California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

To: Board Members

Subject: Agenda Item III. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16, California Code of Regulations Section 1784, Wholesaler Dangerous Drugs and Devices Self-Assessment (17M-26), Including Comments Received

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Background:

At the November 7, 2017 Board meeting, the Board approved proposed regulation text to amend Section 1784 related to the Wholesaler/3PL self-assessment forms. This proposal updates Self-Assessment form 17M-26 as incorporated by reference in Title 16 CCR section 1784. Additionally, this regulation updates section 1784 with clarifying language as to the completion and certification requirements of the self-assessment form.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on September 17, 2021, which ended on November 1, 2021, related to form 17M-26. No comments were received during this comment period.

At the January 2022, the Board amended the self-assessment forms and proposed text to address changes to pharmacy law that occurred since the forms were last approved by the Board. The amended language and self-assessment form were released for 15-day public comment.

The 15-day public comment period began on February 15, 2022 and ended on March 2, 2022. One comment was received during the comment period. Attached following this memo are the following:

1. The proposed text and self-assessment form released for the 15-day public comment period.
2. Board staff prepared summarized comment with recommendations.
3. Comment received during the 15-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 on February 15, 2022 for the 15-day comment period.
2. Amend the regulation to address concerns expressed by stakeholders and notice the modified text for a second 15-day comment period.

Possible Adoption Language:

Accept the Board staff recommended comment responses and adopt the regulation text and self-assessment form as noticed for public comment on February 15, 2022. Additionally, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Title 16. Board of Pharmacy
Modified Regulation

Proposed changes to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Additional changes to the proposed regulation language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

Amend section 1784 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1784. Self-Assessment of a Wholesaler/Third-Party Logistics Provider by the Designated Representative-In-Charge or Responsible Manager.

(a) ~~The designated representative-in-charge of e~~ Each wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, shall complete a self-assessment of ~~the wholesaler's~~ its compliance with federal and state pharmacy law. The assessment shall be performed by the designated representative-in-charge of the wholesaler, or by the responsible manager of the third-party logistics provider, before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge or responsible manager shall complete a self-assessment within 30 days whenever:

(1) A new ~~wholesaler permit~~ license is issued.~~, or~~

(2) There is a change in the designated representative-in-charge or responsible manager. The new designated representative-in-charge of a wholesaler or responsible manager of a third-party logistics provider is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler or third-party logistics provider to a new address.

(c) ~~The components of this assessment shall be on Form 17M-26 (Rev. 10/14) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws~~

~~and regulations~~. Each wholesaler and third-party logistics provider conducting business in California, through its designated representative-in-charge or responsible manager, shall complete the "Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. ~~09/18~~12/21) which is hereby incorporated by reference. The form shall include the information required by this section.

(1) The designated representative-in-charge or responsible manager shall provide identifying information about the wholesaler or third-party logistics provider including:

(A) Name, license number of the premises, and the license expiration date;

(B) Address, phone number, website address, if applicable, and type of ownership;

(C) Federal Drug Enforcement Administration (DEA) registration number and expiration date and date of most recent DEA inventory;

(D) Verified-Accredited Wholesale Distributor accreditation number and expiration date, if applicable; and

(E) Hours of operation of the licensee.

(2) The designated representative-in-charge or responsible manager shall list the name of each Board-licensed staff person currently employed by the licensee in the facility at the time the self-assessment is completed, the person's license type and number, and the expiration date for each license.

(3) The designated representative-in-charge or responsible manager shall respond "yes", "no" or "not applicable" (N/A) about whether the licensed premises is, at the time of the self-assessment, in compliance with each of the requirements.

(4) For each "no" response, the designated representative-in-charge or responsible manager shall provide a corrective action or action plan to come into compliance with the law.

(5) The designated representative-in-charge or responsible manager shall initial each page of the self-assessment form.

(6) The designated representative-in-charge or responsible manager shall certify, under penalty of perjury, on the final page of the self-assessment that:

(A) He or she has completed the self-assessment of the licensed premises for which he or she is responsible;

(B) Any deficiency identified within the self-assessment will be corrected and the timeframe for correction;

(C) He or she understands that all responses are subject to verification by the Board of Pharmacy; and

(D) The information provided in the self-assessment form is true and correct.

(7) The licensed premises owner, partner or corporate officer shall certify on the final page of the self-assessment that he or she has read and reviewed the completed self-assessment and understands that failure to correct any deficiency identified in the self-assessment could result in the revocation of the license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.

(d) Each self-assessment shall be completed in its entirety and kept on file in the licensed ~~wholesale~~ premises for three years after it is completed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.

(e) The wholesaler or third-party logistics provider is jointly responsible with the designated representative-in-charge or responsible manager, respectively, for compliance with this section.

(f) Any identified areas of noncompliance shall be corrected as specified in the certification.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4022.7, 4043, 4044.5, 4045, 4053, 4053.1, 4059, 4120, 4160, 4161, 4201, 4301 and 4305.5, Business and Professions Code.

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LEGEND: Proposed changes made to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language. Amendments to the proposed changes are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER ~~DANGEROUS DRUGS & DANGEROUS DEVICES~~ SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page ~~21~~22.

All references to "drugs" throughout this self-assessment form refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B~~&~~PC) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

For purposes of completing this assessment, the following abbreviations refer to specified licensing categories:

- WLS = Wholesaler
- 3PL = Third-Party Logistics Provider
- DRIC = Designated Representative-in-Charge
- RM = Responsible Manager
- DR = ~~includes~~ Designated Representative, Designated Representative-3PL, and Designated Representative Reverse Distributor

~~Wholesaler~~ Licensed Premises Name: _____

Address: _____

Phone: _____

~~Wholesaler~~ Licensed Premises E~~-~~mail address: _____

Ownership: Please mark one

○ sole owner ○ partnership ○ corporation ○ LLC

○ non- licensed owner ○ Other (please specify) _____

CA ~~Wholesaler Permit~~ License #_____ Expiration Date_____

Other ~~Permit~~ License #_____ Expiration Date_____
(Use additional sheets if needed.)

DEA Registration #_____ Expiration Date_____

VAWD Accreditation # _____ Expiration Date_____

Date of most recent DEA Inventory _____

Hours: Weekdays _____Sat_____ Sun_____ 24 Hours

~~Designated representative-in-charge (~~DRIC~~)~~ / RM ~~pharmacist (RPH)~~ _____

DR~~IC~~ License # / RPH License #_____ Expiration Date_____

Website Address (optional):_____

Other Licensed ~~Wholesaler~~ Staff (~~designated representative (~~DR~~)~~, pharmacist (RPH)):

1. _____ DR#/RPH#_____ Exp. Date _____

2. _____ DR#/RPH#_____ Exp. Date _____

3. _____ DR#/RPH#_____ Exp. Date _____

4. _____ DR#/RPH#_____ Exp. Date _____

5. _____ DR#/RPH#_____ Exp. Date _____

6. _____ DR#/RPH#_____ Exp. Date _____

7. _____ DR#/RPH#_____ Exp. Date _____

8. _____ DR#/RPH#_____ Exp. Date _____

9. _____ DR#/RPH#_____ Exp. Date _____

10._____ DR#/RPH#_____ Exp. Date _____

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

☐ ☐ ☐ 1.1. Review the current ~~wholesaler permit~~ WLS/3PL license for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B~~&~~PC 4160[a], [c], [f]) **Attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ 1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3], BPC 4082) **Please attach a copy of the list to this document.** (This list should be dated.)

Note: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (B~~&~~PC 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A

☐ ☐ ☐ 2.1.1. Are clean and orderly

☐ ☐ ☐ 2.1.2. Are well ventilated

☐ ☐ ☐ 2.1.3. Are free from rodents and insects

☐ ☐ ☐ 2.1.4. Are adequately lit

☐ ☐ ☐ 2.1.5. Have plumbing in good repair

☐ ☐ ☐ 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see ~~USP 1990 22nd Edition~~ the standards set forth in the latest edition of the USP) (CCR 1780[b])

☐ ☐ ☐ 2.2. Is there a quarantine area for outdated, damaged, deteriorated, adulterated or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs' safety, identity, strength, quality or purity? (CCR 1780[e])

Yes No N/A

☐ ☐ ☐ 2.3. Are dangerous drugs and ~~dangerous~~ devices stored in a secured and locked area? (BPC 4167, CCR 1780[a])

☐ ☐ ☐ 2.4. Is access to areas where dangerous drugs and devices are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where dangerous drugs or devices are stored (list by name or job title):

_____

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ 2.5. Does this business operate only when a ~~designated representative~~ DR or pharmacist is on the premises? (CCR 1781)

2.6. The ~~wholesaler~~ licensed premises is equipped with the following specific security features:

☐ ☐ ☐ 2.6.1. There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

☐ ☐ ☐ 2.6.2. The outside perimeter of the building is well lit (CCR 1780[c][3]).

☐ ☐ ☐ 2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ 2.7. Is this business a "reverse distributor", that is, does the business act as an agent for pharmacies, drug wholesalers, third-party logistics provider, manufacturers, ~~and~~ or others, by receiving, inventorying and managing the disposition of outdated or nonsaleable dangerous drugs or devices? (B~~&~~PC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

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Yes No N/A

☐ ☐ ☐ 2.8. The facility has obtained approval from the board if acting as a reverse distributor which acquires dangerous drugs or dangerous devices from an unlicensed source that was previously licensed with the board for the sole purpose of destruction of the dangerous drugs or dangerous devices (B&PC 4163(c))

Date of approval from the board: _____

☐ ☐ ☐ 2.~~8~~9. The facility is subscribed to the board's email ~~e-mail~~ notifications. (B&PC 4013)

Date Last Notification Received: _____

Email ~~E-mail~~ address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

~~Yes No N/A~~

☐ ☐ ☐ 2.~~9~~10. The facility receives the board's email ~~e-mail~~ notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

Email ~~E-mail~~ address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section ~~12~~ 11 of this document.

3. Designated Representative-in-Charge/ Responsible Manager / Designated Representative-Reverse Distributor / Owner Responsibilities

Yes No N/A

☐ ☐ ☐ 3.1. The owner and the ~~designated representative-in-charge~~ DRIC/RM are both equally responsible for maintenance of the records and inventory of the facility. (B&PC 4081[b])

☐ ☐ ☐ 3.2. Is the ~~designated representative-in-charge~~ DRIC/RM at least 18 years of age and ~~is~~ responsible for the ~~wholesaler's~~ compliance with all state and federal laws for

the ~~wholesale~~ distribution of drugs? The ~~designated representative-in-charge~~ DRIC may be a pharmacist. (B~~&~~PC 4160[d], 4053.1~~([~~[b]~~)~~, 4053.2)

☐ ☐ ☐ 3.3. The owner must notify the board within 30 days of termination of the ~~designated representative-in-charge~~ DRIC/RM ~~or pharmacist~~. (B~~&~~PC 4305.5[a])

~~Yes No N/A~~

☐ ☐ ☐ 3.4. The owner must identify and notify the board of ~~the appointment~~ a proposed ~~of a~~ new ~~designated representative-in-charge~~ DRIC/RM within 30 days of the termination of the former ~~designated representative-in-charge~~ DRIC/RM. (B~~&~~PC 4160[~~d~~f], 4160[g~~e~~], 4331[c]) The appropriate form for this notification is ~~a "Change of Designated Representative-in-Charge," which is~~ available on the board's website.

Yes No N/A

☐ ☐ ☐ 3.5. The ~~designated representative-in-charge~~ DRIC/RM who ends ~~his or her~~ their employment at a ~~wholesaler~~ licensed premises, must notify the board within 30 days. ~~-~~(B~~&~~PC 4305.5[c], 4101[b][c]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

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~~4. Designated Representative/Pharmacist~~

~~Yes No N/A~~

~~☐ ☐ ☐ If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B&PC 4100, CCR 1704)~~

~~CORRECTIVE ACTION OR ACTION PLAN _____~~

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4~~5~~. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

☐ ☐ ☐ ~~5~~4.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B~~&~~PC 4163[b], 4169)

☐ ☐ ☐ ~~5~~4.2. If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B~~&~~PC 4081, 4332)

☐ ☐ ☐ ~~5~~4.3. For license verification, the ~~wholesaler~~ licensed premises may use the licensing information displayed on the board's Internet web site. (B~~&~~PC 4106)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section ~~12~~ 11 of this document.

~~6~~5. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐ ~~6~~5.1. When drugs are received by your business, are they delivered to the licensed ~~wholesale~~ premises, and received by and signed for only by a ~~designated representative~~ DR or a pharmacist? (~~B & P~~ BPC 4059.5[a])

☐ ☐ ☐ ~~6~~5.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

~~7~~6. Drug Stock

Yes No N/A

☐ ☐ ☐ ~~7~~6.1. Is all drug stock open for inspection during regular business hours? (B~~&~~PC 4080)

☐ ☐ ☐ ~~7~~6.2. Are all drugs you order maintained in a secure manner at your licensed ~~wholesale~~ premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (B~~&~~PC 4167)

☐ ☐ ☐ ~~7~~6.3. Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B~~&~~PC 4342[a])

☐ ☐ ☐ ~~7~~6.4. Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☐ ☐ ☐ ~~7~~6.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e]~~, CFR 1307.21~~)

☐ ☐ ☐ ~~7~~6.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e]~~, CFR 1307.21~~)

Yes No N/A

☐ ☐ ☐ ~~7~~6.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e]~~, CFR 1307.21~~)

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~12~~ 11 of this document.

~~8~~7. Sale or Transfer of Drugs by this Business

Yes No N/A

☐ ☐ ☐ ~~8~~7.1. Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

~~8~~7.2. Describe how you verify a business or person is appropriately licensed. (B~~&~~PC 4059.5[a], [b], [d], [g], B~~&~~PC 4169)

_____

_____

~~8~~7.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ ~~8~~7.4. Are drugs only furnished by your business to an authorized person? (B&PC 4163[a]) Note: An authorized person can be a business or natural person.

~~8~~7.5. Does your business only receive drugs from a pharmacy if:

☐ ☐ ☐ ~~8~~7.5.1. the pharmacy originally purchased the drugs from you?

☐ ☐ ☐ ~~8~~7.5.2. your business is a "reverse distributor"?

☐ ☐ ☐ ~~8~~7.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B~~&~~PC 4126.5[a])

Yes No N/A

☐ ☐ ☐ ~~8~~7.6 Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

☐ ☐ ☐ ~~8~~7.6.1. transacted with a business licensed with this board as a ~~wholesaler~~ WLS/3PL or pharmacy?

☐ ☐ ☐ ~~8~~7.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?

☐ ☐ ☐ ~~8~~7.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?

☐ ☐ ☐ ~~8~~7.6.4. **confirmed** to not be beyond their use date (expired drugs)? (B~~&~~PC 4169)

~~8~~7.7. List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

_____

_____

~~8~~7.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

☐ ☐ ☐ ~~8~~7.8.1. comply with all CA pharmacy laws related to the distribution of drugs?

☐ ☐ ☐ ~~8~~7.8.2. comply with the pharmacy law of the receiving state within the United States?

☐ ☐ ☐ ~~8~~7.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?

☐ ☐ ☐ ~~8~~7.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

☐ ☐ ☐ ~~8~~7.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

~~8~~7.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B~~&~~PC 4059.5[e])

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ ~~8.10. When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987).~~

~~Yes No N/A~~

☐ ☐ ☐ 7.10. For products included in the Drug Supply Chain Security Act, transaction histories, transaction information, and transaction statements are provided to authorized trading partners when the products are sold, traded, or transferred. (21 USC 360eee-1[c])

Yes No N/A

☐ ☐ ☐ ~~8~~7.11. If preferentially priced drugs are sold by your business, that sale complies with ~~the Prescription Drug Marketing Act of 1987 and~~ CA Pharmacy Law. (B~~&~~PC 4380)

~~Yes No N/A~~

☐ ☐ ☐ ~~8~~7.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B~~&~~PC 4341, B&PC 651, CCR 1766)

☐ ☐ ☐ ~~8~~7.13. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B~~&~~PC 650)

_____

_____

☐ ☐ ☐ ~~8~~7.14. Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (B~~&~~PC 4066, CFR 1301.25)

_____

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CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~12~~ 11 of this document.

~~9~~8. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H~~&~~SC 150200, 150203, 150204)

Yes No N/A

☐☐☐ ~~9~~8.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (H~~&~~SC 150203, 150204)

☐☐☐ ~~9~~8.2. No controlled substances shall be donated. (H~~&~~SC 150204[c][1])

Yes No N/A

☐☐☐ ~~9~~8.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H~~&~~SC 150204[c])

- ☐ ~~9~~8.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H~~&~~SC 150204[c][2])
- ☐ ~~9~~8.3.2. Have never been in the possession of a patient or individual member of the public. (H~~&~~SC 150204[c][3])
- ☐ ~~9~~8.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H~~&~~SC 105204[d])
- ☐ ~~9~~8.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H~~&~~SC 150204[m])

~~10~~9. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ ~~10~~9.1. Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

☐ ☐ ☐ ~~10~~9.2. Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B~~&~~PC 4166[a])

~~10~~9.3. List the common carriers (shipping or delivery companies) you use.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~12~~ 11 of this document.

~~11~~10. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ ~~11~~10.1. Are all drugs ordered by a pharmacy or another wholesaler are delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (B~~&~~PC 4059.5[a])

~~Yes No N/A~~

☐ ☐ ☐ ~~11~~10.2. Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (B~~&~~PC 4059.5[d])

☐ ☐ ☐ ~~11~~10.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B~~&~~PC 4059.5[c])

☐ ☐ ☐ ~~11~~10.4. If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (B~~&~~PC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

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~~12~~11. Controlled Substances

Yes No N/A

☐ ☐ ☐ ~~12~~11.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

☐ ☐ ☐ ~~12~~11.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

☐ ☐ ☐ ~~12~~11.3. Are DEA requirements for storage of Schedule III, IV and V controlled substances being met? (~~s~~ Specific requirements are listed in CFR 1301.72[b])

☐ ☐ ☐ ~~12~~11.4. Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a], [c], [e])

☐ ☐ ☐ ~~12~~11.5. Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

☐ ☐ ☐ ~~12~~11.6. Does the biennial inventory record document that the inventory was taken at the "close of business" or "opening of business." (CFR 1304.11)

Yes No N/A

☐ ☐ ☐ ~~12~~11.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

~~12~~11.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ ~~12~~11.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

☐ ☐ ☐ ~~12~~11.9. If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)

☐ ☐ ☐ ~~12~~11.10. Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (~~H & S~~ HSC 11153.5[a]¸[b]¸[c])

☐ ☐ ☐ ~~12~~11.11. If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])

☐ ☐ ☐ ~~12~~11.12. If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. –(CFR 1301.74 [a])

~~12~~11.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

_____

_____

☐ ☐ ☐ ~~12~~11.14. If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. (CFR 1301.74[f])

☐ ☐ ☐ ~~12~~11.15. If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are

controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])

Yes No N/A

☐ ☐ ☐ ~~12~~11.16. Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

~~Yes No N/A~~

☐ ☐ ☐ ~~12~~11.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])

☐ ☐ ☐ ~~12~~11.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)

☐ ☐ ☐ ~~12~~11.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1305.13[b])

☐ ☐ ☐ ~~12~~11.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.13[e])

☐ ☐ ☐ ~~12~~11.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)

☐ ☐ ☐ ~~12~~11.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))

☐ ☐ ☐ ~~12~~11.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (B~~&~~PC 4081, CCR 1718, CFR 1304.03, 1305.17[c], 1305.17[a], [b], and H~~&~~SC 11252, 11253~~, 1304.03~~)

☐ ☐ ☐ ~~12~~11.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☐ ~~12~~11.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

☐ ☐ ☐ ~~12~~11.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.~~75~~74[g]~~, 1305.16[b]~~)

☐ ☐ ☐ ~~12~~11.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.17[d])

~~Yes No N/A~~

☐ ☐ ☐ ~~12~~11.28. Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

☐ ☐ ☐ ~~12~~11.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

☐ ☐ ☐ 11.30. Do you report suspicious orders to the Suspicious Orders Report System (SORS)? Suspicious Orders may include, but is not limited to: an order of a controlled substance of unusual size; an order of a controlled substance deviating substantially from a normal pattern, and; orders of controlled substances of unusual frequency (USC 832[a][3], USC 802[57], CFR 1301.74[b])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

~~13~~12. Policies and Procedures

~~13~~12.1. Does this business maintain and adhere to policies and procedures for the following: (CCR 1780[f])

Yes No N/A

☐ ☐ ☐ ~~13~~12.1.1. Receipt of drugs

☐ ☐ ☐ ~~13~~12.1.2. Security of drugs

☐ ☐ ☐ ~~13~~12.1.3. Storage of drugs (including maintaining records to document proper storage)

☐ ☐ ☐ ~~13~~12.1.4. Inventory of drug (including correcting inaccuracies in inventories)

☐ ☐ ☐ ~~13~~12.1.5. Distributing drugs

☐ ☐ ☐ ~~13~~12.1.6. Identifying, recording and reporting theft or losses

☐ ☐ ☐ ~~13~~12.1.7. Correcting errors and inaccuracies in inventories

Physically quarantining and separating:

☐ ☐ ☐ ~~13~~12.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs

☐ ☐ ☐ ~~13~~12.1.9. drugs that have been partially used~~?~~

☐ ☐ ☐ ~~13~~12.1.10. drugs where the outer or secondary seals on the container have been broken

☐ ☐ ☐ ~~13~~12.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug

☐ ☐ ☐ ~~13~~12.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity (CCR 1780[e]¸[f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

~~14~~13. Training

Yes No N/A

☐ ☐ ☐ ~~14~~13.1 Are training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

~~15~~14. Dialysis Drugs

Yes No N/A

☐ ☐ ☐ ~~15~~14.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (B~~&~~PC 4054¸~~)~~ ~~(~~4059[c]) If so, please complete the next 4 questions, if not proceed to Section ~~16~~15.

☐ ☐ ☐ ~~15~~14.2. Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (B~~&~~PC 4059[d])

☐ ☐ ☐ ~~15~~14.3. Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a]¸[b]¸[c])

☐ ☐ ☐ ~~15~~14.4. Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

Yes No N/A

☐ ☐ ☐ ~~15~~14.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

~~16~~15. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ ~~16~~15.1. Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B~~&~~PC 4059[b])

☐ ☐ ☐ 15.2. Does your business maintain transaction histories, transaction information, and transaction statements for products included in the Drug Supply Chain Security Act? (21 USC 360eee-1[c])

☐ ☐ ☐ ~~16~~15.3.~~2.~~ Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (B~~&~~PC ~~4059.5 [a],~~ 4081~~[a]~~, 4105[c], ~~4081,~~ 4332~~, 4059.5~~[a]) ~~Note: A drug pedigree is considered to be a part of the records of purchase and sale and must be retained for three years from the making.~~

☐ ☐ ☐ ~~16~~15.4.~~3.~~ Are all purchase and sales records retained in a readily retrievable form? (B~~&~~PC 4105[a])

☐ ☐ ☐ ~~16~~15.5.~~4.~~ Is a current accurate inventory maintained for all dangerous drugs? (B~~&~~PC 4081, 4332, CCR 1718)

☐ ☐ ☐ ~~16~~15.6.~~5.~~ If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B~~&~~PC 4105[b])

☐ ☐ ☐ ~~16~~15.7.~~6.~~ Are required records stored off-site only if a board issued written waiver has been granted?

~~16~~15.8.~~7.~~ If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address_____

☐ ☐ ☐ ~~16~~15.9.~~8.~~ Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

Yes No N/A

☐ ☐ ☐ ~~16~~15.10.~~9.~~ If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

☐ ☐ ☐ ~~16~~15.11.~~10.~~ Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (B~~ &~~ PC 4105[d][2])

☐ ☐ ☐ ~~16~~15.12.~~11.~~ Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

~~Yes No N/A~~

☐ ☐ ☐ ~~16~~15.13.~~12.~~ Has this licensed premises, or the designated representative-in-charge/responsible manager ~~or pharmacist~~, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so, list each incident with a brief explanation (B~~&~~PC 4162[a][~~4~~5]):

_____

_____

☐ ☐ ☐ ~~16~~15.14.~~13.~~ Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B~~&~~PC 4083)

☐ ☐ ☐ ~~16~~15.15.~~14.~~ Has this ~~business~~ licensed premises received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B~~&~~PC 4315[~~e~~ f])

☐ ☐ ☐ ~~16~~15.16.~~15.~~ If this ~~business~~ licensed premises dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~12~~ 11 of this document.

~~17~~16. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ ~~17~~16.1. A designated representative-in-charge/responsible manager who terminates employment at this business, must notify the board within 30 days of the termination (B~~&~~PC 4101[b], 4305.5[c].

☐ ☐ ☐ ~~17~~16.2. The owner must report to the board within 30 days the termination of the designated representative-in-charge or responsible manager ~~or pharmacist~~ (B~~&~~PC 4305.5[a])

☐ ☐ ☐ ~~17~~16.3. The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)

☐ ☐ ☐ ~~17~~16.4. The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

~~Yes No N/A~~

☐ ☐ ☐ ~~17~~16.5. Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

☐ ☐ ☐ ~~17~~16.6. The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B~~&~~PC 4201[~~i~~j], CCR 1709[b])

☐ ☐ ☐ ~~17~~16.7. When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B~~&~~PC 4164[a])

☐ ☐ ☐ ~~17~~16.8. ~~Effective January 1, 2006 your~~ The wholesaler ~~business will develop and~~ maintains a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:

- ☐ ~~17~~16.8.1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long term care facilities
- ☐ ~~17~~16.8.2. identify purchases of any dangerous drugs at preferential or contract prices
- ☐ ~~17~~16.8.3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (B~~&~~PC 4164[b])

☐ ☐ ☐ ~~17~~16.9. I understand that this ~~wholesaler~~ license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new

owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (B~~&~~PC 4201[g])

Yes No N/A

☐ ☐ ☐ ~~17~~16.10. The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)

☐ ☐ ☐ ~~17~~16.11. If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

☐ ☐ ☐ 16.12. Upon discovery, the business notifies the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler as required by BPC 4169.1.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

~~18~~17. Additional Licenses/Permits Required

~~18~~17.1. List all licenses and permits required to conduct this business, including local business licenses, ~~wholesale~~ licenses held in other states, permits or licenses required by foreign countries or other entities (B~~&~~PC 4059.5[e], 4107, CFR 1305.11[a]) ~~-~~Use additional sheets if necessary.

_____

_____

DESIGNATED REPRESENTATIVE-IN-CHARGE / RESPONSIBLE MANAGER ~~PHARMACIST~~ CERTIFICATION:

I, (please print) _____, ~~DRIC# / RPH #~~ _____ hereby certify that I have completed the self-assessment of this ~~wholesale business~~ licensed premises of which I am the designated representative-in-charge (DRIC) / responsible manager (RM) ~~pharmacist (RPH)~~. Any deficiency identified herein will be corrected by _____. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Responsible Manager (RM) ~~Pharmacist (RPH)~~

ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE OFFICER:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the ~~pharmacy's~~ premises license issued by the California State Board of Pharmacy.

Signature _____ Date _____

Legal References

The following Legal References are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov ~~(see *Laws and Regulations*)~~, at the California State Law Library, or at other libraries or Internet ~~Web sites~~ websites:

Business and Professions Code (BPC), Division 2, Chapter 1 – General Provisions

BPC, Division 2, Chapter 9 – Pharmacy

California Code of Regulations (CCR), Title 16, Division 17 – California State Board of Pharmacy

Code of Federal Regulations (CFR), Title 21, Chapter 2 – Drug Enforcement Administration, Department of Justice

Health and Safety Code (HSC), Division 10 – Uniform Controlled Substances Act

HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law, Chapter 6 – Drugs and Devices

HSC, Division 116 – Surplus Medication Collection and Distribution

USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)

~~California Code of Regulations (CCR), Title 16, unless otherwise noted~~

~~Business and Professions Code (B&PC), Chapter 9, Division 2, unless otherwise noted~~

~~Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act~~

~~Health and Safety Code (H&SC), Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws~~

~~United States Code of Federal Regulations (CFR), Title 21, Chapter II, Part 1300, Drug Enforcement Administration, Food and Drugs and Codified Controlled Substances Act (CSA)~~

~~**California Board of Pharmacy**~~
~~1625 N. Market Blvd., Suite N219~~
~~Sacramento, CA 95834~~
~~Phone: (916) 574-7900~~
~~Fax: (916) 574-8618~~
~~www.pharmacy.ca.gov~~

~~***Pharmacy Law*** may be obtained by contacting:~~
~~LawTech Publishing Co.~~
~~1060 Calle Cordillera, Suite 105~~
~~San Clements, CA 92673~~
~~Phone: (800) 498-0911 Ext. 5~~
~~www.lawtechpublishing.com~~

~~**Pharmacist Recovery Program**~~
~~Phone: (800) 522-9198 (24 hours a day)~~

~~***Prescriber Boards:***~~

~~**Medical Board of California**~~
~~2005 Evergreen St., Suite 1200~~
~~Sacramento, CA 95815~~
~~Phone: (800) 633-2322~~
~~Phone: (916) 263-2382~~
~~Fax: (916) 263-2944~~
~~http://www.mbc.ca.gov~~

~~**Dental Board of California**~~
~~2005 Evergreen St., Suite 1550~~
~~Sacramento, CA 95815~~
~~Phone: (916) 263-2300~~

Fax: (916) 263-2140
http://www.dbc.ca.gov

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
Phone: (916) 322-7697
Fax: (916) 574-8637
http://www.rn.ca.gov/

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
Phone: (916) 575-7170
Fax: (916) 575-7292
http://www.optometry.ca.gov/

Osteopathic Medical Board of California
1300 National Drive, Suite 150
Veterinary Medical Board
2005 Evergreen St., Suite 2250
Sacramento, CA 95815
Phone: (916) 263-2610
Fax: (916) 263-2621
http://www.vmb.ca.gov

Federal Agencies:

Food and Drug Administration – Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.html#drugs

The **Drug Enforcement Administration** may be contacted at:

DEA Website:
http://www.deadiversion.usdoj.gov
Online Registration – New Applicants:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm
Online Registration - Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm
Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html
Sacramento, CA 95834

Phone: (916) 928-8390
Fax: (916) 928-8392
http://www.ombc.ca.gov

Physician Assistant Committee
2005 Evergreen St., Suite 1100
Sacramento, CA 95815
Phone: (916) 561-8780
Fax: (916) 263-2671
http://www.pac.ca.gov

Board of Podiatric Medicine
2005 Evergreen St., Suite 1300
Sacramento, CA 95815
Phone: (916) 263-2647
Fax: (916) 263-2651
http://www.bpm.ca.gov
Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp
Controlled Substance Ordering System (CSOS):
http://www.deaecom.gov/

DEA Registration Support (all of CA):
(800) 882-9539

DEA – Los Angeles
255 East Temple Street, 20th Floor
Los Angeles, CA 90012
Registration: (888) 415-9822 or (213) 621-6960
Diversion or Investigation: (213) 621-6942

DEA – San Francisco
450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
Theft Reports or Diversion: (415) 436-7900

~~**DEA – Sacramento**~~
~~4328 Watt Avenue~~
~~Sacramento, CA 95821~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (916) 480-7250~~

~~**DEA – Riverside**~~
~~4470 Olivewood Avenue~~
~~Riverside, CA 92501-6210~~
~~Registration: (888) 415-9822 or (213) 621-6960~~
~~Diversion or Investigation: (951) 328-6200~~

~~**DEA – Fresno**~~
~~2444 Main Street, Suite 240~~
~~Fresno, CA 93721~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (559) 487-5406~~

~~**DEA – San Diego and Imperial Counties**~~
~~4560 Viewridge Avenue~~
~~San Diego, CA 92123-1637~~
~~Registration: (800) 284-1152~~
~~Diversion or Investigation: (858) 616-4100~~

~~**DEA – Oakland**~~
~~1301 Clay Street, Suite 460N~~
~~Oakland, CA 94612~~
~~Registration: (888) 304-3251~~
~~Diversion or Investigation: (510) 637-5600~~

~~**DEA – San Jose**~~
~~One North First Street, Suite 405~~
~~San Jose, CA 95113~~
~~Registration: (888) 304-3251~~
~~Diversion or Investigation: (408) 291-2631~~

~~**DEA – Redding**~~
~~310 Hensted Drive, Suite 310~~
~~Redding, CA 96002~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (530) 246-5043~~

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

Agenda Item III. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16, California Code of Regulations Section 1784, Wholesaler Dangerous Drugs and Devices Self-Assessment (17M-26), Including Comments Received

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Summarized 15-day Comment Regarding the Self-Assessment with Board Staff Recommendation:

Written Comments from Duane Allison, Eversana,

Comment 1: The commenter recommends that form 17M-26 be amended to remove the VAWD abbreviation to update the form to the current NABP Drug Distributor Accreditation Certificate and add the Facility NABP e-profile number.

Response to Comment 1: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that this comment is outside the scope of the comment period. Additionally, Board staff note that while NABP has updated that Drug Distributor Accreditation Certificate, it still acknowledges the term VAWD. Additionally, Board staff note that the Board's system is not integrated with NABP's system and mandating disclosure of the e-profile number is not necessary.

Comment 2: The commenter requested that section 2.4, which requests the list of personnel with keys that have access to the dangerous drugs (Rx Drugs) be replaced with a list of personnel that have access to the controlled substance cage or vault area. The commenter states that the list of personnel with access to Rx Drugs would include almost the entire facility staff and not be practical for organizations with over 350 personnel.

Response to Comment 2: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that the requirement to limit access to all prescription drugs is a requirement in law, specifically, California Code of Regulations (CCR) section 1780(c). The law does not limit that access to controlled substances only, as such staff with access to prescription drugs must be listed.

Comment 3: The commenter states that it is impossible and impractical for all incoming shipments to be received by the DRIC (designated representative in charge) or manager as shipments are received over the course of the day from 8am to 10pm. The commenter indicates that the form should be revised to state

"shipments received by personnel under the supervision and training of the DRIC or Manager".

Response to Comment 3: Board staff have reviewed this comment and do not recommend any changes to the text based thereon. Board staff note that this comment is outside the scope of the comment period; In addition, it is not a requirement for incoming shipments to be received by the DRIC or responsible manager depending on the license type. The requirement, as specified in Business and Professions Code section 4059.5(a), is that incoming shipments be received by a pharmacist or a designated representative. The designated representative does not need to be the DRIC of the facility.

From: Duane Allison <Duane.Allison@Eversana.com>
Sent: Tuesday, February 15, 2022 2:43 PM
To: Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>
Subject: Proposed Changes to the CA Self-Assessment of a Wholesaler/Third-Party Logistics Provider Form

[EXTERNAL]: Duane.Allison@Eversana.com

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Lori,

I have listed below the comments regarding the proposed changes to the California Self-Assessment of a Wholesaler/Third-Party Logistics Provider Inspection Form.

1. Update the document to reflect the current NABP Drug Distributor Accreditation Certificate. Remove the VAWD abbreviation and added the
   Facility NABP e-profile number. Current NABP Drug Distributor Accreditation Certificate do not contain a number.
2. Revise the paragraph requesting the list of personnel with keys that have access to the dangerous drugs (Rx Drugs) be replaced with list of personnel
   that have access to the controlled substance cage or vault area. The list of personnel with access to Rx Drugs would include almost the entire facility staff
   and not practical (over 350 personnel).
3. Receiving of incoming shipments should be revised to state “shipments received by personnel under the supervision and training of the DRIC or Manager”. For a large Wholesaler receiving between 50-100 shipments per day from 8am to 10pm the DRIC cannot be required to receive all incoming shipments by himself. This requirement would be impossible and impractical.

Thank you,

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