COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

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Date: March 18, 2020

Subject: Rulemaking Hearing Concerning 6 CCR 1015-10 Cancer Drug Repository Program

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The Division is proposing to repeal the rules pertaining to the Cancer Drug Repository Program. Senate Bill 19-081 repealed the Colorado Cancer Drug Repository Act and dissolved the Colorado Cancer Drug Repository Program. The Department no longer has statutory authority to perform these duties, and the rules are no longer authorized. The Division is requesting to repeal of 6 CCR 1015-10.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
For Repeal of
6 CCR 1015-10, Cancer Drug Repository Program

Basis and Purpose:
The Cancer Drug Repository Act was signed into law in 2005. It created the Cancer Drug Repository Program in the Colorado Department of Public Health and Environment (CDPHE) and directed the State Board of Health, in consultation with the State Board of Pharmacy, to promulgate rules necessary for the implementation and administration of the program. The program allowed a cancer patient or the patient's family to donate unused cancer drugs or medical devices to a participating health care facility, medical clinic or pharmacy. A pharmacist could accept and dispense the drugs and devices donated under the program if the pharmacist determined that the drug or device was safe for redistribution. The health care facility, medical clinic or pharmacy that received the donation under the program could distribute the cancer drug or device to another eligible facility, clinic or pharmacy for use under the program. The Board of Health promulgated 6 CCR 1015-10 to implement the legislation.

However, in a subsequent analysis conducted by the Department, staff found that facilities were not willing to participate in the program. They were reluctant to take on the risk of accepting medications and devices because it was very difficult to ensure the medications were kept and handled properly. In 2007, the legislature passed SB07-231 removing the requirement for the Board of Health to promulgate rules related to eligibility criteria for individuals receiving donations through the Program. The eligibility rules were left to the health care facilities, medical clinics or pharmacies participating in the program. However, concerns regarding liability remained and facilities and pharmacies were unwilling to participate.

New solutions began to emerge. HB14-1207 created the Colorado Household Medication Takeback Program. While the goals are different, this program is accessible for all consumers. It allows consumers to donate all medications, regardless of the expiration date or usage. It protects the local water supply and removes medication from the home (a risk factor for theft and addiction). During the 2015 session, legislators passed HB15-1039 allowing patients, residents or the patients or residents next of kin in licensed facilities to donate unused medications or medical supplies to be redispensed to another patient or donated to a nonprofit entity that has the legal authority to possess the materials. This bill removed the limit on cancer drugs and also addressed the civil and criminal liability issue that facilities cited as a barrier to participation in the cancer program. A private market solution emerged as well. A company called SIRUM directly accepts unused and noncontrolled medication from manufacturers, pharmacies, wholesalers and health facilities for redistribution. SIRUM will also accept unused medication from individuals and donate through one of their partners.

In 2019, the Colorado Statutory Review Committee repealed the Cancer Drug Repository Act (SB19-081) citing the Act duplicative of another program in CDPHE. Therefore, the Department no longer has statutory authority to perform these duties, and the Board of Health is no longer authorized to promulgate these rules.

Specific Statutory Authority.
The Colorado Cancer Drug Repository Program rules are being repealed pursuant to SB19-081. Section 25-35-104, C.R.S. (repealed).

Is this rulemaking due to a change in state statute?

___X___ Yes, the bill number is SB19-081. Repeal is ___ authorized _X__ required.

Does this rulemaking include proposed rule language that incorporate materials by reference?

_____ Yes ___ URL

___X___ No

Does this rulemaking include proposed rule language to create or modify fines or fees?

_____ Yes

___X___ No

Does the proposed rule language create (or increase) a state mandate on local government?

_X__ No

REGULATORY ANALYSIS
For Repeal of 6
CCR 1015-10, Cancer Drug Repository Program

1. **A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.**

The repeal of the rule does not negatively impact any classes; those that benefit from repealing an obsolete rule include:

C = Health care facilities, medical clinics or pharmacies eligible to participate in the program.
S = American Cancer Society, Colorado Chapter.
B = Cancer patients and families.

2. **To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.**

C = There is no economic impact for the repeal of this rule. In an analysis conducted by the Department, staff found that facilities were not willing to participate in the program. Facilities were not willing to take on the risk of accepting medications and devices because it was very difficult to ensure the medications were kept and handled properly.
S = This organization supported the original legislation in 2005 and was concerned about the repeal in 2019. CDPHE staff communicated other programs exist in the state to redistribute or donate drugs and devices. Staff also suggested promotion of these programs could lead to a higher uptake rate for facilities.
B = No facilities participated in this program to the department's knowledge; therefore, the repeal of this rule should not have an impact on cancer patients or their families. There are still some gaps; patients or their families may not donate all medications for redistribution, and they cannot donate if they are not associated with a licensed health care facility. However, they can donate through the Medication Take-back program or SIRUM. All medications, regardless of use, expiration or classification, can be donated through the Medication Take-back program. Additional outreach for these programs may contribute to increased participation by facilities, patients and families.

3. **The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.**

No funds were appropriated for the implementation of this legislation, or its repeal. CDPHE anticipates the time spent repealing the rule will be absorbed into regular program administration duties.

4. **A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.**

Along with the costs and benefits discussed above, the proposed revisions:

___ Comply with a statutory mandate to promulgate rules.

_X_ Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
___ Maintain alignment with other states or national standards.
___ Implement a Regulatory Efficiency Review (rule review) result
___ Improve public and environmental health practice.
___ Implement stakeholder feedback.

Advance the following CDPHE Strategic Plan priorities (select all that apply):

1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO2e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO2e per year by June 30, 2020 and to 113.144 million metric tons of CO2e by June 30, 2023. ___ Contributes to the blueprint for pollution reduction ___ Reduces carbon dioxide from transportation ___ Reduces methane emissions from oil and gas industry ___ Reduces carbon dioxide emissions from electricity sector
2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023. ___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry. ___ Supports local agencies and COGCC in oil and gas regulations. ___ Reduces VOC and NOx emissions from non-oil and gas contributors
3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023. ___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes. ___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation. ___ Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing.
4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023. ___ Ensures access to breastfeeding-friendly environments.
5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023. ___ Reverses the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.

___ Performs targeted programming to increase immunization rates.
___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).

6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.

___ Creates a roadmap to address suicide in Colorado.
___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate.
___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries.
___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.

7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020.

___ Conducts a gap assessment.
___ Updates existing plans to address identified gaps.
___ Develops and conducts various exercises to close gaps.

8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023.

___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident.
___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment.
___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.

9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023.

___ Implements the CDPHE Digital Transformation Plan.
___ Optimizes processes prior to digitizing them.
___ Improves data dissemination and interoperability methods and timeliness.

10. Reduce CDPHE's Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023.

___ Reduces emissions from employee commuting
___ Reduces emissions from CDPHE operations

11. Fully implement the roadmap to create and pilot using a budget equity

assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023.

___ Used a budget equity assessment

___ Advance CDPHE Division-level strategic priorities.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include:

Inaction is not an option as the rules are no longer authorized under Colorado law.

5. **A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.**

There is no other less costly or less intrusive method to repeal the Colorado Cancer Drug Repository Program rules. The rules are no longer authorized by state statute.

6. **Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.**

There are no other alternative methods for achieving the purpose of this rulemaking.

7. **To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.**

Senate Bill 19-081 serves as the basis for the request to repeal these rules.

STAKEHOLDER ENGAGEMENT
For Repeal of
6 CCR 1015-10 Cancer Drug Repository Program

Early Stakeholder Engagement:
The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

The Department developed the proposed repeal.

The following individuals and/or entities were notified that this rule-making was proposed for consideration by the Board of Health and had the opportunity to provide feedback:

- American Cancer Society, Colorado Chapter
- Colorado Cancer Caucus
- Colorado Cancer Coalition
- Komen
- Department of Regulatory Agencies

Stakeholder engagement activities:

- The Department announced the need for rulemaking at the Colorado Cancer Coalition's Annual Symposium (November 7-8, 2019), invited the community to provide feedback to the Department, and worked with the Colorado Cancer Coalition to distribute to members.
- The individuals listed above were notified directly and invited to reach out to the department with any concerns.
- The notice of proposed repeal was distributed in the Cancer Coalition newsletter December 17, 2019.
- Notice of the proposed repeal was posted on the department's website November 11, and remains posted today.
- CDPHE spoke with the American Cancer Society, Colorado Chapter (S), as it was instrumental in the passage of the original Act in 2005. The Colorado Cancer Drug Repository Program was an important first step that allowed Colorado to identify barriers to implement, which in turn led to the development of statutes and improved solutions.

Stakeholder Group Notification
The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

__ __ Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

__X__ Yes. This is selected for the rulemaking to document that timely division notification occurred.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify

the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

To date, the department heard from one stakeholder. The stakeholder, a pharmacist in a health care facility, learned of the potential repeal and was frustrated because the facility was operating under the rules of the program. The department was not aware of any facilities utilizing the program. No facilities were identified when surveyed, and because CDPHE doesn't have the authority to license or track the facilities, CDPHE was unable to identify participating facilitates. CDPHE staff contacted DORA's Board of Pharmacy and was able to provide information to the pharmacist regarding the program created by HB15-1039 which allows patients, residents or the patient's or resident's next of kin in licensed facilities to donate unused medications or medical supplies to be redispensed to another patient or donated to a nonprofit entity that has the legal authority to possess the materials. The facility is exploring solutions that will allow them to continue the program and redistribute medications beyond cancer drugs if they choose.

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.		Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.		Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
	Improves access to food and healthy food options.		Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.		Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.		Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.		Ensures a competent public and environmental health workforce or health care workforce.

X	Other: Ensure rules are current so constituents do not receive inaccurate and outdated information about government programs.		Other:_____

This is a request to repeal the Cancer Drug Repository Program rules pursuant to SB19-081. There are no health equity or environmental justice impacts associated with the repeal.

~~**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.~~