DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Promotion and Disease Prevention Services

CANCER DRUG REPOSITORY PROGRAM

6 CCR 1015-10

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

1.1 Definitions.

(1) "Cancer drug" means a prescription drug that is used to treat cancer or the side effects of cancer.

(2) "Department" means the Colorado Department of Public Health and Environment.

(3) "Dispense" means to interpret, evaluate, and implement a prescription drug order or chart order, including the preparation of a drug or device for a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to or use by a patient.

(4) "Eligible patient" means an uninsured or underinsured cancer patient who meets the eligibility criteria described in these rules.

(5) "Family member" includes persons related by blood, by marriage, or by adoption, as well as any other agent authorized to act on behalf of the cancer patient.

(6) "Health care facility" means a hospital, hospice, or hospital unit that is required to be licensed pursuant to section 25-3-101, C.R.S.

(7) "Medical clinic" means a community health clinic required to be licensed or certified by the department pursuant to section 25-1.5-103, C.R.S.

(8) "Medical device" means an instrument, apparatus, implement, machine, contrivance, implant, or similar or related article including a component, part, or accessory that is:

(a) Recognized in the official national formulary, or the United States pharmacopoeia, or any supplement;

(b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or animals; or

(c) Intended to affect the structure or any function of the human body or animals, that does not achieve any of it's primary intended purposes through chemical action within or on the human body or animals, and that is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

(9) "Other outlet" means any hospital that does not operate a registered pharmacy and any rural health clinic, family planning clinic, school, jail, county health department, community health clinic, university, or college that has facilities in this state registered pursuant to the provisions of article 22 of title 12, C.R.S., and that engages in the compounding, dispensing, and delivery of drugs or devices.

(10) "Pharmacist" means an individual licensed by this state pursuant to the provisions of article 22 of title 12, C.R.S, to engage in the practice of pharmacy.

(11) “Pharmacy” includes both prescription drug outlets and other outlets.

(12) “Practitioner” means a person authorized by law to prescribe any drug or device, acting within the scope of such authority.

(13) "Program" means the Colorado Cancer Drug Repository Program created in section 25-35-103, C.R.S.

(14) “Prescription drug outlet” means any pharmacy outlet registered pursuant to article 22 of title 12, C.R.S. where prescriptions are compounded and dispensed.

(15) "State board" means the State Board of Health.

1.2 Program Goals

(1) The Colorado Cancer Drug Repository Program is established for the purpose of allowing a cancer patient or the cancer patient's family member to donate unused cancer drugs and medical devices to uninsured and underinsured cancer patients in the state of Colorado. The program allows a cancer patient or the patient's family member to donate unused cancer drugs or medical devices to a health care facility, medical clinic, or pharmacy that elects to participate in the program. A health care facility, medical clinic, or pharmacy that receives a donated cancer drug or medical device under the program may distribute the cancer drug to another eligible health care facility, medical clinic, or pharmacy for use under the program or dispense to an eligible cancer patient.

1.3 Program Rules

(1) Facility Participation.

(a) Health care facilities, medical clinics and pharmacies, as defined in section 1.1 above, are eligible to participate in the program.

(b) A health care facility, medical clinic, or pharmacy is not required to participate in the program.

(c) Nothing in these rules is intended to supersede or negate any other state and federal laws and administrative rules applicable to health facilities, medical clinics, or pharmacies participating in the program.

(2) Health Care Facility, Medical Clinic and Pharmacy Requirements for Accepting and Dispensing Donated Cancer Drugs and Devices. A pharmacist may accept and dispense cancer drugs and medical devices donated under the program to eligible patients or health care facilities, medical clinics or pharmacies if all of the following requirements are met:

(a) The cancer drug or medical device is not adulterated or misbranded, as determined by a pharmacist;

(b) The cancer drug or medical device is prescribed by a practitioner for use by an eligible patient and is dispensed by a pharmacist;

(c) The cancer drug meets the requirements defined in section 1.3(8) of these regulations identifying acceptable cancer drugs; and

(d) The cancer drug is not excluded from the program for any of the reasons identified in section 1.3(9) of these regulations.

(3) Distribution to Other Facilities.

(a) A pharmacy may redistribute cancer drugs and medical devices only to pharmacies, health care facilities, and medical clinics registered with the Colorado State Board of Pharmacy.

(4) Storage Requirements.

(a) Donated cancer drugs and devices under this program shall be stored separately from other stock.

(b) Donated cancer drugs and devices shall be stored in the compounding/dispensing area under the manufacturer's recommended storage conditions.

(5) Recordkeeping Requirements.

(a) Health facilities, medical clinics and pharmacies shall maintain records of receipt of returned cancer drugs, which shall include at least the following information:

(i) Date of return to the prescription drug outlet;

(ii) Date dispensed;

(iii) Prescription number;

(iv) Drug name and strength;

(v) Quantity returned;

(vi) Expiration date of drug;

(vii) Manufacturer's name and lot number; and

(viii) Name and address of person donating the drug or device.

(b) Health facilities, medical clinics and pharmacies shall maintain records of cancer drugs distributed to other eligible health care facilities, medical clinics or prescription drug outlets, which shall include at least the following information:

(i) Name and address of receiving entity;

(ii) Name and strength of drug;

(iii) The dosage form, if appropriate;

(iv) The quantity of drug;

(v) Manufacturer's name and lot number;

(vi) The date of distribution;

(vii) The name and address of the distributing pharmacy, health care facility, or medical clinic; and

(viii) Expiration date of drug.

(c) Nothing in these rules is intended to supersede or negate any of the recordkeeping requirements established by the Colorado State Board of Pharmacy for dispensing drugs.

(6) Patient Eligibility to Receive Cancer Drugs and Devices.

(a) Cancer drug and device dispensing shall be prioritized first to cancer patients who are uninsured, then to underinsured, then to other cancer patients if an uninsured or underinsured patient is not available.

(b) A health care facility, medical clinic, or pharmacy that elects to participate in the program shall establish eligibility criteria for individuals to receive donated cancer drugs or medical devices. The dispensing facility shall establish its own process consistent with these regulations to determine patient eligibility.

(c) Patients may demonstrate their eligibility for the program to the facility in the manner established by the facility.

(7) Fees and Resale of Cancer Drugs and Devices.

(a) No cancer drug or device donated under the program may be resold.

(b) A health care facility, pharmacy or medical clinic may charge a handling fee of $4.00 for distributing or dispensing donated cancer drugs and devices.

(8) Cancer Drugs or Medical Devices Acceptable for the Program. Any drug or medical device returned, distributed or dispensed through the program shall meet all of the following requirements:

(a) The drug is used in the treatment of cancer;

(b) The cancer drug or medical device is in its original, unopened, sealed, and tamper-evident packaging or, if in a single-unit dose package, the single unit-dose package is unopened; or

(c) The pharmacist has determined that the cancer drug or medical device is safe for redistribution; and

(d) The cancer drug is not excluded from the program because it meets any of the requirements in section 1.3(9).

(9) Cancer Drugs Not Acceptable for the Program. A cancer drug is not acceptable for donation or distribution through the program if it meets any of the following:

(a) Any drug that is classified as a controlled substance, because federal law prohibits the return of the drug;

(b) The drug bears an expiration date that has expired, because the effectiveness and safety of the cancer drug cannot be ensured;

(c) A cancer drug that the receiving or dispensing pharmacist believes may have been adulterated or misbranded, because the effectiveness and safety of the cancer drug cannot be ensured;

(d) A cancer drug packaging that has been opened, unsealed, or tampered with or that is no longer in its original container, because the effectiveness and safety of the cancer drug can no longer be ensured;

(e) A cancer drug that requires refrigeration, freezing, or other special temperature requirements beyond controlled room temperature, because the effectiveness and safety of the cancer drug cannot be ensured; or

(f) A cancer drug that can only be dispensed to a patient registered with the drug manufacturer, because donation could prevent manufacturers from maintaining patient registration data.

Editor's Notes

History

Entire rule eff. 03/01/2008.