NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

October 28, 2021

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
via email: Lori.Martinez@dca.ca.go

Re: Proposed Rule Changes to 16 CCR §1715.65; Inventory Activities and Inventory Reconciliation Reports of Controlled Substances

Ms. Martinez,

On behalf of our members operating chain pharmacies in the state of California, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment to the California State Board of Pharmacy on the proposed rule revising inventory reconciliation requirements for controlled substances under 16 CCR §1715.65. Although NACDS understands that the Board's stated intent with this rulemaking is to curb diversion of controlled substance medications, we are concerned that the proposed expansion of inventory reconciliation activities to apply to all controlled substances would be a misguided attempt to do so.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org

As frontline healthcare providers confronted daily with the issues of prescription drug abuse facing our nation, chain pharmacy is strongly committed to combatting the problems of abuse that challenge the communities we serve. To that end, NACDS members remain steadfast in their dedication to pursuing and implementing targeted and workable policy solutions to prevent the misuse, abuse and diversion of prescription medications. With respect to issues of diversion, our members have implemented robust internal programs, policies and strategies to root out and prevent this occurrence.

As the Board is likely aware, the federal Drug Enforcement Administration (DEA), which has been given Congressional authority and responsibility for protecting Americans from the dangers of controlled prescription drug diversion and abuse, does not require

pharmacies to perform inventory reconciliation activities. Even as DEA amended its own regulations related to inventory requirements over the years, the agency never imposed requirements as burdensome as those being proposed by the Board when DEA amended its inventory regulations in 1997, 2003, and as recently as 2014. *See DEA regulations at 21 CFR §1304.11, and regulation amendments at 62 FR 13959 (Mar. 24, 1997), at 68 FR 41228 (July 11, 2003) and at 79 FR 53562 (Sept. 9, 2014).* Accordingly, we believe that the Board should look to the authority and leadership of DEA.

We are further concerned that expanding the inventory reconciliation requirements to apply to all controlled substances would have negligible impacts on reducing prescription drug abuse and diversion, while establishing a tremendously cumbersome new process for pharmacies that would require significant resources to accommodate. Accordingly, NACDS urges the Board to reject the proposed rule expansion of the existing inventory reconciliation requirement, and instead continue to apply this requirement only to Schedule II controlled substances.

Additionally, with respect to the inventory reconciliation reports, the Board has proposed hard copy attestation log requirements as a redundancy to certain electronic records. Given the movement in recent years to adopt and implement electronic record practices that are arguably more accurate and harder to alter, such a requirement would be misguided. Accordingly, we recommend revising the language to eliminate the proposed hard copy "physical signature" requirement from the rule language. Please see NACDS' proposed in-text edits on the next page to address these issues.

Lastly, the extensive new inventory reconciliation requirements proposed by the Board will require time and resource intensive updates to pharmacy systems and processes. To accommodate this, we ask the Board to delay implementation of the proposed rule changes for at least one year.

NACDS thanks the Board for considering our feedback on the proposed rule. We appreciate the Board's efforts to ensure that appropriate anti-diversion policies and measures are implemented to protect Californians and enhance the delivery of patient care. If we can provide further assistance, please contact NACDS' Sandra Guckian at SGuckian@NACDS.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

NACDS Suggested Edits to § 1715.65

§ 1715.65. Inventory Activities and Inventory Reconciliation Reports 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 activities and prepare inventory reconciliation ~~functions~~ reports to detect and prevent the loss of federal controlled substances. Except as provided in subdivisions (f) and (g), inventory reconciliation reports **for federal schedule II controlled substances shall be prepared at least once every three months.** ~~**shall be prepared on the following ongoing basis:**~~

~~**(1) For federal Schedule II controlled substances, at least once every three months.**~~

~~**(2) For products containing the following substances in the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months:**~~

~~**(A) Alprazolam, 1 milligram/unit.**~~

~~**(B) Alprazolam, 2 milligrams/unit.**~~

~~**(C) Tramadol, 50 milligrams/unit.**~~

~~**(D) Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.**~~

~~**(3)(A) For any controlled substance not covered by paragraph (1) or (2), no later than three months after any loss of that controlled substance is discovered either by the inventory activities required by subparagraph (B), or in any other manner. The report shall cover the period from the last physical count of the controlled substance before the loss was discovered through the date of discovery.**~~

~~**(B) Inventory activities for each controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years from the performance of the last inventory activities. For purposes of this section, "inventory activities" means inventory and all other functions necessary to identify losses of the controlled substance.**~~

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

(c) ~~A pharmacy or clinic shall compile an~~ An inventory reconciliation report ~~of all federal Schedule II controlled substances at least every three months. This compilation~~ prepared pursuant to this section shall ~~require~~ include all of the following:

(1) A physical count, not an estimate, of all quantities of ~~federal Schedule II~~ ~~**each**~~ federal **schedule II** controlled ~~substances~~ ~~**substance substances covered by the report that the pharmacy or clinic has in inventory**~~, except as provided in

subdivision (h). 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. ~~**An individual who performs the inventory required by this paragraph shall sign and date the inventory or the report in which it is included as provided in subdivision (e)(1);**~~

(2) A review of all acquisitions and dispositions of ~~**each**~~ federal ~~Schedule II~~ **Schedule II** controlled ~~substances~~ ~~**substance**~~ **substances** covered by the report since the last inventory reconciliation report ~~**covering that controlled substance**~~;

(3) A comparison of (1) and (2) to determine if there are any variances;

(4) ~~All~~ Identification of all records used to compile ~~each inventory reconciliation~~ the report, which shall be maintained in the pharmacy or clinic ~~for at least three years in a readily retrievable form~~ pursuant to subdivision (e)(2); ~~and~~

(5) Identification of each individual involved in preparing the report; and

~~(5)~~ (6) 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 federal controlled substances.

(e) (1) ~~The~~ An inventory reconciliation report shall be dated and signed by ~~the individual(s) performing the inventory, and countersigned by~~ the pharmacist-incharge or professional director (if a clinic) ~~and~~ ~~**, in addition to any signature required by subdivision (c)(1)**~~. An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature under this section ~~**if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file pursuant to paragraph (2).**~~

(2) The report, and all records used to compile the report, shall 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)~~ for ~~**all**~~ federal **Schedule II** controlled substances ~~**described in paragraphs (1) and (2) of subdivision (a)**~~ 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)~~ for ~~**those**~~ **federal Schedule II** controlled substances.

(g) ~~For~~ Notwithstanding the periodic reporting requirements specified in paragraphs (1) and (2) of subdivision (a), inpatient hospital pharmacies~~,~~ shall prepare an inventory

reconciliation report ~~or reports covering the~~ **for** federal **Schedule II** controlled substances **described in paragraphs (1) and (2) of subdivision (a)** on a ~~separate~~ quarterly ~~inventory reconciliation report shall be required for federal Schedule II~~ basis. The report or reports shall include controlled substances stored within the pharmacy ~~and for~~, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control.

(h) ~~The pharmacist-in-charge of~~ If an inpatient hospital pharmacy ~~or of a pharmacy servicing onsite or offsite~~ uses an automated drug delivery ~~systems~~ system (ADDS), inventory in the ADDS may be accounted for under subdivision (c)(1) using means other than a physical count. ~~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.~~