



Standard of Care Model: Leveraging Pharmacy to Support Safe, Effective Medication Use

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Unmet Patient Needs

- **California's Senior Population Projected to DOUBLE BY 2030:**
 - Projected growth in over-65 population by **4 million people** with at least 1 million needing some **assistance with self-care** by 2030
- **Approximately 50% of Americans live with ≥ 1 chronic condition¹**
 - For adults 65 and older:
 - Over 3/4th have **at least 1 chronic condition** requiring medication therapy
 - 28% take **5 or more chronic medications** each month



Increasing complexity of patients and their treatment regimens in primary care **requires access to providers** who can manage patients' **medication therapy**, identify **adverse events**, and manage **drug-related problems**

Contemporary Pharmacy Practice

Profession of Pharmacy

*"I will apply my knowledge, experience, and skills to the best of my ability to assure optimal outcomes for all patients."
– Oath of a Pharmacist*



Report to the US Surgeon General 2011 US Public Health Service

"**maximize the expertise and scope of pharmacists**, and minimize expansion barriers of existing and successful health care delivery mode"

Regina Benjamin, MD, MBA, the former U.S. Surgeon General, responded: "expanded pharmacy practice models...improve patient and health-system outcomes" and recommended policymakers determine methods to optimize the pharmacist's role in management and prevention of disease.



U.S. Department of Veterans Affairs

"Clinical pharmacist provides **comprehensive medication management** ...scope of practice support **high level of autonomy** and **independent decision-making**"



The California Pharmacists Association

Supports "...the ability and freedom to **practice their profession to the fullest extent**"



Centers for Medicare & Medicaid Services

"**broadened the concept of 'medical staff'**" that "**allows hospitals to give practitioners**, such as **pharmacists**, the power to perform duties that they are trained for..."



American College of Clinical Pharmacy

"Clinical pharmacists are **practitioners** who provide **comprehensive medication management**..."



High-value pharmacy enterprise project:

"pharmacists provide **comprehensive pharmacy patient care services as providers**..."

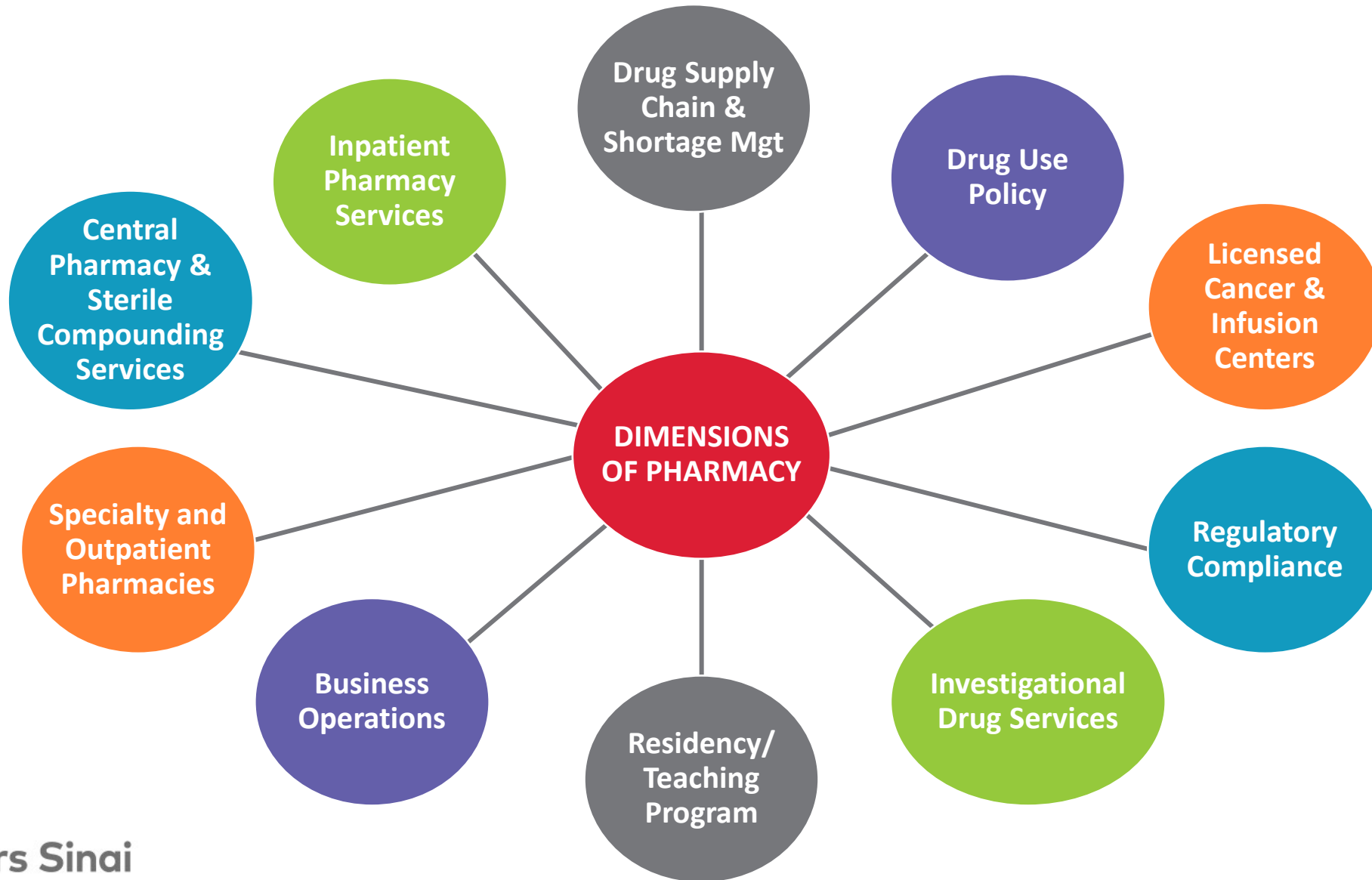
"pharmacists are **accountable for all patient medication-use needs** to support safe and effective drug therapy management:

"pharmacists collaborate with care providers...to **optimize patient health and well-being**"

References (Accessed 3/2//2022):

- ACCP: [scopeofpractice.pdf \(accp.com\)](#); Standards of Practice for Clinical Pharmacists - - 2014 - Pharmacotherapy: The Journal of Human Pharmacology
- AJHP: <https://doi.org/10.2146/ajhp120546>
- APhA/CMS: [https://www.pharmacytoday.org/article/S1042-0991\(15\)31774-6/fulltext](https://www.pharmacytoday.org/article/S1042-0991(15)31774-6/fulltext)
- CPHA: <https://cpha.com/wp-content/uploads/2021/05/CPhA-Policy-Manual-2020.pdf>
- CPHA: <https://cpha.com/about/pharmacist-101-behind-the-white-coat/>
- HVPE: https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/Pharmacy_HVPE_Report_2020_Public.pdf
- JCAPP: <https://jcapp.net/patient-care-process/>
- Oath: <https://pharmacist.com/About/Oath-of-a-Pharmacist>
- US Public Health Service: <https://jcapp.net/wp-content/uploads/2015/09/Improving-Patient-and-Health-System-Outcomes-through-Advanced-Pharmacy-Practice.pdf>
- VA: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7182371/>

Dimensions of Pharmacy Practice



Contemporary Hospital Pharmacy Practice

2018 and 2019 ASHP National Survey evaluating practices and technologies related to prescribing and transcribing

Pharmacists practicing within health system pharmacies:

- Collaborate with interdisciplinary teams to ensure safe and effective use of medications
- Work within the electronic medical record to optimize and monitor all medication therapies
- Serve as a vital member within the emergency response team to provide medication recommendations and support during hospital emergency codes

Pharmacists have authority to write medication orders:

89%

Pharmacists have authority to select product and dosing:

72%

Pharmacists have authority to order serum medication concentration and adjust dosages:

85%

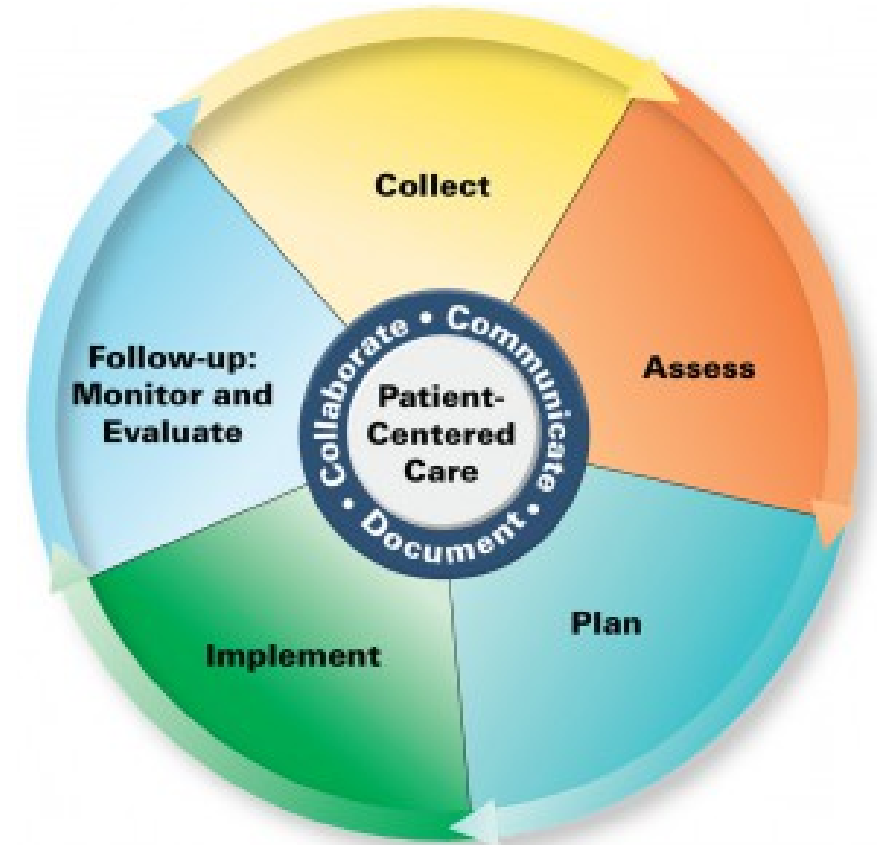
Pharmacists use clinical surveillance data within the electronic health record to assist with daily patient monitoring:

75%

CSMC Clinical Pharmacy Services

Approved by Medical Staff Pharmacy & Therapeutics Committee

Policy & Procedures based on published evidence & best practices	Descriptions
Pharmacy Clinical Service Plans	Define the minimum clinical pharmacy services that all patients shall receive throughout inpatient admission
Autosubstitutions Policies	Approved lists of medications in which pharmacists can substitute per policy to accommodate shortages, formulary restrictions, etc.
Per Pharmacy Policies	<ul style="list-style-type: none"> ➤ Antimicrobials Dosing ➤ Anticoagulation Dosing
Pharmacist Clarification of Medication Orders	Define when pharmacists can initiate clarifications in medication orders (e.g., extend antibiotic orders for select patients in the ED, dose rounding, duplicate therapies)



Pharmacy Staff Improve Patient Outcomes

Why a Standard of Care Model Matters?

Examples	Impact
<p>Antibiotic Redosing in the Emergency Department <i>(CSMC Study: Payne-Cardona M, San Luis VA, Aazami R, et al., 2021)</i></p>	<ul style="list-style-type: none"> • Significant reduction in mortality (3% vs 11%, p=0.02) • Reduced major delays of antibiotic administration (13% vs 48%, p<0.01) • 47% of patients had sepsis
<p>IV to PO Antibiotic Conversion in Stable Bacteremia Patients <i>(CSMC Study: Jan – Jun 2021)</i></p>	<ul style="list-style-type: none"> • Of 463 patients reviewed, 26% (n=120) were eligible for IV to PO conversion of their antibiotic(s) used to treat bloodstream infection • Interdisciplinary IV to PO conversion resulted in: 611 total bed days saved
<p>Admission Medication Reconciliation <i>(CSMC Study: Pevnick JM, et al., 2018)</i></p>	<ul style="list-style-type: none"> • Reduced admission medication history errors by 80%
<p>Postdischarge Follow-Up <i>(CSMC Study: Noh L, Heimerl K, Shane RS, 2020)</i></p>	<ul style="list-style-type: none"> • Of cases identified as medication-related acute care episodes (MACEs), pharmacists prevented 27.9% of readmissions <ul style="list-style-type: none"> • 2.8% of identified drug-related problems were potentially life-threatening • 56.6% of identified drug-related problems were serious or significant

Regulatory Landscape

Standard of Care Approach Across Regulatory Boards

National Association of Boards of Pharmacy	Medical Board of California	Idaho Board of Pharmacy
<p>“Standard of Care’ means the degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances”</p>	<p>“Physicians and Surgeons licensed in the State of California must practice competently and within the applicable medical standard of practice.”</p> <p>The standard of care owed to patients is the “level of skill, knowledge and care in diagnosis and treatment ordinarily possessed and exercised by other reasonably careful and prudent physicians in the same or similar circumstances at the time in question.”</p>	<p>“...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.”</p>

Scope of Medication Management: Pharmacists and Allied Health Professionals

PHARMACISTS

Article 3; “Notwithstanding any other law, a pharmacist may do all of the following...”

- 4050- • Various “permitted procedures by pharmacist” are listed in detail in Article 3, including prescriptive
4068 provisions to initiate/furnish HIV pre/postexposure prophylaxis, emergency contraception, vaccinations,
 and other medication-related services

PHYSICIAN ASSISTANTS

3502.1a “The PA shall furnish or order a drug or device in accordance with the practice agreement and consistent with
 the PA’s educational preparation or for which clinical competency has been established and maintained.”

NURSE PRACTITIONERS

2836.1a “Drugs furnished or ordered by NP in accordance with standardized procedures or protocols developed by the
 NP and the supervising physician and surgeon when the drugs or devices furnished or ordered are consistent
 with the practitioner’s educational preparation or for which clinical competency has been established and
 maintained.”

Pharmacists are allowed **permitted procedures with prescriptive provisions** whereas other allied health professionals have broader authority for medications based on the **practitioner’s educational preparation**.

Selected Idaho “Standard of Care” Pharmacy Laws

Rule 27.01.01.020 provides guidance to licensees as they determine whether a specific act is permissible. First, a licensee should **consider whether the act is expressly prohibited by any state or federal law**.

To navigate this change from prescriptive rules to professional judgement, ask oneself:

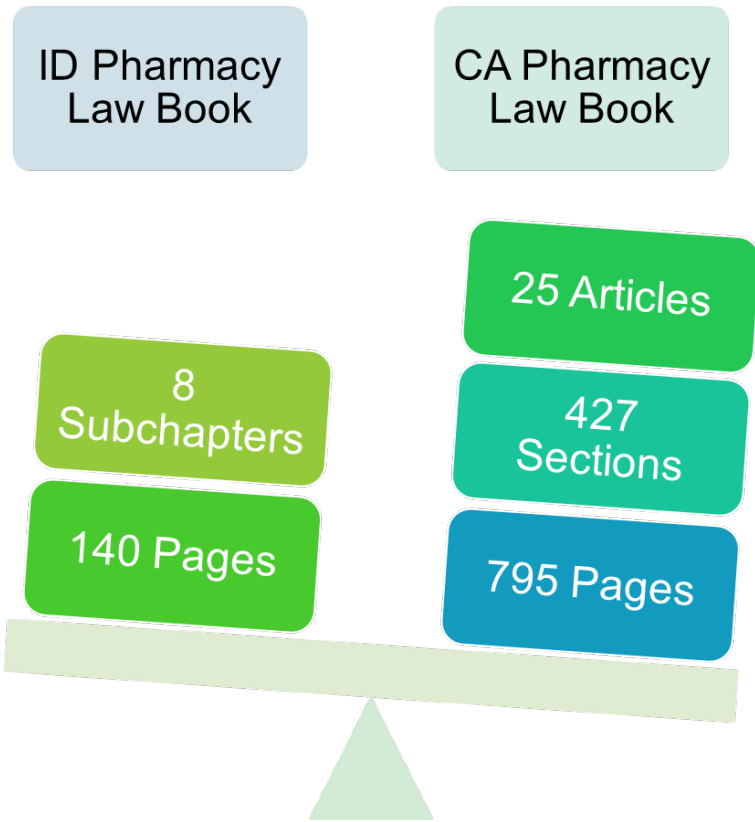
1. **If someone asks why I made this decision, can I justify it as being consistent with good patient care and with law?**
2. **Would this decision withstand a test of reasonableness?**

Pharmacist Prescribing	Filling Prescription Drug Orders	<u>Benefits</u>
<p>“Pharmacist may independently prescribe drugs provided general requirements are met”:</p> <ul style="list-style-type: none"> • Patient-prescriber relationship • Patient assessment* • Collaboration with other healthcare professionals • Evidence-based prescribing (e.g., medications for cold sores, seasonal flu, antibiotics for strep throat, urinary tract infections and statins for diabetic patients) • Follow-up care plan 	<ul style="list-style-type: none"> • Pharmacist may select drug product “between therapeutic equivalent drugs” • “Pharmacist may also refill a prescription for non-controlled drug to ensure continuity of care” • “Pharmacist may change dosage form of the prescription if it is in the best interest of patient care...” • “Pharmacist may complete missing information on a prescription if there is evidence to support the change” 	<ul style="list-style-type: none"> • Improve clinical outcomes by leveraging pharmacist’s knowledge, skills and expertise • Minimize delays in care • Support continuity of care • Reduce disruption to physicians

**The pharmacist must obtain adequate information about the patient’s health status to make appropriate decisions based on the applicable standard of care and the best available evidence*

Examples of California and Idaho Current Regulations

California Complexity



California Current State Examples	Idaho Current State Examples
Article 3. Scope of Practice and Exemptions ; Sections 4051 - 4052.5 (e.g., furnishing NRT, HIV pre/post exposure prophylaxis, selecting different form of medication with same active ingredient)	Subchapter D – Rules Governing Pharmacist Prescriptive Authority; Rules 350 - 399 Pharmacist may independently prescribe non-controlled drugs provided general requirements are met .
Article 7. Pharmacies; Section 4115. Pharmacy Technician: Activities Permitted ; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratio	Technician. A term to indicate an individual authorized by registration with the Board to perform pharmacy support services under the direction of a pharmacist.
Article 4.5 Compounding ; Sections 1735 – 1735.8	Subchapter H- Rules Governing Drug Compounding, Sections 700 – 704
Article 7. Sterile Compounding ; Sections 1751 – 1751.10	In consideration of applicable USP chapters

Proposed Standard of Care Guiding Principles and Recommendation

Responsible Medication Management:

- Pharmacists have a responsibility to **participate in all aspects of medication management** in partnership with patients and/or their caregivers
- Leverage quality assurance programs to ensure continuous safe and quality patient care under the standard of care model
- The practice is consistent with licensee's **education, training** or **practice experience**; and
- The practice is 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

Guiding Questions:

1. If someone asks why I made this decision, can I justify it as being the most **safe, ethical, and optimal** for my patient?
2. Would my decision withstand a **test of reasonableness** (e.g., would this practice be exercised by other **reasonably careful and prudent pharmacists** in the same or similar practice setting)?

Recommendation:

Revise current permitted regulations to a “standard of care” regulatory model based on published evidence, guidelines and best practices.

Appendix

CSMC Clinical Service Plans

Minimum clinical pharmacy services that shall be provided to all patients admitted to the inpatient areas

Pharmacists assess the following information on a daily basis:

- Patient data for all new orders
- Daily patient review to serve as quality assurance of the medication regimen
 - *Antimicrobials – evaluated daily for escalation, de-escalation and dose optimization opportunities*
 - *Monitor medications with Boxed Warnings*
 - *Review relevant labs*
 - *Assess risk for preventable adverse drug events*
 - *Evaluate for IV to PO opportunities*
- Medication reconciliation for high-risk patients
- Management of per-pharmacy drug therapy protocols
- Drug formulary management
- Drug information and education
- Emergency response