TITLE 16. BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing scheduled

Subject Matter of Proposed Regulation: Medication-Assisted Treatment Protocol

Section Affected: Add section 1746.6 to Article 5 to Division 17 of Title 16, California Code of Regulations (CCR)

Background and Statement of the Problem

The California State Board of Pharmacy (Board) is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (Business and Profession Code (BPC) sections 4000, et seq.). The Board's mandate and mission are to protect the public (BPC section 4001.1).

An estimated 1.4 million Americans are addicted to opioid painkillers and 438 thousand have a heroin-related opioid addiction. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), treatment for opioid addiction requires continuing care and not an acute-care approach. Many of those with an opioid addiction benefit from treatment with medication for varying lengths of time, including lifelong treatment. Medication-Assisted Treatment (MAT) is used to treat substance use disorders, as well as to sustain recovery and prevent overdose. Medications used in MAT are approved by the Food and Drug Administration, and MAT programs are clinically driven and tailored to meet each patient's needs. This patient-centered care empowers patients with information that helps them make better treatment decisions with the healthcare professionals involved in their care.

As published by SAMHSA, "Research shows that a combination of medication and therapy can successfully treat substance use disorders, and for some people struggling with addiction, MAT can help sustain recovery. MAT is also used to prevent or reduce opioid overdose."

Previously, any prescriber who wished to treat an opioid use disorder with the prescription medication buprenorphine was required to obtain a DATA Waiver (X-waiver) from SAMHSA to do so lawfully, and had to complete several hours of specialized training to be approved for the waiver. The federal government loosened those requirements in 2021, allowing prospective prescribers to obtain a waiver without completing training, as long as they limited the number of patients they treated with buprenorphine to thirty. Effective January 1, 2023, federal law was amended to expand access to MAT, including removing the X-waiver requirement. As such, and as permitted by applicable state law, all practitioners who have a current DEA registration that includes Schedule III authority may now prescribe buprenorphine to treat Opioid Use Disorder.

Existing Pharmacy Law at BPC section 4052(a)(14) (as amended in 2022) authorizes pharmacists to provide MAT pursuant to a state protocol, to the extent authorized by federal law. The Board proposes establishing the state protocol (required by BPC section 4052(a)(14)), specifically the requirements of appropriate education and training, providing a confidential area for services, performing an assessment, developing a treatment plan, specific documentation, and collaborating with health care providers.

The protocol was developed in consultation with experts in the field, including:

1. Dr. James Gasper, BCPP, Psychiatric and Substance Use Disorder Pharmacist, California Department of Health Care Services.
2. Dr. Talia Puzantian, BCPP, Professor of Clinical Sciences, KGI School of Pharmacy and Health Sciences.
3. Dr. Michelle Geier, BCPP, Psychiatric Pharmacy Supervisor, San Francisco Department of Public Health, Behavioral Health Services.

Anticipated Benefits of the Proposed Regulatory Action

The Board has determined that this regulatory proposal will have the following benefits to the health and welfare of California residents, and will have no effect on worker safety and the state's environment.

Protection of the public is the Board's highest priority in exercising its licensing, regulatory, and disciplinary functions. The proposed regulation will ensure that there is proper oversight of practitioners who provide MAT.
With the change in the federal law and the Board's proposed regulation, pharmacists that choose to provide MAT will be well-positioned to serve as important access points for patients in need of MAT. This will benefit the health and welfare of California residents.

Specific Purpose of Regulatory Proposal and Rationale for Proposed Changes

The Board proposes adding the following language:

Subsection (a), the purpose of which is to define medication-assisted treatment to include all medication used to treat a substance use disorder. This definition is necessary to ensure that any Federal Food and Drug Administration (FDA) approved medication for substance use disorder can be utilized for medication-assisted treatment, as specified in Section 8.12(h)(1) of Title 42, Chapter 1, Subchapter A, Part 8, of the Code of Federal Regulations. Currently, there are three FDA-approved medications for opioid abuse treatment: methadone, buprenorphine, and naltrexone. However, by not specifying the medication, as the FDA approves new medications, they can also be utilized in treatment plans.

Subsection (b), which states the authority for pharmacists to initiate, modify, administer, or discontinue MAT. This subsection reads "A pharmacist may initiate, modify,

administer, or discontinue medication-assisted treatment pursuant to Business and Professions Code section 4052(a)(14), consistent with all relevant provisions of federal law, and shall satisfy the requirements of this section." The purpose of this subsection is to provide reference to the BPC section that authorizes a pharmacist to provide MAT. The subsection is necessary to inform and the regulated public about their legal obligations under BPC section 4052(a)(14) and the proposed regulation section, as pursuant to BPC section 4052(a)(14), pharmacists that provide MAT must do so pursuant to a protocol.

Subsection (b)(1), which implements the requirement that pharmacists possess the appropriate education and training to provide MAT. The purpose of this addition is to ensure that pharmacists provide MAT consistent with the established standard of care used by other health care practitioners, including nationally accepted guidelines. This language is necessary to ensure education and training are aligned with BPC section 4052(b), and the pharmacist, who is authorized to issue an order to initiate or adjust a controlled substance therapy, must be personally registered with the federal Drug Enforcement Administration (DEA). Consistent with Federal requirements, "appropriate education and training" will vary by individual based on their education, training, or work experience. The Federal requirement states that "Each person engaged in the treatment of [substance abuse] disorders must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions." (42 C.F.R. section 8.12.) The Board determined that Pharmacists must use their professional judgment, consistent with the standard of care, to determine whether their education and training is appropriate to provide medication-assisted treatment. Pharmacist professional judgment involves using accumulated knowledge, experience, and critical reasoning to make informed decisions in patient care, medication management, and related areas, always prioritizing patient safety and well-being. The DEA requires compliance with state law and licensure requirements. Additionally, effective June 21, 2023, due to the Consolidated Appropriations Act (2023), pharmacists must complete no less than 8 hours of training, on the treatment and management of patients with opioid or other substance use disorders, provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Associates, or any other organization approved or accredited by the Assistant Secretary for Mental Health and Substance Use or the Accreditation Council for Continuing Medical Education. This requirement also complies with Federal requirements, specifically, section 8.12(d) of Title 42, Chapter 1, Subchapter A, Part 8, of the Code of Federal Regulations.

Subsection (b)(2), which establishes the requirement that a pharmacist must make available a confidential patient care area to use when providing MAT services. The patient may not waive consultation. The purpose of this addition, in alignment with BPC section 4052(c)(1) (which ensures the confidentiality of medical records) is to provide patients with confidential care services. This addition is necessary not only to ensure compliance with the law, but also because the pharmacist must conduct a physical

examination and develop a treatment plan with the patient, and these are best done in a confidential patient care area. Additionally, consultation cannot be waived as the patient must submit to a physical and laboratory examination.

Subsection (b)(3), the purpose of which is to establish the requirement that an assessment be performed, including physical and laboratory examinations, for signs and symptoms of substance use disorder. Initial assessment may be waived if the patient is referred to the pharmacist for treatment following diagnosis by another health care provider. This addition is necessary to ensure a complete physical evaluation is performed, including serology tests, in compliance with Section 8.12(f)(2) of Title 42, Chapter 1, Subchapter A, Part 8 of the Code of Federal Regulations, and so that the patient receives proper and thorough treatment.

Subsection (b)(4), the purpose of which is to ensure that pharmacists develop a treatment plan for a patient's substance use disorder, which may include referral to medical services, case management, psychosocial services, substance use counseling, and residential treatment. This addition is necessary to inform the regulated public of the required components of a treatment plan for substance abuse. These requirements also comply with Federal requirements, specifically, Section 8.12(f)(4) and (5) of Title 42, Chapter 1, Subchapter A, Part 8, of the Code of Federal Regulations.

Subsection (b)(5), the purpose of which is to establish the requirement that the pharmacist's assessment, clinical findings, plan of care, and medications dispended and administered are documented in a patient record system and shared with a patient's primary care provider or other prescriber, if one is identified. This language is necessary to ensure that a pharmacist providing MAT care has a comprehensive treatment plan in place, that is individualized and updated regularly throughout the course of treatment, so the patient completes the objectives as prescribed by the MAT provider, and that the patient record is complete to ensure the continuity of patient care. Ensuring that the patient record is complete and that the patient's primary care provider is notified will ensure that providers are aware of the clinical findings, care plan, and medications provided to the patient, should the patient seek treatment from other health care providers. These requirements also comply with Federal requirements, specifically, Section 8.12(f)(1)-(4) of Title 42, Chapter 1, Subchapter A, Part 8, of the Code of Federal Regulations.

Subsection (b)(6), which establishes that pharmacists providing MAT must do so in collaboration with other health care providers. The purpose of including this language is to recognize the unique traits of various healthcare professionals and inform on the importance of integrating pharmacists into the MAT team. This inclusion is necessary to ensure collaboration and, therefore, thorough patient care, given pharmacists must refer patients for psychosocial services, substance use counseling, and residential treatment. This requirement also complies with Federal requirements, specifically, Section 8.4(h)(1) of Title 42, Chapter 1, Subchapter A, Part 8, of the Code of Federal Regulations.

Underlying Data

1. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held February 6-7, 2023 (Agenda Item XII & Relevant Meeting Minutes).
2. Relevant Meeting Materials and Minutes from Licensing Committee Meeting held January 24, 2023 (Agenda Item V & Relevant Meeting Minutes).
3. Medication for the Treatment of Alcohol Use Disorder, Pocket Guide. https://store.samhsa.gov/sites/default/files/d7/priv/sma15-4907pocketguid.pdf
4. Medication for Opioid Use Disorder for Healthcare and Addiction Professionals, Policymakers, Patients, and Families, Updated 2021. https://www.ncbi.nlm.nih.gov/books/NBK574910/pdf/Bookshelf_NBK574910.pdf
5. Substance Abuse and Mental Health Services Administration, Medications for Substance Use Disorders; https://www.samhsa.gov/medications-substance-use-disorders
6. Substance Abuse and Mental Health Services Administration, Waiver Elimination (MAT Act); https://www.samhsa.gov/medications-substance-use-disorders/waiver-elimination-mat-act
7. Code of Federal Regulations, Title 42, Chapter 1, Subchapter A, Part 8, Medication Assisted Treatment For Opioid Use Disorders, https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8

Business Impact

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses including the ability of California businesses to compete with businesses in other states. This initial determination is based on the absence of testimony to that effect during the public discussion and development of the proposed regulation. The proposed regulation establishes the state protocol pharmacist licensees must follow should they wish to provide MAT; however, there are no additional requirements for businesses.

Economic Impact Assessment

The Board has determined that this proposal will not:
(1) create jobs within California;
(2) eliminate jobs within California;
(3) create new businesses within California;
(4) eliminate of existing businesses within California;
(5) expand businesses currently doing business in the State of California.

The Board determined that this proposal will not create or eliminate jobs or businesses. The proposed regulation establishes the state protocol pharmacist licensees must follow should they wish to provide MAT. Providing MAT to patients is an optional treatment pharmacists may provide and is not mandated. Pharmacists that choose to provide MAT will serve as important access points for patients in need of MAT, which will benefit the health and welfare of California residents. The proposed regulation will not impact worker safety or the state's environment.

Fiscal Impact Assessment:

The proposed regulations do not result in a fiscal impact to the state.

The Board does not anticipate an increase in enforcement activity. Additionally, compliance will be verified through routine pharmacy inspections.

The regulations do not result in costs or savings in federal funding to the state.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. The Board considered not requiring a specific area to provide MAT; however, the Board determined that a confidential patient care area was necessary to ensure confidentiality and privacy during the physical examination and development of the treatment plan.