



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Discussion and Consideration of AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program

Background:

Originally, AB 1069 would have expanded the provisions under which a county-established repository and distribution program allows the transfer of drugs to other counties (not just adjacent counties) and would allow for the advance repackaging of donated medications in advance of a prescription. However, at the July 2016 Board Meeting, the board was advised that AB 1069 was being amended to significantly change the legislation to allow repackaging of medications in advance of the patient presenting at the pharmacy if it is a pharmacy within the county that specifically only deals with these types of medication serving this specific population.

At the time of the July Board Meeting, the amended language was not available and therefore the board did not change its Oppose Unless Amended position.

Recent Update

The measure has been amended twice since the July Board Meeting. In its current form the bill will allow a pharmacy that solely operates a redistribution program to repackage a reasonable quality of donated medication in advance of a prescription. The pharmacy must have policies and procedures in place for identifying and recalling medications and the medication label must include the earliest expiration date.

As established by board policy, staff worked with the Board's president and Chair of the Legislation and Regulation Committee to discuss the amendments and determine what if any changes should be made to the board's position on the measure. As part of the discussion, it was determined that the bill now encourages the use of a pharmacy to operate the redistribution program which provides better safeguards for patients. As such, the position on this measure was changed to support.

The bill was enrolled on August 23, 2016 and is currently awaiting action by the governor.

At this Meeting

The board will have the opportunity to discuss the amendments to AB 1069, and ratify the position taken by the Board President and Chair of the Legislation and Regulation Committee.

Following this memo is a copy of the measure as it will amend the law as well as the support letter that was provided to the author's office has been attached immediately following this memo.



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August 15, 2016

The Honorable Richard Gordon
California State Assembly
State Capitol, Room 3013
Sacramento, CA 95814

RE: Assembly Bill 1069 (As proposed to be amended) – Support

Dear Assembly Member Gordon:

I am pleased to advise you that the Board of Pharmacy will change its position on the above measure to one of support as it relates to the repackaging and redistribution by a pharmacy of donated medicines to indigent patients under specific conditions. The change in the board's position is based on the August 1, 2016 version of the measure as well as the understanding of one additional minor but significant amendment that is forthcoming.

The board is grateful for your work and the work of your staff to address board concerns. The board believes that a dedicated pharmacy model within a county to facilitate the redistribution of donated medications to indigent patients provides important safeguards to such patients.

You are welcome to contact Anne Sodergren at (916) 574-7910 if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Virginia Herold".

VIRGINIA HEROLD
Executive Officer

cc: Department of Consumer Affairs
Senate Business, Professions and Economic Development Committee

SECTION 1. Section 150204 of the Health and Safety Code is amended to read:

150204. (a) (1) A county may establish, by an action of the county board of supervisors or by an action of the public health officer of the county, as directed by the county board of supervisors, a repository and distribution program for purposes of this division. The county shall advise the California State Board of Pharmacy within 30 days from the date it establishes a repository and distribution program.

(2) Only an eligible entity, pursuant to ~~subdivision (a) of~~ Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department and the California State Board of Pharmacy in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4) (A) A participating entity shall disclose to the county health department on a quarterly basis the name and location of the source of all donated medication it receives.

(B) A participating primary care clinic, as described in ~~paragraph (3) of subdivision (a) of Section 150201~~ [Section 150201](#), shall disclose to the county health department the name of the licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division. This physician shall be the professional director, as defined in subdivision (c) of Section 4182 of the Business and Professions Code.

(C) The county board of supervisors or public health officer of the county shall, upon request, make available to the California State Board of Pharmacy the information in this division.

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. If the county board of supervisors, the public health officer of the county, or the California State Board of Pharmacy prohibits an eligible or participating entity from participating in the program, it shall provide written notice to the prohibited entity within 15 days of making this determination. The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy shall ensure that this notice also is provided to one another.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish written procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a participating entity.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a health or care facility, as described in Section 150202, shall have been

under the control of a staff member of the health or care facility who is licensed in California as a health care professional or has completed, at a minimum, the training requirements specified in Section 1569.69.

(d) (1) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program, and once identified, shall be quarantined immediately and handled and disposed of in accordance with the Medical Waste Management Act (Part 14 (commencing with Section 117600) of Division 104).

(2) (A) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code shall not be donated if this inventory transfer is prohibited by that strategy, or if the inventory transfer requires prior authorization from the manufacturer of the medication.

(B) A medication that is the subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code, the donation of which is not prohibited pursuant to subparagraph (A), shall be managed and dispensed according to the requirements of that strategy.

(e) A pharmacist or physician at a participating entity shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist or physician shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor or licensed waste hauler.

(4) (A) Transferred to another participating entity within the county to be dispensed to eligible patients pursuant to this division. Notwithstanding this paragraph, a participating county-owned pharmacy may transfer eligible donated medication to a participating county-owned pharmacy within another adjacent county that has adopted a program pursuant to this division, if the pharmacies transferring the medication have a written agreement between the entities that outlines protocols and procedures for safe and appropriate drug transfer that are consistent with this division.

(B) Medication donated under this division shall not be transferred by any participating entity more than once, and after it has been transferred, shall be dispensed to an eligible patient, destroyed, or returned to a reverse distributor or licensed waste hauler.

(C) Medication transferred pursuant to this paragraph shall be transferred with documentation that identifies the drug name, strength, and quantity of the medication, and the donation facility from where the medication originated shall be identified on medication packaging or in accompanying documentation. The document shall include a statement that the medication may not be transferred to another participating entity and must be handled pursuant to subparagraph (B). A copy of this document shall be kept by the participating entity transferring the medication and the participating entity receiving the medication.

(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed or transferred under this program and shall be either destroyed or returned to a reverse distributor. ~~This medication-~~ *Donated medication that does not meet the requirements of this division* shall not be sold, dispensed, or otherwise transferred to any other entity.

(i) *Medication (1) Except as provided in paragraph (2), medication* donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the

privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.

(2) A pharmacy that exists solely to operate the repository and distribution program may repackage a reasonable quantity of donated medicine in anticipation of dispensing the medicine to its patient population. The pharmacy shall have repackaging policies and procedures in place for identifying and recalling medications. Medication that is repackaged shall be labeled with the earliest expiration date.

(j) Medication donated to the repository and distribution program shall be segregated from the participating entity's other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.

(k) A participating entity shall keep complete records of the acquisition and disposition of medication donated to, and transferred, dispensed, and destroyed under, the repository and distribution program. These records shall be kept separate from the participating entity's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

(l) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, shall include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating entity shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.