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

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

WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page ~~21~~20.

All references to "drugs" throughout this self-assessment form refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (BPC) 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 = Designated Representative, Designated Representative-3PL, and Designated Representative Reverse Distributor

Title 16 of the California Code of Regulations section 1784 requires each wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The designated representative-in-charge or responsible manager must also complete a self-assessment within 30 days whenever: (1) a new license has been issued; (2) there is a change in the designated representative-in-charge or responsible manager; or (3) there is a change in the licensed location of the wholesaler or third-party logistics provider. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Each self-assessment must be kept on file by the wholesaler and third-party logistics provider for three years after it is completed.

Licensed Premises Name: _____

Address: _____

Phone: _____ Licensed Premises Email address: _____

Ownership: Please mark one

○ sole owner ○ partnership ○ corporation ○ LLC

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

License #_____ Expiration Date_____

Other 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

DRIC / RM _____ DRIC/RM Email address:_____

DR License # / RPH License #_____ Expiration Date_____

Website Address (optional): _____

Other Licensed Staff (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 _____

WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted. Additionally, Business and Professions Code is referenced as BPC.

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 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. (BPC 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. (BPC 4082)

☐ ☐ ☐ 1.3. Has there been a transfer of the management or control over the WLS/3PL to a person or entity who did not have management or control over the license at the time the original license was issued? Written notification to the board is required of the transfer within 30 days of the transfer. (CCR 1709[b])
Please attach a copy of the notification letter to the board to this document.

☐ ☐ ☐ 1.4. Is there any beneficial interest of the WLS/3PL held in a trust? (CCR 1709[d])
If yes, please have a copy of the trust readily available for inspection.

CORRECTIVE ACTION OR ACTION PLAN _____

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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 the standards set forth in the latest edition of the USP) (CCR 1780[b])

Yes No N/A

☐ ☐ ☐ 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])

☐ ☐ ☐ 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 or dangerous devices are stored limited to authorized personnel? (BPC 4116, 4167, CCR 1780[c])

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

_____

_____

_____

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

2.6. The 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.

_____

_____

☐ ☐ ☐ 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, or others, by receiving, inventorying, and managing the disposition of outdated or nonsaleable dangerous drugs or dangerous devices? (BPC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

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☐ ☐ ☐ 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. (BPC 4163~~([c))~~])

Date of approval from the board: _____

Yes No N/A

☐ ☐ ☐ 2.9. The facility is subscribed to the board's email notifications. (BPC 4013)

Date Last Notification Received: _____

Email address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

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☐ ☐ ☐ 2.10. The facility receives the board's email notifications through the owner's electronic notice system. (BPC 4013[c])

Date Last Notification Received: _____

Email 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 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 DRIC/RM are both equally responsible for maintenance of the records and inventory of the facility. (BPC 4081[b])

☐ ☐ ☐ 3.2. Is the DRIC/RM at least 18 years of age and responsible for the compliance with all state and federal laws for the distribution of drugs? The DRIC may be a pharmacist. (BPC 4160[d], 4053.1[b], 4053.2)

☐ ☐ ☐ 3.3. The owner must notify the board within 30 days of termination of the DRIC/RM. (BPC 4305.5[a])

☐ ☐ ☐ 3.4. The owner must identify and notify the board of a proposed new DRIC/RM within 30 days of the termination of the former DRIC/RM. (BPC 4160[f], 4160[g], 4331[c]) The appropriate form for this notification is available on the board's website.

☐ ☐ ☐ 3.5. The DRIC/RM who ends their employment at a licensed premises, must notify the board within 30 days. (BPC 4305.5[c], 4101[b][c]). This notification is in addition to that required of the owner.

☐ ☐ ☐ 3.6. The DRIC/RM has provided an electronic mail address to the board and shall maintain a current electronic mail address, if any, with the board and must notify the board within 30 days of any change of electronic mail address, giving both the old and new electronic mail address. (CCR 1704[b])

CORRECTIVE ACTION OR ACTION PLAN _____

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

Yes No N/A

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

☐ ☐ ☐ 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? (BPC 4081, 4332)

☐ ☐ ☐ 4.3. For license verification, the licensed premises may use the licensing information displayed on the board's Internet web site. (BPC 4106)

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 11 of this document.

5. Receipt of Drugs by this Business

Yes No N/A

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

☐ ☐ ☐ 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 _____

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

6. Drug Stock

Yes No N/A

☐ ☐ ☐ 6.1. Is all drug stock open for inspection during regular business hours? (BPC 4080)

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

☐ ☐ ☐ 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? (BPC 4342[a])

☐ ☐ ☐ 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)

☐ ☐ ☐ 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])

☐ ☐ ☐ 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])

☐ ☐ ☐ 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])

CORRECTIVE ACTION OR ACTION PLAN _____

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

7. Sale or Transfer of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 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?

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

_____

_____

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

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

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

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

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

☐ ☐ ☐ 7.5.3. the drugs are needed to alleviate a shortage? (and your business only furnishes ~~O~~only a quantity sufficient to alleviate a specific shortage). (BPC 4126.5[a])

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

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

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

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

☐ ☐ ☐ 7.6.4. **confirmed** to not be beyond their use date (expired drugs)? (BPC 4169)

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.

_____

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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

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

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

☐ ☐ ☐ 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?

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

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

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

_____

_____

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])

☐ ☐ ☐ 7.11. If preferentially priced drugs are sold by your business, that sale complies with CA Pharmacy Law. (BPC 4380)

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

☐ ☐ ☐ 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. (BPC 650)

_____

_____

☐ ☐ ☐ 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. (BPC 4066, CFR 1301.25)

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CORRECTIVE ACTION OR ACTION PLAN _____

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

8. Donations of Medication to Voluntary Drug Repository and Distribution Programs (HSC 150200, 150203, 150204)

Yes No N/A

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

☐ ☐ ☐ 8.2. No controlled substances shall be donated. (HSC 150204[c][1])

☐ ☐ ☐ 8.3. Drugs that are donated are unused, unexpired and meet the following requirements: (HSC 150204[c])

- ☐ 8.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])
- ☐ 8.3.2. Have never been in the possession of a patient or individual member of the public. (HSC 150204[c][3])

☐ 8.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])

☐ 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. (HSC 150204[m])

9. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ 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])

☐ ☐ ☐ 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? (BPC 4166[a])

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 of controlled substances – these additional requirements are in Section 11 of this document.

10. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ 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? (BPC 4059.5[a])

☐ ☐ ☐ 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? (BPC 4059.5[d])

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

☐ ☐ ☐ 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. (BPC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

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11. **Controlled Substances**

Yes No N/A

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

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

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

☐ ☐ ☐ 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])

☐ ☐ ☐ 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])

☐ ☐ ☐ 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)

☐ ☐ ☐ 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)

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

_____

_____

Yes No N/A

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

☐ ☐ ☐ 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)

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

☐ ☐ ☐ 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])

☐ ☐ ☐ 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])

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

_____

_____

Yes No N/A

☐ ☐ ☐ 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])

☐ ☐ ☐ 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])

☐ ☐ ☐ 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)

☐ ☐ ☐ 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])

☐ ☐ ☐ 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)

☐ ☐ ☐ 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])

☐ ☐ ☐ 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])

☐ ☐ ☐ 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)

☐ ☐ ☐ 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))

Yes No N/A

☐ ☐ ☐ 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? (BPC 4081, CCR 1718, CFR 1304.03, 1305.17[c], 1305.17[a], [b], and HSC 11252, 11253)

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

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

☐ ☐ ☐ 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 1301.74[g])

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

☐ ☐ ☐ 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])

☐ ☐ ☐ 11.29. Does the owner of your business notify the board ~~of any loss of controlled substances~~ within 30 days of discovering the loss of the following:~~?~~

☐ Any loss of a controlled substance, 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. (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. (21 USC 832[a][3], 21 USC 802[57], 21 CFR 1301.74[b])

CORRECTIVE ACTION OR ACTION PLAN _____

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12. Policies and Procedures

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

Yes	No	N/A	
☐	☐	☐	12.1.1. Receipt of drugs
☐	☐	☐	12.1.2. Security of drugs
☐	☐	☐	12.1.3. Storage of drugs (including maintaining records to document proper storage)
☐	☐	☐	12.1.4. Inventory of drug (including correcting inaccuracies in inventories)
☐	☐	☐	12.1.5. Distributing drugs
☐	☐	☐	12.1.6. Identifying, recording and reporting theft or losses
☐	☐	☐	12.1.7. Correcting errors and inaccuracies in inventories

Physically quarantining and separating:

Yes	No	N/A	
☐	☐	☐	12.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs
☐	☐	☐	12.1.9. drugs that have been partially used;
☐	☐	☐	12.1.10. drugs where the outer or secondary seals on the container have been broken
☐	☐	☐	12.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug
☐	☐	☐	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 _____

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13. Training

Yes	No	N/A	
☐	☐	☐	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 _____

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14. Dialysis Drugs

Yes No N/A

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

☐ ☐ ☐ 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])

☐ ☐ ☐ 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

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

CORRECTIVE ACTION OR ACTION PLAN _____

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15. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ 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? (BPC 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])

☐ ☐ ☐ 15.3. Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (BPC 4081, 4105[c], 4332)

☐ ☐ ☐ 15.4. Are all purchase and sales records retained in a readily retrievable form? (BPC 4105[a])

☐ ☐ ☐ 15.5. Is a current accurate inventory maintained for all dangerous drugs? (BPC 4081, 4332, CCR 1718)

Yes No N/A

☐ ☐ ☐ 15.6. 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? (BPC 4105[b])

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

☐ ☐ ☐ 15.8. 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_____

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

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

~~Yes No N/A~~

☐ ☐ ☐ 15.11. 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? (BPC 4105[d][2])

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

☐ ☐ ☐ 15.13. Has this licensed premises, or the designated representative-in-charge/responsible manager, 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: (BPC 4162[a][5])~~:~~

_____

_____

☐ ☐ ☐ 15.14. 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. (BPC 4083)

☐ ☐ ☐ 15.15. Has this 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. (BPC 4315[f])

☐ ☐ ☐ 15.16. If this 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 _____

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

16. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ 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. (BPC 4101[b], 4305.5[c]~~.~~

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

☐ ☐ ☐ 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)

☐ ☐ ☐ 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])

☐ ☐ ☐ 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)

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

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

☐ ☐ ☐ 16.8. The wholesaler 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:

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

☐ ☐ ☐ 16.9. I understand that this 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. (BPC 4201[g])

☐ ☐ ☐ 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)

☐ ☐ ☐ 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.

☐ ☐ ☐ 16.13. The wholesaler/third-party logistics provider shall notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. Closure dates will be public information. A temporary closure shall not include a routine closure (including weekends or state and federal holidays), unless that closure exceeds four consecutive calendar days. (CCR 1708.1)

CORRECTIVE ACTION OR ACTION PLAN _____

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17. Additional Licenses/Permits Required

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

_____

_____

DESIGNATED REPRESENTATIVE-IN-CHARGE / RESPONSIBLE MANAGER CERTIFICATION:

I, (please print) _____, hereby certify that I have completed the self-assessment of this licensed premises of which I am the designated representative-in-charge (DRIC) / responsible manager (RM). Any deficiency identified herein will be corrected by _____(Date). 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)

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 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, at the California State Law Library, or at other libraries or Internet 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)