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Toward Pharmacist Full Practice Authority

Bold Strategies, New Partners

Presented by:

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Learning Objectives

- **Define** full practice authority as it relates to independently providing pharmacy services.
- **Explain** how standard of care and regulatory capture impact the ability to fully implement full practice authority.
- **Examine** the intersection between new business opportunities across practice settings and future advocacy needs to fully implement full practice authority within a standard of care regulatory framework.
- **Propose** innovative solutions to address barriers to full practice authority and enhance the role of pharmacy professionals in various healthcare settings.

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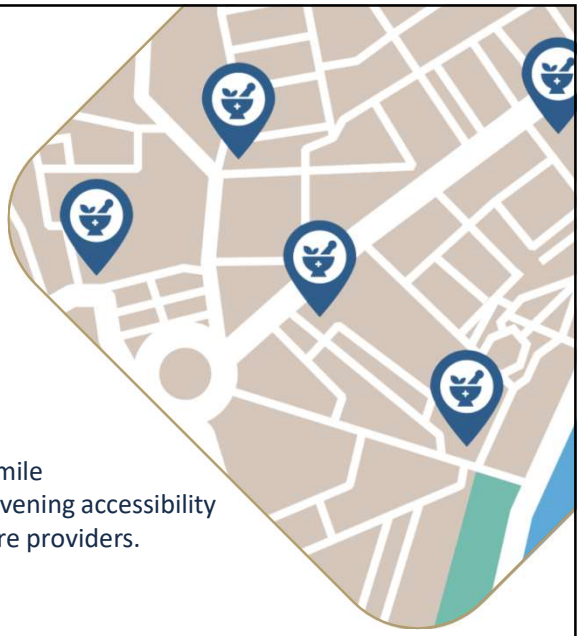
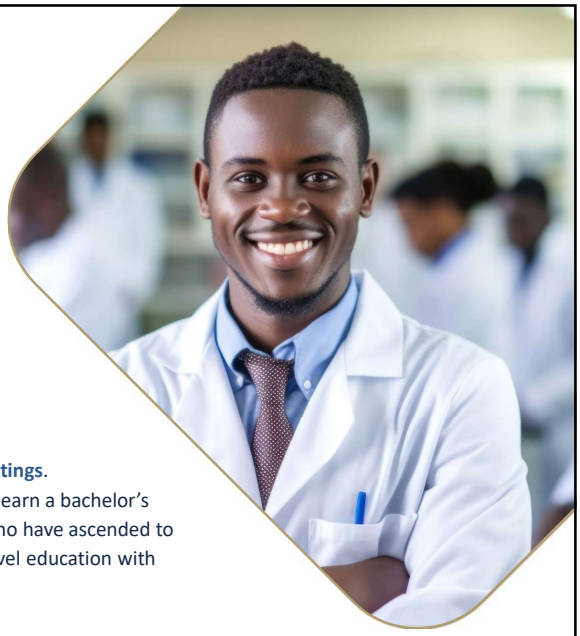
Background and Problem

- **More than 30 percent** of Americans don't have a primary healthcare provider, and those who do often face long wait times to get an appointment with a physician experiencing burnout.
- **Pharmacists are poised** to solve primary care shortages, diagnose and manage chronic diseases and minor ailments, decrease unnecessary emergency room visits, and deliver preventative health outcomes.
- **Nearly 90%** of Americans live within five miles of a community pharmacy, with urban Americans in a two-mile radius of pharmacy services. The weekend hours and evening accessibility make pharmacists one of the most accessible healthcare providers.



Pharmacist Education and Training as Healthcare Providers

Education and Training



- Pharmacist education and training standards are consistent across all states requiring prospective pharmacists to graduate from a Doctor of Pharmacy (PharmD) program accredited by the Accreditation Council for Pharmaceutical Education (ACPE) and pass the North American Pharmacist Licensure Examination (NAPLEX) to demonstrate clinical competence.
- Pharmacists receive **four years of post-graduate education** that includes **1,740 hours of clinical patient care training in all practice settings**. All of that is commonly preceded by the four years it typically takes to earn a bachelor's degree. Comparatively, advanced practice registered nurses (APRN) who have ascended to full practice authority in more than 35 states, complete a doctorate-level education with 750 hours of clinical patient training.

Pharmacists' Patient Care Process (PPCP) issued by the Joint Commission of Pharmacy Practitioners (JCPP) in 2014

1. Collecting subjective and objective patient information
2. Assessing the information collected and analyzing the clinical effects of the patient's therapy
3. Developing an individualized patient-centered plan that is evidence-based and cost-effective
4. Implementing and documenting the care plan
5. Patient follow-up to monitor and evaluate the effectiveness of the care plan

The ACPE 2016 Standards adopted the PPCP establishing consistency in pharmacist education across all practice settings on differential diagnosis and prescribing.

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ACPE Standards 2025

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Required Elements of the Didactic Doctor of Pharmacy Curriculum
Clinical Laboratory Data Application of clinical laboratory data to disease state management, including screening, diagnosis, progression, and treatment evaluation.
Medication Prescribing, Preparation, Distribution, Dispensing, and Administration Prescribing, preparing, distributing, dispensing, and administering medications including, but not limited to: injectable medications, identification and prevention of medication errors and interactions, maintaining and using patient profile systems, prescription processing technology and/or equipment including oversight of support personnel, and ensuring patient safety. Educating about appropriate medication use and administration for various disease states including substance use disorder. All students must receive training in immunizations.
Patient Assessment Evaluation of patient function and dysfunction through the performance of tests and assessments leading to objective (e.g., physical assessment, health screening, and lab data interpretation) and subjective (patient interview) data important to the diagnosis and provision of care.
Pharmacotherapy Evidence-based clinical decision making, therapeutic treatment planning (including diagnosing and prescribing), and medication therapy management strategy development for patients with specific diseases and conditions that complicate care and/or put patients at high risk for adverse events. Emphasis on patient safety, clinical efficacy, pharmacogenomic and pharmacoeconomic considerations, and treatment of patients across the lifespan.
Self-Care Pharmacotherapy Therapeutic needs assessment, including the need for triage to other health professionals, drug product recommendation/selection, diagnosis, prescribing, and counseling of patients on non-prescription drug products, non-pharmacologic treatments, and health and wellness strategies, including nutraceuticals.

The intersection between ACPE accreditation standards, the PPCP, and impeding state laws on pharmacists' full practice authority is nicely summarized by Adams and Weaver:

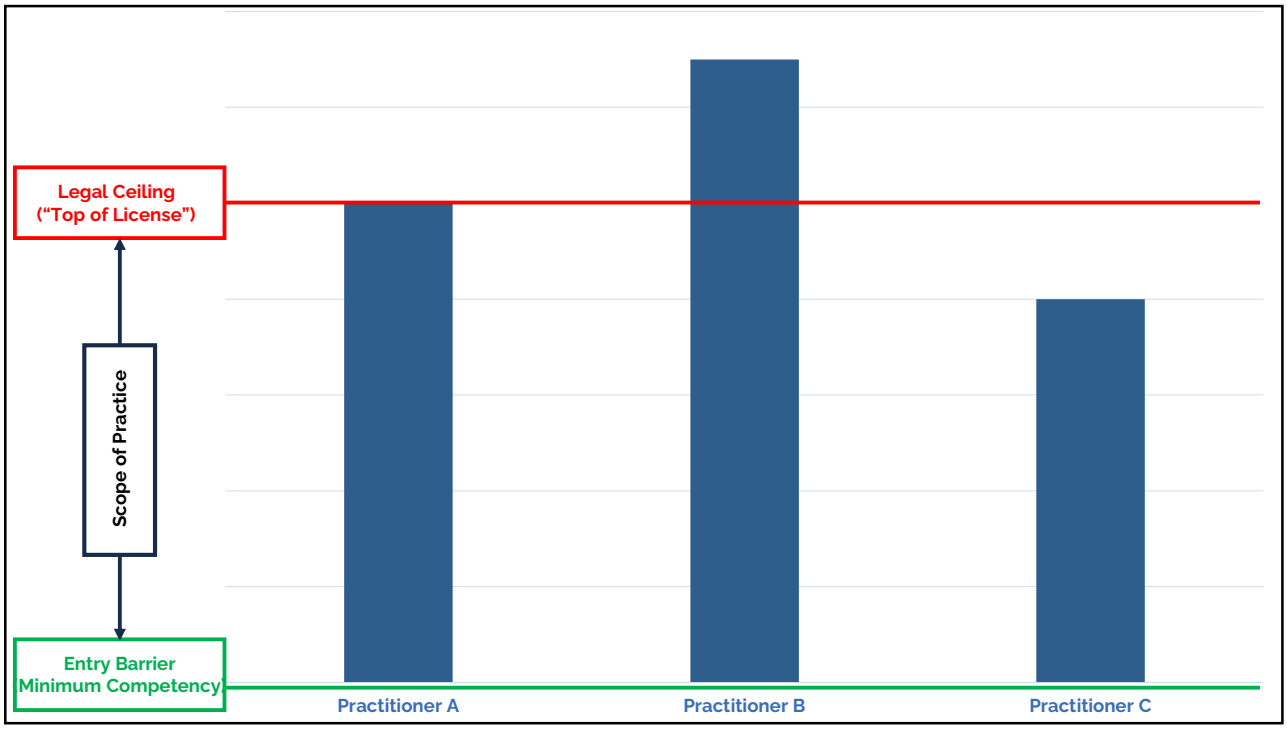
> *"For pharmacists to fully engage in the Pharmacists' Patient Care Process, state laws must enable full participation. By unleashing pharmacists to fully engage in the process, patient care delivery and outcomes can be improved, and total health care costs can be reduced."*

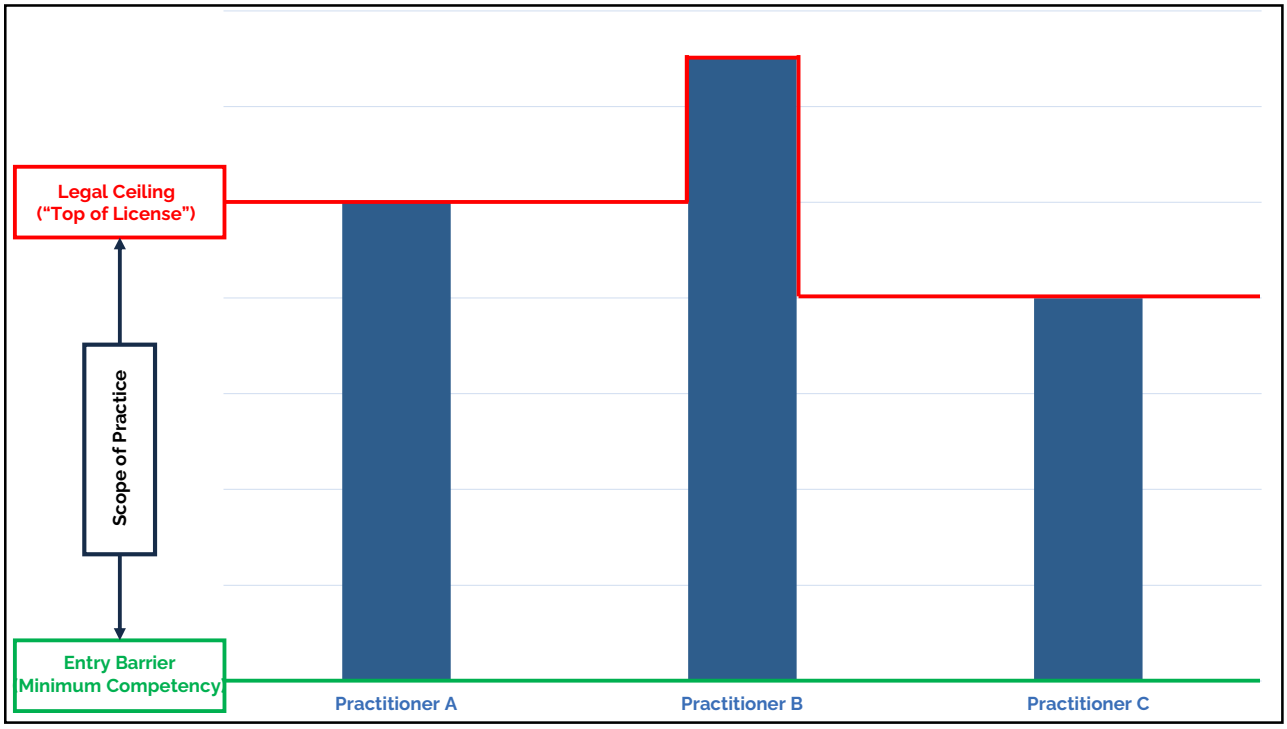
Clinical Services are Overregulated

Why can't patients skip the doctor's office altogether and simply rely on their pharmacist as the primary destination for minor healthcare?

The answer is overregulation.

Regulatory strings prevent pharmacists from practicing at the top of their education, training, and experience.


Legal Ceiling
("Top of License")
Scope of Practice
Entry Barrier
Minimum Competency
Practitioner A
Practitioner B
Practitioner C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Discussion

If pharmacists had full practice authority and no regulatory barriers, what high-impact patient care service would you lead to meet future healthcare needs and transform how pharmacy delivers value?

Policy Prescription for Bridging Clinical Services Gaps

Adopt Standard of Care

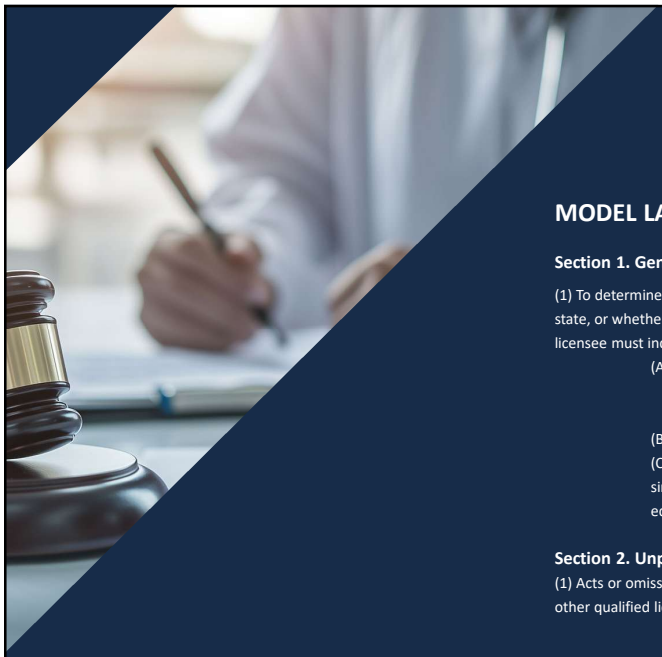
Adopt Full Practice Authority

Defining Standard of Care

- The term “standard of care” in the medical context refers to **a healthcare provider acting as a reasonable and prudent provider with similar qualifications in similar circumstances and settings**.
- Standard of care is the regulatory benchmark to measure the actions of healthcare providers and ensure they are performing their duties to prevent patient harm.
- If a physician, pharmacist, physician assistant, or nurse fails to meet the standard of care for their practice, the licensing board and even the courts will find the provider negligent and guilty of unprofessional conduct or malpractice for failing to meet an adequate community standard of care.

Benefits of Standard of Care

- The paramount benefit of standard of care is that standards do not come from top-down government elitist and “expert” regulators, but rather from bottom-up external market forces.
- New scope of practice allowances, novel patient services, and technological advancements do not require government permission but are inherently authorized by a healthcare professional if acting according to the community standard of care.



MODEL LANGUAGE: STANDARD OF CARE

Section 1. General Standard of Pharmacy Practice

(1) To determine whether a specific act is within the scope of pharmacy practice in or into the state, or whether an act can be delegated to other individuals under a licensee's supervision, the licensee must independently determine whether the act is

(A) expressly prohibited by

(i) this chapter; or

(ii) any applicable state or federal laws;

(B) consistent with the licensee's education, training, and experience; and

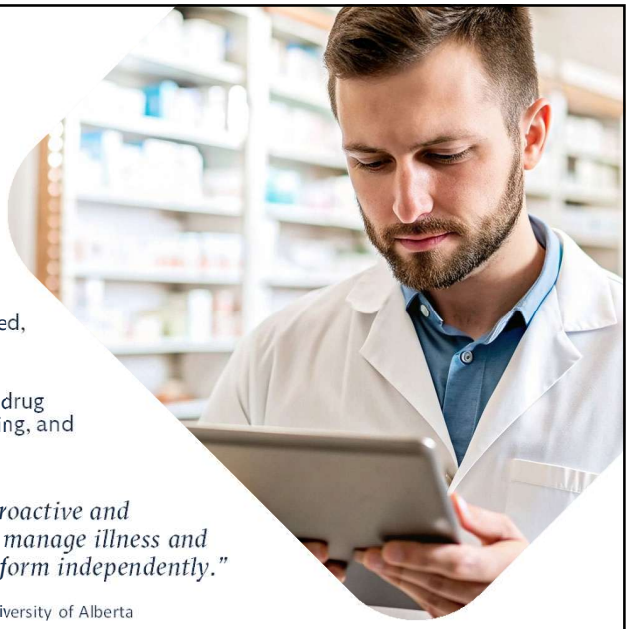
(C) within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee with similar education, training, and experience.

Section 2. Unprofessional Conduct/Disciplinary Standards

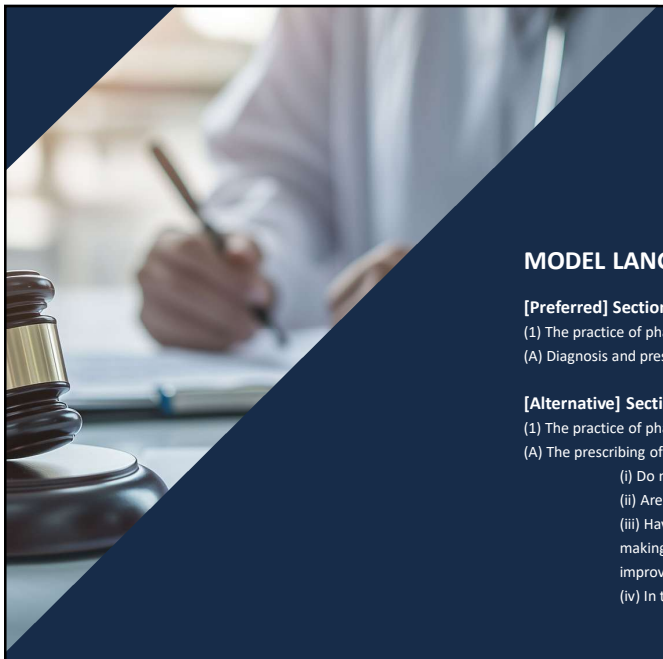
(1) Acts or omissions within the practice of pharmacy which fail to meet the standard provided by other qualified licensees or registrants in the same or similar setting.

Defining Full Practice Authority

- At the core of achieving full practice authority is the underpinning of independent authority and evidence-based practice unhindered by outdated legislation and regulatory restrictions.
- Stop referring to pharmacy practice services as "expanded, enhanced, or expanded scope of practice"
- The goal is a pathway towards full scope that includes independent performance of prescribing, deprescribing, drug administration, prescription adaptation, laboratory testing, and continuation of therapy.



> *"Full-scope pharmacist services include all proactive and comprehensive interventions that prevent or manage illness and are within an individual's competency to perform independently."*
>
> —Dr. Ross Tsyuki, Chair of the Department of Pharmacology, University of Alberta



MODEL LANGUAGE: DIAGNOSIS AND PRESCRIBING

[Preferred] Section 1. Practice of Pharmacy
(1) The practice of pharmacy means:
(A) Diagnosis and prescribing

[Alternative] Section 1. Practice of Pharmacy
(1) The practice of pharmacy means:
(A) The prescribing of drugs, drug categories, or devices that are 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; or
(iv) In the professional judgment of the pharmacist, are patient emergencies

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Standard of Care:

Balancing Scope Expansion and Patient Safety

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Pharmacy Practice after Implementing a Standard of Care Regulatory Model

Adopt SOC → BOP Rewrite

- **Idaho (2017 & 2024):** Adopting SOC spurred two different repeal and replace rewrites of the Board of Pharmacy rule chapter, removing over 110 pages of administrative rules
- **Alaska (2023):** Adopting SOC spurred a spring-cleaning of administrative rules, including expanding pharmacist scope of practice and continuation of therapy, and more recently becoming the fourth state to remove the Multistate Pharmacy Jurisprudence Examination (MPJE) as a prerequisite of pharmacist licensure.
- **Iowa (2024):** Adopting SOC spurred a zero-based regulation executive order to repeal and replace the rule chapter. The Iowa Board of Pharmacy is poised to remove 13 chapters, 141 rules, and 36,000 words from the books.

A NEW PRESCRIPTION CALLS FOR THE KANSAS BOARD OF PHARMACY TO REPEAL AND REPLACE THE ADMINISTRATIVE RULES THAT CREATE UNNECESSARY BARRIERS AND IMPEDE PATIENT ACCESS TO PHARMACIST SERVICES

State laws and/or regulations should be silent on the following topics deferring to the standard of care:

- Do not limit authority to post-diagnostic categories
- Do not connect practice authority to collaborative practice agreements or standing orders
- Do not require specific patient assessment and diagnosis criteria such as mandatory clinical guidelines, protocols, or static documents
- Do not require a new advanced practice designation or prescribing certificate/license
- Do not specify liability insurance requirements or thresholds
- Do not require mandatory continuing education requirements for each drug category
- Do not require new training requirements for each drug category
- Do not create patient age limitations
- Do not limit prescribing to only FDA approved indications and allow for off-label considerations
- Do not mandate primary care provider notification requirements
- Do not require specific referral criteria, allowing professional judgment when to referring patients to an appropriate venue of care

State laws and/or regulations should be silent on the following topics deferring to the standard of care:

- Do not connect authority to only protocols, standing orders, or collaborative practice agreements
- Do not create venue restrictions limiting where a pharmacist may administer, such as only institutional, hospital, or within the licensed pharmacy space
- Do not create a list or limited categories of drugs or devices a pharmacy may administer
- Do not limit the administration of controlled substance drugs for treatment of substance use disorder
- Do not require mandatory liability insurance, continuing education, or specific education/ training requirements
- Do not prevent pharmacist delegation of drug administration to qualified healthcare professionals, such as pharmacy technicians or medical assistants

State laws and/or regulations should be silent on the following topics deferring to the standard of care:

- Do not create a list of specific authorized tests
- Do not limit testing to only CLIA-waived tests
- Do not require a physician medical director as a prerequisite to perform testing or imaging
- Do not limit testing or imaging to limited or specific patient settings "institutional or hospital only"
- Do not limit testing or imaging to limited or specific patient settings "institutional or hospital only"
- Do not require additional continuing education or specific education/training requirements for laboratory testing or imaging
- Do not require additional mandatory liability insurance requirements or thresholds
- Do not create restrictions that prevent pharmacist delegation of simple testing, such as CLIA-waived tests to qualified healthcare professionals, such as pharmacy technicians or medical assistants
- Do not limit testing or imaging to only occurring in the licensed pharmacy space/location

Restrictive → **Permissive**

Indiana Example:

IC 25-26-13-31.2

Administration of immunizations; emergency immunizations; immunization data

- Requires a physician standing order
  - Details how the order is provided
- Lists 12 specific vaccines that may be administered
- Includes age restrictions
- Specifies emergency allowances
- Includes information about posting information about the prescribing physician visibly in the pharmacy

Alaska Example:

Sec. 08.80.168. ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS. (a) A pharmacist may independently prescribe and administer a vaccine and related emergency medication if the pharmacist has completed an immunization training program approved by the board…

- Specifies training requirements and emergency supplies in regulation
- Includes specific best practices in regulation (VAERS reporting, disposal, etc.)

Idaho Example:

54-1704(46)

"Practice of pharmacy" means the safe interpretation, evaluation, compounding, administration, and dispensing of prescription drug orders, patient counseling, collaborative pharmacy practice, provision of pharmaceutical care services, proper storage of drugs and devices, and prescribing of drugs and devices as may be further defined in this chapter.

- General prescribing guidelines apply

Decreased patient access to care → **Increased patient access to care**

Implementation of SOC

- Adopt a Broad Definition of "Practice of Pharmacy"
- Allow Elasticity for Scope of Practice Advancement Over Time
- Decide Which Limited Instances Still Necessitate Prescriptive Regulation
- Eliminate All Remaining Unnecessary Regulations
- Strengthen Accountability Mechanisms and Oversight

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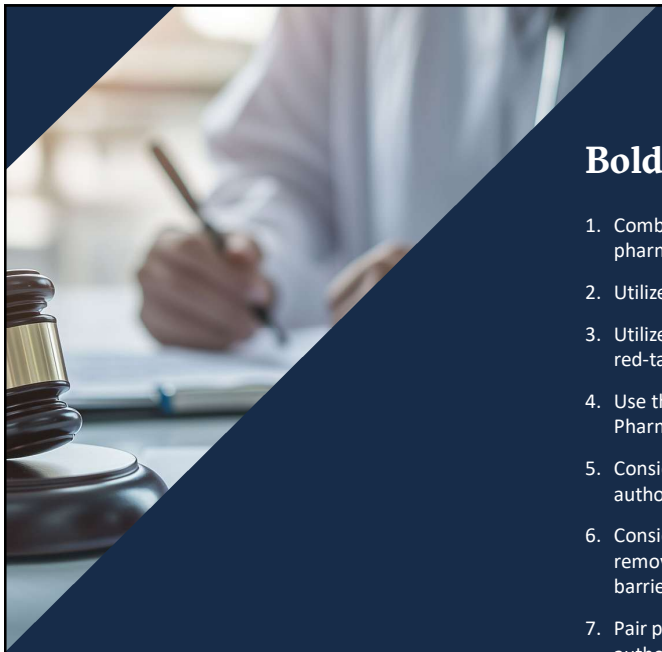

Bold Strategies to Create Opportunity

1. Combine standard of care adoption with the update to the practice of pharmacy definition to prevent concessions
2. Utilize omnibus bills and statute sunset clauses
3. Utilize Board of Pharmacy regulation sunset clauses and governor red-tape reduction executive orders
4. Use the Administrative Procedures Act to petition the Board of Pharmacy for rulemaking to adopt standard of care
5. Consider inserting changes into multi-healthcare profession practice authority update bills
6. Consider including statute definitions consolidation in the bill or removal of the MPJE in the bill as “clean-up” and overall removal of barriers
7. Pair prescriber/physician dispensing with pharmacist full practice authority to remove “conflict of interest” debates

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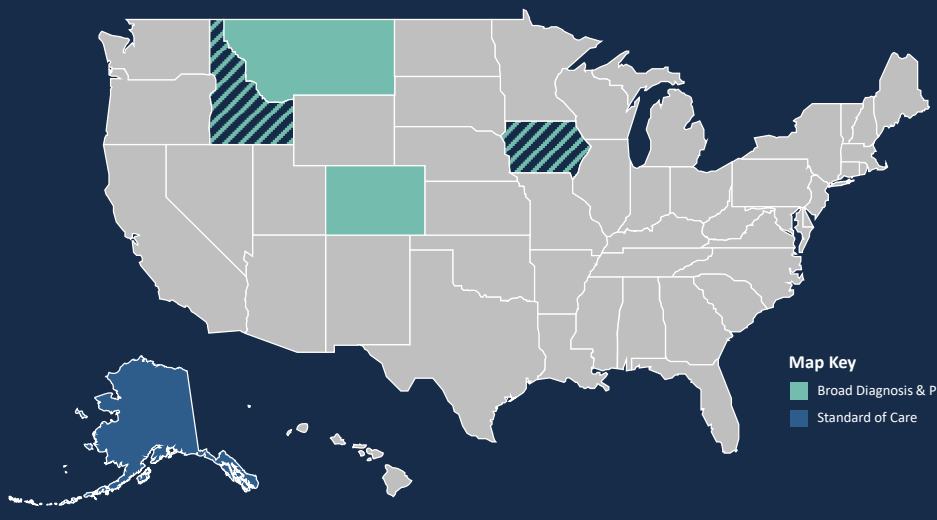
Toward Pharmacist Full Practice Authority



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New Partners:

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Other think tanks that have publications on pharmacist full practice authority:

CATO INSTITUTE

ALEC American Legislative Exchange Council

West Virginia University. JOHN CHAMBERS COLLEGE OF BUSINESS AND ECONOMICS

MERCATUS CENTER George Mason University

GOLDWATER INSTITUTE

R Street Free markets. Real solutions.

The Cicero Approach

- ✓ Supportive Approach
- ✓ Emphasize Alignment
- ✓ Leverage Resources
- ✓ Aggressive Incrementalism
- ✓ Long-term Strategy

- X ~~Confrontational Approach~~
- X ~~Critical of Lawmakers~~
- X ~~Adversarial Negotiation~~
- X ~~All or Nothing Strategy~~
- X ~~Short-term Vision~~

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Coalition Building

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Offensive Coalitions

- Insurers (+state & national associations)
- Hospital Associations (+individual hospitals)
- American Association of Retired Persons (AARP)
- Farm Bureau
- Colleges of Pharmacy (+deans)
- Patient advocacy groups & associations (e.g. diabetes, HIV)

Defensive Coalitions

- Neutralize powerful lobbyists when client conflict exists
- Neutralize powerful associations when healthcare-provider conflict exists

Medical Opposition Arguments

1. Pharmacists do not have the education and training, compared to that of physicians
2. Fragmentation of the patient-centered medical home model since pharmacists in community settings do not have access to a shared EHR medical record
3. The only safe access includes physician supervision requirements over pharmacists, recommending collaborative practice agreements as the gold standard
4. Increases access to poor quality and unsafe care, advocating that unsafe care is far worse than no patient care
5. Creates liability concerns and insurance issues, focusing on recent national and state pharmacy association reports of pharmacist burnout and workplace conditions

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60% OF VOTERS SUPPORT

increasing affordable urgent care access by **allowing pharmacists to practice to the full scope of their training**.

DEMOGRAPHICS

PARTY ID			AGE			GENDER	
33% GOP	34% IND	33% DEM	43% 18–44	32% 45–65	25% 65+	48% MALE	52% FEMALE

The survey was conducted October 7–11, 2024. The margin of sampling error is ±2.94 percentage points.

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Are External Market Forces Working?

- **Consumer Acceptance & Demand:** Continues to grow—remains an opportunity and not a mandate
- **State Payor Policies:** Idaho HHS Medicaid and their third-party administrator (e.g. Gainwell) recognizes pharmacists as "ordering and rendering" providers.
- **Private Payor Policies:** Private payors were slow in the first two years, but have continued to support and adopt recognition as rendering providers (e.g. Blue Cross of Idaho, Regence)
- **Private Credentialing and Privileging:** COVID grants assisted in credentialing efforts. Drug Enforcement Administration (DEA) are issuing registrations to pharmacists as professionals.
- **Facility Policies (e.g. risk mitigation):** Protocols were simplified, and removed for many treatment categories
- **Liability Insurance:** No increases
- **Civil/Criminal Law:** No complaints from patients, pharmacists, or non-pharmacist providers
- **Professional Ethics & Self-Restraint:** Confidence continues to grow

Strategy

- **New Partners:** Team up with the Cicero Institute/Cicero Action and begin coalition building before and during legislative session.
- **Pitch Matters:** Framing conversations properly with Republicans and Democrats and adjust your approach accordingly to the controlling legislative party (+governor party affiliation).
- **Bold Strategies:** Do not start language negotiation with concession language already built in and defer to standard of care to defend against concessions.
- **Be First to Advocacy:** Start by deactivating physician opposition arguments and marginalizing outdated views with legislators and governor's office.
- **Payer Caution:** Consider not tackling scope of practice battles with payment mandates at the same time.
- **Unique APA Opportunities:** Consider omnibus statute and regulatory chapter sunsets as the venue for achieving standard of care and full practice authority.
- **Keep Calm:** Be thoughtful before celebrating bill introductions through press releases or drawing unnecessary attention to legislation early in the process.
- **Point-Counterpoint:** Prepare to respond and counter every single stakeholder and legislator opposition argument throughout the process from introduction to governor signature.

Discussion

How will you advocate for pharmacist full practice authority moving forward?

MORE INFORMATION:

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