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

Wholesaler and Third-Party Logistics Provider Self-Assessment

Business and Professions Code section 4102 requires the designated representative-in-charge of a wholesaler or responsible manager of a third-party logistics provider licensed under Chapter 9 of Division 2 of the Business and Professions Code to complete a self-assessment of the wholesaler's or third-party logistics provider's compliance with federal and state law. **The assessment shall be performed by July 1 of every odd-numbered year. The designated representative-in-charge or responsible manager must also complete a self-assessment within 30 days of any of the following: (1) a new wholesaler or third-party logistics provider license is issued; (2) there is a change of designated representative-in-charge or responsible manager, and they become the new designated representative-in-charge or responsible manager; (3) there is a change in the location to a new address. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

For purposes of completing this self-assessment, the following abbreviations refer to specific licensing categories:

Abbreviation	Full Reference	Definition
3PL	Third-Party Logistics Provider	BPC 4045
DR	Designated Representative	BPC 4022.5(a)
DRIC	Designated Representative-in-Charge	BPC 4022.5(b)
DR 3PL	Designated Representative 3-PL	BPC 4022.7(a)
DR RD	Designated Representative Reverse Distributor	BPC 4022.6
R-3PL	Reverse Third-Party Logistics Provider	BPC 4044.5
RD	Reverse Distributor	BPC 4040.5
RM	Responsible Manager	BPC 4022.7(b)
WLS	Wholesaler	BPC 4043

Please mark the appropriate box (Yes, No, or N/A) for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If the specific legal requirement referenced in the question clearly and objectively does not apply, then mark the box "N/A". If more space is needed, you may add additional sheets. The self-assessment must be completed in its entirety. It may be completed online and printed, initialed, and signed (use original signatures or digital signatures that

comply with California Code of Regulations, title 16, section 1700). The completed form shall be kept on file with the wholesaler or third-party logistics provider and made available to the Board upon request. A new self-assessment form must be filled out each time the self-assessment process is required to be completed; do not use or copy from a previous self-assessment form. Each self-assessment must be kept on file with the wholesaler or third-party logistics provider for three years after it is performed.

Notes:

- This self-assessment is not an all-inclusive compilation of all laws and regulations that may apply to wholesalers and/or third-party logistics providers. The designated representative-in-charge is responsible for ensuring a wholesaler's compliance with all state and federal laws and regulations pertaining to wholesalers, regardless of whether such laws or regulations are referenced on this self-assessment. The responsible manager is responsible for ensuring compliance of the licensed place of business with state and federal laws with respect to dangerous drugs and dangerous devices received by, stored in, or shipped from the licensed place of business of the third-party logistics provider, regardless of whether such laws are referenced on this self-assessment.

Facility Name:				
Address:		**Telephone:**		
License #:		**Expiration Date:**		
Other Permit #:		**Expiration Date:**		
Other Permit #:		**Expiration Date:**		
NABP Accreditation #:		**Expiration Date:**		
DEA Registration #		**Expiration Date:**		
Date of DEA Inventory:				
Hours:	Weekdays	Saturday	Sunday	24 Hours
Designated Representative-in-Charge or Responsible Manager:		**License#:**		
		Expiration Date:		

Type of Facility Check all that apply. (See list of abbreviations on p. 1)	
	WLS
	3PL
	RD
	R-3PL
Types of Products	
	Dangerous drugs
	Dangerous devices
	Acupuncture needles and supplies
	Dental equipment and supplies
	Diabetic equipment and supplies
	Diagnostic agents; contrast medium for x-rays
	Dialysis solutions and supplies
	Hypodermic needles and syringes
	Medicinal gases
	Veterinary Drugs
	List Others:

*Facilities are not legally required to identify the types of products they provide; however, this can be helpful to both the Board and the licensee in assessing compliance.

Wholesaler's/Third-Party Logistics Provider's Licensed Staff:

Attach additional sheets as necessary

(**RPH**=Pharmacist; see list on p.1 for other abbreviations)

Name:		**RPH#:**		**Expiration Date:**	
		DR#:		**Expiration Date:**	
		DR 3PL#:		**Expiration Date:**	
		DR RD#:		**Expiration Date:**	
Name:		**RPH#:**		**Expiration Date:**	
		DR#:		**Expiration Date:**	
		DR 3PL#:		**Expiration Date:**	
		DR RD#:		**Expiration Date:**	
Name:		**RPH#:**		**Expiration Date:**	
		DR#:		**Expiration Date:**	
		DR 3PL#:		**Expiration Date:**	
		DR RD#:		**Expiration Date:**	
Name:		**RPH#:**		**Expiration Date:**	
		DR#:		**Expiration Date:**	
		DR 3PL#:		**Expiration Date:**	
		DR RD#:		**Expiration Date:**	
Name:		**RPH#:**		**Expiration Date:**	
		DR#:		**Expiration Date:**	
		DR 3PL#:		**Expiration Date:**	
		DR RD#:		**Expiration Date:**	

Name:		**RPH#:**		**Expiration Date:**	
		DR#:		**Expiration Date:**	
		DR 3PL#:		**Expiration Date:**	
		DR RD#:		**Expiration Date:**	
Name:		**RPH#:**		**Expiration Date:**	
		DR#:		**Expiration Date:**	
		DR 3PL#:		**Expiration Date:**	
		DR RD#:		**Expiration Date:**	
Name:		**RPH#:**		**Expiration Date:**	
		DR#:		**Expiration Date:**	
		DR 3PL#:		**Expiration Date:**	
		DR RD#:		**Expiration Date:**	
Name:		**RPH#:**		**Expiration Date:**	
		DR#:		**Expiration Date:**	
		DR 3PL#:		**Expiration Date:**	
		DR RD#:		**Expiration Date:**	
Name:		**RPH#:**		**Expiration Date:**	
		DR#:		**Expiration Date:**	
		DR 3PL#:		**Expiration Date:**	
		DR RD#:		**Expiration Date:**	

References:

Abbreviation	Full Reference
BPC	Business and Professions Code
CC	Civil Code
CCR	Title 16 California Code of Regulations
21 CFR	Code of Federal Regulations
HSC	Health and Safety Code
21 USC	United States Code

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Section 1: Facility Requirements/Operation Standards/Security

	Reference	Item	Yes	No	N/A	Corrective Action Plan
1.1	CCR 1780	The premises, fixtures and equipment therein are maintained in a clean and orderly condition, the premises are well ventilated, free from rodents and insects, and adequately lighted, and plumbing is in good repair.				
1.2	CCR 1780	Temperature and humidity monitoring is conducted to assure compliance with the standards set forth in the latest edition of the United States Pharmacopeia.				
1.3	CCR 1780	Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated are placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.				
1.4	CCR 1780	Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used are identified as such, and are placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.				
1.5	BPC 4160 CCR 1781	A pharmacist or a DR (in the case of a WHS), or a DR 3PL (in the case of a 3PL), is present and in control of the licensed premises during the conduct of business.				
1.6	CCR 1780	All facilities are equipped with (1) an alarm system to detect entry after hours, and (2) a security system that will provide suitable protection against theft and diversion; and the outside perimeter of the premises is well-lighted.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
1.7	BPC 4013	The facility is subscribed to the Board's email notification system, and updates its email address with the Board's email notification system within 30 days of a change in the facility's email address.				

Section 2: Drug and Device Inventory

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.1	BPC 4116 BPC 4167 CCR 1780	The facility stores dangerous drugs and dangerous devices in a secured and lockable area and entry into the area is limited to authorized personnel.				
2.2	BPC 4059 BPC 4059.5 BPC 4160 BPC 4161 BPC 4126.5 BPC 4163 BPC 4169 HSC 11209 CCR 1783	The facility only obtains dangerous drugs and dangerous devices from, and furnishes dangerous drugs and dangerous devices to, persons or entities authorized by pharmacy law.				
2.3	BPC 4059.5	When dangerous drugs or dangerous devices are received at the facility, they are delivered to the licensed premises, and received by and signed for only by a DR- or a pharmacist.				
2.4	BPC 4059.5	All dangerous drugs and dangerous devices delivered by the facility to a hospital are delivered either to the hospital pharmacy premises or to a central receiving area within the hospital.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.5	BPC 4059.5	If dangerous drugs or dangerous devices are delivered by the facility 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 or dangerous device delivered.				
2.6	BPC 4080 BPC 4167	All stock of any dangerous drug or dangerous device is open to inspection by authorized officers of the law at all times during business hours and is maintained on the licensed premises.				
2.7	21 USC 331 21 USC 351 21 USC 352 BPC 4059.5 BPC 4169 BPC 4342 HSC 111250 HSC 111255 HSC 111335 CCR 1718 CCR 1718.1 CCR 1780	The facility's drug stock is within expiry and maintained to prevent misbranding and adulteration.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.8	BPC 4126.5	Your facility only receives dangerous drugs from a pharmacy if your facility is: 1. A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired; 2. A licensed wholesaler acting as a reverse distributor; or 3. A wholesaler alleviating a temporary shortage of a dangerous drug that could result in the denial of health care, and in such case you only receive a quantity sufficient to alleviate the temporary shortage.				
2.9	CCR 1780	If the conditions under which a prescription drug has been returned to the facility cast doubt on the drug's safety, identity, strength, quality or purity, the drug is destroyed or returned to the supplier, unless testing or other investigation proves that the drug meets the standards set forth in the latest edition of the United States Pharmacopeia.				
2.10	21 USC 360eee-1	The facility complies with applicable provisions of the Drug Supply Chain Security Act (DSCSA).				
2.11	BPC 4380	All sales of preferentially priced drugs by the facility comply with applicable state and federal laws.				
2.12	BPC 4166 CFR 1301.74	The facility uses a common carrier (e.g. USPS, UPS, FEDEX, etc.) for delivery of drug orders to customers which provides adequate security to guard against in-transit losses.				

Section 3: Designated Representative-In-Charge, Responsible Manager, Ownership Responsibilities

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.1	BPC 4082	When called upon by an inspector, the owner or manager is able to furnish the inspector with the names of the owner or owners, manager or managers, and employees together with a brief statement of the capacity in which these persons are employed on the premises.				
3.2	CCR 1780	The facility establishes and maintains lists of officers, directors, managers and other persons in charge of drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.				
3.3	BPC 4201 CCR 1709	Written notification is submitted to the Board within 30 days of either of the following: 1. Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in the licensee to a person or entity who did not hold a beneficial interest at the time the original license was issued. 2. Any transfer of the management or control over the licensee to a person or entity who did not have management or control over the license at the time the original license was issued.				
3.4	BPC 4053.1 BPC 4053.2 BPC 4160	The facility is supervised or managed by a DRIC/RM, who is responsible for the facility's compliance with state and federal laws applicable to the facility and its operations.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.5	BPC 4160 BPC 4305.5	The facility notifies the Board within 30 days of the termination of employment of the DRIC/RM. The facility notifies the Board in writing within 30 days of the date when a DRIC/RM ceases to act as the DRIC/RM.				
3.6	BPC 4160	The facility notifies the Board in writing of a proposed new DRIC/RM within 30 days of the date when the former DRIC/RM ceases to act as the DRIC/RM.				
3.7	CCR 1704 BPC 4013	The DRIC/RM of the facility is subscribed to the Board's email notification system, and updates their email address with the Board's email notification system within 30 days of a change in the licensee's email address.				
3.8	CCR 1780	The facility provides adequate training and experience to assure compliance with licensing requirements by all personnel.				

Section 4: Record Keeping

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.1	BPC 4081	The owner and DRIC/RM of the facility are jointly responsible for maintaining the records and inventory described in BPC 4081.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.2	BPC 4059 BPC 4059.5 BPC 4081 BPC 4105 BPC 4332 HSC 11252 HSC 11253 CCR 1718 21 CFR 1301.74 21 CFR 1304.03 21 CFR 1304.04 21 CFR 1305.03 21 CFR 1305.06 21 CFR 1305.13 21 CFR 1305.15 21 CFR 1305.16 21 CFR 1305.17 21 CFR 1305.21 21 CFR 1305.22	All records of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices are retained on the licensed premises in a readily retrievable form for at least three years from the date of making and are otherwise maintained and preserved in compliance with state and federal requirements.				
4.3	BPC 4059	The facility's sales and purchase records for dangerous drugs and dangerous devices include all the required elements.				
4.4	BPC 4105 CCR 1707	All records or other documentation required to be maintained by the facility are maintained on the licensed premises, or, if not, the facility has received a waiver from the Board to store records offsite.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.5	CCR 1780	The facility has established, maintains, and adheres to written policies and procedures for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.				

Section 5: Controlled Substances

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.1	BPC 4164 CCR 1718 21 CFR 1301.71 21 CFR 1301.72 21 CFR 1301.74 21 CFR 1301.92 21 CFR 1304.11	The facility complies with applicable federal and state laws related to the ordering, storage and security of controlled substances.				
5.2	CCR 1718 CCR 1780 21 CFR 1304.11	The facility completes an inventory of all controlled substances every two years.				
5.3	21 CFR 1305.05	Each person allowed to order Schedule II controlled substances has a power of attorney.				
5.4	21 CFR 1301.90	The facility follows the employee-screening procedures recommended by DEA to assure the security of controlled substances.				
5.5	HSC 11153.5	Controlled substances are furnished only for a legitimate medical purpose.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.6	21 CFR 1305.03 21 CFR 1305.06 21 CFR 1305.13 21 CFR 1305.21 21 CFR 1305.22	Unless an exemption applies, all Schedule II controlled substances are ordered pursuant to a DEA 222 form or Controlled Substance Ordering System (CSOS) and reconciled appropriately upon receipt.				
5.7	21 CFR 1305.13	When the facility partially fills a Schedule II controlled substance order, the balance is provided within 60 days.				
5.8	21 CFR 1301.74 21 CFR 1301.91	The facility reports drug losses to DEA within the time limits required by law and regulations.				
5.9	BPC 4164 CCR 1782	The facility reports to the Board all sales of dangerous drugs and controlled substances that are subject to abuse as required by law and regulations.				
5.10	21 CFR 1301.92	If any employee of this business illicitly possesses, sells, uses or diverts controlled substances, the employer assesses the seriousness of the employee's violation and other appropriate factors recommended by DEA in determining whether to suspend, transfer, terminate or take other action against the employee.				
5.11	21 USC 802 21 USC 832 BPC 4169.1 21 CFR 1301.74	Suspicious orders are reported to the Board and the DEA Suspicious Orders Report System (SORS).				

Additional References

Licensees are encouraged to review the additional references provided below for more information about the listed topics. Licensees are advised that the below is a list of selective references that licensees may find helpful, but not an exhaustive list of all pharmacy laws and regulations that may apply to any given topic or in any specific case.

Reference	Topic
BPC 651 BPC 4341 CCR 1766	Advertisement of dangerous drugs.
BPC 4054 BPC 4059 CCR 1787 CCR 1790 CCR 1791 CCR 1792	Dialysis Drugs
CCR 1705 CCR 1708.2 21 CFR 1301.52 21 CFR 1301.54	Discontinuance of business and notification of bankruptcy, etc.
21 CFR 1301.74 21 CFR 1305.17	Distribution and records requirement for thiafentanil, carfentanil, etorphine HCL and/or diprenorphine
BPC 4164	Sales of dangerous drugs at preferential or contract prices
BPC 650	Rebates, refunds, commissions, discounts, preferences or other consideration for referring patients or customers.
CCR 1776.5	Reverse Distributors accepting dangerous drugs from drug take back facilities.
BPC 4163	Reverse Distributors accepting dangerous drugs/devices from unlicensed sources
BPC 4164 CCR 1782	Reports of sales of dangerous drugs or controlled substances subject to abuse
CCR 1708.1	Temporary closure
HSC 150200 HSC 150203 HSC 150204	Voluntary Drug Repository and Distribution Programs

DESIGNATED REPRESENTATIVE-IN-CHARGE/RESPONSIBLE MANAGER CERTIFICATION:

I, (please print) _____, RPH #/DR #/RM # _____ hereby certify that I have completed the self-assessment of this facility of which I am the designated representative-in-charge/responsible manager to the best of my professional ability. Any deficiency identified herein will be corrected by _____(date). I understand that all responses are subject to verification by the Board of Pharmacy. I acknowledge the self-assessment will be readily available for review during any inspection by the Board. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature* _____ Date: _____
(Designated Representative-in-Charge/Responsible Manager)

ACKNOWLEDGEMENT BY FACILITY OWNER OR AUTHORIZED OFFICER:

I, (please print) _____, hereby certify 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 action by the California State Board of Pharmacy.

Signature* _____ Date: _____
Facility Owner or Authorized Officer

*Consistent with 16 CCR Section 1700, the Board will accept digital signatures.