January 29, 2023

Anne Sodergren

Executive Officer, California State Board of Pharmacy

Dear Anne,

Thank you for the opportunity to provide comments regarding the draft Standard of Care report. First, my appreciation to the members of the Ad Hoc Committee for the excellent summary of presentations, survey results, questions and answers and recommendations. Overall, the report demonstrates significant progress in advancing this model to support the pharmacist's essential role in safe, optimal medication therapy. The following comments represent areas that I felt might benefit from some additional consideration.

- Consistent with standards of care for other health professionals, pharmacists would be evaluated based on how other pharmacists with similar knowledge and skills would perform their duties in a similar situation. This could be further elaborated by indicating that standards of practice would be based on standards and guidelines from national professional organizations such as ASHP, ACCP, APhA and evolving literature.
- Pharmacists who have expanded patient care responsibilities as part of standard of care should have ongoing access to patient information, regardless of the practice setting, to ensure patient safety.
- Standards of care cannot be the same across all practice sites since the role and responsibilities for the pharmacists are specific to the setting. Further, even within the same setting, such as independent pharmacies, there may be differences in patient care responsibilities depending on priorities and resources. For example, one independent pharmacy may provide training and monitoring services to diabetic patients and another one may limit patient care responsibilities to counseling.
- Standards of Care local oversight considerations
    - The Pharmacist-in-Charge, as recommended in the report, should be responsible for approving the pharmacist's responsibilities based on the priorities, resources and individual pharmacist's knowledge and experience.
    - Performance Improvement: Monitoring and evaluation of patient outcomes should be periodically performed to determine opportunities for improvement.
- Clarification of incomplete and erroneous prescriptions often delays care and can be disruptive to physician workflow. When the elements of the medication order based on current compendia are missing or inaccurate, the pharmacist should be able to modify the order to provide timely, safe medications to patient. Therefore, having language such as Idaho has adopted related to prescription adaptation services as part of standard of care would support patient safety.
- Competency considerations
    - Patient care responsibilities can vary widely from clarification of prescriptions as mentioned above to initiating and managing drug therapy in collaboration with the healthcare team. As a result, a single standard for competency may not be feasible across all sites.

    - The majority of pharmacists practicing in California have a Pharm.D. and all are licensed demonstrating that they have acquired the knowledge, skills and abilities (KSA's) necessary to practice pharmacy.
    - Post-graduate residency training is equivalent to 3 years of direct patient care experience (source: ACCP) and therefore, represents a higher level of KSA's which may be needed depending on the roles and responsibilities of the pharmacist's practice setting.
    - Depending on the practice site and respective pharmacist responsibilities, there may also be site-specific requirements for KSA's which are assessed and/or provided as part of training.
    - Under the Standard of Care model, credentials, i.e., training and education, post-graduate training requirements and job-specific competencies would be determined by the Pharmacist-in-Charge in collaboration with designated stakeholders.
- Where national standards exist such as for sterile compounding and drug supply chain integrity, having the Board adopt these as Standards of Care would reduce both the Board's and institutional administrative workload.
- With respect to concerns expressed about workload and staffing, I believe this subject which the Board is evaluating with respect to medication errors, is separate from Standard of Care. Even with insufficient staffing, Standard of Care guidelines that support order clarification would improve efficiency.

Thank you again for the opportunity to share my thoughts. I would be happy to continue to participate in the discussions and next steps as this important model evolves.

Sincerely,

Rita Shane

Rita Shane, Pharm.D., FASHP, FCSHP

Vice President, Chief Pharmacy Officer

Professor of Medicine

Cedars-Sinai Medical Center

January 30, 2023

Anne Sodergren, Executive Director
California State Board of Pharmacy

Comments Regarding Draft Standard of Care Report:

I appreciate having the opportunity to comment on the draft report of the *Ad Hoc* Committee on Standard of Care. I believe the process has served to effectively engage the Board and the public in this very important topic. I particularly appreciate the valuable input provided by a broad base of constituents and the thoughtful and probing questions posed by committee members.

Defining Standard of Care is an essential first step in moving toward a Standard of Care Regulatory or Enforcement Model. According to the NABP Model Act, Standard of Care is defined as "the degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances." This conforms with the definition provided in the presentation by the representative of the Medical Board of California, i.e., "Standard of Care [is] that 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 circumstance at the time in question." The focus of these definitions is on "care", which should not be confused with clear violations of laws or regulations. Implementation of a Standard of Care model would not alter the Board's responsibility and authority to enforce statutes or regulations.

Among the drawbacks cited and questions raised was that of applying standard of care based on location or practice setting (e.g., urban versus rural, community chain pharmacy versus independent pharmacy versus hospital). The locality rule (urban versus rural) had its origin in case law (Massachusetts Supreme Court, Small v. Howard) in 1880. That decision, which has since been overturned, ruled that rural physicians could not be held to the same standard of care as urban physicians since they did not have access to advances in medical care, recent literature, or newer technology. Furthermore, medical education had not been standardized at that time. The locality rule is now difficult to justify because medical (and pharmacy) education both follow national standards and access to information for patient care is available to all. In addition, healthcare providers are required to maintain currency in their profession. As of 2017, only five states continued to allow some form of locality rule (Arizona, Arkansas, Idaho, New York, and Pennsylvania). In terms of services provided by pharmacists in different practice settings, pharmacists should only be providing services for which they are qualified in settings that support the delivery of that service. Clearly, institutional settings can support certain services that could not be supported in community practice settings, just as community practice settings are in a better position to provide some preventative healthcare services.

The report asks if the Board should set minimum requirements on education and training. The Board has already set minimum requirements for licensure working with the Accreditation Council for Pharmacy Education, NABP, and California's schools and colleges of pharmacy. Post-PharmD education and training are handled nationally through residency accreditation, the Board of Pharmacy Specialties, and other professional certifying bodies. As was pointed out in my Standard of Care presentation, the American Board of Medical Specialties recognizes 40 specialties and 87 subspecialties for the practice of medicine. The Medical Board of California is not involved in setting requirement for education and training beyond the MD or DO degrees.

Moving toward a Standard of Care Regulatory/Enforcement Model is not tied to an expansion of scope of practice. The standard of care model provides an environment that supports pharmacists as health care providers. It provides a framework for handling quality of care issues in the pharmacy practice setting that are not clear violations of statutes or regulations. The following draft framework provides guidance to pharmacists and the Board on Standard of Care decision making:

Identify, describe, or clarify the activity under consideration: _____

1. Is the activity specifically prohibited by pharmacy laws, rules, or regulations? If Yes, STOP
2. Is performing the activity consistent with evidence-based health care literature?
3. Are there practice setting policies and procedures that support performing the activity?
4. Does the pharmacist have the necessary education and training to safely perform the activity?
5. Is there documented evidence of the pharmacist's current competency (knowledge, skills, ability, judgement) to safely perform the activity?
6. Does the pharmacist have the appropriate resources to perform the activity in the practice setting?
7. Would the pharmacist be able to exercise the degree of care that a prudent qualified pharmacist would be able to provide under the same or similar circumstances?
8. Is the pharmacist prepared to accept accountability for the activity and for the related outcomes?

If the answers to questions 2-8 are YES, the pharmacist may perform the activity under the prevailing standard of care.
(Adapted liberally from J.Nurs Reg 2016;7(3):49-51)

Thank you for allowing me to comment on the SOC report. I believe we are making great progress and I anxiously look forward to continued participation in this important process.

Sincerely,

Daniel Robinson, PharmD, FASHP
Emeritus Dean and Professor
College of Pharmacy
Western University of Health Professions

USC Mann
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Steven W. Chen, PharmD, FASHP, FCSHP, FNAP
Professor, Titus Family Department of Clinical Pharmacy
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Director, USC Titus Center for Medication Safety and Population Health
Director, California Right Meds Collaborative

January 31, 2023

Anne Sodergren
Executive Officer
California State Board of Pharmacy

SUBJ: Comments on draft report- Standard of Care Enforcement Model in the Practice of Pharmacy

Dear Anne,

I am providing comments to the excellent draft Standard of Care Enforcement Model in the Practice of Pharmacy report for the board's consideration. The Ad Hoc Committee did an outstanding job in framing the issue, providing in-depth summaries of presentations and findings, and compiling key questions and answers. The draft report reflects thoughtful consideration of a Standard of Care model for pharmacy practice, prioritizing patient health and safety while ensuring that pharmacists are positioned to practice at maximum scope. My comments include general feedback for consideration as well as requests for clarifications / corrections related to my presentation to the Ad Hoc committee.

Page 5, paragraph 4:
"The standard of care may vary based on location or practice settings (e.g., urban versus rural, community chain pharmacy versus independent pharmacy versus hospitals), *creating different patient care standards for California patients*."

I believe the italicized portion of this paragraph is inaccurate. Patient care standards do not change, but the context of patient care requires flexibility in application of standard of care. As Kerrie Webb from the medical board stated, "…the SOC Model is flexible and depends on the facts, circumstance, location, patient history, patient compliance, and state of emergency." I'd recommend either eliminating the italicized portion or revising as, "…and is flexible depending on the facts, circumstance, location, patient history, patient compliance, and state of emergency, consistent with application of SOC to other health professions."

Page 6, paragraph 3:
"2. Should a pharmacist's scope of practice be broadened based on self- determined education and skill, instead of detailed protocols?"

Standard of Care does not broaden or change current pharmacist scope of practice. Standard of care removes barriers for allowing pharmacists to practice at legally allowed scope; it does not provide pharmacists with blanket authority to provide any clinical services. Health plans and health systems determine the credentialing and privileging requirements for pharmacists to provide and be compensated for specific services at specific locations for specific patients. This is the same as in medical practice, e.g., a physician cannot order tests, procedures, labs, etc. unless credentialed and privileged by the hospital / clinic. Furthermore, stakeholder partnerships and programs such as the California Right Meds Collaborative

incorporate several key processes for ensuring that pharmacists provide safe and optimal care including continuous ongoing training and rigorous continuous quality improvement in alignment with evidence-based guidelines / standards and health plan / system requirements. Participation in these processes is mandated by health plans for pharmacists to provide and receive payment for services.

Page 14, paragraph 2:
"Members and interested stakeholders also received information on the California Right Meds Collaborative, encompassing comprehensive medication management and *making sure the right medication is chosen for a patient's diagnosis at the right dose.*"

This description of comprehensive medication management is consistent with the core responsibilities of most practicing pharmacists. For accuracy and differentiation, could it be modified as follows: "…making sure the optimal medications are selected and dosed correctly for every patient's medical condition, avoiding harmful drug-drug and drug-disease interactions, ensuring patients can use medication-related devices as intended, ensuring patients can afford medications, following up with patients until treatment goals are reached, and working collaboratively with the patient's primary care or referring physician."

Page 14, paragraph 4: Can this be revised for accuracy as follows-
"Members and interested stakeholders were also informed about a $12 million grant for the USC/AltaMed Center for Medicare and Medicaid Innovation Healthcare Innovation Award: Specific Aims, which included 10 teams (pharmacist, resident and clinical pharmacy technician) including a telehealth team providing comprehensive medication management, evaluating the impact on the following outcomes: healthcare quality, safety, total cost/ROI, patient and provider satisfaction and patient access."

Page 14, last paragraph: Can this be revised for accuracy and completeness as follows-
"Presenters reviewed the California Right Meds Collaborative's (CRMC) vision and mission and provided an overview of the program. Presenters advised attendees that health plans sent high-risk patients to specifically trained pharmacists at locally accessible community pharmacies. The presenter explained the perpetual training and ongoing support pharmacists receive as a condition of participation in the program and noted that the keys to making the program work including partnering with vetted pharmacies, continuing professional training programs, and rigorous continuous quality improvement process. The presenter reviewed the process for developing the value-based payment for CMM, quality improvement report card, health plan partnership, and preliminary impact results. Attendees were also advised of the identified next steps as increasing the number of pharmacies and patients as well as health plan partners with the addition of a psychiatric component. CRMC is listed as a vendor under Covered California. Dr. Chen reviewed the value summary for patients, front-line providers, and health plans / payers."

Thank you for your time and consideration of these comments / requests. I'm very excited with the progress being made towards optimizing patient health and safety through legislation that supports pharmacists practicing at maximum scope while removing barriers and inefficiencies. Please feel free to contact me if you have any questions, or if I can be of any assistance.

Sincerely,

Steven W. Chen, PharmD, FASHP, FCSHP, FNAP
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