

MEDICATION DONATION PROGRAM

Chapter 2

Section 1. Authority.

This Chapter is promulgated by the Department of Health pursuant to the Drug Donation Program Act, Wyoming House of Representatives Bill No. 0194 to be codified as W. S. § 35-7-1601 et seq. and the Wyoming Administrative Procedures Act as W. S. § 16-3-101 et seq.

Section 2. Purpose and Applicability.

(a) It is the purpose of this program to develop and implement the voluntary Medication Donation Program consistent with public health and safety through which unused prescription medications other than scheduled and compounded drugs may be donated to Wyoming residents.

(b) The Department shall issue forms to interpret the provisions of this Chapter. Such forms shall be consistent with and reflect the policies contained in this Chapter. The forms shall be subordinate to the provisions of this Chapter.

(c) The Department shall issue Manuals, Bulletins, or both to interpret the provisions of this Chapter. Such Manuals and Bulletins shall be consistent with and reflect the policies contained in this Chapter. The provisions contained in Manuals or Bulletins shall be subordinate to the provisions of this Chapter

(d) The incorporations by reference of any external standard is intended to be the incorporation of that standard as it is in effect on the effective date of this chapter.

Section 3. Severability.

If any provision of these rules or the application thereof to any person, program, service, or circumstance is held invalid, the invalidity shall not affect other provisions or applications of these rules. To the extent that these rules can be given effect without the invalid provision; the provision of these rules are severable.

Section 4. General Provisions.

(a) This Chapter is intended to be read in conjunction with the Drug Donation Program Act, Wyoming House Bill No. 0194 to be codified as W. S. § 35-7-1601 et seq., and the Wyoming State Board of Pharmacy laws and regulations and all applicable federal rules and regulations.

(b) In accordance with Section 1 of 2005 Wyoming House Bill 0194, W.S. § 35-7-1601 et seq., nothing in this Chapter shall be construed as providing an individual with an entitlement to this program.

Section 5. Definitions.

The following definitions shall apply in the interpretation and enforcement of these rules. Where the context in which words are used in these rules indicates that such is the intent, words in the singular number shall include the plural and vice versa. Throughout these rules gender pronouns are used interchangeably except where the context dictates otherwise. The drafters have attempted to utilize each gender pronoun in equal numbers in random distribution. Words in each gender shall include individuals of the other gender.

(a) "Act." The Drug Donation Program Act, Wyoming House of Representatives Bill 0194 to be codified as W.S. § 35-7-1601.

(b) "Applicant." A pharmacy, hospital, physician's office, health care facility or charitable health clinic or non-profit clinic whose written application for the Medication Donation Program has been submitted to the Department of Health, but there has been no final determination of eligibility.

(c) "Audit." Refers to a review may be conducted periodically, after the effective date of eligibility.

(d) "Caregiver." Refers to a person, other than a natural parent or legal guardian, who is at least eighteen (18) years of age and is the primary physical custodian or relative.

(e) "Charitable Clinic." Refers to a charitable nonprofit corporation or a facility organized as a not-for-profit site where prescriptions are dispensed.

(f) "Controlled Substances." Refers to controlled substances defined by the Wyoming Controlled Substances Act, W. S. § 35-7-1001 et seq.

(g) "Department." Refers to the Wyoming Department of Health, its agent, designee, or successor.

(h) "Dispense." Refers to delivering a medication to an ultimate user pursuant to the lawful order of a practitioner, including the packaging, or labeling.

(i) "Donor." An individual who has voluntarily donated unused medications.

(j) "Donor Representative." An individual who represents the donor.

(i) May be a caregiver, relative or person who is otherwise authorized to represent donor.

(k) "Eligible." Refers to an applicant who meets the requirements to participate in the program.

(l) "Expiration Date." The date placed on the immediate container label of a medication that designates the date through which the product is expected to remain within specifications.

(m) "Health Care Facility." Refers to a long term care hospital, a mental health center, nursing facility, a pharmacy, a psychiatric or mental hospital, a public health facility, a rehabilitation hospital, a skilled nursing facility.

(n) "Hospital." Refers to a facility where diagnosis, treatment, medical care, nursing care, or related services are provided on an inpatient or outpatient basis for a period of more than twenty-four consecutive hours.

(i) Hospital includes a facility for long-term care hospital, a critical access hospital, or a psychiatric or mental hospital.

(o) "Identifying marks." Refers to any mark or label that will identify patient specific information.

(p) "Labeling." Includes all written, printed, or graphic matter on the container or package containing consumer commodity.

(q) "Lot Number." Refers to a distinctive combination of symbols, alphabet characters or numerals which identifies a medication that is intended to be uniform in character and quality, produced during the same cycle of manufacturing.

(r) "Medication." Refers to a medication or device which is prescribed to treat or prevent illness as defined in the U.S. Food, Drug and Cosmetic Act which is required under federal law to be dispensed with a medical practitioner's prescription.

(i) For purposes of this program it does not include controlled substances or compounded medications.

(s) "NDC." Refers to National Drug Code.

(i) Identifies the manufacturer or distributor, drug product, trade package size and type.

(t) "Over the Counter Medical Supplies." Refers to medication and supplies that do not require a medical practitioner's prescription.

(u) "Participating Donation Site." Refers to a physician's office, pharmacy, hospital, health care facility, or charitable health clinic that has voluntarily elected to accept and dispense donated medications.

(v) "Participating Donation Site Registry." Refers to a registry of Participating Donation Sites established and maintained by the Department of Health that includes the Participating Donation Site name, address, and telephone number, and identifies whether the Participating Donation Site is a physician's office, a pharmacy, a hospital, a health care facility or charitable health clinic.

(w) "Patient Counseling." Effective oral communication by the Participating Donation Site to provide information to the recipient or care giver in order to ensure proper use of the medication.

(x) "Pharmacy." Refers to a facility licensed by the Wyoming State Board of Pharmacy to operate as a retail or institutional pharmacy.

(y) "Physician." A person licensed to practice medicine or osteopathy by the Wyoming State Board of Medical Examiners.

(z) "Physician's office." Refers to the office of the person licensed to practice medicine.

(aa) "Prescribing practitioner." Refers to a health care practitioner who is authorized to prescribe medications.

(bb) "Prescription Medication." Refers to any medication required to be dispensed only by a prescription, by virtue of the Federal or State laws and regulations.

(cc) "Program." The Medication Donation Program established by the Department of Health.

(dd) "Recipient." Refers to an individual who receives donated medications.

(ee) "Relative or Related." Refers to the relationship of parent, stepparent, grandparent, great-grandparent, sibling, stepsibling, half sibling, uncle, aunt, or spouse connected with another by blood or affinity.

(ff) "Repackage." Refers to package medication in a new container.

(gg) "Resident." Refers to a person who resides in the State of Wyoming.

(hh) "Tamper Evident." Refers to a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal.

(ii) "Transfer." Refers to moving donated medication from one Participating Donation Site to another Participating Donation Site within the program.

(jj) "Unit-dose." Refers to a packaging system that contains individual sealed doses of a medication.

Section 6. Immunity.

(a) Any person or entity, which exercises reasonable care in donating, accepting, distributing, dispensing medications under the Drug Donation Program Act or rules and regulations adopted and promulgated under this act shall be immune from civil or criminal liability or professional disciplinary action of any kind for any related injury, death or loss.

(i) Immunity provided shall not decrease or increase the civil or criminal liability of a drug manufacturer, distributor or Participating Donation Site that would have existed but for the donation.

Section 7. Requirements for Participating Donation Sites.

(a) Must be a physician's office, pharmacy, hospital, health care facility, or charitable health clinic that has voluntarily elected to accept and dispense donated medications.

(b) To register as a Participating Donation Site notify the program manager in writing include name, street address, telephone number, e-mail (if available) and a statement indicating that the applicant meets the eligibility requirements.

(i) Contact information can be found on the Department of Health website.

(c) A Participating Donation Site may withdraw at any time upon written notification to the program manager.

(d) Participation in the program is voluntary.

(e) It is the responsibility of the Participating Donation Site to notify the program manager of any changes to name, address, telephone number, e-mail (if available) or Participating Donation Site type.

Section 8. Eligibility Requirements for Acceptable Donated Medications.

(a) Medications shall be accepted or dispensed if they are in their unopened, sealed packaging or, the contents are single unit doses, blister packs or bingo cards that are individually contained.

(b) The medication packaging must not have any physical signs of tampering.

(c) The medication may be accepted/dispensed if it bears an expiration date that is earlier than six months after the date the drug was donated.

(i) If Expiration date not listed on medication, 1 (one) year from original dispense date should be used.

(d) Controlled substances and compounded medications will not be accepted into the program.

(e) Medications that require storage temperatures other than normal room temperature as specified by the manufacturer shall not be donated or accepted because of the inability to guarantee proper storage.

Section 9. Standards and Procedures for Participating Donation Site.

(a) The Participating Donation Site shall be responsible to determine that the donated medication is safe and shows no sign of tampering; no medication shall be dispensed in which the integrity cannot be assured.

(b) The Participating Donation Site shall ensure donated medications are inventoried and kept separate from normal stock.

(c) Participating Donation Sites accepting the donated medication will place his/her initials on the label upon receipt.

(d) All marks identifying the original owner will be obliterated from the packaging.

(e) Donated medications may be transferred from one Participating Donation Site to another Participating Donation Site by a person authorized by the State Board of Pharmacy.

(f) Hard copies of all prescriptions dispensed must be maintained by the Participating Donation Site as required by the Pharmacy Act W. S. § 33-24-101 et seq.

(g) Donated non-controlled substances that are not suitable for dispensing shall be destroyed or returned to the original donor.

(i) Destruction shall be performed by a pharmacist.

(h) Controlled substances shall not be accepted for donation.

(i) If accepted in error, controlled substances shall be destroyed, or returned to original donor. Destruction must be witnessed by two individuals (at least one pharmacist) and documented.

(i) Dispense donated medications upon the valid prescription of a licensed health care practitioner.

(j) Participating Donation Sites shall comply with all aspects regarding recipient medication counseling.

(k) If a medication is recalled and the eligible Participating Donation Site does not have the lot number on the label to differentiate between the recall and non-recalled, all such donated medications shall be destroyed and documented using standard procedures.

(l) Participating Donation Site may remove medication from original container, and repackage for dispensing.

(m) Sample medications must remain in original package as required under federal law and shall not be removed from original packaging for dispensing. Retail pharmacies may not accept sample medications for this program.

Section 10. Eligibility Criteria for Donor.

(a) Any person or entity, including but not limited to private citizens, drug manufacturers, physicians, or health care facilities, may donate medications to the program.

(b) A person who was legally dispensed a prescription medication may elect to sign and date an ownership form prior to donating a medication, which shall state “from this day forward I wish to donate all my remaining unused medications to a Participating Donation Site”.

Section 11. Eligibility Criteria for Recipient.

- (a) Resident of Wyoming.
- (b) Has limited resources to purchase prescription medication, as determined by the Participating Donation Site.
- (c) Has a current prescribing physician/practitioner prescription.
- (d) Each recipient must sign a release form stating they understand the immunity provisions of the program and acknowledging that medication was originally dispensed to another patient and has been donated to the Medication donation program for re-dispensing.

Section 12. Record Keeping Requirements for Participating Donation Site.

(a) Participating Donation Site under this act shall keep records in conformance with the record keeping requirements of this program, and all applicable federal and state laws, rules and regulations, as required by the Pharmacy Act W.S. § 33-24-101 et seq.

- (b) The following information shall be documented for each medication.
 - (i) Brand name of medication or generic name.
 - (ii) Name of manufacturer or national drug code number (NDC#).
 - (iii) Quantity and strength of medication.
 - (iv) Lot number of medication. (If available)
 - (v) Expiration date of medication.
 - (vi) Date medication donated and/or dispensed.
 - (vii) Name of donor or donor representative and/or recipient.
 - (viii) Prescribing physician/practitioner prescription.
- (c) A copy of the Donor and Recipient forms must be maintained for two (2) years.

(d) Transfer medication forms, from one Participating Donation Site to another Participating Donation Site, must be maintained by the participants for two (2) years.

(i) A copy of the form will be prepared by the transferring Participating Donation Site and maintained by the receiving Participating Donation Site.

(e) Destruction Form shall be kept of unused medications that are expired, adulterated and/or recalled for two (2) years.

Section 13. Forms.

(a) Forms will be provided by the Department of Health.

(b) Participating Donation Sites may use their own forms, provided they include all information listed in Section 12.

(c) Donor Form shall include the following information.

(i) Participating Donation Site name, address, telephone number, and signature of dispensing participant.

(ii) Medication name, strength, quantity, expiration date, NDC number, and prescribing practitioner name.

(iii) Donor name and signature, or donor representative name and signature.

(iv) Donor release for future medications.

(d) Recipient Form shall include the following information.

(i) Participating Donation Site name, address, telephone number, and signature of participating donation site representative.

(ii) Medication name, strength, quantity, expiration date, NDC number, and prescribing practitioner name.

(iii) Recipient name and signature, or donor representative name and signature, and address.

(iv) Acknowledgement and immunity acceptance.

(v) Handling fee charged, if any.

(e) Transfer Form shall include the following information.

(i) Transferring Participating Donation Site Name, address, telephone number, signature of participating site representative and date.

(ii) Medication name, strength, quantity, expiration date, NDC number, and manufacturer.

(iii) Receiving Participating Donation Site Name, address, telephone number, signature of receiving participating site representative and date.

(f) Destruction Form shall include the following information.

(i) Participating Donation Site Name, address, telephone number and signature of participating site representative.

(ii) Medication name, strength, quantity, expiration date, NDC number, and manufacturer.

(iii) Reason for destruction of medication.

(iv) Participating Site Representative signature, signature of witness and date.

Section 14. Handling Fee.

(a) Handling fee may be charged to the recipient to whom the medication is dispensed. The handling fee must not exceed \$10 (ten dollars) per medication to cover dispensing or distributing costs.

(b) Donated medications and supplies may not be sold.

Section 15. Labeling.

(a) All previous patient or pharmacy labeling on unused medication will be redacted or removed by the Participating Donation Site.

(b) New prescriptions shall be labeled according to Chapter 2, Section 11, Wyoming Pharmacy Act Rules and Regulations.

Section 16. Over the Counter Medical Supplies.

(a) Over the Counter medications and supplies including but not limited to, bandages, drainage bags, and syringes are not subject to the provisions of this Chapter. Accepting such items is at the discretion of the individual Participating Donation Site.

Section 17. Participating Donation Sites Registry.

(a) The Department of Health shall establish and maintain a Participating Donation Site Registry for the program. The Participating Donation Site registry shall include the Participating Donation Site name, address, telephone number, and shall identify whether the Participating Donation Site is a physician's office, a pharmacy, a hospital, a health care facility or charitable health clinic.