DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:
Central Fill Pharmacies

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (Board) proposes taking the rulemaking action described under the heading Informative Digest/Policy Statement Overview below, after considering all comments, objections, and recommendations regarding the proposed action.

PUBLIC HEARING
The Board has not scheduled a public hearing on this proposed action. However, the Board will 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 Persons" 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 December 1, 2025, or must be received by the Board at the hearing, should one be scheduled.

Authority and Reference: Pursuant to the authority vested by Business and Professions Code (BPC) section 4005, the Board proposes amending section 1707.4 of Division 17 of Title 16 of the California Code of Regulations (CCR).

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

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

Existing regulation at Title 16, CCR section 1707.4, which has not been updated in over twenty years, generally provides authority for a pharmacy licensed by the Board to process a request for refill of a prescription received by a pharmacy within California under specified conditions, including:

1. The pharmacy that refills the prescription either has a contract with or has the same owner as another pharmacy that received the prescription.
2. The prescription container meets labeling requirements and includes the name and address of the pharmacy refilling the prescription and/or the name and address of the pharmacy that receives the refilled prescription.
3. The patient is provided with written information about which pharmacy to contact if the patient has any questions.

4. Both pharmacies maintain records as specified.
5. Both pharmacies are responsible for ensuring the order is filled correctly.
6. The originating pharmacy is responsible for compliance with maintaining medication profiles, conducting patient consultations, and reviewing medication profiles and drug therapy records prior to prescription drug delivery.

In October 2023, the Board decided to review these requirements and determine whether changes were necessary. The Board and stakeholders had robust discussions and several presentations were given, across multiple public committee and Board meetings. The discussions and presentations addressed several provisions in the draft regulations, including final product verification and the use of technology in central fill pharmacies.

The proposed amendments to the regulation are intended to clarify the current law based on comments received from the regulated public suggesting the current language is not clear or seeking guidance on how to interpret or implement the language. Specifically, references to "refill" are being removed, clarifying language is being added to ensure that the central fill pharmacy is licensed by the Board and operated within California, and to ensure that the originating and central fill pharmacies have the flexibility to include the name and address of both pharmacies on the written information provided to patients if pharmacies so choose. Additionally, language is being added to allow originating pharmacies to perform final product verification before dispensing and allow for the final product verification to be done by viewing images in lieu of a physical visual inspection. Finally, a definition of central fill pharmacy is being added.

Anticipated Benefits of Proposal

The Board's highest priority in exercising its licensing, regulatory, and disciplinary functions is protecting the public. The Board has determined that this regulatory proposal will benefit the health and welfare of California residents.

This proposal clarifies current law based on comments received from the regulated public suggesting the current language is not clear or seeking guidance on how to interpret or implement the language. Specifically, clarifying language is being added to ensure that the central fill pharmacy is licensed by the Board and operated within California and that the originating and central fill pharmacies have the flexibility to include the name and address of both pharmacies on the written information provided to patients if pharmacies so choose. Additionally, the amendments allow originating pharmacies to perform final product verification before dispensing and permit final product verification to be done by viewing images in lieu of a physical visual inspection. The amendments to this regulation will benefit licensees and consumers by increasing transparency to consumers, ensuring patients know that a Central Fill facility filled their prescriptions and who to contact with any questions—thereby benefitting the health and welfare of California consumers—and allow pharmacies flexibility regarding labeling and product verification.

This regulatory proposal does not affect employee safety or the state's environment.

Evaluation of Consistency and Compatibility with Existing State Regulations

During the process of 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.

DISCLOSURES REGARDING THIS PROPOSED ACTION

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: The proposed regulation does not result in a fiscal impact to the state.

Additionally, the Board does not anticipate additional workload or costs resulting from the proposed regulation. Currently, Central Fill Pharmacies are regulated via routine Board inspections, and this process will continue.

The proposed regulation does not result in a fiscal impact to the state in the form of federal funding or any cost or savings to any state agency.

Nondiscretionary Costs/Savings to Local Agencies: None.

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.

The proposed amendments to the regulation are intended to clarify the current law based on comments received from the regulated public who have suggested the current language is not clear or have sought guidance on how to interpret or implement the language. The amendments also provide increased flexibility regarding labeling and product verification. This regulation will benefit licensees and consumers and will not have any adverse effects.

Cost Impact on Representative Private Person or Business:
The Board is not aware of any negative cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/New Businesses:

The Board concludes that this proposal will not:

(1) create jobs within California;
(2) eliminate jobs within California;
(3) create new businesses within California;
(4) eliminate existing businesses within California; and
(5) expand businesses currently doing business in the State of California.

Benefits of Regulation:

The Board determined this proposal will not create or eliminate jobs or businesses. This proposal clarifies current law based on comments received from the regulated public suggesting the current language is not clear or seeking guidance on how to interpret or implement the language. Specifically, clarifying language is being added to ensure that the central fill pharmacy is licensed by the Board and operated within California and that the originating and central fill pharmacies have the flexibility to include the name and address of both pharmacies on the written information provided to patients if pharmacies so choose. Additionally, the amendments allow originating pharmacies to perform final product verification before dispensing and permit final product verification to be done by viewing images in lieu of a physical visual inspection. The amendments to this regulation will benefit licensees and consumers by increasing transparency to consumers, ensuring patients know that a Central Fill facility filled their prescriptions and who to contact with any questions—thereby benefitting the health and welfare of California consumers—and allow pharmacies flexibility regarding labeling and product verification.

This regulatory proposal does not affect employee safety or the state's environment.

Business Reporting Requirements

This regulatory proposal does not require businesses to file a report with the Board.

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 determined that the proposed regulatory action impacts Central Fill Facilities and those pharmacies that utilize that business model to

fill prescriptions. However, the Board anticipates that these licensees, by their nature, are medium to large businesses.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5(a)(13), the Board must determine that no reasonable alternative it considered, 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, would be as effective and less burdensome to affected private persons than the proposed action, or would be 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—relevant to the above determinations—in writing, at the address listed below for the Contact Persons, during the written comment period, or at the hearing if one is scheduled or requested.

AVAILABILITY OF 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.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, the Initial Statement of Reasons, and 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 persons designated in this Notice as the Contact Persons 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:	Board of Pharmacy 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:	Board of Pharmacy 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 regulations 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.