



STANDARD OF CARE

Representing:

*California Advancing Pharmacy Practice
Working Group*

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Personal Experience

- Member - 2021-22 APhA Policy Committee
Standard of Care Regulatory Model for State Pharmacy Practice Acts.
- Member – NABP Task Force to Develop Regulations Based on
Standard of Care, 2018
- Chair, California Advancing Pharmacy Practice Working Group (2019-present)

Oath of a Pharmacist

- “I promise to devote myself to a lifetime of service to others through the profession of pharmacy...”
- Vows
- I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public.”



A Social Contract

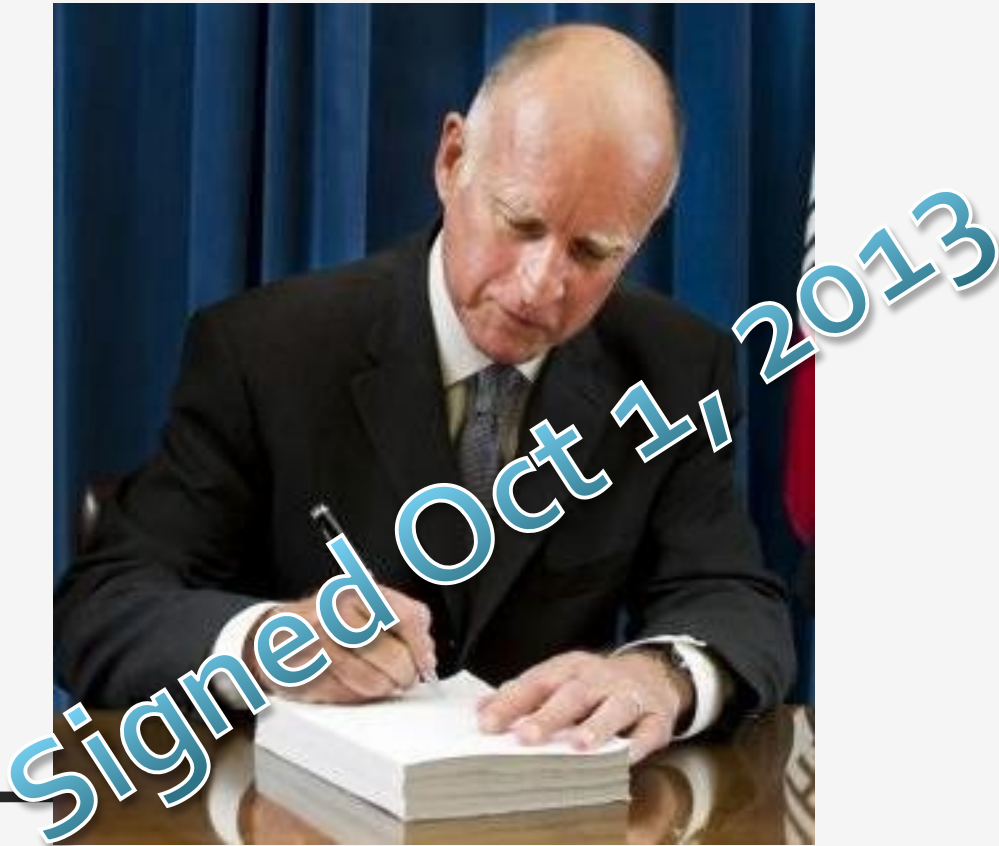
- There is an implicit agreement between health professionals and society.
 - Provide altruistic service
 - Maintain professional competence
 - Maintain morality and integrity
-

Delegated Self-Regulation

- The profession's right to self-regulation has been delegated by society via federal and state legislation through boards of medicine, pharmacy, dentistry, nursing, etc. Hence, boards:
 - Set standards for education, training, and entry into practice
 - Regulate practice
 - Ensure standards are met, and remediate or discipline unethical, immoral, or incompetent practices

SB 493 Pharmacy Practice

Amended BPC 4050 – Declares that pharmacists are health care providers

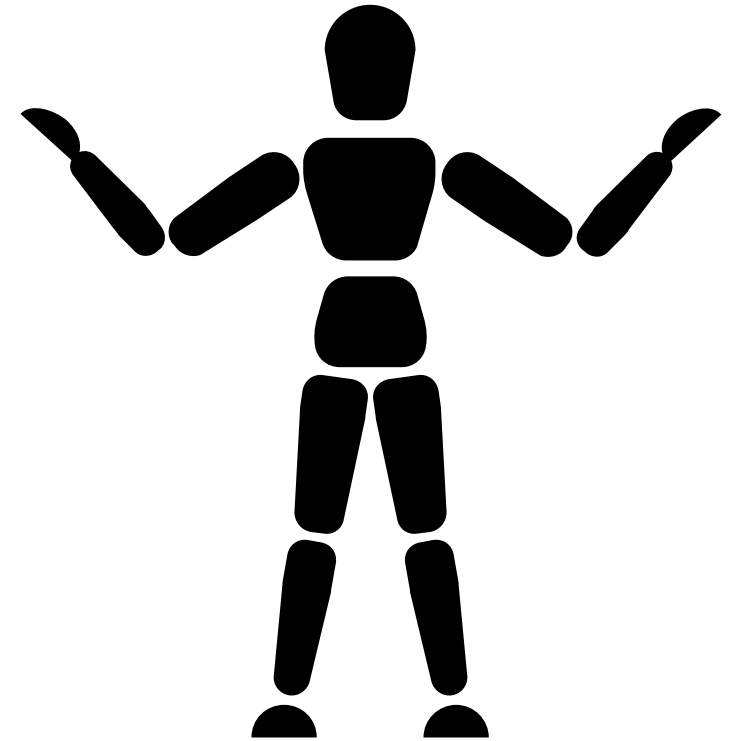


Bill amended 10 sections and added 6 sections to the BPC.

However,
The bill did not make conforming or technical changes that would allow pharmacists to fully function as health care providers.

What is Missing?

- Existing language in the Business and Professions Code was implemented before the legislature declared that pharmacists are health care providers
- Landmark legislation (SB493) put into statute many decisions that should have been at the provider's discretion.



Examples of Statutory Handcuffs

4052.3 Self-administered hormonal contraceptives.



The Board of Pharmacy and the Medical Board of California are both authorized to ensure compliance with this subsection.

Pharmacist may furnish in accordance with standardized procedures or protocols developed and approved by the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists

Examples of Statutory Handcuffs (2)



4052.01 Naloxone.

Pharmacist may furnish naloxone in accordance with standardized procedures or protocols developed and approved by both the Medical Board of California in consultation with the California Society of Addiction Medicine.

Examples of Statutory Handcuffs (3)



4052.02 HIV Preexposure prophylaxis.

The (pharmacy) board shall consult with the Medical Board of California as well as relevant stakeholders, but not limited to, the Office of AIDS (Dept of Public Health) on training programs.

Examples of Statutory Handcuffs (4)



4052.8 Vaccines (adding COVID)

Pharmacists were previously authorized to administer vaccines.

COVID vaccine required a change in pharmacy law.

No corresponding change required for medicine **because change is inevitable and constant.**

Removing the Handcuffs



Delegated Self-Regulation - Recommended Change to Pharmacy Law

No state agency other than the board of pharmacy may define or interpret the practice of pharmacy for those licensed pursuant to the provisions of this chapter or develop standardized procedures or protocols pursuant to this chapter.

NABP Model State Pharmacy Practice Act - 2021

- Section 212 empowers Boards to make such rules as are necessary to fully administer and implement the Act ... with the greatest possible flexibility and autonomy.

Guidelines for the Structure & Function of State Medical & Osteopathic Boards, May 2021

- The medical practice act should provide for a separate state medical board, acting as a governmental agency to regulate the practice of medicine
- Furthermore, the medical practice act should not apply to those practicing dentistry, nursing, optometry, psychology, or any other healing art in accord with and as provided by the laws of the jurisdiction.

Precedents

- BPC 2725(e). Nursing Scope of Regulations.
 - No state agency other than the board may define or interpret the practice of nursing for those licensed pursuant to the provisions of this chapter *(effective 1/1/2004)*
- BPC 3702.5 Respiratory Therapy
 - Except for the [Respiratory Care] board, a state agency may not define or interpret the practice of respiratory care for those licensed pursuant to this chapter. *(effective 1/1/2019)*

Scope of Practice

- Professional Scope of Practice - Services that a profession's members are trained and competent to perform. Evolves to integrate new developments, new knowledge and skills for that profession.
- Legal Scope of Practice – State laws and regulations that define services that may or may not be provided by a profession.

Scope of Practice

- Changes to Legal Scope of Practice require legislative and regulatory action, which are:
 - Slow
 - Adversarial
 - Costly

[BPC Chapter 9 Article 3 Pharmacy Scope of Practice and Exemptions]

Note: there is no comparable language in the Medical Practice Act

The Affordable Care Act (2010)

CASE IN POINT

- Enroll an estimated 30 million Americans in health insurance and support innovative ways to organize and deliver care.
- Multidisciplinary teams based on the needs of the population, practice size and type would be essential to optimize outcomes and health resources.

Problems Encountered

From Legal Scope of Practice to Standard of Care Regulatory Model

- Create a regulatory environment in California that maximizes the ability for pharmacists to function as health care providers.

- **Standard of Care** – a regulatory model used by medicine, nursing, dentistry and others.



Pharmacy Yesterday and Today

A 60+ year transition



The Practice of Pharmacy is Diverse

- Provision of acts or services necessary to provide medication management in all practice settings.

According to Health Care Provider Taxonomy version 22, Jan 2022 (NUCC)



NAPLEX Competencies (43)

- Obtain, interpret, assess patient information (7, 18% of test)
- Identify drug characteristics (4, 14% of test)
- Develop or manage treatment plans (12, 35% of test)
- Perform calculations (9, 14% of test)
- Compound, dispense, administer drugs, or manage delivery systems (6, 11% of test)
- Develop or manage practice or medication-use systems to ensure safety and quality (5, 7% of test)

NAPLEX Competencies (43)

All but Area 5 (Compound, Dispense, Administer Drugs, or Manage Delivery Systems) are focused on the assessment, monitoring and treatment of disease, drug selection and dosing, disease prevention, and interdisciplinary practice, i.e., 37 of 43 competency statements.

Accreditation Council for Pharmacy Education (ACPE)

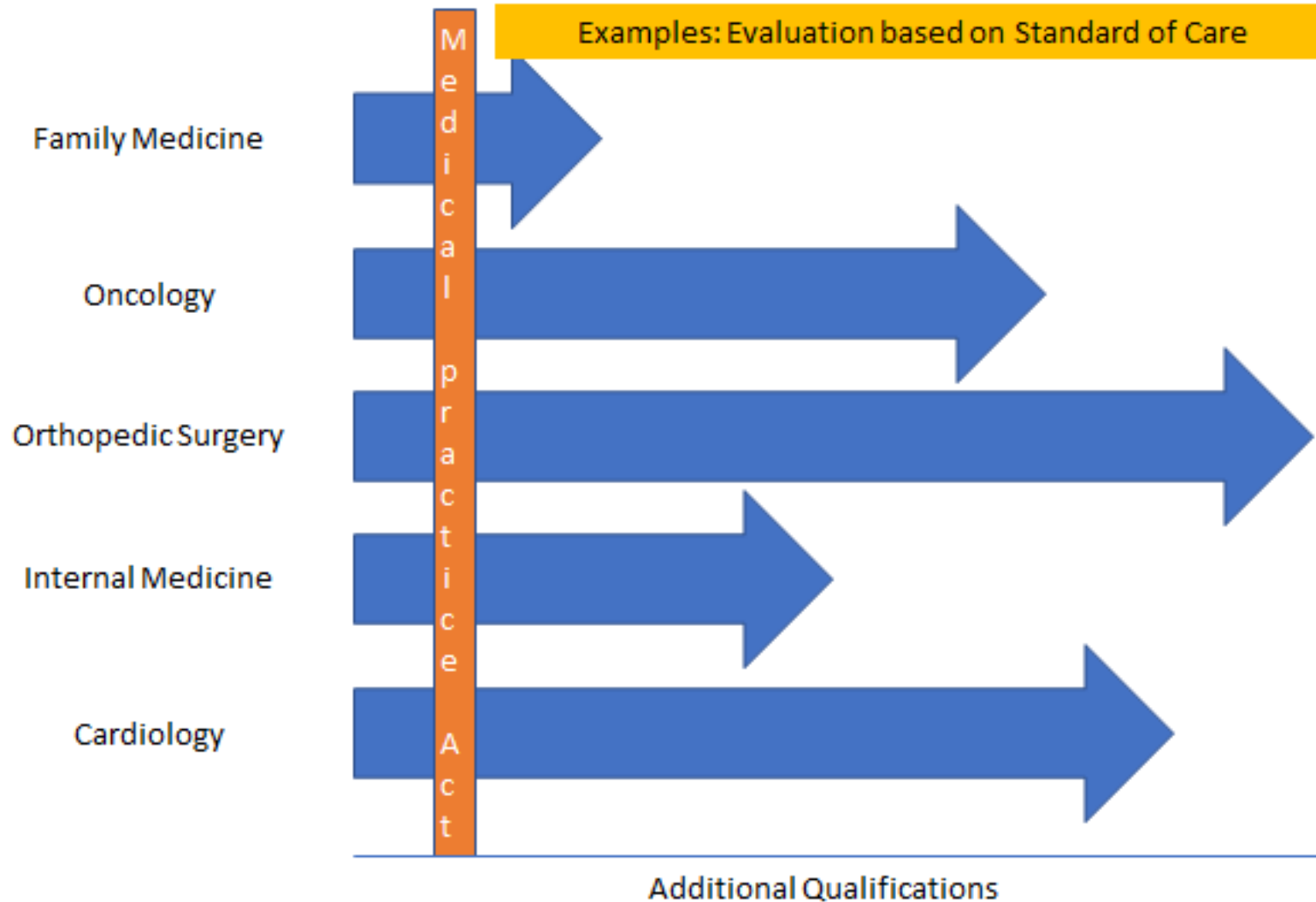
ACPE Standards 2016

- Require that pharmacy school graduates are ready to 1) provide direct patient care in a variety of health care settings (practice-ready) and 2) contribute as a member of an interprofessional collaborative patient care team (team-ready).

Standard of Care - Background

- A license to practice medicine, nursing, dentistry, pharmacy, etc., identifies licensee as possessing foundational knowledge, skills, and abilities to practice that profession.
- American Board of Medical Specialties recognizes 40 specialties and 87 subspecialties.
- The Board of Pharmacy Specialties recognizes 14 specialties

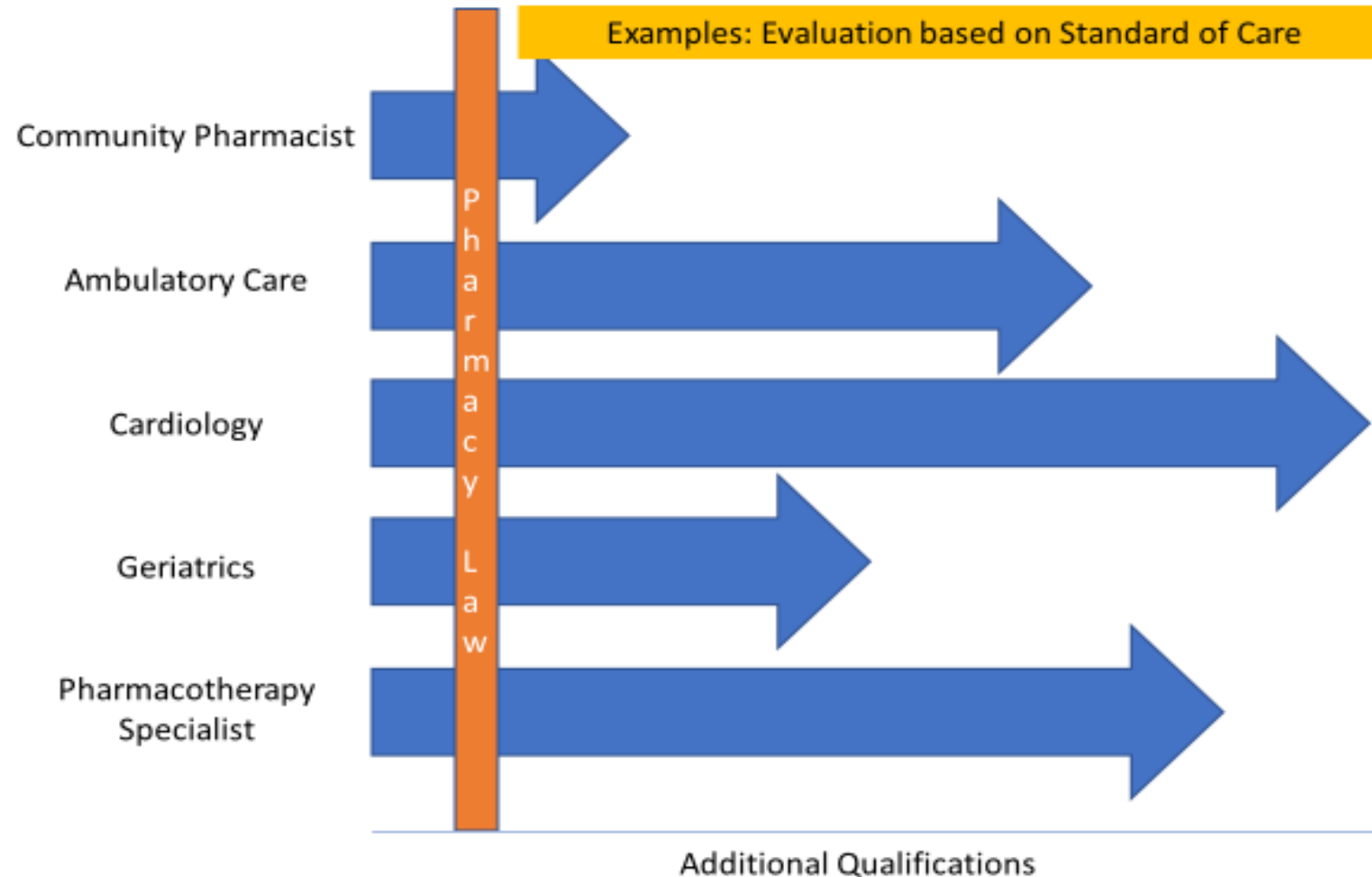
Medicine – Standard of Care Model



Medicine - Standard of Care

- A physician who receives a quality-of-care complaint would be reviewed by a medical expert or experts with pertinent education, training, and expertise specific to the Standard of Care issue (see 2220.08 BPC Enforcement)

Pharmacy – Standard of Care Model



Pharmacy - Standard of Care *Proposed*

- A pharmacist who receives a quality-of-care complaint would be reviewed by a pharmacy expert or experts with pertinent education, training, and expertise specific to the Standard of Care issue

Standard of Care

Details

- Under the new regulatory model, pharmacists providing health care services would be held to the standard of care that would be provided in a similar setting by a reasonable and prudent licensee with similar education, training and experience.

Advantages of a Standard of Care Model

- Utilizes full competence and ability of the health professional
- Determined by education, training, and experience
- Recognizes professional heterogeneity
- Advances with new education, technology, science, and practice standards
- Avoids tying fixed regulations to an entire class of health professional
- Avoids lengthy statutory and regulatory changes as practice and health care evolve

APhA House of Delegates Policy Statement

Standard of Care Regulatory Model for State Pharmacy Practice Acts

1. APhA requests that state boards of pharmacy and legislative bodies regulate pharmacy practice using a standard of care regulatory model similar to other health professions, thereby allowing pharmacists to practice at the level consistent with their individual education, training, experience, and practice setting.

APhA House of Delegates Policy Statement

Standard of Care Regulatory Model for State Pharmacy Practice Acts

2. To support implementation of a standard of care regulatory model, APhA reaffirms 2002 policy that encourages states to provide pharmacy boards with the following: (a) adequate resources; (b) independent authority, including autonomy from other agencies; and (c) assistance in meeting their mission to protect the public health and safety of consumers.

NABP Task Force to Develop Regulations Based on Standards of Care

Task Force Recommendation 2018

- The task force recommends that NABP encourage state boards of pharmacy to consider regulatory alternatives for clinical care services that require pharmacy professionals to meet the standard of care.

Question or Concerns - Standard of Care Model

- Would all licensed pharmacists be able to provide the full scope of services under a standard of care model?
 - No!!! Only those who have the education, training, experience, and practice environment to provide the service or activity.

Question or Concerns - Standard of Care Model

- Is there a credentialing process for pharmacists?
 - Yes!!! Pharmacists maintain a record of their credentials, which would include license, residency certificate, board certification, continuing pharmacy education, and training certificates. APhA provides a comprehensive verification system through Pharmacy Profiles that could be used by employers, health systems, etc.

Question or Concerns - Standard of Care Model

- Should pharmacists be required to follow clinical practice guidelines?
 - No!!! Science, health care delivery, and evidence-based practice are continually evolving. AHRQ National Guideline Clearinghouse, with 8,228 guidelines, was defunded in 2018 because of limited usefulness.

Question or Concerns - Standard of Care Model

- Do we really need pharmacists to play a greater role in medication management?
 - Yes!!! Of all the health professions, pharmacists have by far the greatest understanding of drugs, drug selection, drug management, and their safe use. Over \$528 billion in avoidable spending is attributed to suboptimal use of medications in the U.S.

Summary

Standard of Care Model

- Implementing a standard of care regulatory model for pharmacy practice would improve access to health care services, promote health equity within geographic or medically underserved communities, and remove unnecessary barriers between patients and vital medication management and preventative health care services provided by pharmacists.

Acknowledgement

Members of the Advancing Pharmacy Practice Working Group

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Lisa Kroon, UCSF Jeffery Goad, Chapman Michael Hogue, Loma Linda Ron Jordan, Chapman Susan Bonilla, CPhA Rajan Vaidya, CPhA Steve Chen, USC Loriann DeMartini, CSHP	Keith Yoshizuka, Touro (CSHP) Giny Herold, Retired (Board of Pharmacy) Lisa Gunther Lum, CSHP James Scott, Touro (CSHP) Randy McDonough, Loma Linda (Iowa) Pam Schweitzer, Former RADM, Assistant Surgeon General Sarah McBane, UCI Richard Dang, USC (CPhA)

Questions?

If you ever want to truly understand something, try to change it.

*Thank you,
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