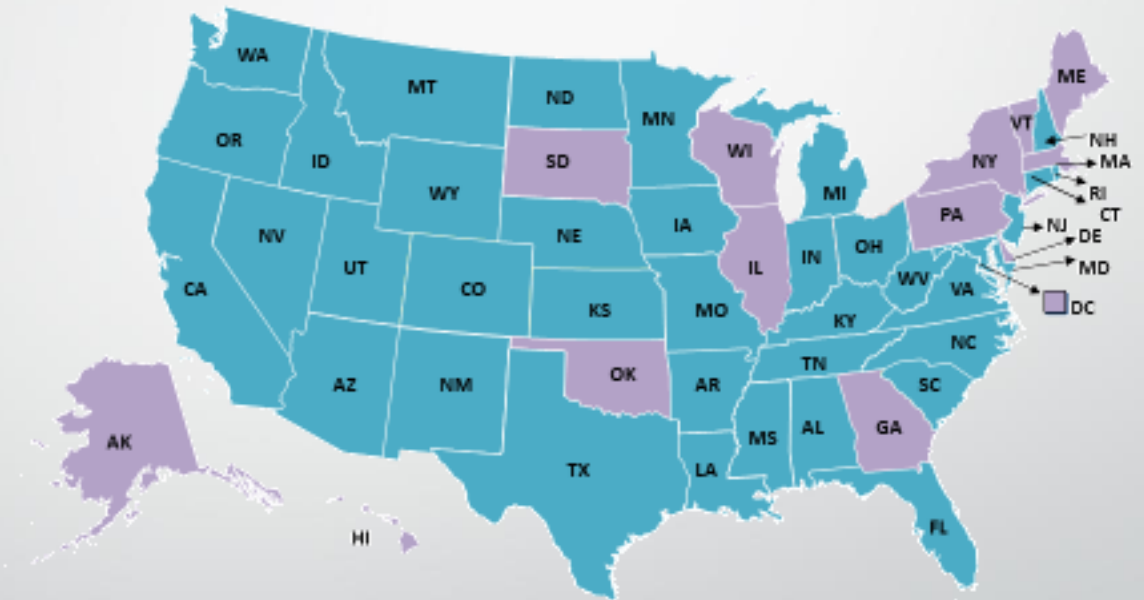
PASSED!

- LB 37
- Includes statutory definition of pharmacists as “practitioners”
- Definition would be in the Prescription Drug Safety Act

Current Landscape of Provider Designation

State Level Provider Designation

Based on data collected by NASPA (September 2014)



■ State with provider designation
■ State without provider designation

37

- Provider designation

35

- State statute

9

- Medicaid



Optimization of the Pharmacy Practice Act



What Services?

Collaborative practice provisions

Immunization/administration
authority

Order/interpret labs, CLIA waived
tests

Statewide protocols to enhance
public health



2015 Activity



Indiana

- SB 358
- Allows pharmacists to collaborate with NPs and PAs
- Defines MTM

PASSED!



Kentucky

- HB 377
- Allows multiple pharmacists, practitioners and patients to be included on one agreement

PASSED!



Maryland

- HB 657; SB 346
- Allows pharmacists to administer medications

PASSED!



2015 Activity



Maryland

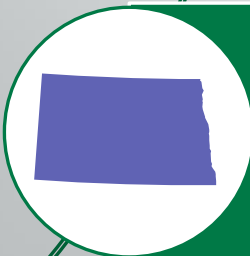
- HB 716; SB 347
- Allows pharmacists to collaborate with NPs
- Allows pharmacists to initiate therapy

PASSED!



New York

- SB 5805
- Collaborative practice authority (currently limited to teaching hospitals)



North Dakota

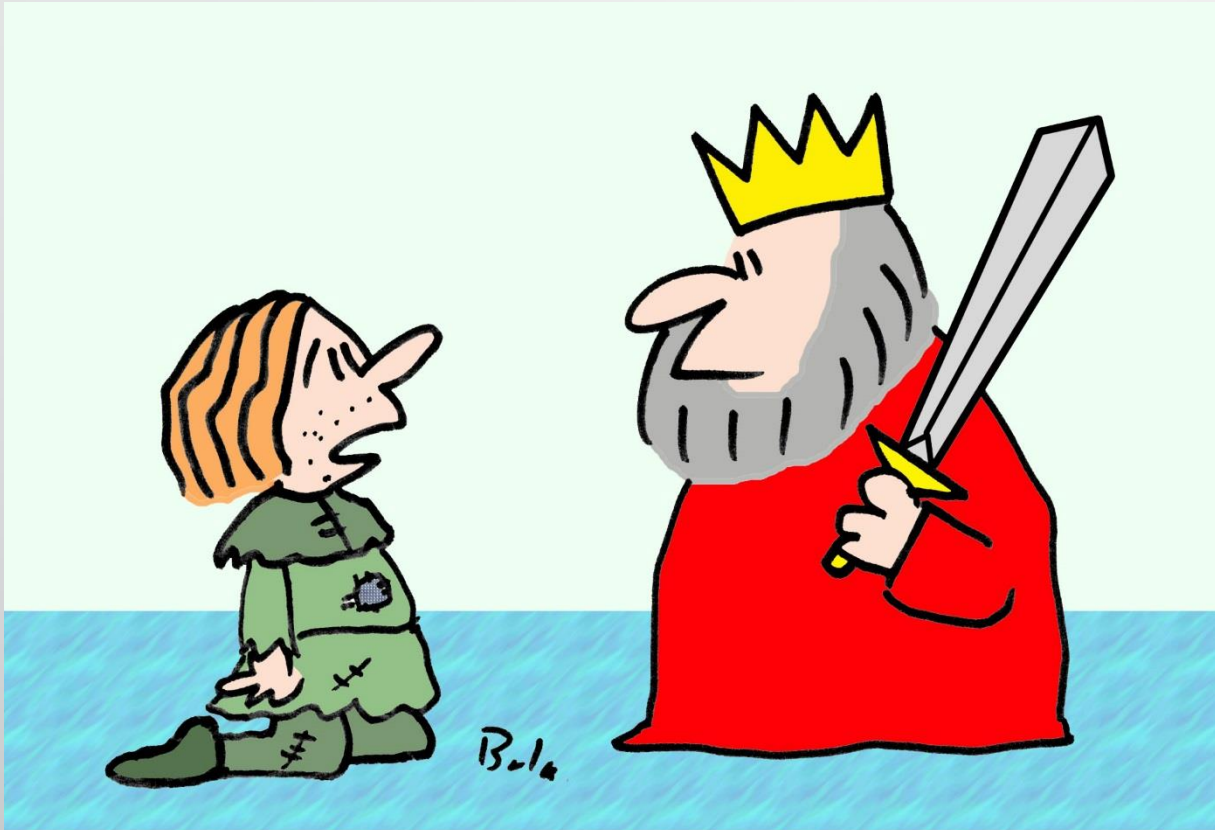
- SB 2173
- Allows pharmacists to collaborate with nurse practitioners in addition to physicians

PASSED!



Payment for Services



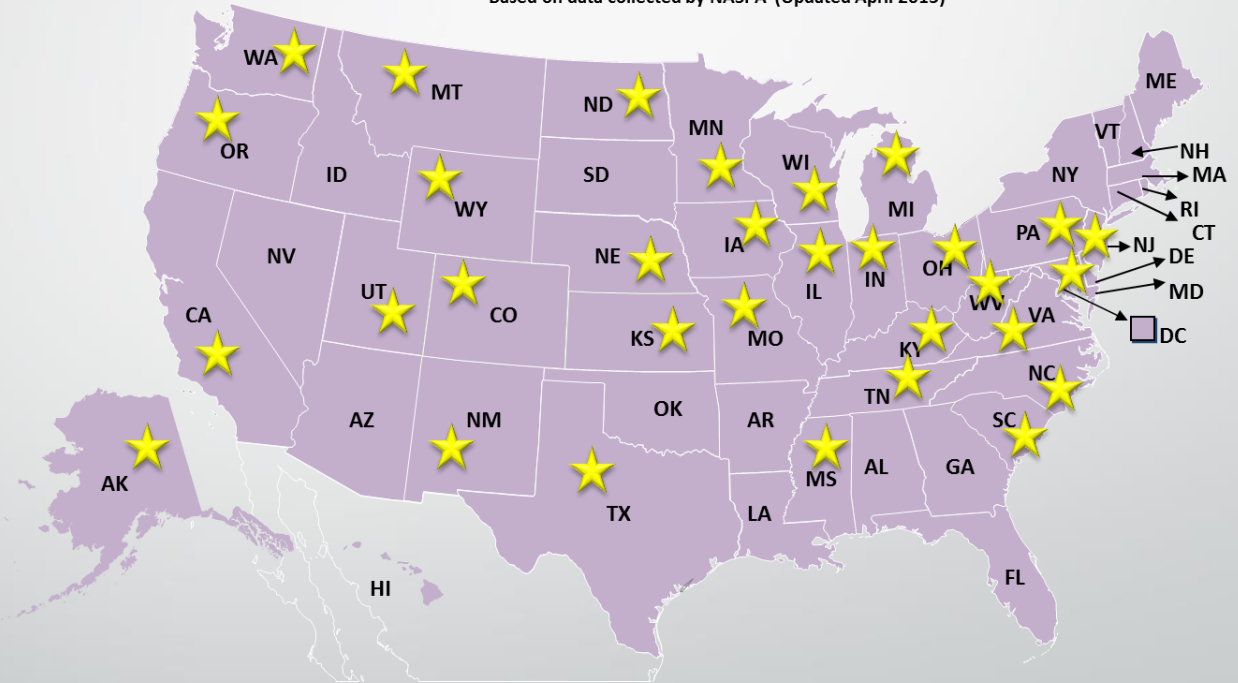


"Instead of a knighthood, Sire, could I maybe just have the money instead?"

Payment for Services

States with Payment for Pharmacist Services

Based on data collected by NASPA (Updated April 2015)



31

- Some kind of Payment

17

- Some Medicaid Service

12

- Medicaid MTM

6

- State Employee MTM



2015 Payment Legislation



Connecticut

- HB 6157; Introduced 1.22.15
- Adds MTM as a covered benefit in Medicaid



North Dakota

- SB 2320; Introduced 1.20.15
- Adds MTM as a covered benefit in Medicaid

PASSED!

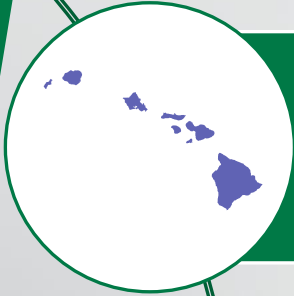


Oregon

- SB 558
- Requires that a health benefit plan cover pharmacists' consultation services under certain conditions

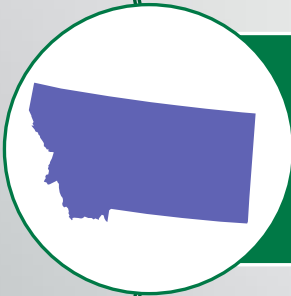


2015 Payment Legislation



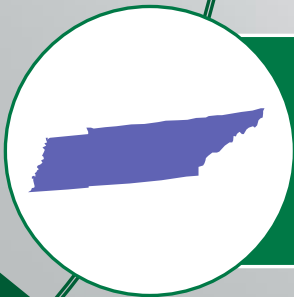
Hawaii

- HB 614
- Requires coverage of lab tests ordered by pharmacists



Montana

- HB 455; LC 134
- Adds comprehensive medication management as a covered benefit in Medicaid



Tennessee

- SJR 104
- Resolution to encourage TennCare to cover MTM for Medicaid recipients

Discuss and Share

- Examine your state's collaborative practice authority
 - Best interest of the patient?
 - Aligned with pharmacist education and training?
- Does the current authority present barriers or opportunities to enhance patient care?
- Do legislative or regulatory changes need to be made?
- Has your state used or considered statewide protocols? What are the barriers/opportunities?
- Can pharmacists in your state administer medications beyond immunizations?
- What barriers are preventing patient access to pharmacists' services in your state?



Questions?

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