

July 18, 2024

[submitted electronically via: Anne.Sodergren@dca.ca.gov]

Anne Sodergren
Executive Officer
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

RE: Discussion and Consideration of Proposed Amendments to Pharmacy Law to Transition to a More Robust Standard of Care Model for Some Pharmacist-Provided Patient Care Services

Dear Ms. Sodergren:

The American Pharmacists Association (APhA) appreciates the opportunity to comment on the California State Board of Pharmacy standard of care draft language. Overall, we are supportive of the draft language and provide the following recommendations and questions to minimize any unintended consequences from the proposed changes.

The transition to a standard of care regulatory approach is aligned with how other health care professionals are governed and will allow for a greater alignment of the role of the pharmacist with their education and training. This will positively impact patients and the health care system, as substantial published literature clearly documents the proven and significant improvement in patient outcomes¹ and reduction in health care expenditures² when pharmacists are optimally leveraged as the medication experts on patient-care teams. These changes will allow pharmacists to efficiently provide care through the Pharmacists' Patient Care Process, as endorsed by the Joint Commission of Pharmacy Practitioners.³

In addition to our overall support, we would like to provide some recommendations and questions:

- We recognize the intention that Business and Professions Code Section 4052.5 is being replaced with 4052(a)(5). 4052.5 does not require a pharmacist to obtain patient consent prior to performing therapeutic interchange, however, 4052(a)(5) is proposing to now require a pharmacist to receive patient consent prior to performing therapeutic interchange. We are concerned that this will add

¹ Giberson S, Yoder S, Lee MP. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General. Office of the Chief Pharmacist. U.S. Public Health Service. Dec 2011. Available at: https://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf

² Murphy EM, Rodis, JR, Mann HJ. Three ways to advocate for the economic value of the pharmacist in health care. Journal of the American Pharmacists Association. August 2020. Available at: <https://www.sciencedirect.com/science/article/abs/pii/S1544319120303927>

³ https://www.cdc.gov/dhds/pubs/docs/PPCP_Guide_June2021-508.pdf

administrative burden to pharmacists' practice and result in less efficient delivery of care to patients.

- We recommend the removal of "This section shall not allow a pharmacist to furnish a medication for off-label use," from Business and Professions Code Section 4052(a)(10). Off-label use of medications is a common and safe practice. Studies have found that one-third of all prescriptions of common medications are written for off-label indications and "up to 97% of drug use in some patient populations" are for off-label indications. Additionally, other states, such as Idaho⁴ and Montana,⁵ that have taken a standard of care approach to regulate pharmacists have not restricted pharmacist prescribing to labeled or off-label indications.
- We are concerned that the removal of Business and Professions Code Section 4052.7 will impact a pharmacy's ability to repackage medications for patients according to requirements detailed in 4052.7. We recommend the reinsertion of this language.

Additionally, we support comments and recommendations provided by the California Pharmacists Association on July 12, 2024.⁶

Thank you for the opportunity to provide these supportive comments and recommendations. If you have any questions or require additional information, please don't hesitate to contact E. Michael Murphy, PharmD, MBA, APhA Advisor for State Government Affairs by email at mmurphy@aphanet.org.

Sincerely,



Michael Baxter
Vice President, Government Affairs

cc: Susan Bonilla MEd, California Pharmacists Association Chief Executive Officer

About APhA: APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health. In California, with 35,980 licensed pharmacists and 41,420 pharmacy technicians, APhA represents the pharmacists and students that practice in numerous settings and provide care to many of your constituents. As the voice of pharmacy, APhA leads the profession and equips members for their role as the medication expert in team-based, patient-centered care. APhA inspires, innovates, and creates opportunities for members and pharmacists worldwide to optimize medication use and health for all.

⁴ <https://legislature.idaho.gov/wp-content/uploads/statutesrules/idstat/Title54/T54CH17.pdf>

⁵ [https://laws.leg.mt.gov/legprd/LAW0210W\\$BSIV.ActionQuery?P_BILL_NO1=112&P_BLTP_BILL_TYP_CD=SB&Z_ACTION=Find&P_SESS=20231](https://laws.leg.mt.gov/legprd/LAW0210W$BSIV.ActionQuery?P_BILL_NO1=112&P_BLTP_BILL_TYP_CD=SB&Z_ACTION=Find&P_SESS=20231)

⁶ https://www.pharmacy.ca.gov/meetings/agendas/2024/24_jul_lic_mat_sup.pdf