

Standard of Care Model for Pharmacy Practice in California

Presented by

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Outline

- Standard of Care Model
- History of Pharmacy Practice in California
- Case Studies

Direct Enforcement Model (current)

- Pharmacists are bound by specific practice “allowances” in law on how or what they can practice, as determined by state statutes and Board of Pharmacy regulations.
 - Allowances must be added by statute or regulation, which at minimum, take a year to implement.
 - Additionally, statutes and regulations that are outdated or no longer applicable also take a year or longer to remove from the law and can cause conflicts or, at minimum, confusion.

Standard of Care Model: Definitions

- Defined by **The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)** (ver 8/21)¹:
 - “The degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances.”
- Defined by the **National Institute of Health (NIH)** ²:
 - “Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy.”
- Defined in an **American Medical Association** Journal of Ethics publication (2005) ³:
 - “...a measure of the duty practioners owe patients to make medical decisions in accordance with any other prudent practioner's treatment of the same condition in a similar patient.”

1. <https://nabp.pharmacy/members/board-resources/model-pharmacy-act-rules/>

2. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/standard-of-care>

3. <https://journalofethics.ama-assn.org/article/importance-standard-care-and-documentation/2005-11>

Standard of Care Model: Use Cases

- Two states have adopted standard of care models for pharmacy practice
 - Idaho:
 - *“defines a pharmacist’s scope of practice to allow a pharmacist to engage in acts not expressly prohibited by law as long as such acts are consistent with the licensee’s education, training, or practice experience, and if performance of the act falls within the accepted standard of care.”*
 - Washington:
 - Washington’s codes are similar to how California physicians are regulated.
 - They have enacted a series of definitions, prohibited practices, and an appropriate range of sanctions to those prohibited practices applicable to all health care providers (pharmacists are included) in Chapter 246-16 of the Washington Annotated Code (246-16-010 through 246-16-890).
- Existing models with the Board of Medicine

Standard of Care Model: Benefits

- Standard of care allows pharmacists the necessary flexibility within their scope of practice to make the best determination, as health care providers, on how to take care of their patients. It also allows the progression of the practice of pharmacy to transition towards appropriate direct patient care (e.g. Comprehensive Medication Management, Medication Therapy Management, etc.)
- Standard of care allows the Board of Pharmacy to establish a clear framework, consistent with those of other healthcare providers, for the oversight, regulation, and enforcement of direct patient care services to most effectively protect the public

KEY MOMENTS FOR PHARMACY PRACTICE IN CALIFORNIA

1972: AB 717

- Granted prescriptive authority to pharmacists involved in the California Health Manpower Pilot Projects. Areas of authority included management of anticoagulation, drug dosing, and other therapeutic areas



1981: AB 1868

- Granted authority to pharmacists in acute and intermediate health care facilities to adjust dosages pursuant to a prescriber's authorization, order drug therapy-related laboratory tests, order or perform routine drug therapy-related patient assessment procedures, and administer drugs and biologics (orally, topically, or by injection)



1983: SB 502

- Granted authority to pharmacists, in a licensed health care facility, to not only adjust dosages but to initiate therapy pursuant to a prescriber's order



1994: AB 1759

- Expanded authority to pharmacists in ambulatory care clinics and systems licensed as health care plans



KEY MOMENTS FOR PHARMACY PRACTICE IN CALIFORNIA

1996: SB 1596

- Permitted payment for nondispensing pharmacist activities by health care service plans



2003: SB 545/SB 490

- Granted authority to pharmacists to furnish emergency contraception



2012: SB 1481

- Granted authority to independently perform CLIA-waived tests for blood glucose, hemoglobin A1C, and cholesterol





2013: SB 493

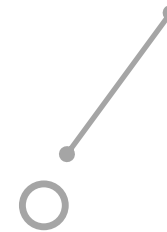
- Pharmacists recognized as health care providers
- Granted authority to pharmacists to initiate/administer routine immunizations, and furnish medications for self-administered hormonal contraception, nicotine replacement, international travel
- Granted authority to order and interpret tests for managing/monitoring drug therapy
- Granted authority to administer drugs and biologicals pursuant to a prescriber's order
- Established Advanced Practice Pharmacist designation



KEY MOMENTS FOR PHARMACY PRACTICE IN CALIFORNIA

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- 2015: AB 1114**
- Established that pharmacist services are a benefit under the Medi-Cal program; required fee schedule of 85% of physician services

- 
- 2019: SB 159**
- Granted authority to furnish HIV PrEP and PEP and included as a Medi-Cal benefit



2020-2021: COVID-19 Pandemic

- A significant amount of executive orders, waivers, and legislative/statute updates during the public health emergency related to pharmacists authority to provide direct patient care services, notably:
- Allow pharmacists to perform COVID19 testing
- Allow pharmacists to perform CLIA-waived, point-of-care COVID-19 tests
- **AB 1710 (2020):** Granted authority to initiate/administer COVID-19 vaccines
- **AB 1064 (2021):** Granted authority to initiate/administer all FDA approved/authorized and CDC ACIP recommended vaccines
- **SB 409 (2021):** Expanded authority to perform CLIA-waived tests beyond blood glucose, A1c, and cholesterol

2021: AB 1533

- Granted authority to any pharmacist to initiate, adjust or discontinue patient therapy under a collaborative practice agreement (CPA) with any health care provider who has prescriptive authority
- Granted authority to provide medication-assisted therapy (MAT)
- Granted authority to advanced practice pharmacists to initiate, adjust, or discontinue therapy without restriction of a CPA/protocol



AAMC

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AAMC Report Reinforces Mounting Physician Shortage

June 11, 2021

According to new data published today by the AAMC (Association of American Medical Colleges), the United States could see an estimated shortage of between 37,800 and 124,000 physicians by 2034, including shortfalls in both primary and specialty care.

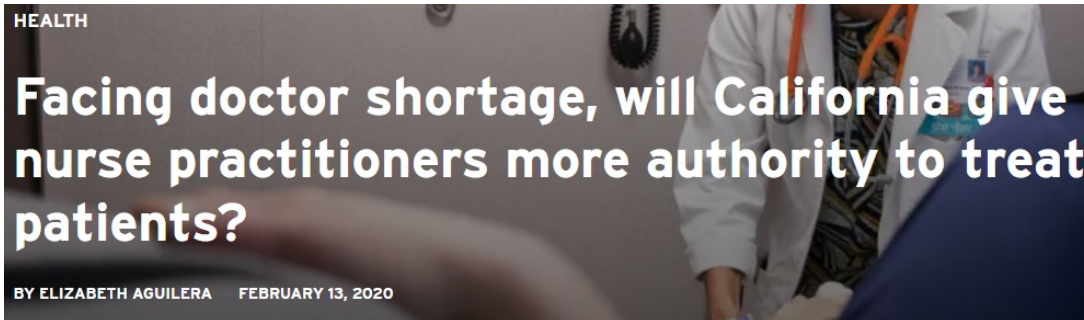
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"The COVID-19 pandemic has highlighted many of the deepest disparities in

SCIENCE ↻

The Post-COVID Doctor Shortage Is a Ticking Time Bomb. Here's How to Diffuse It.

DO NO HARM



HEALTH

Facing doctor shortage, will California give nurse practitioners more authority to treat patients?

BY ELIZABETH AGUILERA FEBRUARY 13, 2020



HEALTH

Paging more doctors: California's worsening physician shortage

BY ELIZABETH AGUILERA , AUGUST 16, 2019 UPDATED FEBRUARY 13, 2020

Nurse shortages in California reaching crisis point



BY KRISTEN HWANG , AUGUST 26, 2021 UPDATED SEPTEMBER 28, 2021



HEALTH CARE

Many Doctors are Switching to Concierge Medicine, Exacerbating Physician Shortages

Practices that charge sometimes hefty membership fees promise more personalized care. But the high costs and low patient volumes may limit access for everyone

By Michelle Konstantinovskiy on October 19, 2021

Home / News / Health News

Shortage of Primary Care Doctors Is Costing American Lives

March 23, 2021, at 12:21 p.m.



Research • August 15, 2017

California Demand for Primary Care Providers to Exceed Supply by 2030

UCSF Report Shows Potential Shortfall of 4,700 Clinicians as Soon as 2025

By Scott Maier

“California faces a looming shortage of primary care clinicians in the coming decades... If we continue along our current path, more and more Californians will need to visit the emergency room for conditions like asthma, ear infections or flu because they lack a primary care provider.”

– Dr. Janet Coffman, PhD, MA, MPP (2017)

Standard of Care: Keeping Up

- The nondispensing role of pharmacists in direct patient care services has become more prominent.
- As pharmacists increasingly become part of the patient care team, it makes sense to, at minimum, adopt a form of regulation that is consistent with other health care providers who are treating the same patients/conditions/situations.
- NABP, in their December 2018 Report of the Task Force to Develop Regulations Based on Standards of Care, discusses how nursing and medicine are both using one or more of the following types of regulation:
 - Standards of care-based regulation
 - Right-touch regulation
 - Evidence-based regulation
- Science and best practices are also constantly evolving as new evidence becomes available

Given the evolution of the practice of pharmacy in California over the last 10+ years, CPhA believes it's appropriate to **adopt** and begin transitioning pharmacy to a **standard of care model** that allows both pharmacists to be able to practice to the top of their license in direct patient care and give the Board of Pharmacy sufficient and necessary tools to continue protecting patients in California.

Appendix: CPhA Policy Statements

- **Standards of Practice:** The California Pharmacists Association supports the establishment of standards of practice that are adopted by the profession to assure the health and safety of the public.
- **Advanced Training:** The California Pharmacists Association encourages pharmacists to seek advanced training.
- **Prescriber Scope of Practice:** The California Pharmacists Association supports limiting prescribing authority to the prescriber's recognized scope of practice.
- **Pharmacist Activities:** The activities of pharmacists and pharmacy personnel shall be commensurate with their level of training, skill, and experience.
- **Provision of Services:** Pharmacists shall provide pharmacist care services and referrals consistent with the health needs of their patients.
- **Pharmacist Care Services:** The California Pharmacists Association defines pharmacist care as a service that optimizes therapeutic outcomes for patients and improves their quality of life. This service may or may not occur in conjunction with the provision of a medication or device. Collaborative efforts of an inter-disciplinary patient care team are important to the provision of meaningful pharmacist care.

Benefits to the State and to the Public

- Benefits of allowing pharmacists to provide direct patient care services in a standard of care model,
 - Address healthcare challenges
 - Primary care provider shortage
 - High healthcare costs
 - Improved health outcomes for Californians
 - Increased access to healthcare providers, especially in rural and underrepresented areas

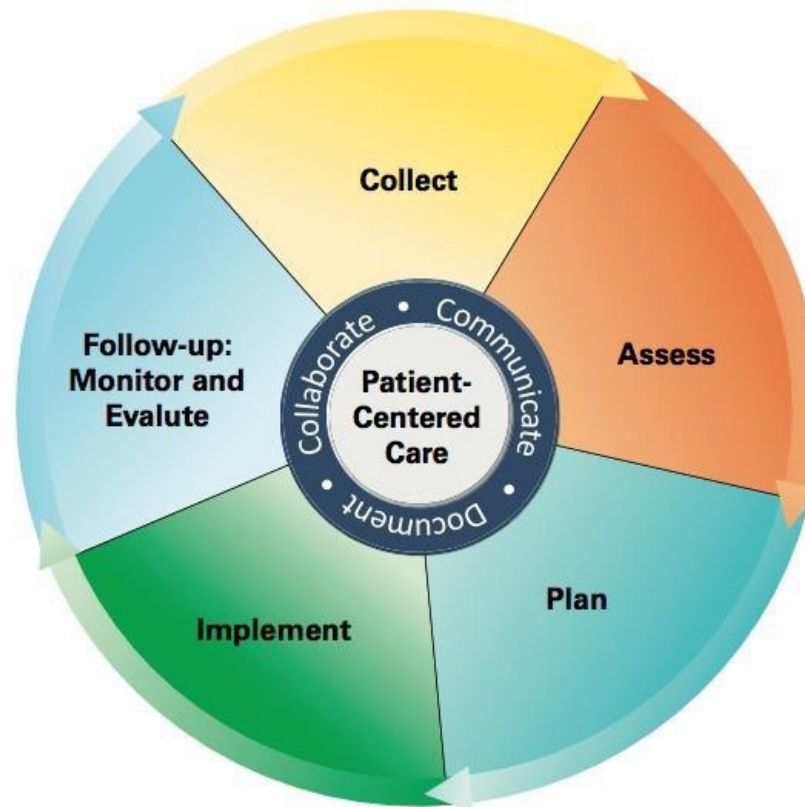
1. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6789634/>

2. <https://jcpc.net/wp-content/uploads/2015/09/Improving-Patient-and-Health-System-Outcomes-through-Advanced-Pharmacy-Practice.pdf>

3. <https://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp-content/uploads/2016/10/GetTheMedicationsRight.v22final-5.20.pdf>

4. <https://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp-content/uploads/2017/11/CPF-Forecast-brief-final.pdf>

JCPP 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.

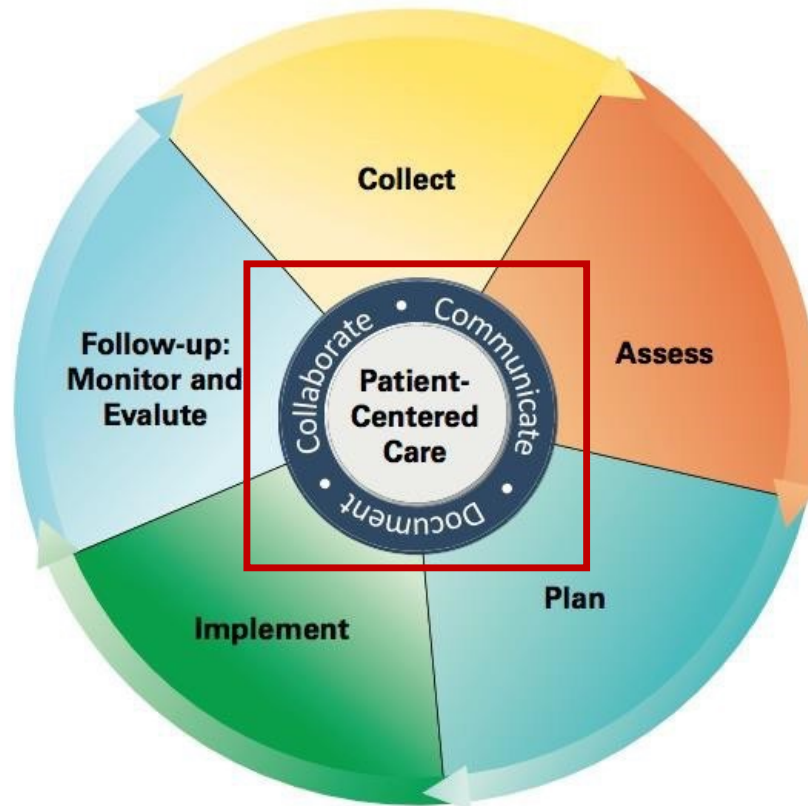
Implement

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

Follow-up: Monitor and Evaluate

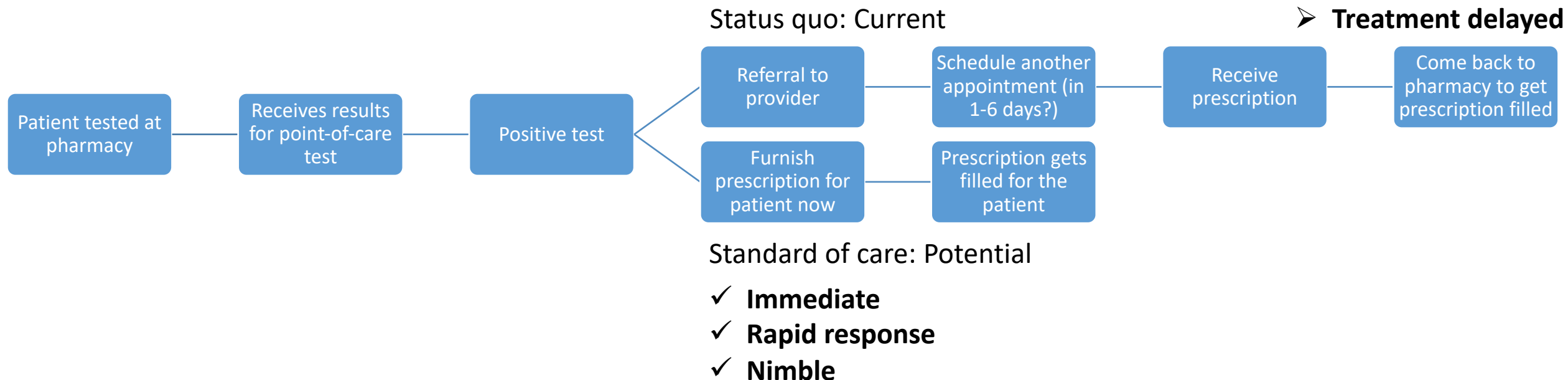
The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed.

JCPP Pharmacists' Patient Care Process



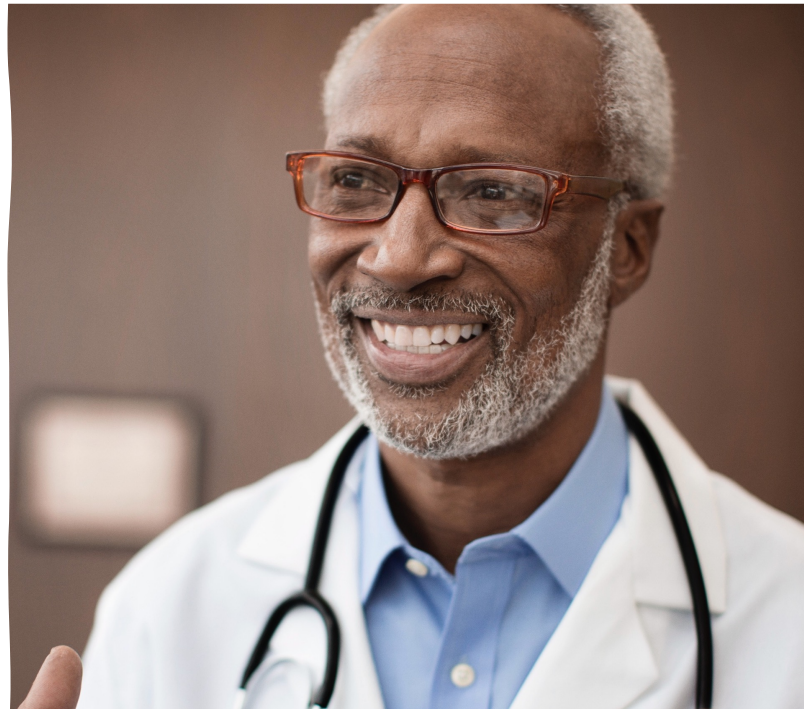
Case Study - A

Pharmacy-based, point-of-care testing and “test and treat”



Case Study - B

Patient picking up their usual prescriptions for **metformin** and **insulin glargine**. During the patient consultation, the patient tells the pharmacist that they have not visited their primary care provider for the last 1 and half and that their blood sugar readings at home have been high.



RPh with 8 years experience with residency training
MTM and diabetes certificate
Board Certified Ambulatory Care Pharmacist (BCACP)

Standard of Care: Summary

- It is not a one size fits all approach
- It is not an open-ended authority free from oversight and enforcement
- It does not overhaul the regulatory framework for oversight of existing authorities related to dispensing services
- Allows pharmacists to provide patient care services **commensurate to their training** to optimize medication therapy and improve health outcomes
- Allows pharmacists to provide individualized patient care services
- Allows pharmacists to respond to rapidly evolving and/or emergent needs of Californians
- Benchmarks pharmacist performance to the “**best practices**” of peer providers (pharmacists and other medical providers)
- Allows the BOP to create appropriate regulatory framework for patient care services to protect the public