

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Wholesaler Self-Assessment Form

Sections Affected: Add 1784

Specific Purpose of the Proposed Changes:

This section establishes requirements for the designated representative in charge (DRC) of a licensed wholesaler to complete a self-assessment form to ensure compliance with pharmacy law. This self-assessment form is to assist wholesalers in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the proposal would make the pharmacy inspection process more meaningful and provide relevant information to wholesalers and their DRC.

Factual Basis

The board is charge with protecting the public health, safety and welfare. Board of Pharmacy inspectors and staff accomplish this task in part by conducting inspections of wholesalers.

The DRC is responsible to assuring the premises compliance with state and federal requirements. Completing a self-assessment form would allow the DRC to increase the wholesaler's compliance with legal requirements without awaiting board inspection. The benefit to the public when a wholesaler is in compliance with the law is significant.

An inspector conducting an inspection is frequently asked questions regarding aspects of the inspections as well as clarifications and requirements of pharmacy law. This self-assessment form would provide an easy reference guide to the DRC when an inspector is not available.

The self-assessment form would confirm a DRC's understanding of the following pharmacy laws relevant to the operation of a licensed wholesaler including, facility standards, drug stock, the sale or transfer of drugs by the business, the proper controls for controlled substances and record keeping requirements. Specific sections referenced in the self assessment document include citations of the Business and Professions Code (B & P), California Code of Regulations (CCR), Health and Safety Code (H & S) and Code of Federal Regulations (CFR). Below is a brief description of the relevant sections of state and federal law referenced.

B & P 4160 details when a wholesaler license is required.

CCR 1780 defines the minimum standards for wholesalers

CCR 1781 defines the minimum standards for veterinary food-animal drug retailers.

B & P 4040.5 defines a "reverse distributor."

B & P 4181 discusses the licensing requirements, policies and procedures and who may dispense.

B & P 4331 details unlicensed activity and determines is to be misdemeanor.

B & P 4101 details the notification requirements for a designated representative in charge who terminates his or her employment at a licensed wholesaler.

B & P 4100 details the notification requirements for a designated representative who changes his or her name or address.

CCR 1704 details the reporting requires for licensees to notify the board of any change in address.

B & P 4163 prohibits the sale of drugs to unauthorized persons and the duty of the wholesaler to determine appropriate licensure prior to the sale of drugs.

B & P 4169 details the prohibitions for a wholesaler to sell to unlicensed entities.

B & P 4081 details the requirements for record keeping.

B & P 4332 makes it a misdemeanor for anyone who fails to maintain records as defined in pharmacy law.

B & P 4059.5(a) details who may order dangerous drugs and devices.

B & P 4167 prohibits the acquisition of drug product by a wholesaler that it cannot properly maintain and secure.

B & P 4342 authorizes the board to take action to prevent the sale of drugs under defined conditions.

CCR 1718 discusses the mandatory inclusion of the manufacturer's date on prescription drugs.

CFR 1307.21 details the procedure for disposing of controlled substances.

B & P 4163 details unauthorized furnishing by a manufacturer or wholesaler

B & P 4126.5 discusses furnishing dangerous drugs by a pharmacy.

H & S 111250 defines a drug or device that is adulterated.

H & S 111335 defines a drug or device that is misbranded.

B & P 4059.5 details the conditions under which dangerous drugs and devices may be ordered by a licensed entity.

B & P 4380 describes the prohibitions of the resale of preferentially priced drugs.

B & P 4341 discusses the advertisement of prescription drugs and devices.

B & P 651 details the professional advertising requirements.

CCR 1766 prohibits false or misleading advertising as described in Section 17500 of the B & P.

B & P 650 discusses the prohibition of rebates or discounts for referrals.

B & P 4066 details the procedures for a wholesaler to provide dangerous drugs to the master or first officer of an ocean vessel.

CFR 1301.25 discusses the registration regarding ocean vessels, aircraft and other entities.

B & P 4166 discusses the shipping of dangerous drugs and devices by a wholesaler or manufacturer.

CFR 1301.71 discusses general security requirements to ensure effective controls and procedures to guard against theft and diversion of controlled substances.

CFR 1301.72 (a) details the physical security controls for non-practitioners; narcotics treatment programs and compounders for narcotic treatment programs.

CFR 1304.11 details the inventory requirements.

CFR 1305.07 discusses the applicability of "power of attorney."

CFR 1301.90 discusses the employee screen procedures.

CFR 1301.92 discusses the employer's duties to address illicit activities by employees.

H & S 11153.5 prohibits the furnishing of controlled substances for anything other than a legitimate medical purpose.

CFR 1301.74 details other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

CFR 1305.03 discusses the order form required for each distribution of a Schedule I or II controlled substances as well as the exceptions.

CFR 1305.06 details the procedures for executing order forms.

CFR 1305.09 details the procedures for filling order forms.

CFR 1305.11 described the proper handling of an order form that is unaccepted or defective.

CFR 1305.12 details the procedure for executing DEA Forms 222.

CFR 1305.13 details the procedure for filing DEA forms 222.

H & S 11252 details the preservation of federally required forms.

H & S 11253 details the duration of retention of records.

CFR 1304.03 describes the requirements for persons required to keep records and file reports.

CFR 1304.04 details the maintenance and records of inventories.

CFR 1301.75 describes the physical security controls for practitioners.

CFR 1305.16 defines the procedures to address a lost or stolen DEA Form 222.

B & P 4054 allows a wholesaler to provide certain dialysis drugs and devices.

B & P 4059 prohibits the furnishing of dangerous drugs and devices without a prescription and details exceptions to this prohibition.

CCR 1787 discusses the authorization to distribute dialysis drugs and devices.

CCR 1790 details the information that must be maintained for shipment or expanded invoices and the duration of time the records must be kept for home dialysis drugs and devices.

CCR 1791 details the labeling requirements for home dialysis drugs and devices

B & P 4105 details the storage and retention of records for the acquisition and disposition of drugs.

CCR 1707 allows for the off-site storage of pharmacy records under certain conditions.

B & P 4162 details the surety bond requirement for wholesalers.

B & P 4083 discusses "orders of corrections."

B & P 4315 discusses "letters of admonishment."

B & P 4305.5 specifies the reporting requirements for the wholesaler when a change in designated representatives in charge occurs and that failure to notify appropriate can result in disciplinary action.

CCR 1715.6 details the reporting requirements for drug loss.

CFR 1301.91 details an employee responsibility to report drug diversion.

B & P 4201 details application requirements and notification requirements for a change of ownership.

B & P 4164 details reports required for controlled substances.

CCR 1705 details the reporting requirements for notification of bankruptcy, receivership or liquidation of licensed premises.

CCR 1708.2 details the reporting requirements for any licensee that is discontinuing business.

CFR 1301.52 details the termination of a registration issued and the conditions under which a transfer may occur upon a discontinuance of business.

CFR 1305.14 describes the requirement to return unused order forms.

B & P 4107 details the limitation on the number of licenses per site.

The board desires to provide all parties who must complete the self-assessment with a document that is straightforward and accurately represents the information they need to comply with California and federal requires for the practice of pharmacy.

Underlying Data

Business and Profession Code
California Code of Regulations
California Health and Safety Codes
Code of Federal Regulations

Business Impact

This regulation will not have a significant adverse economic impact on businesses.

This action would provide a DRC with the specific compliance information that the board seeks when conducting a wholesaler inspection. The requirements for conducting a wholesaler outlined in the self-assessment are not new requirements and wholesalers are already required to comply with them.

Using this form would benefit public safety.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.