

**Proposed Regulation:**  
**DONATION OF UNUSED MEDICATION, MEDICAL DEVICES AND MEDICAL SUPPLIES**

*The language proposed below would be added to 6 CCR 1011-1, Chapter II - General Licensure Standards as Part 7.200 - Donation of Unused Medication, Medical Devices and Medical Supplies*

7.200 DONATION OF UNUSED MEDICATIONS, MEDICAL DEVICES AND MEDICAL SUPPLIES

7.201 STATUTORY AUTHORITY AND APPLICABILITY

(1) AUTHORITY TO ESTABLISH MINIMUM STANDARDS THROUGH REGULATION AND TO ADMINISTER AND ENFORCE SUCH REGULATIONS IS PROVIDED BY SECTIONS 25-1.5-103 AND 25-3-101, C.R.S., ET SEQ.

(2) APPLICABILITY

(a) THIS PART 7.200 APPLIES TO MEDICATIONS, MEDICAL DEVICES AND MEDICAL SUPPLIES DONATED BY THE PATIENT, RESIDENT OR HIS OR HER NEXT OF KIN TO THE FOLLOWING HEALTH CARE ENTITIES: ACUTE TREATMENT UNITS, ASSISTED LIVING RESIDENCES, COMMUNITY MENTAL HEALTH CENTERS, COMMUNITY RESIDENTIAL HOMES FOR PERSONS WITH DEVELOPMENTAL DISABILITIES, INTERMEDIATE CARE FACILITIES FOR THE DEVELOPMENTALLY DISABLED, HOSPICES, HOSPITALS (INCLUDING GENERAL HOSPITALS, PSYCHIATRIC HOSPITALS, MATERNITY HOSPITALS AND REHABILITATION CENTERS), HOSPITAL UNITS AND LONG TERM CARE FACILITIES.

(b) NOTWITHSTANDING SECTION 7.201 (2)(a), THIS PART 7.200 DOES NOT APPLY TO ITEMS DONATED:

(i) BY THE PATIENT, RESIDENT, OR HIS OR HER NEXT OF KIN DIRECTLY TO A PHARMACIST EMPLOYED OR CONTRACTED BY THE HEALTH CARE ENTITY SUBJECT TO 3 CCR 719-1, SECTION 3.00.80. *{Explanatory note: the Board of Pharmacy has established regulations regarding the donation of unused medications, medical devices and medical supplies that cover pharmacists, pharmacies, and other outlets registered with the Colorado Board of Pharmacy.}*

(ii) THE CANCER DRUG REPOSITORY PROGRAM ESTABLISHED PURSUANT TO SECTION 25-35-101, ET SEQ. C.R.S AND 6 CCR 1015-10. *{Explanatory note: the donation of cancer drugs and medical devices to the repository program is governed by statute and regulations that address issues such as procedures for dispensing and eligibility criteria.}*

7.202 DEFINITIONS

(1) "CUSTOMIZED PATIENT MEDICATION PACKAGE" MEANS A PACKAGE PREPARED AND DISPENSED BY A PHARMACIST THAT CONTAINS TWO OR MORE DIFFERENT DRUGS.

*Amendments are shown in SMALL CAPS and striketype. The explanatory notes would not become part of the regulatory language.*

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(2) "DONOR" MEANS A PATIENT, RESIDENT OR A PATIENT'S OR RESIDENT'S NEXT OF KIN WHO DONATES UNUSED MEDICATIONS, MEDICAL DEVICES OR MEDICAL SUPPLIES.

(3) "HEALTH CARE ENTITY" MEANS A LICENSED ACUTE TREATMENT UNIT, ASSISTED LIVING RESIDENCE, COMMUNITY MENTAL HEALTH CENTER, COMMUNITY RESIDENTIAL HOME FOR THE DEVELOPMENTALLY DISABLED, INTERMEDIATE CARE FACILITIES FOR THE DEVELOPMENTALLY DISABLED, HOSPICE, HOSPITAL (INCLUDING A GENERAL HOSPITAL, MATERNITY HOSPITAL, PSYCHIATRIC HOSPITAL, OR REHABILITATION CENTER), HOSPITAL UNIT OR LONG TERM CARE FACILITY.

(4) "MEDICATION" MEANS A DRUG DISPENSED PURSUANT TO AN ORDER TO A PATIENT OR RESIDENT OF THE HEALTH CARE ENTITY.

(5) "MEDICAL DEVICE" MEANS AN INSTRUMENT, APPARATUS, IMPLEMENT, MACHINE, CONTRIVANCE, IMPLANT, OR SIMILARLY RELATED ARTICLE THAT IS REQUIRED TO BE LABELED PURSUANT TO 21 CFR PART 801.

(6) "MEDICAL SUPPLY" MEANS A CONSUMABLE SUPPLY ITEM THAT IS DISPOSABLE AND NOT INTENDED FOR REUSE.

(7) "PERSON LEGALLY AUTHORIZED TO DISPENSE MEDICATIONS" MEANS, IN ACCORDANCE WITH SECTION 12-22-121 (6)(a), C.R.S., A PHARMACIST OR A PRACTITIONER AUTHORIZED TO PRESCRIBE MEDICATIONS.

(8) "PHARMACIST" MEANS A PHARMACIST LICENSED IN THE STATE OF COLORADO.

(9) "RELIEF AGENCY" MEANS A NONPROFIT ENTITY THAT HAS THE EXPRESS PURPOSE OF PROVIDING MEDICATIONS, MEDICAL DEVICES, OR MEDICAL SUPPLIES FOR RELIEF VICTIMS WHO ARE IN URGENT NEED AS A RESULT OF NATURAL OR OTHER TYPES OF DISASTERS.

(10) "UNUSED ITEM" MEANS UNUSED MEDICATION, MEDICAL DEVICE OR MEDICAL SUPPLY.

**7.203 ACCEPTING UNUSED ITEMS FROM DONORS**

(1) PRIOR TO ACCEPTING UNUSED ITEMS, THE HEALTH CARE ENTITY SHALL HAVE DOCUMENTED EVIDENCE THAT THE PATIENT, RESIDENT OR HIS OR HER NEXT OF KIN CONSENTED TO THE DONATION OF THE ITEMS. THE HEALTH CARE ENTITY SHALL MAINTAIN SUCH DOCUMENTATION FOR TWO YEARS AFTER THE UNUSED ITEM WAS DONATED.

***{Explanatory note: One way facilities can implement this is by having patients/residents sign a consent form upon admission or other occasion seeking ongoing consent for donations.}***

(2) ITEMS ELIGIBLE FOR DONATION. AS APPLICABLE, A HEALTH CARE ENTITY SHALL ONLY ACCEPT UNUSED ITEMS THAT MEET THE FOLLOWING CRITERIA:

(a) ITEMS INTENDED FOR USE WITHIN THE HEALTH CARE ENTITY BY THE PATIENT OR RESIDENT.

(b) MEDICATIONS PACKAGED AS FOLLOWS:

(i) IF LIQUID, THE VIAL MUST BE SEALED AND PROPERLY STORED.

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- 1 (ii) INDIVIDUALLY PACKAGED AND THE PACKAGING HAS NOT BEEN DAMAGED.  
2  
3 (iii) IN THE ORIGINAL, UNOPENED, SEALED AND TAMPER-EVIDENT UNIT DOSE PACKAGING.  
4  
5 (iv) WITH LABELLING THAT IDENTIFIES: NAME AND STRENGTH OF THE MEDICATION, AND IN THE  
6 CASE OF A SINGLE DOSE PACKAGE, THE TOTAL NUMBER OF INDIVIDUAL TABLETS OR CAPSULES  
7 PER DOSE; THE MEDICATION'S EXPIRATION DATE; THE IDENTITY OF THE MANUFACTURER OR  
8 DISTRIBUTOR; AND THE MANUFACTURER'S OR DISTRIBUTOR'S LOT NUMBER.  
9  
10 (c) SINGLE USE DISPOSABLE DEVICES PACKAGED IN THE MANUFACTURER'S ORIGINAL SEALED PACKAGING.  
11  
12 (d) ITEMS WITH AN EXPIRATION DATE AT LEAST SIX MONTHS OR MORE FROM THE DATE OF THE DONATION.  
13  
14 (3) ITEMS NOT ELIGIBLE FOR DONATION. A HEALTH CARE ENTITY SHALL NOT ACCEPT MEDICATIONS THAT:  
15  
16 (a) WERE DISPENSED IN A TRADITIONAL BROWN OR AMBER PILL BOTTLES.  
17  
18 (b) ARE CONTROLLED SUBSTANCES.  
19  
20 (c) REQUIRE REFRIGERATION, FREEZING, OR SPECIAL STORAGE.  
21  
22 (d) REQUIRE SPECIAL REGISTRATION WITH THE MANUFACTURER.  
23  
24 (e) ARE ADULTERATED OR MISBRANDED, AS DETERMINED BY THE HEALTH CARE ENTITY.  
25  
26 (f) ARE DISPENSED IN A CUSTOMIZED PATIENT MEDICATION PACKAGE.  
27  
28 (g) ARE COMPOUNDED DRUGS.  
29  
30 (h) ARE PACKAGED BY A PHARMACIST AS SPLIT TABLETS OR CAPSULES.  
31  
32 (4) POLICIES AND PROCEDURES. HEALTH CARE ENTITIES THAT ACCEPT UNUSED ITEMS SHALL DEVELOP AND  
33 IMPLEMENT POLICIES AND PROCEDURES REGARDING:  
34  
35 (a) STORAGE. UNUSED ITEMS SHALL BE STORED:  
36  
37 (i) IN A MANNER THAT RETAINS THE ITEMS' MEDICAL EFFICACY AS PROVIDED FOR BY STORAGE  
38 PROTOCOLS APPROVED BY A LICENSED PHARMACIST. ~~SUCH~~ PROTOCOLS SHALL BE REVIEWED  
39 AND APPROVED BY A LICENSED PHARMACIST AT LEAST EVERY THREE YEARS.  
40  
41 (ii) SEPARATELY FROM NON-DONATED UNUSED ITEMS.  
42  
43 (b) INVENTORY CONTROL. THE HEALTH CARE ENTITY SHALL:  
44  
45 (i) DEVELOP PROCESSES FOR THE PREVENTION AND DETECTION OF DIVERSION OF DONATED  
46 UNUSED ITEMS THAT MAY BE ILLEGALLY SOLD. WHEN DIVERSION IS DETECTED, PROMPT  
47 APPROPRIATE CORRECTIVE MEASURES SHALL BE IMPLEMENTED.

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(ii) ADEQUATELY DISPOSE OF UNUSED DONATED ITEMS NOT TRANSFERRED TO A PHARMACIST OR A RELIEF AGENCY.

(c) TRANSPORTING UNUSED ITEMS. IF THE HEALTH CARE ENTITY IS RESPONSIBLE FOR TRANSPORTING UNUSED ITEMS, IT SHALL DO SO IN A MANNER THAT RETAINS THE ITEM'S MEDICAL EFFICACY.

**7.204 TRANSFERRING UNUSED ITEMS FROM THE HEALTH CARE ENTITY**

1) IN ACCORDANCE WITH SECTION 12-22-133 (2), C.R.S., A HEALTH CARE ENTITY MAY:

(a) RETURN UNUSED ITEMS TO A LICENSED PHARMACIST WITHIN THE HEALTH CARE ENTITY OR A PRESCRIPTION DRUG OUTLET.

(b) DONATE UNUSED MEDICATIONS TO A PERSON LEGALLY AUTHORIZED TO DISPENSE THE MEDICATIONS ON BEHALF OF A RELIEF AGENCY.

(2) THE FACILITY SHALL MAINTAIN A RECORD, TO BE RETAINED FOR TWO YEARS AFTER THE UNUSED ITEM WAS TRANSFERRED FROM THE HEALTH CARE ENTITY, OF THE:

(a) NAME OF THE DONOR AND THE DATE THE UNUSED ITEM WAS DONATED TO THE HEALTH CARE ENTITY, AS APPLICABLE.

(b) NAME OR A BRIEF DESCRIPTION OF THE UNUSED ITEM.

(d) QUANTITY OF THE UNUSED ITEM.

(e) DATE THE UNUSED ITEM(S) WAS TRANSFERRED FROM THE HEALTH CARE ENTITY, TO WHOM IT WAS TRANSFERRED, AND SIGNED RECEIPT BY THE RECIPIENT.

(f) MANNER THAT IT TRANSPORTED THE UNUSED ITEM AND THAT SUCH TRANSPORTATION RETAINED THE ITEM'S MEDICAL EFFICACY, AS APPLICABLE.

(3) UPON TRANSFER FROM THE FACILITY, UNUSED ITEMS SHALL NOT INCLUDE IN THEIR LABELING ANY IDENTIFYING PATIENT OR RESIDENT INFORMATION.

**CONFORMING AMENDMENTS**

*In response to legislation enacted in 2006 regarding donated medications, regulations were promulgated for assisted living residences, hospices and nursing homes. Below are amendments to conform with the proposed changes to Chapter II.*

6 CCR 1011-1, CHAPTER VII - ASSISTED LIVING RESIDENCES

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104 (5)(n) ~~Accepting Donated Medications for Redispensing by a Pharmacist. A policy under this subsection (l) is required only if the facility accepts unused donated medications in accordance with state law, including section 12-22-133, C.R.S. (2005). The policy shall address at minimum the following:~~

~~(i) documented evidence that the resident or the resident's next of kin donated the medications;~~

~~(ii) the name(s) and contact information of the pharmacist(s) who have agreed to accept donated medications from the facility and the types of medication that such pharmacist(s) will accept;~~

~~(iii) inventory control, including but not limited to, documentation of the date the medication was donated, type and quantity of medication, and the date the pharmacist received the medication evidenced by signature of the pharmacist or his/her representative;~~

~~(iv) secure storage of the medication, including but not limited to ensuring that donated medications will not be intermingled with other medications, and prevention of diversion; and~~

~~(v) adequate disposal of donated medications either not accepted by the pharmacist or in the facility inventory for longer than 90 days after the date of the donation.~~

6 CCR 1011-1, CHAPTER XXI - HOSPICES

11.2.2 Medications shall be destroyed when:

- 1) the label is mutilated or indistinct.
- 2) the medication is beyond the expiration or shelf life date.
- 3) unused portions remain due to discontinuance, death, or discharge, EXCEPT FOR MEDICATIONS RETURNED TO A PHARMACIST OR TRANSFERRED TO A RELIEF AGENCY PURSUANT TO CHAPTER II, PART 7.200 DONATION OF UNUSED MEDICATIONS, MEDICAL DEVICES AND MEDICAL SUPPLIES. ~~Notwithstanding the provisions of this subsection 11.2.2 (3), in accordance with state law, including Section 12-22-133, C.R.S. (2005), the hospice may return unused medications to a pharmacist for redispensing if those medications were donated to the hospice by the patient or the patient's next of kin. For purposes of this paragraph, unused medications means prescription medications that are not controlled substances. If a hospice accepts donated medications for redispensing by a pharmacist it shall implement a written policy that addresses inventory control and prevents the diversion of such medications. [Eff. 07/30/2006]~~

6 CCR 1011-1, CHAPTER V - LONG TERM CARE

16.6 DISPOSITION OF MEDICATIONS

16.6.2 Except as provided ~~herein~~ UNDER 6 CCR 1011-1, CHAPTER II, PART 7.200 DONATION OF UNUSED MEDICATIONS, MEDICAL DEVICES, AND MEDICAL SUPPLIES, all prescriptions and other drugs (except controlled substances) remaining upon death or discharge shall be destroyed by the administrator, a registered nurse, and a pharmacist who shall record the quantity of the drugs

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1                    destroyed. In accordance with state law, including Section 12-22-133, C.R.S. (2005), the facility  
2                    may return unused medications to a pharmacist for redispensing if those medications were  
3                    donated to the facility by the resident or the resident's next of kin. For purposes of this  
4                    paragraph, unused medications means prescription medications that are not controlled  
5                    substances. If a facility accepts donated medications for redispensing by a pharmacist, it shall  
6                    implement a written policy that addresses inventory control and prevents the diversion of such  
7                    medications.

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