



Healthcare Distribution Alliance

PATIENTS MOVE US.

AGENDA ITEM VI(F)

July 22, 2017

Virginia Herold, Executive Director
California State Board of Pharmacy
1625 North Market Blvd., Ste N219
Sacramento, CA 95834

RE: Healthcare Distribution Alliance (HDA) Comments on proposed regulations requiring wholesalers reporting of suspicious orders.

Dear Ms. Herold:

The Healthcare Distribution Alliance (HDA) and our primary wholesale distributor members are pleased to provide the following comments on the proposed regulations addressing suspicious order reporting in California. We appreciate the California Board of Pharmacy's desire to work collaboratively with the wholesale distributor industry to address this important issue, and hope our comments are used to help the Board achieve its goals in the most effective manner possible. HDA and our members are committed to working closely with all regulatory and enforcement entities to address the prescription drug abuse epidemic impacting our nation and to serving as a resource to the Board of Pharmacy.

Primary pharmaceutical wholesale distributors are the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDA member companies work around the clock to ensure that 15 million prescription medicines and healthcare products are delivered safely and efficiently to more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and other settings of care nationwide. The most important goal for all HDA members is to provide medication delivery in the most safe, secure and efficient manner possible.

The prescription drug abuse and diversion epidemic is a serious healthcare challenge that threatens both patient safety and the security of the healthcare supply chain. The manner in which primary wholesale distributors analyze customer orders for suspicious activity has evolved significantly in recent years. Today, the pharmaceutical wholesale industry supports and employs a multilayered approach to help combat the epidemic including employing sophisticated automated analytical systems to monitor customer orders for any "suspicious order" activity. This information is mandated to be provided regularly to federal enforcement entities.

HDA offers the following recommended changes to the Board of Pharmacy's proposal, which we believe will assist the Board in achieving their objective of implementing an effective suspicious order reporting system. Additionally, we emphasize that the following comments repeat the views of the wholesale distribution industry as a whole.

Upon discovery, A wholesale distributor must notify the board in writing by letter, email or fax of suspicious orders of controlled substances to be distributed in California upon

discovery by providing a copy of the information which the wholesale drug distributor provides to the U.S. Drug Enforcement Administration regarding such suspicious orders. Suspicious orders include, but are not limited to orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

HDA members understand the goal of the Board of Pharmacy is to be informed of when a wholesale distributor identifies a “suspicious order.” Suspicious orders are defined as “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” Wholesale distributors are required to regularly submit suspicious order reports to the DEA and understand the interest for state Boards of Pharmacy to request the same information on state activity. HDA and our member companies are agreeable to providing the same suspicious order reports in the same format and frequency to the California Board of Pharmacy.

HDA offers these comments to summarize the wholesale distribution industry’s position and provide regarding recommendations to the California Board of Pharmacy’s proposed regulations. HDA is committed to working with the California Board of Pharmacy to reach an agreeable solution that achieves the Board’s goals.

Sincerely,

A handwritten signature in black ink that reads "Leah D. Lindahl". The signature is written in a cursive, flowing style.

Leah Lindahl
Senior Director, Western Region, State Government Affairs