California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

To: Board Members

Subject: Agenda Item XV. Discussion and Consideration of Adoption of Board Approved Regulation, 16 California Code of Regulations Section 1715.6 Related to Reporting Drug Losses

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Background:

At the January 2020 Board meeting, the Board approved proposed regulation text to amend Section 1715.6 related to Reporting Drug Losses. This proposal amends the drug loss reporting requirements to further define when drug losses must be reported and to increase clarity for the regulated public.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on June 4, 2021, which ended on July 19, 2021. Several comments were received during the comment period. Attached following this memo are the following:

1. The proposed text released for 45-day public comment.
2. Board staff prepared summarized comments with recommendations
3. Comments received during the 45-day comment period

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation text as noticed for 45-day comment on June 4, 2021.
2. Amend the regulation to address concerns expressed by stakeholders and notice the modified text for a 15-day comment period.

Possible Adoption Language:

Accept the Board staff recommended comment responses and adopt the regulation language as noticed for 45-day comment on June 4, 2021. Additionally, delegate to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

Reporting Drug Losses
16 CCR § 1715.6

§ 1715.6. Reporting Drug Loss.

(a) The owner shall submit ~~report~~ to the Board a report containing the information in subdivision (b) ~~within~~ no later than thirty (30) days after the date of discovery of the following:

(1) ~~any~~ Any loss of ~~the~~ a controlled substance~~s, including their~~ in one of the following categories that causes the aggregate amount of unreported losses discovered in that category on or after the same day of the previous year to equal or exceed:

(A) For tablets, capsules, or other oral medication, 99 dosage units.

(B) For single-dose injectable medications, lozenges, film, suppositories, or patches, 10 dosage units.

(C) For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose vials, infusion bags, or other containers.

(2) Any loss of a controlled substance, regardless of the amount, attributed to employee theft.

(3) Any other ~~substantial~~ significant loss as determined by the pharmacist-in-charge.

(b) All reports under this section shall specify the identity, amount~~s~~ and strength~~s~~ of each controlled substance lost, and date of discovery of the loss, for all losses that have made the report necessary.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081 and 4332, Business and Professions Code.

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Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Reporting Drug Losses

Summarized 45-day Comments Regarding Reporting Drug Losses with Board Staff Recommendations:

Written Comments from Flynn Lew, PharmD.

Comment 1: The commenter indicated that there is no quantity specified for oral liquid-controlled substances and recommended that this be addressed.

Response to Comment 1: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff notes that subsection (a)(1)(A) states "other oral medication" which would apply to oral liquid-controlled substances.

Written Comments from Dale Costantino, PharmD.

Comment 1: The commenter recommended that the quantities of controlled substance losses be changed from an absolute value to a percentage of doses dispensed to "normalize the burden and criteria for reporting" across large and small pharmacies.

Response to Comment 1: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. The Board previously discussed reporting percentages and determined that losses should not be reported as a percentage as the loss of 100 pills is a significant loss no matter the size of the pharmacy when public welfare is considered. Current law requires a single dose loss to be reported. This proposal eliminates the reporting of single dose losses.

Written Comments from BJ Bartleson, California Hospital Association

Comment 1: The commenter expressed concern about the administrative burden to maintain single dose losses as well as having to tabulate the losses over the one-year reporting time frame. The commenter recommends that subsection 1715.6(a)(1) be amended to remove the aggregate total requirement as the commenter believes it creates a cumbersome manual tracking process.

Response to Comment 1: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff do not agree that tabulating losses over a one-year time frame is burdensome. As indicated in the response to the previous commenter, the log could be a simple excel spreadsheet or even pen and paper. A large portion of pharmacies use a perpetual inventory system to track medication supply. Based on the needs of the pharmacy, as determined by the pharmacy, something similar could be utilized. Again, the pharmacy would

need to review their processes and develop a system that meets their needs. Board staff notes that the regulation does not prohibit a licensee from reporting an aggregate loss of less than the specified doses on a more frequent basis as the aggregate total will otherwise be available to the Board through their own review of the reports.

Comment 2: The commenter recommends that subsection 1715.6(a)(1)(A) – 1715.6(a)(1)(C) be amended as follows: (Commenters recommendations are in double underline for additions/double strikeout for deleted language).

(1) ~~any~~ Any loss of ~~the~~ a controlled substance~~s, including their~~ in one of the following categories ~~that causes the aggregate amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed~~:

(A) For tablets, capsules, or other non-solid oral medication, 20 (twenty) or more ~~99~~ dosage units.

(B) For single-dose injectable medications, lozenges, film, ~~such as oral~~, buccal and sublingual, suppositories, or patches, 10 (ten) or more dosage units.

(C) For injectable multi-dose medications, medications administered by ~~continuous~~ infusion, or any other ~~multi-dose unit~~ medication not described in subparagraph (A) or (B), five ~~two~~ or more multi-dose vials, infusion bags, or other containers.

Commenter believes that the recommended reporting amounts would ensure timely reporting of "concerning losses."

Response to Comment 2: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. As mentioned in the comment above, the regulation does not prohibit a licensee from reporting an aggregate loss of less than the specified doses on a more frequent basis. A review of the record shows that the language reflects deliberate choices based on Board member discussion at several Board and Committee meetings.

Comment 3: Commenter recommends that a subsection 1715.6(A)(4) be added that reads "Any loss or theft reported to the Drug Enforcement Agency (DEA)" as they feel the Board should be notified of any loss reported to the DEA.

Response to Comment 3: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff do not believe this addition is necessary as subdivision (a)(1)(3) identifies "Any other significant loss as determined by the pharmacist-in-charge." If the loss was determined to be significant to require reporting to the DEA, the PIC should also be submitting the report to the Board per this subdivision.

Comment 4: Commenter recommends the section 1715.65(d) be amended to remove the 14-day reporting timeframe for drug losses due to theft, diversion, or self-use to match the 30-day requirement for the report identified in CCR 1715.6(a).

Response to Comment 4: Board staff have reviewed this comment and do not recommend any changes to the text based thereon as it is outside the scope of this rulemaking, which is specific to CCR section 1715.6.

Comment 5: Commenter recommends the Business and Professions Code section 4104(c) be amended to change the reporting timeframe from 14 days to 30 days when the loss is due to a licensed employee to match the 30-day requirement for the report identified in CCR 1715.6(a).

Response to Comment 5: Board staff have reviewed this comment and do not recommend any changes to the text based thereon as it is outside the scope of this rulemaking, which is specific to CCR section 1715.6. Additionally, Board staff note that statutory language cannot be amended through the regulatory process.

Comment 6: Commenter recommends the Business and Professions Code section 4134(g) be amended to change the reporting timeframe from 14 days to 30 days when the loss is due to theft, diversion, or self-use to match the 30-day requirement for the report identified in CCR 1715.6(a).

Response to Comment 6: Board staff have reviewed this comment and do not recommend any changes to the text based thereon as it is outside the scope of this rulemaking, which is specific to CCR section 1715.6. Additionally, Board staff note that statutory language cannot be amended through the regulatory process.

Written Comments from John Gray, PharmD., Kaiser Permanente

Comment 1: Commenter recommends that subsection 1715.6(a)(1) and (2) be amended to add "from the licensed facility's inventory." Additionally, commenter recommends the (a)(3) be amended to add "of a controlled substance from the licensed facility's inventory" as the licensee should not be accountable for drug losses that occurred prior to the medication arriving at the facility or after it has left the facility.

Response to Comment 1: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff believe that the recommended change would eliminate the reporting of drug shipments lost in transit as they would no longer be considered part of any licensee's inventory. Drug shipments lost in transit must be reported. Reporting a drug loss to the Board does not determine accountability for the loss.

Comment 2: Commenter recommends that section 1715.6(a) be further amended to reduce the one-year reporting timeframe to the previous "90 calendar days" to facilitate more "timely discovery and reporting" of losses, as well as, encourage pharmacies to complete the required quarterly inventory.

Response to Comment 2: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. As indicated in a prior comment response, the regulation does not prohibit a licensee from reporting an aggregate loss of less than the specified doses on a more

frequent basis as the aggregate total will otherwise be available to the Board through their own review of the reports.

Comment 3: Commenter recommends that subsection 1715.6(a)(1)(A), (B), and (C) be amended to reduce the reporting quantities, specifically, reducing 99 dosage units to 25 in (A) and 10 dosage units to 5 in (B) to coincide with the reduction in the reporting timeframe to 90 days. Additionally, commenter recommends that the requirement that the drug loss be from the same NDC number be added to each subsection to clarify how multiple small losses should be combined.

Response to Comment 3: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. As previously mentioned, the regulation does not prohibit a licensee from reporting an aggregate loss of less than the specified doses on a more frequent basis as the aggregate total will otherwise be available to the Board through their own review of the reports. Additionally, the Board previously considered determining losses based on NDCs; however, determined that the aggregate total should be based on total dosage units as reflected in the language.

Reporting Drug Losses 45-day Comments

From: Flynn Lew <flynn.lew@medplusltc.com>
Sent: Friday, June 4, 2021 10:49 AM
To: Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>
Subject: Proposed Action to amend section 1715.6 to Title 16

[EXTERNAL]: flynn.lew@medplusltc.com

CAUTION: THIS EMAIL ORIGINATED OUTSIDE THE DEPARTMENT OF CONSUMER AFFAIRS!
DO NOT: click links or open attachments unless you know the content is safe.
NEVER: provide credentials on websites via a clicked link in an Email.

Hello Lori,
I notice on the proposed text, there is no quantity requirement with regards to oral liquid control substances. This gap may need to be addressed.

--
Flynn H. Lew Pharm.D.
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Flynn.Lew@medplusltc.com

From: Costantino, Dale <dcostant@KaweahHealth.org>
Sent: Friday, June 4, 2021 1:33 PM
To: Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>
Subject: Reporting Drug Loss

Hello,

I would like to comment on the proposed changes to 1715.6. Please consider changing the definitions providing clarity with respect to the quantities of controlled substance losses that must be reported to the Board. Please consider using a percent of doses dispense as a criteria instead of an absolute value. This would normalize the burden and criteria for reporting for both small and large pharmacies.

Thanks
Dale

Dale Costantino, Pharm.D.
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kaweahhealth.org

Kaweah Health
MORE THAN MEDICINE. LIFE.

July 15, 2021

Lori Martinez
California Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Via Email: Lori.Marinez@dca.ca.gov

SUBJECT: Board of Pharmacy Proposed Regulations, Amend Section 1715.6 to Title 16 of the California Code of Regulations, Reporting Drug Loss

Dear Ms. Martinez:

The California Hospital Association and its 400 plus members appreciate the opportunity to comment on section 1715.6 Reporting Drug Loss Regulations. These proposed regulations seek to eliminate excessive reporting and more closely align the state's regulations with federal regulation by providing increased clarity with respect to the quantities of controlled substance losses that must be reported to the board. While the federal DEA requires reporting of any significant loss, as defined by the provider, the Board of Pharmacy determined that establishing a threshold would resolve the ambiguity present when using the term "significant" by each provider.

While CHA and its members applaud the Board of Pharmacy's attempt to reduce the administrative burden for hospitals due to excessive reporting, the proposed regulations are adding burdensome cumulative reporting and tracking to hospital pharmacies. The proposed regulations would require hospital to keep detailed annotations of single drug losses, as done presently, as well as tabulating single drug losses over time cumulatively to meet the new regulatory requirements.

Instead, CHA and member hospitals offer a process by which one time drug loss reporting can continue to occur based on reasonable one-time reporting volumes for oral, injectable and other medication types. We also offer comments that align California regulations with federal regulations, as well as suggesting alignment with reporting timelines in 17.65(d), 4104(c), and 4134 (g).
Attached is a "Proposed Regulatory Grid" with comments describing the changes above. CHA and the Medication Safety Team appreciates the opportunity to provide comment on these regulations.

Sincerely,

BJ Bartleson, RN, MS, NEA-BC
Vice President, Nursing and Clinical Services

California State Board of Pharmacy § 1715.6. Reporting Drug Loss

Proposed Regulations – Comments

Subdivision	Proposed Language	Recommendation/Comments:
1715.6	(a) The owner shall submit ~~report~~ to the Board a report containing the information in subdivision (b) ~~within~~ no later than thirty (30) days after the date of discovery of the following: (1) ~~any~~ Any loss of ~~the~~ a controlled substance~~s,~~ ~~including their~~ in one of the following categories that causes the aggregate amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed: (A) For tablets, capsules, or other oral medication, 99 dosage units. (B) For single-dose injectable medications, lozenges, film, such as oral, buccal and sublingual, suppositories, or patches, 10 dosage units. (C) For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose vials, infusion bags, or other containers. (2) Any loss of a controlled substance, regardless of the amount, attributed to employee theft. (3) Any other significant loss as determined by the pharmacist-in-charge. (b) All reports under this section shall specify the identity, amount~~s~~ and strength~~s~~ of each controlled	**Recommendation:** Revise proposed regulations to: " (a) The owner shall submit ~~report~~ to the Board a report containing the information in subdivision (b) ~~within~~ no later than thirty (30) days after the date of the following: (1) ~~any~~ Any loss of ~~the~~ a controlled substance~~s, including their~~ in one of the following categories ~~that causes the aggregate amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed~~: (A) For tablets, capsules, or other non-solid oral medication, **20 (twenty) or more ~~99~~** dosageunits. (B) For single-dose injectable medications, lozenges, film, ~~such as oral~~, buccal and sublingual, suppositories, or patches, 10 (ten) or more dosage units. (C) For injectable multi-dose medications, medications administered by ~~continuous~~ infusion, or any other ~~multi-dose unit~~ medication not described in subparagraph (A) or (B)**, five ~~two~~** or more multi-dose vials, infusion bags, or other containers. (2) Any loss of a controlled substance, regardless of the amount, attributed to employee theft. (3) Any other significant loss as determined by the pharmacist-in-charge. **(4) Any loss or theft reported to the Drug Enforcement Agency (DEA)** **Comments:** • As outlined in the "Initial Statement of Reasons", one of the intents of the proposed regulations is to reduce the administrative burden for licensees related to excessive reporting. Adding a requirement to track and report losses year over year would create a cumbersome manual tracking process for pharmacies would not meet the goal of diversion detection. Loss data would continue to be documented and maintained in the pharmacy including actions taken to evaluate and reduce losses when warranted. These would be available to Board inspectors during inspections as needed. Furthermore, should a licensee

	substance lost, and date of discovery of the loss, for all losses that have made the report necessary	experience an individual loss that meets one of the proposed thresholds, such loss would qualify for reporting to the DEA based on standard of practice and should be reported to the Board • The addition of "non-solid medications in (A) and deletion of "oral" in (B) was done to clarify confusion related to oral liquid medications and the use of the term "oral" in both (A) and (B) • (C) was modified to be more broad by removing continuous as well as providing a section to capture any drug loss not defined in (A) and (B) • For tablets, capsules, and other oral medications, pharmacies would be concerned with individual losses amounting to 20 or more tablets as they may be indicative of a process failure or potential employee pilferage. Would consider lowering the reporting threshold for oral medications from 99 to 20 toensure timely reporting of potentially concerning losses. • Per the "Initial Statement of Reasons", the Board is selecting loss thresholds based on common package size. For injectable medications, the manufacturer package size usually contains between 5 and 25 individual vials/bags/containers,so would recommend using 5 or more as the reporting threshold • Finally, the proposed regulations aim at aligning with federal regulations so itwould be important for the Board of Pharmacy to be informed of any losses/theft reported to the DEA.
1715.65 (d)	(d) A pharmacy or clinic shall report in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use. in which case the report shall be made within 14 days of discovery.	**Recommendation:** (d) A pharmacy or clinic shall report in writing identified losses (**CCR 1715.6)** and known causes to the board within 30 days of discovery. ~~**unless the cause of the loss is theft, diversion, or self-use. in which case the report shall be made within 14 days of discovery.**~~ **Comments:** The proposed regulation states that reporting of any loss of a controlled substance, regardless of the amount, attributed to employee theft shall be made within 30 days of discovery which would be in conflict with existing 1715.65(d) regulations. Consider revising 1715.65(d) as recommended to ensure alignment with proposed regulations.

California State Board of Pharmacy § 1715.6. Reporting Drug Loss

Proposed Regulations – Comments

4104 (c)	(c) Every pharmacy shall report and provide to the board, within 14 days of the receipt or development thereof the following information with regard to any licensed individual employed by or with the pharmacy: (1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.	**Recommendation:** (c) Every pharmacy shall report and provide to the board, within ~~14~~ 30 days of the receipt or development thereof the following information with regard to any licensed individual employed by or with the pharmacy **Comments:** The proposed regulation states that reporting of any loss of a controlled substance, regardless of the amount, attributed to employee theft shall be made within 30 days of discovery which would be in conflict with existing BPC 4104 (c) regulations.
	(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs. (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice. (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual. (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice. (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.	Consider revising BPC 4104 (c) as recommended to ensure alignment with the proposed regulations

California State Board of Pharmacy § 1715.6. Reporting Drug Loss

Proposed Regulations – Comments

4134 (g)	(g) A remote dispensing site pharmacy shall report to the board, in writing, any identified losses of controlled substances and possible causes of the loss within 30 days of discovering the loss unless the cause of loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovering the loss.	**Recommendation:** (g) A remote dispensing site pharmacy shall report to the board, in writing, ~~any~~ identified losses of controlled substances and possible causes of the loss **that meet CCR 1715.6** no later than thirty (30) days after the date of discovery ~~within 30 days of discovering~~ of the loss ~~unless the cause of loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovering the loss.~~ **Comments:** The proposed regulation states that reporting of any loss of a controlled substance, regardless of the amount, attributed to employee theft shall be made within 30 days of discovery which would be in conflict with existing BPC 4134 (g) regulations. Consider revising BPC 4134 (g) as recommended to ensure alignment with the proposed regulations.

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July 19, 2021

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

Submitted via electronic mail to: Lori Martinez, California State Board of Pharmacy

RE: ***Proposal to Amend Section 1715.6 of Article 2 of Division 17 of Title 16 of the California Code of Regulations***

Dear Ms. Martinez:

Kaiser Permanente appreciates the opportunity to respond to the California Board of Pharmacy's request for comments on the proposed amendments to the Board's regulations pertaining to the requirement that Board-licensed facilities report controlled substance losses to the Board.

Kaiser Permanente comprises the non-profit Kaiser Foundation Health Plan, the non-profit Kaiser Foundation Hospitals; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan. These entities work together seamlessly to meet the health needs of Kaiser Permanente's nine million members in California. Kaiser Permanente's pharmacy enterprise in California is comprised of hundreds of licensed pharmacies that are staffed by thousands of individual pharmacy licentiates.

Applicability of Loss Reporting Requirement

The statutory foundation for this regulation is, in part, Business and Professions code section 4081, which requires the owner of a pharmacy together with the pharmacist-in-charge to maintain a current inventory of dangerous drugs and dangerous devices together with records of sale, acquisition, receipt, and disposition. While the majority of loss reports are the result of a ***verified*** controlled substance loss from a licensee's inventory, a licensee may become aware of a ***potential*** loss of a controlled substance either before it is received into the facility's inventory or after it is dispensed, sold, or otherwise distributed out of the facility's inventory. Because the facility's owner is not required to, nor is it practicable to, maintain records related to controlled substances that are not within the facility's inventory, it is likely that the owner would not possess all of the information required to investigate and confirm such a potential loss. Therefore, we recommend clarifying that an owner's obligation to report controlled substance losses applies to losses from the inventory of the owner's licensed facility. Our suggested modifications to the regulation are below:

(1) ~~any~~ Any loss of ~~the~~ a controlled substance~~s, including their~~ from the licensed facility's inventory in one of the following categories that causes the aggregate amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed:
…
(2) Any loss of a controlled substance from the licensed facility's inventory, regardless of the amount, attributed to employee theft.
(3) Any other significant loss of a controlled substance from the licensed facility's inventory as determined by the pharmacist-in-charge.

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Loss Reporting Look-Back Period

Kaiser Permanente appreciates the Board's recognition that the current requirement to report all controlled substance losses, including infrequent losses of small quantities of controlled substances creates administrative burdens for both licensees and the Board while, in many cases, failing to provide meaningful information about the security of controlled substances within the licensed facility. We support the Board's decision to adopt thresholds for reporting controlled substance losses. However, we believe that a shorter look-back period coupled with lower loss reporting thresholds would facilitate more timely discovery and reporting of controlled substance losses and would likely be easier for licensees to operationalize. One approach would be to utilize a 90-day look-back period rather than the one-year look-back period proposed in 1715.6(a)(1). This approach may also incentivize licensed pharmacies to conduct their required quarterly inventory reconciliation activities pursuant to the California Code of Regulations section 1715.65 on a 90-day cadence such that the physical inventories taken as part of inventory reconciliation could easily be used to identify and further investigate any required loss reports.

It is clear from the text of the proposed regulation that the Board intends for a licensed facility to make a loss report if the aggregate number of dosage units lost exceeds the specified threshold during the specified look-back period. However, the proposed regulation is unclear on how losses should or should not be aggregated. In order to provide clarity to the regulated public, we suggest that the regulation should include specific parameters for how multiple small losses that occur during the specified look-back period should be aggregated. We believe that directing licensees to aggregate losses using the National Drug Code (NDC) would provide a reliable, unambiguous standard. Proposed changes to the regulation to implement a shorter look-back period, lower reporting thresholds, and specific guidance for aggregating small losses within the look-back period are provided below:

(1) ~~any~~ Any loss of ~~the~~ a controlled substance~~s, including their~~ from the licensed facility's inventory in one of the following categories that causes the aggregate amount of unreported losses discovered in that category, ~~on or after the same day of the previous year~~ in the previous 90 calendar days, to equal or exceed:

(A) For tablets, capsules, or other oral medication, ~~99~~ 25 dosage units with the same NDC number.

(B) For single-dose injectable medications, lozenges, film, such as oral, buccal and sublingual, suppositories, or patches, ~~10~~ five dosage units with the same NDC number.

(C) For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose vials, infusion bags, or other containers with the same NDC number.

Kaiser Permanente appreciates the opportunity to provide feedback in response to the proposed amendments to the Board's regulations pertaining to reporting losses of controlled substances. If you have questions, please contact John Gray (562.417.6417; john.p.gray@kp.org) or Rebecca Cupp (562.658.3501; rebecca.l.cupp@kp.org).

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Respectfully submitted,

John P. Gray, PharmD, MSL
Director, National Pharmacy Regulatory and Legislative Affairs
Kaiser Permanente