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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item V – Discussion and Consideration of Draft Frequently Asked Questions (FAQs) Relating to Inventory Reconciliation Reports of Controlled Substances (Title 16, California Code of Regulations, Section 1715.65)

Attachment 1

Relevant Sections:
Title 16, California Code of Regulations (CCR) section 1715.65 requires that every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.

Regulation Timeline:

July 28, 2016	Board Approved Text for Rulemaking
Sept. 16- Oct. 31, 2016	45-day Comment Period
Dec. 23, 2016 – Jan. 7, 2017	15-day Comment Period
May 16 – 31, 2017	15-day Comment Period
Jan. 25, 2018	Approved by the Office of Administrative Law
April 1, 2018	Effective Date of Regulation

Recent Update:
Since the adoption of the regulation the executive officer and board inspectors have received numerous questions from licensees regarding the new requirements for controlled substance inventory. In order to provide additional guidance to the regulated public, board staff worked with the DCA counsel to draft FAQ's which will be made available on the board's website and in a future publication of *The Script*.

At this Meeting:
The board will have the opportunity to review and discuss the draft FAQs. **Attachment 1** includes a copy of the approved regulation text as well as the draft FAQs.

Should the board approve the FAQs, the following motion could be used.

Motion: Approve the frequently asked questions (FAQs) relating to inventory reconciliation reports of controlled substances (Title 16, California Code of Regulations, Section 1715.65) and post the FAQs on the board's website and publish them in the next issue of *The Script.*

Attachment 1

Title 16. Board of Pharmacy
Order of Adoption

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Inventory Reconciliation Report of Controlled Substances

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.

(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.

(c) A pharmacy or clinic shall compile an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require:
   (1) A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;
   (2) A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report;
   (3) A comparison of (1) and (2) to determine if there are any variances;
   (4) All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and
   (5) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

(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. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances.

(e) The inventory reconciliation report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or professional director (if a clinic) and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.

(f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report as identified in subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report as required in subdivision (c).

(g) For inpatient hospital pharmacies, a separate quarterly inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.

(h) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:

(1) All controlled substances added to an automated drug delivery system are accounted for;

(2) Access to automated drug delivery systems is limited to authorized facility personnel;

(3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and

(4) Confirmed losses of controlled substances are reported to the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4008, 4037, 4080, 4081, 4101, 4104, 4105, 4105.5, 4110, 4113, 4119.1, 4180, 4181, 4182, 4186, 4190, 4191, 4192, and 4332, Business and Professions Code and 1261.6, Health and Safety Code.

On April 1, 2018, a new board regulation took effect – California Code of Regulations, title 16, section 1715.65, "Inventory Reconciliation Report of Controlled Substances."

The board believes that this regulation will aid pharmacies and clinics in preventing and identifying losses of controlled drugs earlier than without such measures.

The following information is intended to respond to questions asked of the board regarding this new regulation. As with any regulation, the board seeks compliance at the earliest possible time. For the first few months, the board will focus on education to promote understanding about the regulation. During the transition, any inspection will focus on the pharmacy or clinic's good faith efforts to comply with the regulation."

The text of the regulation can be found here:
http://www.pharmacy.ca.gov/laws_regs/1715_65_ooa.pdf

Here is a summary of regulation section 1715.65 by subsection:

(a) -- Requires all pharmacies, and all clinics licensed under Business and Professions Code section 4180 or 4190 ("clinics"), to perform periodic inventory and reconciliation functions for all controlled drugs. (Note: No frequency of these duties is specified in the regulation except for C-II drugs.)

(b) -- Requires the pharmacist-in-charge (PIC) or the clinic's consultant pharmacist to:
(1) establish and maintain secure methods to prevent losses of controlled drugs;
(2) establish written policies and procedures for performing reconciliation reports; and
(3) review all inventory and reconciliation reports.

(c) -- Requires each pharmacy or clinic to prepare a **quarterly** inventory reconciliation report of all federal Schedule-II medications, which is based on:
(1) A physical count of all federal Schedule-II medications at the time of each inventory;
(2) A review of all acquisition and disposition records since the last inventory;
(3) A comparison of 1 and 2 to identify any differences (losses or overages).
(4) Collection and retention of records to compile each inventory report
(5) Written identification of sources of losses or overages in the report. The report must identify the possible causes of losses or overages.

(d) – Requires a pharmacy or clinic to file a report of losses to the board within 30 days of discovery or within 14 days if theft, self-use or diversion by a board licensee is the cause. If the cause is unknown, requires the pharmacy or clinic to further investigate to identify the causes and to take corrective action to prevent additional losses.

(e) – Requires the inventory reconciliation report to be signed and dated by the individuals performing the inventory, and countersigned by the PIC or professional director (for a clinic).

(f) – Requires a new PIC to complete an inventory reconciliation report within 30 days of becoming PIC. Encourages the outgoing PIC to do an inventory reconciliation report before leaving.

(g) -- For INPATIENT HOSPITAL PHARMACIES: Requires a separate quarterly inventory reconciliation report for federal Schedule-II drugs stored within the pharmacy and for each of the pharmacy's satellite locations.

(h) – For any pharmacy servicing an AUOMATED DRUG DELIVERY SYSTEM (regardless of location), requires the PIC to:

(1) Ensure that all controlled substances added to any automated drug delivery system are accounted for;

(2) Ensure that access to any automated drug delivery system is limited to authorized facility personnel only;

(3) Ensure that any discrepancy or unusual access to the controlled substances in the automated drug delivery system is evaluated; and

(4) Ensure that confirmed losses are reported to the board timely.

Frequently Asked Questions:

Q: The regulation took effect April 1, 2018. Must I conduct my initial inventory beginning on April 1, 2018?

A: No, the board expects pharmacies and clinics to transition to satisfy the regulation's inventory reconciliation requirements over a short period of time, but not necessarily by April 1.

Q: Are there any drugs in addition to federal Schedule-II controlled substances affected by the requirement to do a physical count and reconciliation each quarter?

A: No, the regulation requires a quarterly count and reconciliation of only federal Schedule-II drugs. California and the federal government have separate controlled substances drug schedules, although there is much similarity between the two. Nevertheless, the board determined that the federal Schedule-II drug list is a more current and complete schedule, as well as the federal system's list are the references for reporting dispensing into the Controlled Substances Utilization Review and Evaluation System (CURES) in California.

Q: Can a pharmacy or clinic estimate (instead of physically counting) federal Schedule-II medications for the quarterly inventory?

A: No, a physical count of every Schedule-II medication is required for the quarterly inventory reconciliation report.

Q: Subsection (a) of the regulation requires a pharmacy or clinic to "periodically" perform inventory and reconciliation functions for controlled substances. Does this mean every quarter I must count and reconcile all controlled substances?

A: No. However, periodically (and under federal law at least every two years) all controlled substances must be inventoried. The board encourages more frequent counting of controlled medications to prevent losses of Schedule III, IV and V drugs. The regulation only specifies the frequency of reconciliation duties for federal Schedule-II drugs; the appropriate frequency for all other controlled drugs should be determined by the standard

of practice in the community under the circumstances of the pharmacy.

Q: Is a perpetual inventory system satisfy the requirements of this regulation?

A: No, the use of a perpetual inventory system does not satisfy the regulation. The regulation requires both a physical count and reconciliation with all acquisitions and dispositions must be performed every 90 days.

Q: If I use a perpetual inventory, can I use the physical counts made for the perpetual inventory instead of physically counting the drugs specifically for the inventory reconciliation report?

A: It depends. The regulation requires a physical count of each C-II medication every quarter, which is then used as part of the inventory reconciliation analysis and report. If, for example, the pharmacy or clinic physically counts the specific drug stock each time a C-II drug is dispensed or acquired, that count might be used to fulfill the physical count required by the inventory reconciliation regulation, but the PIC or consultant will need additional data. For any drug where there were no dispositions or acquisitions during the quarterly reconciliation period (and therefore no physical count through the perpetual inventory system), a physical count of the C-II drug must be made because each drug must be physically counted at least quarterly.

Q: I have a recent physical count for each C-II drug. What do I compare that to? What do I do with that information?

A: For each medication, the PIC or consultant would start with the physical count of the medication from the last inventory reconciliation report and:

1. Add all acquisitions, and subtract all dispositions, that occurred during the reconciliation period (no greater than 90 days) to identify the amount of drug stock that should be on hand (expected drug stock).
2. Compare the expected drug stock to the actual physical inventory count.
3. If there is a difference, attempt to identify the source of overage or shortage. **NOTE:** If there is a discrepancy and the recent physical count is from a perpetual inventory system, the board urges the facility to initiate a supplementary physical count of the medication. Determine if the facility needs to take corrective action, including to: modify its policies and procedures, conduct an investigation, institute additional security or modify its practices.
4. Whether or not there is a discrepancy, the results must be recorded in your inventory reconciliation report.

Q: Does an inpatient hospital pharmacy or any pharmacy that services onsite or offsite automated drug delivery systems (ADDS) have to complete an inventory reconciliation report for Schedule-II controlled substances contained within the ADDS?

A: No, there is no quarterly reconciliation report required for an ADDS machine that is operated by a pharmacy. However, the regulation (in subsection (h)) requires that such pharmacies:

- Account for all controlled substances (not just Schedule-II drugs) stored in or removed from the ADDS. **The pharmacy's transfer of stock to an ADDS would, however, be reflected as a disposition in the pharmacy's reconciliation report**.
- Limit access to the ADDS to authorized facility staff.
- Perform ongoing evaluations of discrepancies or unusual access to controlled substances stored in the ADDS.
- Report all controlled substances losses from an ADDS to the board.

Q: Does an inpatient hospital pharmacy or a pharmacy servicing onsite or offsite emergency kits (e-kits) have to complete an inventory reconciliation report for the Schedule-II controlled substances contained within the e-kits?

A: There is no specific reconciliation report for the kits themselves, although a pharmacy's replenishment of Schedule-II drugs removed from the emergency kits would be part of a pharmacy's disposition of medication.

Q: An inventory reconciliation report of all Schedule-II controlled substances shall be compiled at least every 3 months, and in order to complete such a report the inventory must be compared with a review of drugs that entered and left the pharmacy since the previous inventory reconciliation. Since no reconciliation report exists before April 1, 2018, does that mean that the first inventory reconciliation report will not be due before July 1, 2018?

A: To initiate the reconciliation process and establish a baseline for future inventory reconciliation reports, a physical count of all Schedule-II medications must be undertaken. The board would generally expect a pharmacy to perform this count sometime on or after April 1, 2018. To allow pharmacies and clinics time to develop meaningful written policies and procedures for the inventory reconciliation process, the board recommends a pharmacy or clinic perform the inventory counts sometime within the first 90 days after April 1 (i.e., August 1, 2018).

Additionally, any new PIC of a pharmacy on or after April 1, 2018, is required to prepare a report. Within the first three months after April 1, 2018, the board would expect the new PIC, within 30 days, to have performed an inventory count of all Schedule-II medications consistent with to the requirements to prepare an inventory reconciliation report.

Q. An initial inventory does not appear to be required as part of this rule change. Since a reconciliation report cannot be compiled without an initial reference count, would it be appropriate for pharmacies or clinics to perform a physical count of all Schedule II drugs during the initial 3-month period (after April 1st), and then begin reconciliation processes after July 1st?

A: Yes. See the response above.

Q: A new PIC must complete an inventory reconciliation report within 30 days of becoming pharmacist-in-charge. If there is a PIC change on April 1st, 2018, how can the PIC create a reconciliation report, given there may not be a recent inventory or reconciliation report to refer to?

A: In this specific case, if prior data was unavailable because of the implementation date of the regulation, the board would expect the PIC to at least perform an inventory of all Schedule-II medications consistent with the requirements to prepare the reconciliation report within 30 days (May 1, 2018).

Q. Should the inventory reconciliation report encompass only significant losses, as defined by the DEA, or should the report encompass any discrepancy? If the former, doesn't a pharmacy's or clinic's filing of DEA Form 106 with the DEA already provide the requested information to the Board of Pharmacy, if the Board of Pharmacy receives a copy of that report?

A: California law requires that any loss of controlled substances be reported to the board within 30 days, and reported within 14 days where drug theft, self-use or diversion have been committed by a board licensee. These are existing requirements, predating the inventory reconciliation requirements. The regulation restates the reporting of drug loss requirements for clarity. A DEA Form 106 may be used to make this report to the board.

Q. If my pharmacy or clinic is unable to identify the cause of the loss, should we wait to report the loss to the board until the cause is determined?

A: No, reporting is required for any loss of controlled substances within, at most, 30 days regardless if a cause of the loss was identified. Should a cause of the loss be identified later, an additional report can be made to the board. If the cause of the loss is theft, diversion or self-use by a board licensee, the report must be made within 14 days.

However, the regulation also directs that "further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substance" where the source of a loss cannot be readily identified.

Q: Will the board be creating a new process for reporting Schedule-II controlled substances drug losses? Is there a standard form or email address to submit this information?

A: The board will not create a new or additional process for reporting the loss of controlled substances. A DEA Form 106 or a written statement containing specified details of the loss is sufficient. The current processes are detailed here: http://www.pharmacy.ca.gov/licensees/facility/dea106.shtml

Q: Does a pharmacy have to maintain actual paper documents of the records used to compile each inventory reconciliation report? Are electronic records acceptable?

A: All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in readily retrievable form. Provided the records are readily retrievable, electronic records are acceptable.

Q. Can the Inventory Reconciliation Report be completed by multiple persons?

A. Yes, all persons involved in performing the inventory must sign and date the report, which also must be countersigned by the PIC or professional director (if a clinic).