

## **CHAPTER 43-15.2**

### **LEGEND DRUG DONATION AND REPOSITORY PROGRAM**

**43-15.2-01. Definitions.** In addition to the definitions under section 43-15-01, in this chapter unless the context otherwise requires:

1. "Donor" means a person that donates to the program legend drugs, devices, or supplies needed to administer such drugs.
2. "Participant" means a practitioner or pharmacy that has elected to participate in the program and accepts legend drugs, devices, and supplies from donors for the program.
3. "Program" means the legend drug donation and repository program established under this chapter.
4. "Supplies" means any supplies used in the administration of a legend drug.

#### **43-15.2-02. Administration.**

1. The state board of pharmacy shall establish and contract with a third party to administer a legend drug donation and repository program.
2. The board may develop and maintain a participant registry for the program. A participant registry created under this subsection must include the name, address, and telephone number of the participants. A participant registry created under this subsection must be available through the board or on the board's web site.
3. The board may cooperate with nongovernmental organizations to maintain a web-based list of legend drugs, devices, or supplies that have been donated and are available through the program and the participants from which the donated items may be available.

#### **43-15.2-03. Conditions for participation.**

1. A donor may donate legend drugs, devices, or supplies to the program through a practitioner or pharmacy that meets the criteria established for such participation. Legend drugs, devices, or supplies may not be donated directly to a specific patient and donated items may not be resold.
2. The items donated to the program may be prescribed for use by an individual by a practitioner who is authorized by law to prescribe and only a participant may dispense donated items.

#### **43-15.2-04. Conditions for acceptance of a donation.**

1. A drug donated, prescribed, or dispensed under the program must be in the original, unopened, sealed, and tamper-evident unit dose packaging, except a drug packaged in single-unit doses may be accepted and dispensed if the outside packaging has been opened and the single-unit-dose package is unopened.
2. A drug may not be accepted or dispensed under the program if the drug has reached its expiration date or if the drug is adulterated or misbranded as determined under subsection 3.
3. Before being dispensed to an eligible individual, the legend drugs, devices, and supplies donated under the program must be inspected by a pharmacist to

determine that the legend drugs, devices, and supplies are not adulterated or misbranded.

**43-15.2-05. Storage, distribution, and dispensing.**

1. A participant that accepts donated legend drugs, devices, or supplies under the program shall comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of the donated legend drugs, devices, or supplies.
2. A participant may charge an individual a handling fee that does not exceed two hundred fifty percent of the medicaid prescription dispensing fee for dispensing donated legend drugs, devices, or supplies under the program.
3. A dispenser of donated legend drugs, devices, or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payer for the cost of donated legend drugs, devices, or supplies dispensed to any eligible individual under the program. A public or private third-party payer is not required to provide reimbursement to a dispenser for the cost of donated legend drugs, devices, or supplies dispensed to any eligible individual under the program.

**43-15.2-06. Liability.**

1. A donor of legend drugs, devices, or supplies, or any participant in the program, that exercises reasonable care in donating, accepting, distributing, prescribing, and dispensing legend drugs, devices, or supplies under the program and the rules adopted to implement this chapter is immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to personal property relating to such activities.
2. In the absence of intentional misconduct, a pharmaceutical manufacturer is immune from civil or criminal liability for any claim, injury, death, or loss to person or property arising from transfer, donation, dispensing, or acceptance of any legend drugs, devices, or supplies under this chapter, including liability for failure to transfer or communicate product or consumer information regarding the transferred legend drugs, devices, or supplies as well as the expiration date of the legend drugs, devices, or supplies under the program.

**43-15.2-07. Recordkeeping.**

1. A participant shall retain separate records detailing the receipt, distribution, and dispensing of legend drugs, devices, and supplies under this program.
2. The records of receipt must include:
  - a. The name and address of the donor;
  - b. The drug name and strength;
  - c. The manufacturer of the legend drugs, devices, or supplies;
  - d. The manufacturer lot number;
  - e. The drug expiration date;
  - f. The date received; and
  - g. The quantity received.

3. Records of distribution and dispensing must include:
  - a. The name and address of the participant;
  - b. The drug or device name;
  - c. The drug strength;
  - d. The quantity distributed;
  - e. The identity of the manufacturer of the legend drugs, devices, or supplies;
  - f. The manufacturer lot number;
  - g. The expiration date;
  - h. The date of distribution or dispensing; and
  - i. The name and address of the individual to whom the donated item was distributed.
  
4. Records of dispensing must include:
  - a. The requirements for a prescription label; and
  - b. The manufacturer's lot number.