TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED REGULATORY ACTION CONCERNING: REPORTING DRUG LOSS

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. Written comments, 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 by July 19, 2021.

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.

The Board may, after considering all timely and relevant comments, adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations 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 will be available 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 or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Section 4005 of the Business and Professions Code (BPC) authorizes the Board to adopt this regulation. The proposed regulation implements, interprets, and makes specific sections 4081, 4104, and 4332 of the Business and Professions Code.

Informative Digest/Policy Statement Overview

The Board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, hospital pharmacies, clinics, wholesalers, third-party logistics providers, and outsourcing facilities. The Board's mandate and its mission is to protect the public (BPC section 4001.1).

Existing pharmacy law requires the owner of a licensed facility to report any loss of controlled substances to the Board within 30 days of the discovery of the loss. The report must include the amount and strengths of the loss (16 CCR 1715.6). Additionally, existing federal law requires that registrants notify the Drug Enforcement Agency (DEA), in writing, of the theft of significant loss of any controlled substances within one business day of discovery of such loss or theft (21 Code of Federal Regulation (CFR) 1301.76(b)).

As existing state law requires that any loss of controlled substance be reported to the Board, licensed facilities are required to report losses of all sizes, including single dose losses. For example, if one tablet falls on the floor while counting out the tablets to fill a prescription, that tablet must be disposed of and is considered a loss. Therefore, the licensed facility would have to report the loss of one tablet. This creates an administrative burden for both the licensee and the Board to prepare, review, and document the reported loss. This type of minimal loss reporting is not required by the DEA.

This proposal seeks to eliminate this excessive reporting and more closely align the Board's regulation with the federal regulation by providing increased clarity and consistency with respect to the quantities of controlled substance losses that must be reported to the Board. While the DEA requires the reporting of any "significant" loss, the Board determined that establishing a minimum reporting threshold will eliminate the ambiguity of the term "significant" and ensure clarity for the regulated public. The proposal does permit additional reporting of losses the pharmacist-in-charge deems "significant" in their professional judgment.

Anticipated Benefits of the Proposed Regulations

This proposal will increase clarity for the regulated public by establishing a minimum drug loss reporting threshold within regulation. Establishing a minimum threshold will also eliminate the need for single tablet loss reporting, which will reduce some of the administrative burden on licensees with respect to drug loss reporting. As indicated below, the reduction is drug loss reporting will also result in a cost savings to the State by eliminating the review of minor drug loss reports. Additionally, this proposal will more closely align the Board's regulation with the federal drug loss reporting requirement for consistency.

Consistency and Compatibility with Existing State Regulations

While developing these regulations and amendments, the Board conducted a search of similar regulations on this topic and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations. As noted above, these amendments make state law more consistent with federal law.

Fiscal Impact and Related Estimates

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: The proposed regulations will reduce the number of licensed facilities reporting a drug loss from approximately 10,000 reports per year to 6,667 per year. According to the Board, an Associate Governmental Program Analyst (AGPA) typically takes five minutes to process each report at a cost of approximately $3 per report.

As a result, the anticipated decrease of 3,333 reports received and processed by the Board each year is anticipated to result in cost savings of approximately $10,000 per year.

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

Business Impact:
The Board has determined that the proposed regulatory action will have no significant statewide adverse economic impact directly affecting businesses and/or employees. This initial determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over several months in numerous Board and committee meetings. Additionally, licensed facilities are already required to report drug losses by existing law. The Board has determined that this proposal will reduce the number of drug loss reports being submitted by eliminating the requirement to report "all" drug losses, as the proposed regulation establishes a minimum threshold that is not currently specified in regulation.

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 proposed action.

The proposed regulations are estimated to result in a reduction of 3,333 reports completed and generally submitted by fax per year. According the Board, a typical report takes approximately 10 minutes to complete at an average cost savings of $11 per report (based on $66 average hourly Pharmacist's salary), which would result in total annual costs savings of $36,663 per year and up to $366,630 over a ten-year period.

Effect on Housing Costs: None

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 have a significant adverse economic impact directly affecting small businesses. Although the proposed regulation will directly affect businesses statewide, which may include small businesses, the Board does not anticipate any adverse economic impact, including the ability of California businesses to compete with businesses in other states. And, the time savings noted above will most likely have a positive financial effect upon smaller pharmacy businesses, as they have less staff available to complete forms currently necessary to report insignificant drug losses to the Board.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

The Board concludes that:

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

Benefits of Regulation:
The Board has determined that this regulatory proposal will not impact the health and welfare of California residents, worker safety, or the state's environment. The proposal establishes a minimum threshold for reporting drug losses not currently specified in regulation. This will eliminate the requirement to report "all" drug losses. This will reduce the quantity of drug loss reports that licensed facilities are currently required to submit, as they will no longer be required to report single dose losses.

Consideration of Alternatives

The Board must determine that no reasonable alternative that it considered to the regulation, or that has otherwise been identified and brought to its attention, would either 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 proposal described in this Notice, 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 present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person during the written comment period.

Initial Statement of Reasons and Information

The Board has prepared an Initial Statement of Reasons for the proposed action and has available all the information upon which the proposal is based.

Text of Proposal

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of 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.

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 Person

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) 518-3078
Fax No.:	(916) 574-8618
E-Mail Address:	Lori.Martinez@dca.ca.gov

The backup contact person is:

Name:	Debbie Damoth
Address:	2720 Gateway Oaks Drive, Ste. 100 Sacramento, CA 95833
Phone No.:	(916) 518-3090
Fax No.:	(916) 574-8618
E-Mail Address:	Debbie.Damoth@dca.ca.gov

Website Access

Materials regarding this proposal can be found at the Board of Pharmacy's website: www.pharmacy.ca.gov.