DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:
Medication-Assisted Treatment Protocol

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (Board) proposes taking the rulemaking action described below, under the heading Informative Digest/Policy Statement Overview. Any person interested may present statements or arguments relevant to the action proposed in writing.

PUBLIC HEARING
The Board has not scheduled a public hearing on this proposed action. The Board will, however, hold a hearing if it receives a written request for a public hearing from any interested person, or that person's authorized representative, no later than 15 days prior to the close of the written comment period. A hearing may be requested by making such request in writing, addressed to the individuals listed under "Contact Person" in this notice.

WRITTEN COMMENT PERIOD
Written comments relevant to the action proposed, including those sent by mail, facsimile, or e-mail to the addresses listed under "Contact Person" in this Notice, must be **received by the Board at its office no later than August 4, 2025**, or must be received by the Board at the hearing, should one be scheduled.

Authority and Reference: Pursuant to the authority vested by section 4052 of the Business and Professions Code (BPC), the Board is considering adding section 1746.6 to Title 16 of the California Code of Regulations (CCR).

Informative Digest/Policy Statement Overview

The California State Board of Pharmacy is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (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.

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's 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 Regulation

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 medication-assisted treatment (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.

Evaluation of Consistency and Compatibility with Existing State Regulations

While developing this regulatory proposal, the Board conducted a search of any similar regulations on this topic and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: None. The proposed regulations do not result in a fiscal impact to the state.

The Board does not anticipate the proposed regulation resulting in an increase in workload, enforcement activity, or costs. Additionally, compliance will be verified through routine pharmacy inspections.

Cost to any Local Agency or School District for which Government Code Sections 17500-17630 Require Reimbursement: None

Mandate Imposed on Local Agencies or School Districts: None

Significant Effect on Housing Costs: None

BUSINESS IMPACT ESTIMATES

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, 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.

Cost Impact on Representative Private Person or Business:

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Small Business**:**

While the Board does not have, nor does it maintain, data to determine if any of its licensees (pharmacies and clinics) are a “small business,” as defined in Government Code section 11342.610, the Board has made an initial determination that the proposed regulatory action will not affect small businesses. All pharmacists have the option of providing MAT should they wish to meet the federal requirements and comply with the proposed regulation, whether they work at a small community pharmacy or a large chain pharmacy.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/Businesses:

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.

Benefits of Regulation:

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 medication-assisted treatment (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.

Business Reporting Requirements

The regulatory action does not require businesses to file a report with the Board.

Effect on Small Business

The Board has determined that the proposed regulations may affect small businesses. Although small businesses owned by licensees of the Board may be impacted, the Board does not maintain data relating to the number or percentage of licensees who own a small business; therefore, the number or percentage of small businesses that may be impacted cannot be predicted.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5(a)(13), the Board determined that no reasonable alternative that it considered to the regulation, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the purpose for which the action is proposed, as effective and less burdensome to affected private persons than the proposal described in this Notice, or more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may submit comments, in writing, relevant to the above determinations at the address listed for the Contact Person during the written comment period, or at the hearing if one is scheduled or requested.

AVAILABILITY OF TEXT OF PROPOSAL, INITIAL STATEMENT OF REASONS, AND RULEMAKING FILE

The Board has compiled a record for this regulatory action, which includes the Initial Statement of Reasons (ISOR), proposed regulatory text, and all the information upon which the proposal is based. This material is contained in the rulemaking file and is available for public inspection upon request to the contact persons named in this notice. Copies of the exact language of the proposed regulations and the Initial Statement of Reasons, as well as all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 2720 Gateway Oaks Drive, Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy's website at http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml..

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments, the Board, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal, with the modifications clearly indicated, will be available for review and written comment for 15 days prior to its adoption from the person designated in this Notice as the Contact Person and will be mailed to those persons who submit written comments or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file, which is available for public inspection by contacting the person named below.

You may obtain a copy of the Final Statement of Reasons, once it has been prepared, by making a written request to the Contact Person named below or by accessing the website listed below.

CONTACT PERSONS

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Lori Martinez
Address:	2720 Gateway Oaks Drive, Ste. 100 Sacramento, CA 95833
Phone No.:	(916) 518-3100
Fax No.:	(916) 574-8618
E-Mail Address:	PharmacyRulemaking@dca.ca.gov

The backup contact person is:

Name:	Debbie Damoth
Address:	2720 Gateway Oaks Drive, Ste. 100 Sacramento, CA 95833
Phone No.:	(916) 518-3100
Fax No.:	(916) 574-8618
E-Mail Address:	PharmacyRulemaking@dca.ca.gov

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulation with modifications noted, as well as the Final Statement of Reasons when completed, and modified text, if any, can be accessed through the Board of Pharmacy's website at: https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.