

DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

BOARD OF PHARMACY

CONDENSED MINUTES OF THE SPECIAL MEETING HELD JUNE 20, 2023

(DRAFT)

Date: June 20, 2023

Time: 4:00pm – 6:00pm

Location: Zoom Teleconference

Attending: Board Members: Ashley Schaber, James Henderson, Carla Hebert, Ramsey Bell, Sara Rasmussen
Staff: Michael Bowles

Absent:

Agenda Item #1. Roll Call/Call to Order

On the record at 4:03pm.

Roll Call:

Ashley Schaber - Present
Sara Rasmussen - Absent
James Henderson - Present
Carla Hebert - Present
Ramsey Bell – Absent
Sylvain Nouvion - Present

Agenda Item #2 Review/Approve Agenda

Ashley Schaber discussed the purpose of the meeting: focusing on prescriptive authority for pharmacists and the pharmacist's role in Medication Assisted Treatment (MAT).

Motion: Carla Hebert moved to approve the agenda for Special Board Meeting; James Henderson seconded the motion.

Recorded Votes:

Ashley Schaber - Yes
Sara Rasmussen - Absent
James Henderson - Yes
Carla Hebert - Yes
Ramsey Bell – Absent
Sylvain Nouvion – Yes

It was resolved to approve the agenda for the Special Board Meeting by a majority vote.

Agenda Item #3 Ethics Disclosures

Brief Discussion: Ashley Schaber disclosed she is a member of the AKPhA Legislative Committee.

Agenda Item #4

Discussion:

- Matthew Kirkland, PharmD, BCGP, Alaska Veterans Affairs (VA)
 - Introduced himself to the audience and provided a presentation on pharmacist led Medication Assisted Treatment (MAT)/Substance Use Disorder (SUD)
- Sara Rasmussen and Ramsey Bell joined the meeting at 4:18pm.
- Anna Nelson, Executive Director, Interior AIDS Association commented on the slide presentation and stated she was impressed with services provided by the VA.
- Dr. Shamsideen Musa, public attendee, commented and asked about the availability of these services throughout Alaska outside of the federal system. Answer by Matthew Kirkland - no ability, only available in federal facility.
- Anna Nelson discussed Alaska's Opioid Treatment Program (OTP) centers as being a methadone program.
 - Patients have to appear daily until stability is demonstrated.
 - Counseling is required.
 - Drug screening is required.
 - The VA system is similar to Alaska OTP centers.
 - Structure is 90% of what makes it work. Just throwing drugs at a problem doesn't fix it.
 - Delicate balance of keeping people alive going from street drugs to prescribed medications.
 - In Fairbanks they offer suboxone and methadone.
- Jennifer Stuke, Chief Operating Officer, Narcotic Drug Treatment Center, Inc.
 - Center has been operating in Alaska since 1974.
 - Currently provides seven programs throughout Alaska.
 - Highly regulated.
 - Always available for questions, keep a lot of data.
 - Stated her appreciation that a pharmacist is involved in the treatment program in the VA system since many of the traditional methods of treatment are difficult due to how difficult it is to treat fentanyl.
 - Methadone is the only treatment offered in Anchorage.
- See presentation below titled "Pharmacist led MAT/SUD team".

Agenda Item #5

Discussion:

- Jennifer Adams, PharmD, EdD, FAPhA, FNAP, Idaho State University
 - Introduced herself to the audience and provided a presentation covering the following topics:
 - Define standard of care and bright line regulation as they relate to pharmacy practice.
 - Describe the pharmacist patient care process and how it was developed.
 - Discuss how regulatory models and regulatory capture impact the pharmacist's ability to fully implement the pharmacist patient care process.

- Describe lessons learned from one state that has implemented standard of care regulation.
- Nicki Chopski, Executive Director, Idaho Board of Pharmacy
 - Discussed pharmacist prescriptive authority and Alaska’s statutory authority alongside Idaho’s stator authority.
 - Standard of Care model for regulatory and statutory guidance.
 - Bright Line Regulation.
 - Integrating “Standard of Care” into the guidelines for prescriptive authority.
- Suggested regulation change language provided to the board.
- James Henderson thanked Jennifer and Nicki for the information provided and stated this information will be helpful in addressing issues moving forward.
- Carla Hebert stated this presentation is very interesting and a lot for the board to think about.
- See presentation below titled “Perspectives on Implementing Standard of Care Regulation and its Impact on Pharmacist Independent Prescribing”.

Agenda Item #6 Statutes and Regulations Committee

Discussion:

- Eric Metterhausen, PharmD, BCPS, CPP, CPH, Indian Health Service (IHS)
 - Introduced himself to the audience and provided a presentation on pharmacist prescriptive authority.
- James Henderson stated he appreciated the presentation and the information provided to the board.
- See presentation below titled “Pharmacist Prescriptive Authority – North Carolina Clinical Pharmacist Practitioners”.

Agenda Item #7 Adjourn

- Ashley Schaber stated the statute and regulation committee is planning a meeting for August 02, 2023, from 4:00pm – 6:00pm.
- Next Quarterly meeting for the board is August 10, 2023, full day.

Motion: Carla Hebert motioned to adjourn, seconded by James Henderson.

Recorded Votes:

Ashley Schaber - Yes
Sara Rasmussen - Absent
James Henderson - Yes
Carla Hebert - Yes
Ramsey Bell – Yes
Sylvain Nouvion – Yes

It was resolved to adjourn at 5:58pm.

Pharmacist led MAT/SUD team

Presenter: Matthew Kirkland PharmD, BCGP

Anchorage Alaska VA SUD/MAT Overview

Step 2 program model


- Referral from Specialty Mental Health, Primary Care, Self referred
- Primary focus is to treat OUD/AUD patients and cooccurring disorders
- Patients require frequent follow ups, with closer lab monitoring/UDS
- Goal of 50 patients per provider
- Patients reevaluated every 90 days

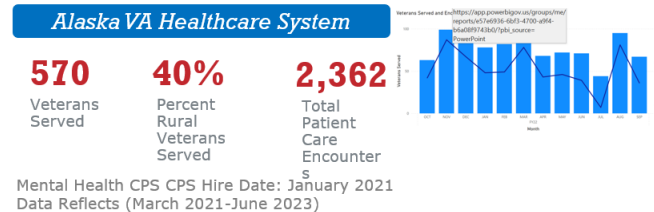
Team members

- Prescriber with XDEA, APRN
- Pharmacist with prescribing privileges
- SUD nurse, RN
- Addition therapist, LCSW


Pharmacist with Prescribing Privileges

- Diagnosis must be in chart!!!
- Prescribe MAT for AUD (naltrexone, topiramate, acamprosate, disulfiram) + comfort meds
- Prescribe MAT for OUD (naltrexone only) plus comfort meds
- Prescribe/adjust medication for cooccurring disorder (PTSD, Depression, Schizophrenia, etc.)
- Administer screenings (AUDIT-C, CIWA, PHQ-9, GAD-7, PCL-5 etc)
- Lab ordering, monitoring
- Enter consults for additional services (Job placement, Therapy, Inpatient treatment, Detox, etc.)
- Population management

 Clinical Pharmacy Specialist (CPS) Rural Veteran Access Initiative (CRVA): SUD/PCMHI CPS Integration and Impact




CPP Key Practice Highlights
 Dr. Matthew Kirkland, PharmD, BCGP
Care Team: Primary Care Mental Health Integration (PCMHI) and Substance Use Disorder (SUD)
Practice Focus: Substance Use Disorder (SUD), medication-assisted treatment, and mental health treatment
Top Interventions: Mental health, alcohol use disorder, opioid use, substance use disorder, pain, tobacco use disorder, and comprehensive health education

 Having Dr. Kirkland on our team has not only helped us as a team to grow and improve exponentially, but our veterans are finding hope beyond their substance use disorder." – Robin Scanlon RN

CPS Care Modalities

Telephone	44.2%
Chart Consult	5.7%
Face to Face	26.6%
VVC	19.0%

 **In Focus: Facility Quality Metrics**

Metric	Base-line	Impact date
Any AUD Rx	10.8%	14.7%
Naltrexone LAI	2.3%	4.5%
Acamprosate	0.9%	2.13%



Summary of CPP delivered Comprehensive Medication Management Services, Focus and Impact



Prescribing Challenges Encountered without DEA

- Unable to order controlled medications (Benzodiazepine and Z-drug tapers, Outpatient alcohol withdrawal, buprenorphine/naloxone, ADHD medications)
- HUGE TIME SINK!!
 - Needing DEA Provider to write for controls without seeing patient
 - Stigma
 - Difficulty finding provider for timely prescription
- Obtained Idaho pharmacist license in Sept 2021
- DEA license in October 2021

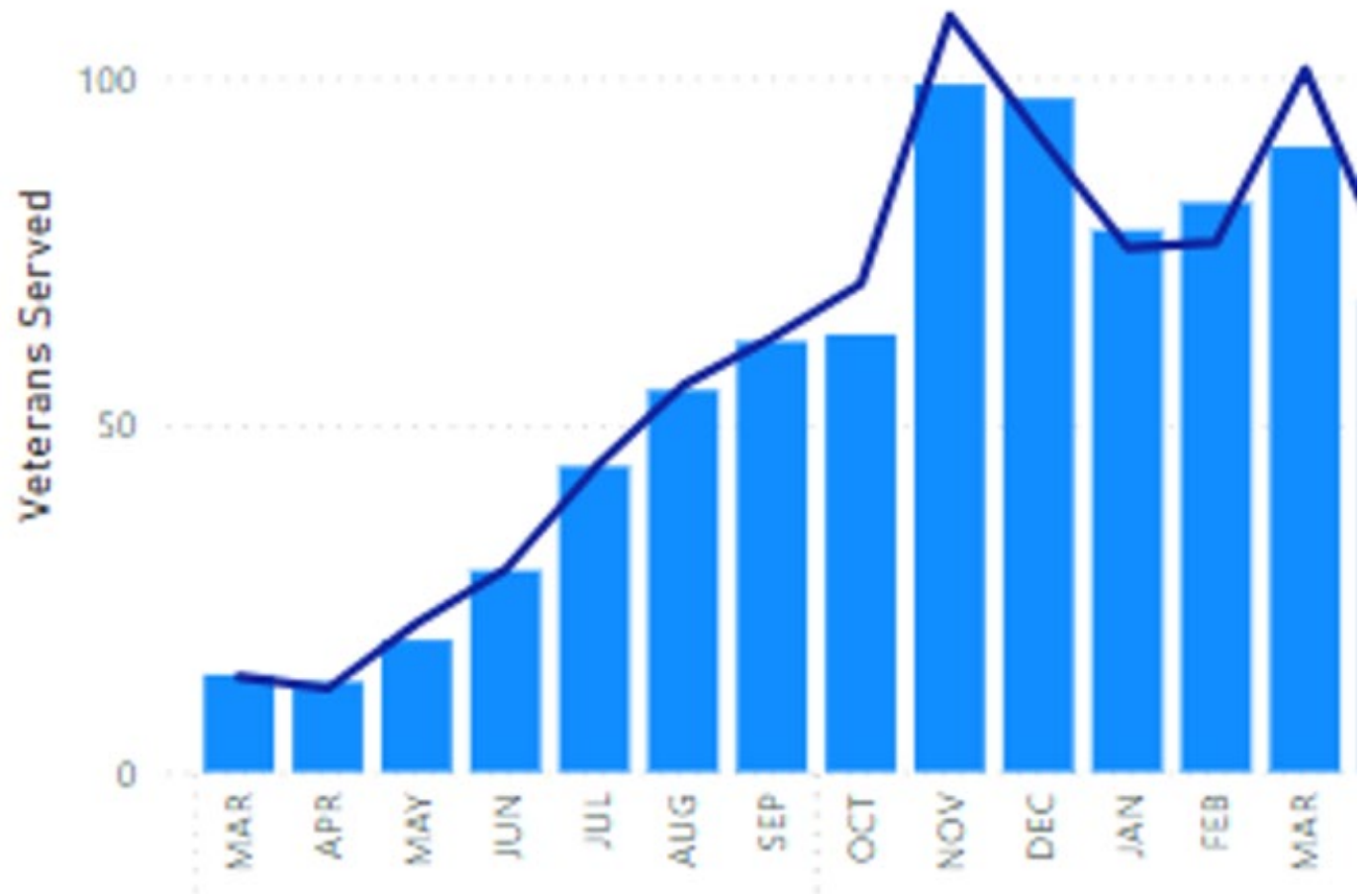
Loss of XDEA prescriber

XDEA prescriber moved to lower 48 in October 2021, at that time MAT/SUD team had 7 Veterans utilizing buprenorphine/naloxone

- Initially discussed what to do with these patients. Ultimately patients were transferred to PharmD for monitoring
- SUD team unable to do buprenorphine/naloxone initiations
- These Veterans have been sent to community

SUD team relied heavily on referring providers and SUD therapist for diagnosing Veterans with AUD/OUD

XDEA requirement removed 12/29/22



Outcome of PharmD lead SUD team

AUD

- MAT prescribing for AUD increased from 10.8%-15.7% (VISN 11.69%)
- Naltrexone LAI 4.5% at Alaska VA compared to 0.58% at VISN level
- More severe AUD was able to remain with SUD team.
 - Outpatient alcohol withdrawal protocols initiated and continued by PharmD

OUD

- All 7 Veterans transferred to PharmD were maintained on buprenorphine/naloxone to present day
 - Most Veterans tapered dose or converted to buprenorphine LAI
- SUD team currently have 15 Veterans utilizing buprenorphine for OUD
- Increase from 7-15 Veterans in 2 months

High Census was able to demonstrate continued need

- SUD psychiatrist hired April 2023
- VA has hired additional SUD/MAT pharmacist who is currently in training
- Expect continued increase in OUD patients with pharmacists being a critical component

2,362

Encounters

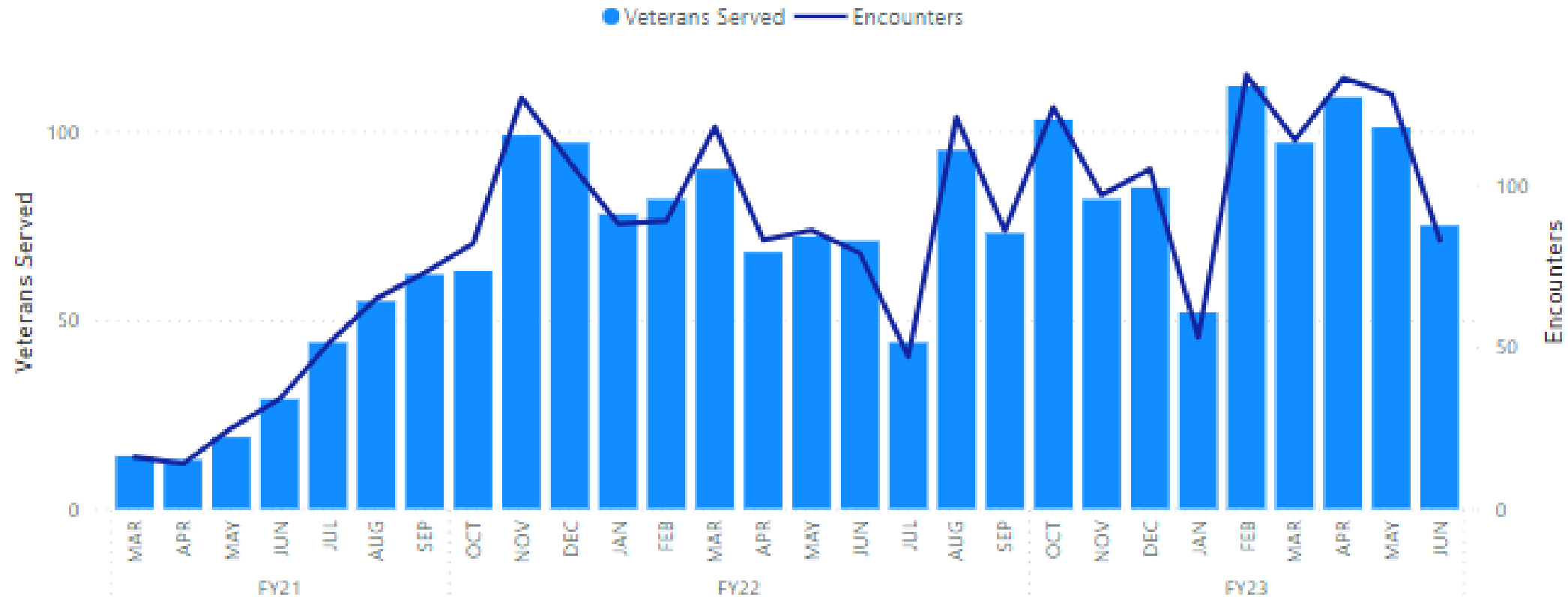
570

Veterans Served

Encounter Modalities

Modality	Encounters	% of Total
Telephone	1,044	44.20%
Face-to-Face	628	26.59%
VVC	448	18.97%
Chart Consult	135	5.72%
Group	47	1.99%
CVT	30	1.27%
Secure Messaging	30	1.27%
Total	2,362	100.00%

Veterans Served and Encounters by Fiscal Year and Month



Perspectives on Implementing Standard of Care Regulation and its Impact on Pharmacist Independent Prescribing

Jennifer L. Adams, PharmD, EdD, FAPhA, FNAP
Associate Dean for Academic Affairs,
Associate Professor
Idaho State University
College of Pharmacy

Nicole Chopski, PharmD, ANP
Executive Officer
Idaho State Board of Pharmacy

Bureau Chief – Health Professions
Division of Occupational and Professional Licenses



Learning Objectives

- Define standard of care and bright line regulation as they relate to pharmacy practice.
- Describe the pharmacist patient care process and how it was developed.
- Discuss how regulatory models and regulatory capture impact the pharmacist's ability to fully implement the pharmacist patient care process.
- Describe lessons learned from one state that has implemented standard of care regulation.



Learning Activity

- _____ population-based CPA
- _____ standard of care regulation
- _____ bright line regulation
- _____ pharmacist patient care process

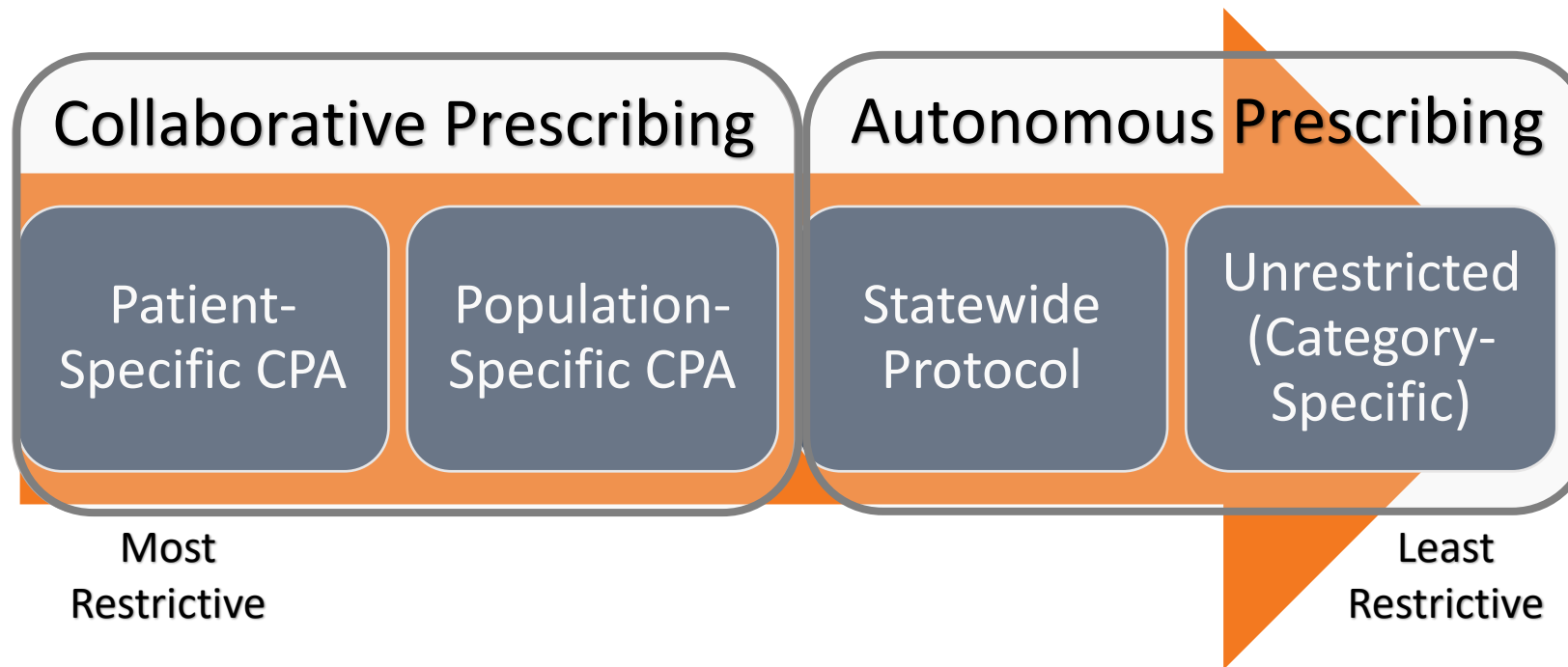


Definitions of Prescribing Activities

Activity	Definition
Select	When pharmacotherapy is necessary, and after review of an individual patient's history, medical status, presenting symptoms, and current drug regimen, the clinician chooses the best drug regimen among available therapeutic options.
Initiate	After selecting the best drug therapy for an individual patient, the clinician also determines the most appropriate initial dose and dosage schedule and writes an order or prescription.
Monitor	Once drug therapy is initiated, the clinician evaluates response, adverse effects, therapeutic outcomes, and adherence to determine if the drug, dose, or dosage schedule can be continued or needs to be modified.
Continue	After monitoring the current drug therapy of a patient, the clinician decides to renew or continue the same drug, dose, and dosage schedule.
Modify	After monitoring a patient's drug therapy, the clinician decides to make an adjustment in dose and/or dosage schedule, or may add, discontinue, or change drug therapy.
Administer	Regardless of who initiates a patient's drug therapy, the clinician gives the drug directly to the patient, including all routes of administration.



Continuum of Pharmacist Prescriptive Authority





Idaho Pharmacist Prescribing Laws - History

- Dietary fluoride supplements
- Immunizations, for patients ≥ 6 years old
- Opioid antagonists
- Epinephrine auto-injectors
- Tobacco Cessation
- TB Skin Testing
- ...or under Collaborative Practice Agreements
- ~~Chapter 4 of Idaho Board of Pharmacy Rules~~

Idaho Pharmacist Prescribing Laws - History

54-1704 Provisions for pharmacist prescribed products

- 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 (*CLIA-waived test*); or
 - (iv) In the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such cases, only sufficient quantity may be provided until the patient is able to be seen by another provider.
- The board shall not adopt any rules authorizing a pharmacist to prescribe a controlled drug.



Idaho Pharmacist Prescribing Laws

Idaho State
University

15 SECTION 1. That Section [54-1704](#), Idaho Code, be, and the same is hereby
16 repealed.

40 ~~(3349)~~ "Practice of pharmacy" means the safe interpretation, evalu-
41 ation, compounding, administration, and dispensing of prescription drug
42 orders, patient counseling, collaborative pharmacy practice, provision of
43 pharmaceutical care services, proper storage of drugs and devices, and pre-
44 scribing of drugs and devices as may be further defined in this chapter.



Existing Independent Prescribing Authority in AK

- ~~Collaborative Practice Authority~~
- AS 08.80.168(a) – vaccines and related emergency medications
- AS 08.80.168(b) – opioid overdose drug



AS 08.80.337 Other patient care services .

(a) A pharmacist may, under a collaborative practice agreement with a written protocol approved by a practitioner, provide patient care services.

(b) A pharmacist may independently provide patient care services for

(1) general health and wellness;

(2) disease prevention; or

(3) a condition that (A) is minor and generally self limiting; (B) has a test that is used to guide diagnosis or clinical decision-making and the test is waived under 42 U.S.C. 263a (Clinical Laboratory Improvement Amendments of 1988); or (C) falls under a statewide standing order from the chief medical officer in the Department of Health.

(c) This section does not authorize a pharmacist to prescribe a prescription drug that the pharmacist is not otherwise authorized to prescribe.

(d) In this section, "patient care services" means medical care services given in exchange for compensation intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.



Standard of Care Regulation

- The “medical standard of care” is typically defined as the level and type of care that a reasonably competent and skilled health care professional, with a similar background and in the same medical community, would have provided under the circumstances. This is often considered within the context of actions that led to alleged malpractice.¹
- The regulatory model based on the “standard of care” is determined by the individual circumstances that present in practice rather than specific requirements codified in law, allowing for flexibility as practice guidelines change, technology changes, and new knowledge is identified. This model requires less regulatory modification to keep pace with change.¹
 - Example: IDAPA 24.36.01.104.16 **Standard of Care**. 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.



Bright Line Regulation

- An objective rule that resolves a legal issue in a straightforward, predictable manner. A bright-line rule is easy to administer and leaves little room for varying interpretation.
 - Example: *Miranda v. Arizona* (1966) establishing Miranda warning of rights to criminal suspects
 - Example: IDAPA 24.36.01.213 Each pharmacist must complete fifteen (15) CPE hours each calendar year between January 1 and December 31.



Scope of Practice

The services that a qualified health care professional is deemed competent to perform and permitted to undertake in keeping with the terms of their professional licensure.

Scope of Practice

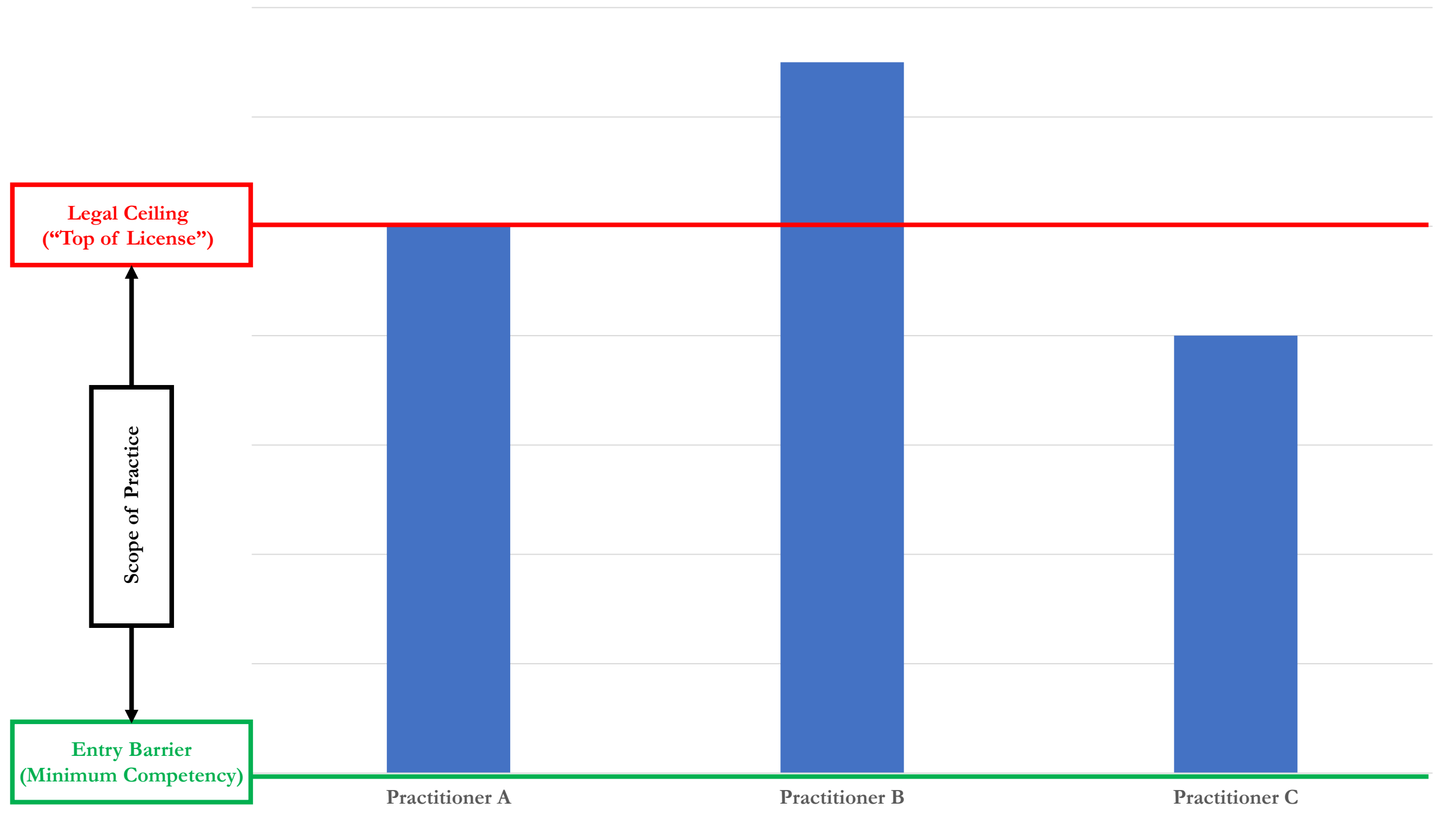
- The activities that a health professional is permitted to engage in as defined by state laws and regulations
- Determined by the political process = geographical differences
- One-size-fits all: applies to all professionals in class
- Static (aside from law changes)

Clinical Ability

- The true competence and ability of the health professional
- Determined by education, training, career experience, and practice environment
- Individualistic: recognizes professional heterogeneity
- Dynamic; advances with new education, technology, etc.

MAY

CAN



Legal Ceiling
("Top of License")

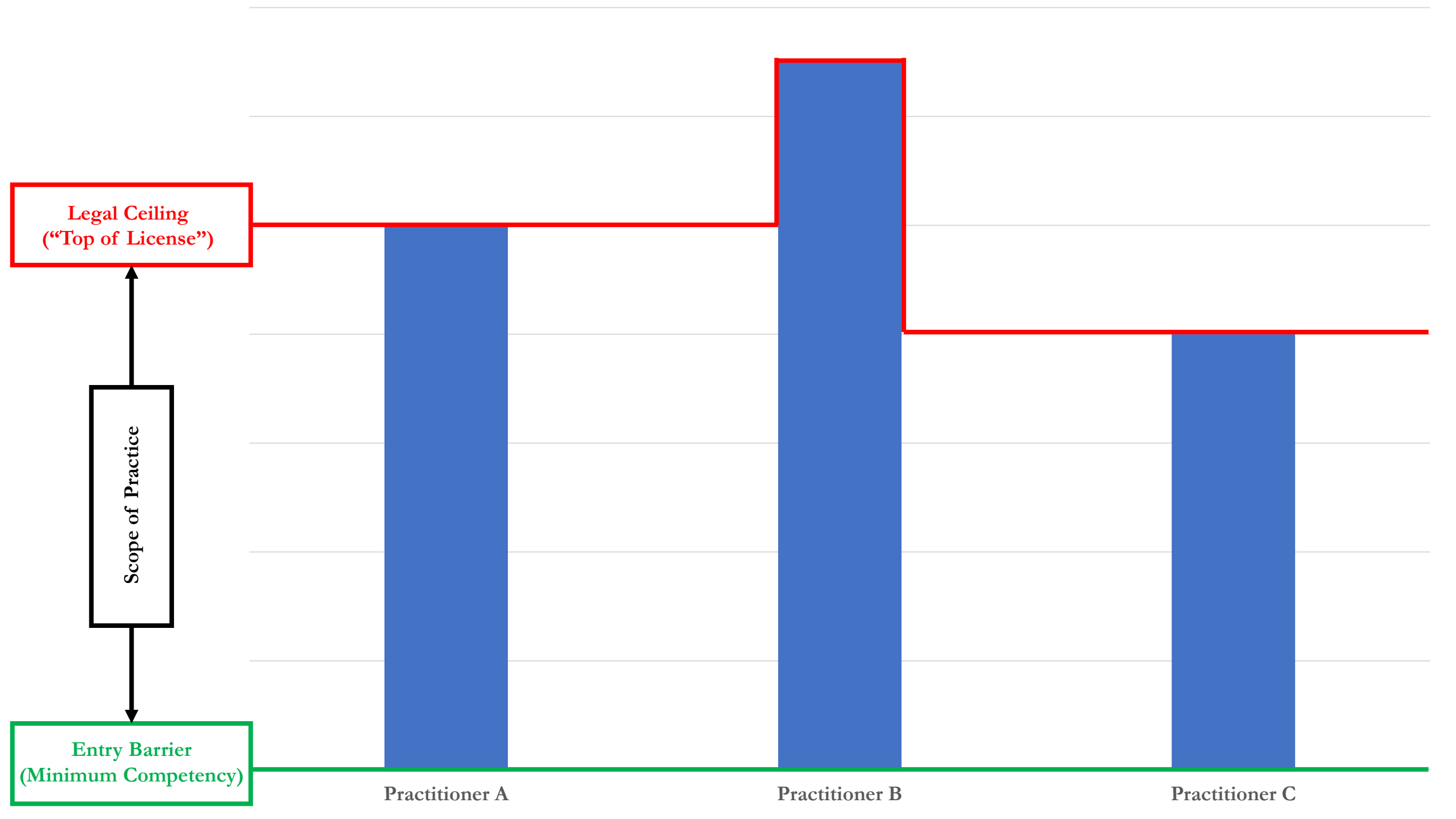
Scope of Practice

Entry Barrier
(Minimum Competency)

Practitioner A

Practitioner B

Practitioner C



Legal Ceiling
("Top of License")

Scope of Practice

Entry Barrier
(Minimum Competency)

Practitioner A

Practitioner B

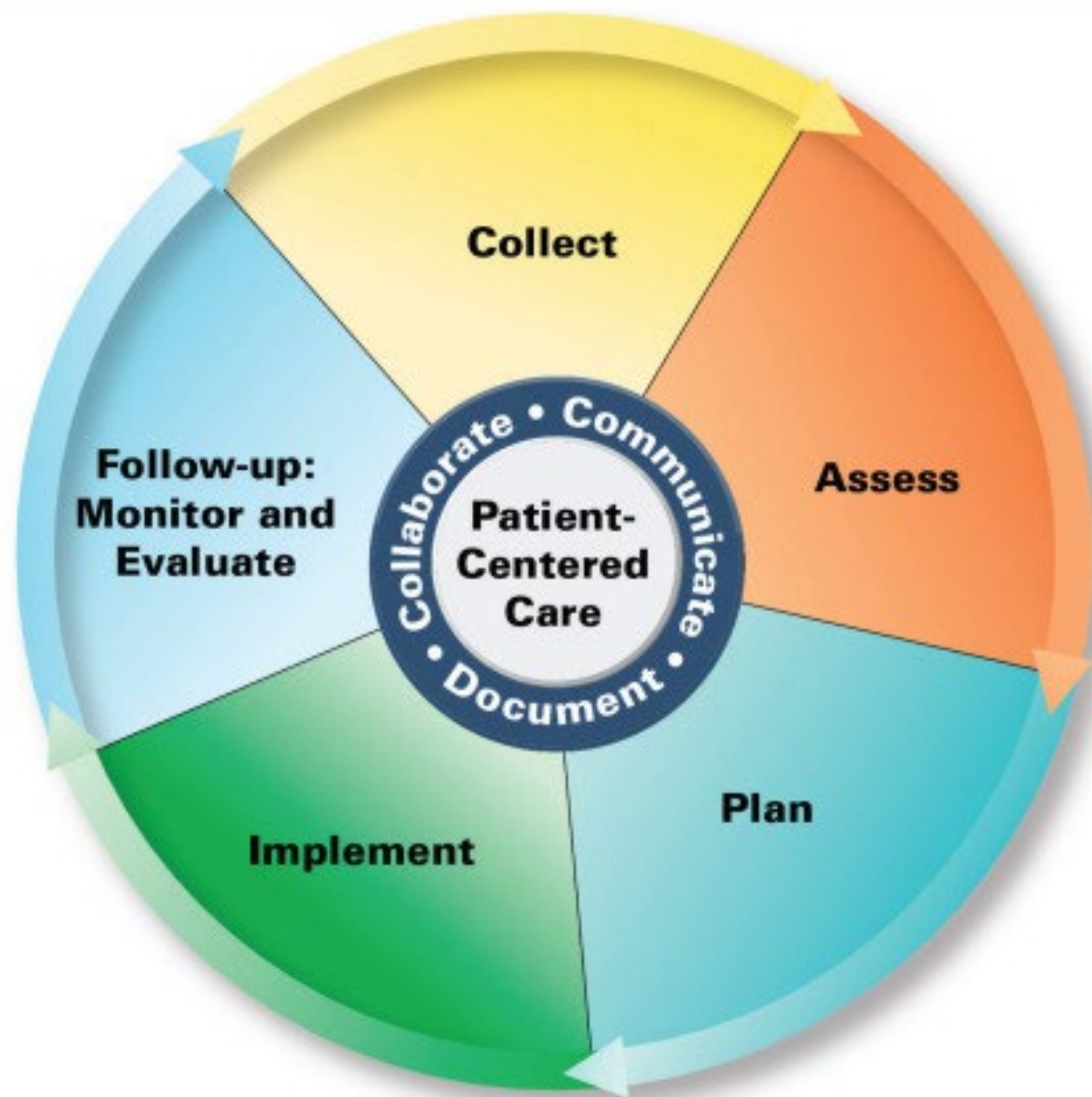
Practitioner C



Pharmacists Patient Care Process (PPCP)

- In 2014, the Joint Commission of Pharmacy Practitioners (JCPP) developed and released the Pharmacists' Patient Care Process
- The PPCP is the profession's systematic approach for pharmacist provision of care, regardless of the type of service or the pharmacy practice setting
- ACPE requires pharmacy schools include in curricula
- Consistent implementation across the profession is critically important to effectively measure the outcomes and value of pharmacists' services, and so that consumers, health care providers, and payers have consistent expectations for the services they receive from pharmacist

Pharmacists' Patient Care Process



Pharmacists' Patient Care Process

Pharmacists use a patient-centered approach in collaboration with other providers on the health care team to optimize patient health and medication outcomes.

Using principles of evidence-based practice, pharmacists:

Collect

The pharmacist assures the collection of the necessary subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient.

Assess

The pharmacist assesses the information collected and analyzes the clinical effects of the patient's therapy in the context of the patient's overall health goals in order to identify and prioritize problems and achieve optimal care.

Plan

The pharmacist develops an individualized patient-centered care plan, in collaboration with other health care professionals and the patient or caregiver that is evidence-based and cost-effective.

Implement

The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver.

Follow-up: Monitor and Evaluate

The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed.



Scope of Practice Activity	Brief Description	PPCP¹ Step Impacted
Order and Interpret Laboratory Tests	Laboratory tests may be “waived” or “non-waived” according to CLIA. Pharmacies commonly hold CLIA certificates of waiver to provide simply, low-risk tests, like those for testing blood glucose, cholesterol, or for influenza. Laboratory tests may be used to monitor medication therapy outcomes or disease progression.	Collect; Follow-Up
Participate in Collaborative Practice Agreements (CPA)	A CPA is a formal agreement between pharmacists and other healthcare providers in which the pharmacist is authorized to perform services that are otherwise outside of his or her legal scope of practice, but for which the pharmacist is educationally and clinically prepared. CPAs are the primary vehicle through which pharmacists may initiate, modify, or discontinue medications. Though not preferred, in some states CPAs are the only current vehicle through which pharmacists can order and interpret laboratory tests, adapt medications, or administer medications.	Collect; Implement; Follow-Up
Independently Prescribe Certain Medications	Independent prescribing refers to a pharmacist selecting a medication for a patient, along with the dosing regimen for a medication without the need for a CPA. Some states currently allow pharmacists to independently prescribe certain medications, such as hormonal contraceptives or tobacco cessation medications.	Implement



Scope of Practice Activity	Brief Description	PPCP ¹ Step Impacted
Adapt Medications	Adapting a medication is differentiated from independently prescribing in that it results in modifying a prescription from another prescriber. Today independent adaptation is generally limited to modifying the quantity of a prescription (e.g., converting from a 30-day supply to a 90-day supply) or, less commonly, engaging in therapeutic substitution.	Implement
Administer Medications	A pharmacist most commonly administers a medication to a patient by injection, though administration encompasses many routes of delivery (oral, topical, sub-dermal, subcutaneous, intramuscular, intranasal, etc.).	Implement
Effective Delegation to Support Personnel	Effective delegation involves empowering pharmacists with the discretion to delegate tasks to technicians and student pharmacists under their supervision. Most states restrict which tasks pharmacists can delegate to support personnel, and studies show this may redirect pharmacist time to low-value tasks and away from the PPCP.	Collect; Implement; Follow-Up
Cognitive Services	Cognitive services such as evaluating medication therapy-related problems and formulation of a care plan are not typically restricted by scope of practice in states, as professional judgment is inherent in the pharmacists' work. Payment for services continues to be an issue, though this is a separate matter from scope of practice.	All steps, though particularly the Assess and Plan steps



Benchmarking the Regulatory Environment

Table 1
Pharmacy regulatory innovation index

Category/subcategory and points	Score adjustments Cut the score in half if:	Notes
1. CPA A. Patient-specific: 10 points B. Population-specific: 20 points	Two or more restrictions apply: 1. Limits on which prescribers may enter into a CPA; 2. Limits on which pharmacists may enter into a CPA (e.g., training requirement); 3. Limits on practice setting; 4. Limits on type of prescribing authority (e.g., limited to modification of therapy); or 5. CPA must be reviewed or approved by a regulatory body.	A and B are mutually exclusive. Minimum score = 0; maximum score = 20
2. Order and administer laboratory tests and interpret the results ^a A. Only specific tests allowed: 5 points B. Any test allowed: 10 points	Either of the following apply: 1. Limits on which pharmacists can perform tests (e.g., specific training requirements); or 2. State restrictions above federal CLIA laws (e.g., requiring a physician laboratory director).	A and B are mutually exclusive. Minimum score = 0; maximum score = 10
3. Administer vaccines ^a A. Limited to vaccines listed in statute or rule: 5 points B. All FDA-approved vaccines: 10 points	Any of these restrictions apply: 1. Limits on which patients may be vaccinated (e.g., age limits); 2. Limits on which pharmacists may vaccinate (e.g., training requirement); or 3. Limits on following specific state or national guidelines (e.g., CDC guidelines).	A and B are mutually exclusive. Minimum score = 0; maximum score = 10
4. Administer other medications (i.e., nonvaccines) ^a A. Limited to medications listed in statute or rule: 5 points B. Any medication: 10 points	There are limits on which pharmacists can administer other medications (e.g., training requirement).	A and B are mutually exclusive. Minimum score = 0; maximum score = 10



Benchmarking the Regulatory Environment

<p>5. Prescription adaptation services^a</p> <ul style="list-style-type: none"> A. Renew prescription (i.e., extend a refill of at least 30 days): 5 points B. Perform therapeutic substitution: 5 points C. Change the quantity (e.g., 30- to 90-day switch, extend for medication synchronization, and so on): 5 points 	<p>Any of these restrictions apply to their respective categories:</p> <p>A: 1. Limits on which pharmacists can renew prescription (e.g. training requirement); or 2. Authority limited to governor-declared emergency.</p> <p>B: 1. Limits on practice setting (e.g., institutional only); or 2. Restricted to certain drug classes;</p> <p>C: 1. Initial 30-day prescription required before quantity changes allowed; or 2. Restricted to certain drug classes.</p>	<p>A, B, and C are not mutually exclusive.</p> <p>Score adjustments apply only to their respective subcategory.</p> <p>Minimum score = 0; maximum score = 15.</p>
<p>6. Independent prescriptive authority (direct medication access from pharmacists)^a</p> <ul style="list-style-type: none"> A. Allows independent prescribing of at least 1 prescription drug category: 5 points B. Board of pharmacy or public health department determines which medications pharmacists can prescribe: 15 points C. Pharmacists to determine which medications to prescribe within a broad regulatory framework: 20 points 	<p>Any of these restrictions apply to their respective categories:</p> <ul style="list-style-type: none"> A Specific training is required. B The protocol must be approved or recommended by another regulatory board or committee. 	<p>Include statewide protocols. Do not include OTC drugs or vaccines.</p> <p>A, B, and C should be considered mutually exclusive. Although some states may combine A and B, or A and C, if either B or C are present, these should supersede A for scoring purposes.</p> <p>Minimum score = 0; maximum score = 20</p>
<p>7. Advanced delegation to technicians</p> <ul style="list-style-type: none"> A. Final product verification: 5 points B. Administer vaccines or other medications: 5 points C. Accept verbal orders and transfer prescriptions: 5 points 	<p>Any of these restrictions apply:</p> <ul style="list-style-type: none"> 1. Limits on practice setting (e.g., institutional only). 2. Requires board approval or submission of a technician duty use document. 	<p>A, B, and C are not mutually exclusive; each subcategory is cumulative.</p> <p>Minimum score = 0; maximum score = 15</p>

Abbreviations used: CPA, collaborative practice agreement; CLIA, Clinical Laboratory Improvement Amendments; FDA, Food and Drug Administration; CDC, Centers for Disease Control and Prevention; OTC, over the counter.

^a If a CPA, standing order (including statewide standing order), or physician protocol is needed, no points are awarded.



Lessons Learned: Key Success Factors

- Keep the focus on public safety
- Strategic planning meetings to align the Board around direction and framework before getting into the rulemaking or legislation details
- Empower board staff to draft new rules or statute language and do not wordsmith in public meetings
- Place the burden of proof on those advocating to add back in or increase regulation
- Create proper accountability measures for disciplining standard of care cases



Lessons Learned: Barriers to Reform

- General professional reticence
- Judging policy by your own personal interests
- Treating every issue as brand new and not learning from the experiences of other professions or jurisdictions
- Defining requirements for every new task, business model, or facility type
- Adding new rules without a review/amendment/sunset process for the entire rule or other similar rules



Suggested Rule Changes for AK

OPTION A

Article 2 Personnel

12 AAC 52. 205 PRACTICE OF PHARMACY: GENERAL APPROACH

To determine whether a specific act is within the scope of pharmacy practice in or into Alaska, or whether an act can be delegated to other individuals under their supervision, a licensee or registrant of the Board must independently determine whether:

01. Express Prohibition. The act is expressly prohibited by:

- a. The rules of the Alaska State Board of Pharmacy; or
- b. Any other applicable state or federal laws or regulations.

02. Education, Training, and Experience. The act is consistent with licensee or registrant's education, training, and experience.

03. Standard of Care. The act is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training, and experience.



Suggested Rule Changes for AK

OPTION B

Article 11 General Provisions

12 AAC 52. 996 DEFINITIONS

New (25) “standard of care” means care provided by a licensee or registrant that is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training, and experience.



Suggested Rule Changes for AK

Article 10 Alaska Disciplinary Guidelines

12 AAC 52.920 Disciplinary Guidelines

(15) failing to use reasonable knowledge, skills or judgment in the practice of pharmacy

(a) Standard of Care. 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.



References

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Perspectives on Implementing Standard of Care Regulation and its Impact on Pharmacist Independent Prescribing


Jennifer L. Adams, PharmD, EdD, FAPhA, FNAP
Associate Dean for Academic Affairs,
Associate Professor
Idaho State University
College of Pharmacy

Nicole Chopski, PharmD, ANP
Executive Officer
Idaho State Board of Pharmacy

Bureau Chief – Health Professions
Division of Occupational and Professional Licenses

Pharmacist Prescriptive Authority – North Carolina Clinical Pharmacist Practitioners

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Eric Metterhausen, PharmD, BCPS, CPP, CPH
CDR, United States Public Health Service
Advanced Clinical Pharmacist Supervisor
Cherokee Indian Hospital
Eric.Metterhausen@cherokeehospital.org



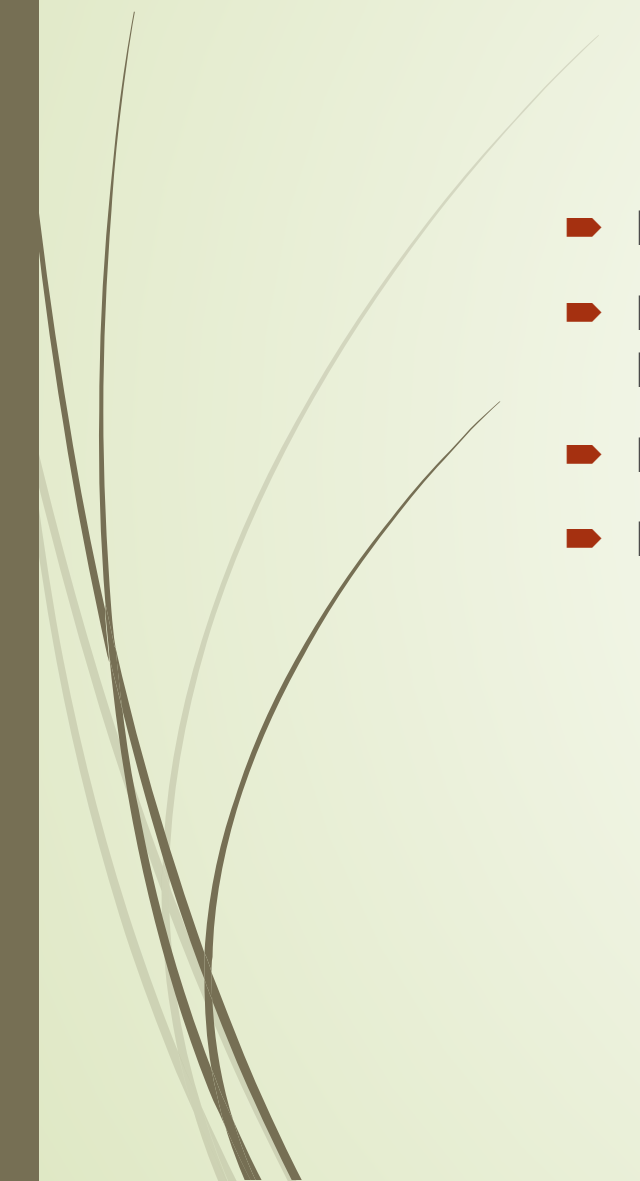
Disclosures



- ▶ I have no relationships with commercial interests related to the content of my presentation.
- ▶ The views expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of the U.S. Department of Health and Human Services, the Indian Health Services, or the U.S. Government



Objectives

- Define Clinical Pharmacist Practitioners (CPPs) in North Carolina
 - Discuss how CPPs have been integrated into practice at Cherokee Indian Hospital
 - Discuss the impact made by CPPs
 - Discuss some strengths and limitations of CPP licensure
- 



Clinical Pharmacist Practitioners

- ▶ A CPP is a licensed pharmacist approved to provide drug therapy management, including controlled substances, under the direction of, or under the supervision of a licensed physician.
- ▶ Additional requirements beyond pharmacist licensure
 - ▶ ASHP Residency and 2 years clinical experience
 - ▶ Doctor of Pharmacy Degree with 3 years clinical experience and 1 certificate program
 - ▶ B.S. Degree with 5 years clinical experience and two certificate programs
 - ▶ 35 hours of CE annually for renewal
- ▶ CPP protocol agreement
 - ▶ List of medical conditions that can be referred to CPP
 - ▶ List of medication classes authorized to be prescribed by CPP
 - ▶ List of tests that can be ordered by CPP
 - ▶ Emergency plan, consultation, supervision, quality control, and review

http://www.ncbop.org/pharmacists_cpp.htm

http://www.ncbop.org/faqs/Pharmacist/faq_CPPs.htm




CPPs at Cherokee Indian Hospital

- Originally utilized local policies and protocols for pharmacists to manage chronic disease states, such as anticoagulation, hypertension, and diabetes
- In Sept. 2017 transitioned to utilizing CPP agreements to directly prescribe medications and greatly expanded disease state managed over time
 - Diabetes, hypertension, asthma, tobacco use, hyperlipidemia, osteoporosis, hepatitis C, COPD, thyroid disorders, obesity, depression, anticoagulation, anxiety, COVID-19
 - Continue to make recommendations in other disease states, but do not prescribe under our own names.
- 6 full time CPPs for ~14,000 empaneled patients
- CPPs begin prescribing upon referral/consult from their supervising physician
 - Referral initiated by physician, CPP, or nursing team
 - CPP sees/calls patient as frequently as necessary
 - Notes sent to PCP and PCP generally continues to see patient every 6 months
 - Consults often completed when patient has reached goal



Relationship Based Care

- ▶ “They don’t care what you know until they know that you care”
- ▶ Patient-Centered Medical Home
 - ▶ High quality, cost-effective primary care
 - ▶ Culturally appropriate, team based approach
 - ▶ Improved patient and provider satisfaction
 - ▶ Preventative Care
- ▶ Cherokee Indian Hospital
 - ▶ Every empaneled patient has an assigned Clinical Pharmacist Practitioner
 - ▶ Learning the patient's story and developing a relationship with patient
 - ▶ Opportunities to impact health behaviors



Diabetes Management During COVID-19

- ▶ CPPs utilized established relationships with patients
- ▶ April 2020 through September 2020
 - ▶ Converted over 1,000 visits to telephone or telehealth visits
 - ▶ For those patients with initial A1cs >8%
 - ▶ 113 patients with 345 visits
 - ▶ 1.52 percentage point average decrease in A1c
 - ▶ 0.5 percentage point average decrease in A1c per each pharmacist visit



CIHA Hepatitis C

- Several staff members received training via in-person ECHO training in 2018
- Originally no HCV treatments on formulary
- Initiated an outpatient pharmacist-operated HCV protocol
- Expanded to an inpatient protocol
- In 2022 alone:
 - 86 patients obtained SVR 12.
 - 35 patients on treatment or awaiting SVR 12 labwork



Additional Impacts

- ▶ Over 800 documented clinical interventions per month in 2022
- ▶ Approximately \$35,000 per month in collections based on visits.
 - ▶ CPPs recognized as providers in NC Medicaid (~20% of patient population)
- ▶ Reduced wait time for Primary Care visits by 60%
- ▶ Brought 60% of consulted hypertension patient within goal with an average BP reduction of 16/5mmHg
- ▶ Decreased the number of patients utilizing tobacco products by 5%



Strengths of CPP licensure

- ▶ Provide ability for CPPs to prescribe medications and order labs, improving patient care and safety
- ▶ Reasonable licensure requirements
- ▶ Allow for additional billing opportunities through NC Medicaid
- ▶ Ability to prescribe controlled substances
- ▶ Ability to utilize back-up physicians



Limitations of CPP licensure

- ▶ Requires referral/evaluation by supervising physician
 - ▶ Many Primary Care Providers are NPs or PAs
 - ▶ Supervising physician can only supervise up to 3 FTE CPPs
 - ▶ Initial quality control meeting with CPP/supervising physician are monthly for the first 6 months, then every 6 months.
- ▶ Lengthy review process upon protocol updates
- ▶ Not recognized as a provider by Medicare or private insurers
- ▶ Inability to diagnose
- ▶ Does not authorize physical examination



Questions?

