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7.200 DONATION OF UNUSED MEDICATIONS, MEDICAL DEVICES AND MEDICAL SUPPLIES

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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.

(2) APPLICABILITY

(a) This Subpart 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 Subpart 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.

(ii) the Cancer Drug Repository Program established pursuant to Section 25-35-101, et seq. C.R.S and 6 CCR 1015-10.

7.202 DEFINITIONS. For the purposes of this Subpart 7.200, the following definitions apply:

- (1) "Customized patient medication package" means a package prepared and dispensed by a pharmacist that contains two or more different drugs.
- (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 similar or 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 an 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.

(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.

(ii) individually packaged and the packaging has not been damaged.

(iii) in the original, unopened, sealed and tamper-evident unit dose packaging.

(iv) with labelling that identifies: name and strength of the medication, and in the case of a single dose package, the total number of individual tablets or capsules per dose; the medication's expiration date; the identity of the manufacturer or distributor; and the manufacturer's or distributor's lot number.

(c) single use disposable devices packaged in the manufacturer's original sealed packaging.

(d) medications with an expiration date at least six months or more from the date of the donation.

(3) Items Not Eligible for Donation. A health care entity shall not accept medications that:

(a) were dispensed in a traditional brown or amber pill bottles.

(b) are controlled substances.

(c) require refrigeration, freezing, or special storage.

(d) require special registration with the manufacturer.

(e) are adulterated or misbranded, as determined by the health care entity.

(f) are dispensed in a customized patient medication package.

(g) are compounded drugs.

(h) are packaged by a pharmacist as split tablets or capsules.

- (4) Policies and Procedures. Health care entities that accept unused items shall develop and implement policies and procedures regarding:
- (a) Storage. Unused items shall be stored:
 - (i) in a manner that retains the items' medical efficacy as provided for by storage protocols approved by a licensed pharmacist. Such protocols shall be reviewed and approved by a licensed pharmacist at least every three years.
 - (ii) separately from non-donated unused items.
 - (b) Inventory control. The health care entity shall:
 - (i) develop processes for the prevention and detection of diversion of donated unused items that may be illegally sold. When diversion is detected, prompt appropriate corrective measures shall be implemented.
 - (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) A health care entity may transfer unused items to pharmacists or nonprofit relief entities as authorized by Section 12-22-133 (2), C.R.S.
- (2) The health care entity 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.
 - (c) quantity of the unused item.
 - (d) date the unused item(s) was transferred from the health care entity, to whom it was transferred, and signed receipt by the recipient.
 - (e) manner that it transported the unused item and that such transportation retained the item's medical efficacy, as applicable.
- (3) Upon transfer from the health care entity, unused items shall not include in their labeling any identifying patient or resident information.

Part 8. PROTECTION OF PERSONS FROM INVOLUNTARY RESTRAINT

8.101 Statutory Authority and Applicability. This part is promulgated pursuant to Sections 26-20-106 and 26-20-108, C.R.S. This part applies to the use of involuntary restraint in all licensed health care facilities, except under the circumstances described:

- (1) for hospitals as provided for in Section 8.103 (l)(a); and