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STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY FOR

6 CCR 1011-1, Standards for Hospitals and Health Facilities

Chapter II - General Licensure Standards

Donation of Unused Medications, Medical Devices, Medical Supplies

December 22, 2010

Basis and Purpose

- The proposed regulations amend existing rule in response to the enactment of Senate Bill 10-115, which broadened the existing authority of health care entities to accept donations of unused medications by patients, residents or their next of kin. As amended, the law authorizes additional types of facilities to accept donations, expands what can be donated, and allows facilities to transfer donated items not only to pharmacists, but also to nonprofit relief agencies. The provisions of the previous and the amended law are set forth below.

	Previous Law (Prior to SB 115)	Current Law (As Amended by SB 10-115)
Facilities authorized to accept donations:	<ul style="list-style-type: none"> ▪ Assisted living residences ▪ Hospices ▪ Hospitals ▪ Hospital units ▪ Nursing homes 	In addition to the 5 facilities previously authorized to accept donations, the new law also authorizes: <ul style="list-style-type: none"> ▪ Acute treatment units ▪ Community mental health centers ▪ Community residential homes for persons with developmental disabilities ▪ Intermediate care facilities for persons with developmental disabilities
What can be donated:	<ul style="list-style-type: none"> ▪ Medications (specifically medications issued pursuant to an order) 	<ul style="list-style-type: none"> ▪ Medications (specifically medications issued pursuant to an order) ▪ Medical devices ▪ Medical supplies
Facilities may transfer the donated items to a:	<ul style="list-style-type: none"> ▪ Pharmacist within the facility 	<ul style="list-style-type: none"> ▪ Pharmacist within the facility or a drug outlet ▪ Person legally authorized to dispense medications on behalf of a nonprofit entity
The pharmacist is authorized to do the following with the donated item:	<ul style="list-style-type: none"> ▪ Redisperse it to a patient/resident in the licensed facility where the donation occurred ▪ Donate it to a nonprofit entity with the legal authority to possess the medication 	<ul style="list-style-type: none"> ▪ Redisperse it to another patient/resident ▪ Donate it to a nonprofit entity that has legal authority to possess the medication ▪ Donate it to a practitioner authorized by law to prescribe medications

Specific Statutory Authority

These rules are promulgated pursuant to Sections 25-1.5-103 and 25-3-105, C.R.S.

Major Factual and Policy Issues Encountered

- Objectives of the Proposed Regulation. The objectives of the proposed regulations are:
- ensuring that items which are the property of the patient, resident or next of kin are accepted by the health care entity through a donation process.

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- safeguarding the medical efficacy of donated items in the custody of the health care entity.
- requiring health care entities to manage the donation process effectively, e.g., by not commingling donated and non-donated items, preventing the diversion of donated items, and tracking the transfer of donated items from the health care entity to pharmacists and relief agencies.

➤ Transferring Donated Items to Pharmacists. The statute authorizes health care entities to transfer donated items to pharmacists within the licensed facility or in a prescription drug outlet.

- The Board of Pharmacy (BOP) promulgated regulations specific to pharmacists accepting donated medications in response to Senate Bill 10-115 (see 3 CCR 719-1, Section 3.00.80 Return of Exchange of Drugs, Prescriptions, Medical Devices, and Medical Supplies for Dispensing or Donation).
- The proposed language regarding what medications are acceptable and not acceptable incorporate statutory and BOP regulatory provisions. The tables below indicate the areas of overlap.

Medications: What is Acceptable for Donation

Proposed Regulation (6 CCR 1011- 1, Chap II, Section 7.203 (3))	State Statute (Section 12-22-133 (2)(b), C.R.S.)	BOP regulation (3 CCR 7.19-1, Section 3.00.84 (b), unless otherwise specified)
Drugs are acceptable for donation if:		
- liquid and the vial is still sealed and properly stored	- same as proposed regulation	- same as proposed regulation
- individually packaged and packaging has not been damaged	- same as proposed regulation	- same as proposed regulation
- in the original, unopened, sealed, and tamper-evident unit dose packaging	- same as proposed regulation	- same as proposed regulation
- labeled to include the name and strength of the medication, expiration date, manufacturer or distribution and lot number	- not addressed	- same as proposed regulation as well additional requirements (see 3.00.84 (c)(4))

Medications: What is Not Acceptable for Donation

Proposed Regulation (6 CCR 1011- 1, Chap II, Section 7.203 (4))	State Statute (Section 12-22-133 (2)(c), C.R.S.)	BOP regulation (3 CCR 7.19-1, Section 3.00.84 (c)
Drugs are <u>not</u> acceptable if they:		
- are dispensed in traditional brown or amber pill bottles	- same as proposed regulation	- are packaged in traditional dispensing system (different terminology for similar concept)
- are controlled substances	- same as proposed regulation	- are controlled substances under either state or federal law
- require refrigeration, freezing or special storage	- same as proposed regulation	- same as proposed regulation
- are adulterated or misbranded, as determined by <i>the health care entity</i>	- are adulterated or misbranded, as determined by <i>the person legally authorized to dispense the medication on behalf of the nonprofit entity</i>	- are adulterated or misbranded as determined by <i>the pharmacist</i>
- are dispensed in a customized patient medication package.	- not addressed	- same as proposed regulation
- are compounded drugs.	- not addressed	- same as proposed regulation

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– are packaged by a pharmacist as split tablets or capsules ¹	– not addressed	– not addressed
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- BOP regulations require that the donated item was properly stored prior to the return or donation to the pharmacist, including storage at the facility and shipment to and from the facility. As such, pharmacists will not accept donated items from health care entities unless they can be assured that the donated item was handled in such a way as to ensure that its medical efficacy was retained.

➤ Transferring Donated Items to Relief Agencies. The statute also authorizes the transfer of donated items to relief agencies that help people who have suffered from natural or man-made disasters (such as the earthquake victims in Haiti). Supplying persons in need with drugs that would otherwise go to waste has great emotional appeal. However, the World Health Organization (WHO), in guidelines for donations developed in conjunction with 14 other international charitable organizations,² cautions against *inappropriate* drug donations. Inappropriate donations can create extra workload in sorting, storage and distribution and can overstretch the capacity of human resources of the recipient country. Some of the concerns specified in the WHO guidelines include:

- donated drugs are often not relevant to the emergency situation.
- some donations reflect a double standard in that the quality of drugs do not comply with the quality control standards of the donor country (e.g., donated drugs should not have expired).
- many donated drugs arrive unsorted and labeled in a language which is not easily understood.
- drugs may be donated in wrong quantities and some stock may have to be destroyed, which creates problems of disposal (as hazardous waste) for the recipient country.

¹ This provision was adopted in response to stakeholder comment.

² World Health Organization, Caritas Internationalis et al. *Guidelines for Drug Donations*. Revised 1999, pp 3-4.