

American Society of Clinical Oncology**Position Statement on Drug Repository Programs****INTRODUCTION**

The cost of pharmaceutical drugs and resulting strain on patients' ability to afford them has become a pervasive issue in the health care system. The cost of drugs represents a large and increasing portion of the financial burden of cancer care. While pharmaceutical drug repository programs, also known as "drug donation and reuse" programs are not new, there is new focus on their potential as a practical way to increase access to prescription drugs for patients.

ASCO members have expressed interest in drug repository programs as a means to alleviate some of the challenges associated with drug affordability, access, and waste. In 2017, ASCO published a Position Statement on the Affordability of Cancer Drugs,¹ affirming its commitment to supporting and promoting practical policy solutions that ensure patients with cancer have access to—and can afford—drugs vital to the treatment of their disease. ASCO also identified waste as a concern in a 2018 Position Statement on Pharmacy Benefit Managers and their Role in Cancer Care². In that statement, ASCO asserted that "each wasted vial of cancer medication represents an important expense for a cancer patient and a lost opportunity for appropriate treatment."

ASCO is committed to helping patients access the right treatment at the right time. **As such, we support drug repository programs solely for oral medications provided they are maintained within a closed system.** A closed system is defined as one in which the delivery to and/or return of prescription medicines from a health care or other institutional facility is maintained in a controlled environment under the supervision of a health care practitioner and not the patient. Drug repository programs within a closed distribution system are compliant with FDA policy on the return of unused prescriptions and ensure that the received surplus medicines are administered in a safe, effective, and private manner which can then be dispensed in accordance with the prescribing clinician's guidance.³ Any state or federal legislation regarding drug repositories must address the concerns that result when a surplus drug leaves an institutional facility to then be re-entered into the drug supply chain (i.e. not in a closed system). Additionally, ASCO makes the following recommendations:

- **States with no such laws should implement drug repository programs that include liability protections for participants and in accordance with their state health regulatory authority.**
- **Patients should receive appropriate notification that they are receiving a donated prescription drug.**
- **ASCO and other professional medical associations should make efforts to educate physicians regarding the existence and value of such programs.**
- **Drug repository programs should be implemented at no additional cost to the patient beyond a handling fee based on Medicaid's standard pharmacy dispensing fee.**

DRUG AFFORDABILITY AND WASTE

The High Costs of Drugs

Cancer drugs represent an increasing portion of health care costs, with United States' spending substantially increasing over the last 5 years, from \$33 billion in 2014 to \$58 billion in 2018; and expected to continue trending upwards.⁴ Cancer drugs often are specialty drugs, which frequently are administered as injections or infusions, sometimes requiring special handling and administration. They tend to be substantially more expensive than more commonly used traditional drugs.⁵ In just one pharmacy benefit managers' nationwide commercial plans, specialty drugs accounted for 45% of drug spending in 2018, with oncology drug pricing increasing at a rate of more than 20% per year.⁶ Overall, prescription drugs sold in retail pharmacies accounted for almost \$344 billion in 2018, up 36% from 2009 – a rising trend that has been consistent over the past 50 years.^{7,8}

Patient Affordability and Access

Costs for prescription drugs have risen to the point where many patients cannot afford them, leading to treatment non-compliance, drug abandonment, and resultant negative health outcomes.^{9,10,11} A small share of the most expensive drugs (8.8 percent) had an out-of-pocket cost of more than \$500, with 2.2% of patients paying over \$1,500; total out-of-pocket expenditures for these drugs was \$61 billion.¹² Research has shown that prescriptions with such high cost sharing for patients often are not filled because of inability for patients to absorb such high out-of-pocket costs. Drug abandonment such as this can have a serious effect on patient health, leading to hospitalizations, extensive health care costs, and even death.^{13,14,15} The abandonment rate for brand-name drugs accounts for 40 percent of all abandoned claims for new patients, in contrast to new patient abandonment rates for generics which are three times lower.^{16,17} One recent study found that distributing essential medicines at no charge led to increased adherence to treatment and some improvement in health outcomes.¹⁸

Drug Waste

In its 2012 report, the National Academies of Science estimated the health care system wastes approximately \$750 billion a year—a quarter of total health care spending.¹⁹ For their part, providers seek to restrain costs and growth in expenditures in their practice through quality improvement and efficient scheduling practices that help reduce waste.²⁰ Factors such as pricing, vial size availability, and drug shortages are fueling the demand to reduce costs associated with drug waste.

There are concerning reports about the amount of drug waste from health care facilities discarding useable drugs. In Colorado, the state's 220 long-term care facilities reportedly throw away 17.5 tons of potentially reusable drugs every year, worth an estimated \$10 million. In 2015, the Environmental Protection Agency estimated that about 740 tons of drugs are wasted by nursing homes every year.^{21,22} State governments, providers, and patients have a common interest in reducing the amount of waste within their healthcare systems.

Unfortunately, many pharmaceuticals used in the treatment of cancer related care are not eligible for drug repository programs. According to a 2016 study in the British Medical Journal, an estimated \$3

billion in leftover cancer drugs are discarded in the United States every year.²³ The expensive leftover injection and infusion drugs that the study describes are generally ineligible for state-level donation programs because they: (i) do not meet the program's unopened packaging requirements; and (ii) have very short timeframes in which the leftover drug would be safe for use. ASCO's position is that drug repository programs are appropriate in cancer care, but only for oral medications and provided the drugs are within a closed distribution system. Widespread use of these programs may incentivize all stakeholders to effect change that could result in decreased costs to patients and unused medications in the outpatient setting.

BACKGROUND ON DRUG REPOSITORY PROGRAMS

Pharmaceutical repository programs facilitate donation of unused prescription drugs to patients. The first known state law permitting use of donated prescription drugs was enacted in Georgia in 1997. Since then, according to a 2018 survey conducted by the National Conference of State Legislatures, a total of 38 states and Guam have passed legislation establishing prescription drug repository programs. Sixteen of these state programs (including Guam and Washington, D.C.) are not currently operational, meaning that although a state has enacted laws allowing for drug repositories, there is no active level of donation and re-dispensing transactions. Currently, 14 states have no law or program.²⁴

These programs are designed to collect unused prescription drugs and redistribute them to eligible patients within the state. Of the states with statutory programs in place, there are 13 that have established drug repository programs specific to unused cancer drugs, supplies, and devices. These cancer-specific programs are intended to reduce prescription drug waste, reduce drug cost to public and private health payers, and increase access to cancer drugs for low-income state residents.

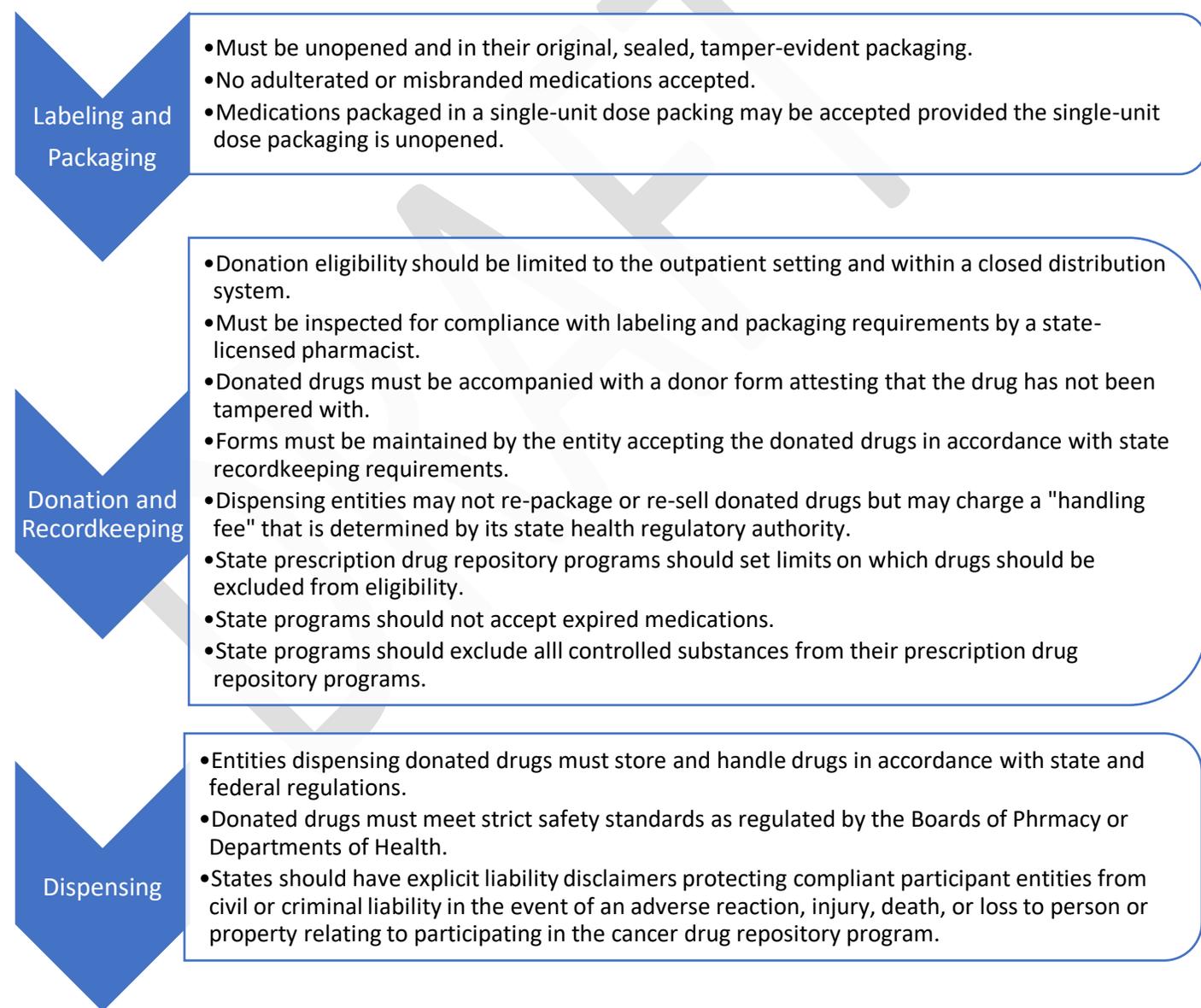
Most drug repository programs exclude controlled substances, expired drugs, and drugs that show any signs of tampering, misbranding, deterioration, compromised integrity, or adulteration. They typically require that all drugs be inspected by a pharmacist, a pharmacy contracted delivery service, or an approved common carrier (i.e. a company that transports the drugs) prior to being dispensed. They commonly include liability protections for both donors and recipients. State programs contain varying provisions governing types of drugs accepted for redistribution and re-dispensing [(all vs. only prescription vs. only over the counter (OTC) or only cancer-specific (oral vs. parenteral)], and eligibility criteria for patients receiving donated drugs. Other differences in legislation include the minimum number of months before expiration date, protocol for transfer and repackaging, maximum dispensing fees, whether there is program funding, and whether the operation is centralized vs. decentralized.

Most state programs allow only state or federally regulated health professionals to donate, accept, inspect, or dispense donated drugs under their state program in order to ensure integrity of donated drugs and patient safety. However, some states allow any individual to donate directly to the programs. Commonly, states require that donated drugs be delivered to a medical or pharmacy facility. Existing state programs are regulated by their respective Boards of Pharmacy or Departments of Health. For a comprehensive list of differences in existing state legislation please see Tables 1 and 2.

The National Association of Boards of Pharmacy (NABP) "endorses the return and reuse of medications that have been maintained in a closed system." The NABP defines a closed system as the "delivery to and/or return of prescription medication from a healthcare or other institutional facility, which is maintained in a controlled environment under a health care practitioner and not the patient." Although

the NABP does not endorse the reuse of medications that have left a closed distribution system, there are drug repository programs in place that distribute donated drugs that have previously left a closed distribution system.²⁵ The American Medical Association (AMA) posits that drug repository programs which include drugs outside of a closed distribution system should be registered and under the jurisdiction of their respective Boards of Pharmacy and be subject to strict criteria, inspection, and be kept in a separate inventory.²⁶ While ASCO supports the protections recommended by the AMA in this respect, we support only drug repository programs for oral medications maintained within a closed system.

While each state's prescription drug repository program is unique, these programs tend to incorporate the following common provisions:²⁷



FINANCIAL IMPACT on STATES

The fiscal impact to operate a drug repository program varies by the operating characteristics of the program, outreach and expected utilization rates. However, based on ongoing successes illustrated by currently operational state programs and the amount of drug waste otherwise generated, there is ample opportunity for cost savings for states that develop drug repository programs. According to an informal collaborative information exchange with the National Council of State Legislators (NCSL) and SIRUM, a non-profit organization that provides logistical support for drug repository programs, cost savings and patient access are substantial for states that have implemented drug repository programs. In Iowa, the state-supported drug repository program reported that between 2007 and 2012, \$5.9M worth of drugs were donated to 26,800 eligible residents.²⁸ Since its program began, Iowa has generated more than \$17.7M in cost savings with over 71,000 patients through 2016.²⁹ Since 2007, Wyoming's program has filled over 150,000 prescriptions worth over \$12.5M, with \$2.4M worth of prescription medications donated in 2016 alone.³⁰ In Oklahoma, 248,305 prescriptions were filled with an estimated savings of \$25.01M through October, 2019.³¹

ASCO'S POSITION ON DRUG REPOSITORY PROGRAMS

In 2017, ASCO published a Position Statement on Addressing the Affordability of Cancer Care Drugs. In that statement, ASCO affirmed the following:

- “ASCO is committed to supporting and promoting practical policy solutions that ensure patients with cancer have access to—and can afford—drugs vital to the treatment of their disease.”
- “ASCO is firm in its position that any policy solutions to address the price of cancer drugs must promote access to care for patients, affordability of drugs vital to their treatment, and innovation in drug development. Regardless of the specific policy recommendations pursued, defining value must underpin the drug pricing debate.”

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- **States with no such laws should implement drug repository programs that include liability protections for participants and in accordance with their state health regulatory authority.**
- **Patients should receive appropriate notification that they are receiving a donated prescription drug.**
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- **Drug repository programs should be implemented at no additional cost to the patient beyond a handling fee based on Medicaid's standard pharmacy dispensing fee.**

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Table 1: State-by-State Analysis of Drug Repository Programs

(Adapted from State-by-State Query of Drug Repository Programs and the National Conference of State Legislatures.)

The information is accurate as of 12/1/2019. Interested parties should review their respective state Department of Health or Board of Pharmacy for updates.

“Operational” refers to a state that has enacted drug repository legislation and has had some level of drug repository transactions. Having an operational drug repository program does not mean that a repository may be open or available in a given geographic area, nor that a potential recipient will be able to receive a prescription drug, or that a requested drug is authorized or available for reuse. For States that have no active program, please see Table 2.

Operational State Programs highlighted in blue indicate states which accept and distribute cancer-related prescription drugs.

Table 1 – Operational State Drug Repository Programs

State/Name/Details	Includes Cancer Provisions	Patient Eligibility	Who can donate	Who can accept	What can be donated
Arizona No formal name	N	State residents who meet eligibility standards set by Board of Pharmacy	Person, manufacturer, or healthcare institution	Physician office, pharmacy, hospital, or healthcare institution	Donated drugs in original sealed & tamper-evident unit dose packaging.
California Santa Clara County Better Health Pharmacy (first and only dedicated drug donation pharmacy) Operated by SIRUM	specific	Medically indigent persons, free of charge	Skilled Nursing Facility (SNF), a SNF designated as an institution for mental disease (IMD), general acute care hospital, psychiatric hospital, intermediate care facility, correctional treatment center, chemical dependency recovery hospital, psychiatric health facility, residential care facility for the elderly, mental health rehabilitation center, and wholesalers	County-owned pharmacy or pharmacy that contracts with the county	Donated drugs must be unexpired, collected and maintained under the authority of a licensed pharmacist, stored properly and received and maintained in their unopened, tamper-proof packaging. Controlled substances are not allowed.
Florida Cancer Drug Donation Program (CDDP)	Y	Residents, except those Medicaid-eligible or under any other prescription drug program funded	A person, health care facility, hospital, pharmacy, drug manufacturer, medical device manufacturer or supplier, wholesaler of drugs or supplies, or any other entity may donate	A physician's office, pharmacy, hospital, hospice, or health care clinic that participates in the program	Donated medications must be in the original, unopened tamper evident unit dose packaging.

		in whole or in part by the state are ineligible to participate			Medications must have been maintained by a health care facility (example: nursing home, hospice, hospital, drug manufacturer, drug wholesalers or a physician who receives cancer drugs from a manufacturer, wholesale distributor or pharmacy). Donated drugs must not be adulterated, misbranded or mislabeled. Donations may not be accepted if there is less than six months remaining until the expiration date. Controlled substances are not eligible for donation.
<p>Georgia</p> <p>Donated Drug Repository Program</p> <p>*Good Pill is affiliated with SIRUM and operates a repository in Georgia</p>	N	Medically indigent person, uninsured, underinsured, or enrolled in a public assistance health benefits program	Any person, including a drug manufacturer, wholesaler, reverse distributor pharmacy, third-party logistics provider, government entity, hospital, or health care facility	Any pharmacy, hospital, federally qualified health center, or nonprofit clinic that participates in the drug repository program and meets criteria for participation in the program	Both prescription and over-the-counter drugs are eligible to be donated, so long as they are in unopened tamper-evidence packaging and will not expire before the date they are likely to be dispensed to a new patient.

<p>Iowa</p> <p>Drug Donation Repository and Cancer Donation Medication Program</p>	<p>Y</p>	<p>Drugs may be donated to individuals or may be distributed to another eligible medical facility or pharmacy for use. Iowans at or below 200% of the federal poverty level as well as individuals who are uninsured or under-insured are eligible to receive donated drugs</p>	<p>Any person or organization may donate prescription drugs and supplies</p>	<p>Medical facilities or pharmacies that elect to participate in the program and meet the requirements established by the department</p>	<p>Prescription drugs, over-the-counter drugs, and supplies.</p>
<p>Kansas</p> <p>Unused Medications Program</p>	<p>N</p>	<p>Medically indigent residents of Kansas</p>	<p>Residents of adult care homes and donating entities that volunteer to participate in the program</p>	<p>A qualifying center or clinic in consultation with a pharmacist</p>	<p>Donated medications must come from a controlled storage unit. Only medications in their original or pharmacist-sealed unit dose packaging or hermetically sealed by the pharmacy in tamper-evident packaging, unit of use or sealed, unused injectables may be donated or dispensed. Expired medications may not be donated. A medication may not be donated or dispensed if the person accepting or dispensing the medication has reason to believe that the</p>

					medication is adulterated. No controlled substances may be donated. Unused medications dispensed for purposes of a medical assistance program or drug product donation program may be accepted and dispensed.
Louisiana No formal name.	N	Appropriately screened and qualified patients free of charge	Any person, including a drug manufacturer, hospital, health care facility, or governmental entity	Charitable pharmacies	Unexpired prescription drugs that haven't been tampered with can be donated. Medications that are federally controlled substances are not accepted.
Maryland Prescription Drug Repository Program	N	A needy patient who is a resident of Maryland, as indicated by the individual's health care practitioner	Any person	Board approved drop-off sites, such as licensed pharmacies, and/or repositories which meet specified criteria	The repository will accept and dispense donated prescription drugs or medical supplies received from approved drop-off sites. The repository must designate a pharmacist to accept and inspect the donated prescription drugs and medical supplies. If the donated prescription drugs are ineligible drugs and/or medical

					supplies, then the repository will dispose of them.
Michigan Cancer Drug Repository Program and Utilization of Unused Prescription Drugs Program	Y	Residents eligible to receive Medicaid or Medicare, or has no health insurance, and otherwise lacks reasonable means to purchase prescription drugs	Residents, guardians of residents, manufacturers, pharmacies, and clinics	A pharmacy, health professional, or charitable clinic that participates in the program	Legally obtained cancer drugs or supplies if the donated drugs have not been dispensed previously. Controlled substances are not eligible.
Montana No formal name for prescription drug program Cancer Drug Repository	Y	Qualified patients for transfer free of charge or at a reduced charge to those individuals	Long-term care facilities	Provisional community pharmacies; Cancer Drug Repository: participating repository pharmacies	Unused prescription drugs, devices, and cancer drugs.
Nebraska Cancer Drug Repository Program	Y	Eligible Nebraska residents	Any person or entity, including, but not limited to, a cancer drug manufacturer or health care facility	Any physician's office, pharmacy, hospital, or health clinic that elects to participate in the program and meets criteria established by the department for such participation	A cancer drug shall only be accepted or dispensed under the program if such drug is in its original, unopened, sealed, and tamper-evident packaging. A cancer drug packaged in single unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened. There shall be no limitation on the number of doses

					that can be donated to the program as long as the donated drugs meet the requirements of this section. An injectable cancer drug may be accepted if it does not have temperature requirements other than controlled room temperature.
New Hampshire No other information found	N	Uninsured or underinsured persons	Any person or entity	Pharmacy, hospital, nursing home, outpatient clinic, veterans home, and correctional facility	A drug donated, or dispensed under the program must be in the original, unopened package, except drugs packaged in single-unit doses, or punch cards, may be accepted and dispensed if the outside packaging has been opened and the single-unit dose package is unopened. A few cases where the shipped package has not been opened may also be allowed.
North Dakota Drug Repository Program	N	Eligible patients who fill out the "Recipient Information Form."	Any person or entity	Practitioners or pharmacies that meets the criteria established for participation in the program	A drug donated, or dispensed under the program must be in the original, unopened package, except drugs packaged in single-unit doses, or punch

					cards, may be accepted and dispensed if the outside packaging has been opened and the single-unit dose package is unopened. A few cases where the shipped package has not been opened may also be allowed.
Ohio Ohio Drug Repository Program *Operated by SIRUM	Y	Individuals that meet the economic eligibility standards	Any person, including a drug manufacturer or health care facility	Any pharmacy, hospital, or nonprofit clinic that participates in the program and meets certain eligibility requirements established in rules adopted by the Board of Pharmacy	Drugs contained in their original sealed and tamper-evident unit dose packaging. Orally administered cancer drugs meaning: an orally administered dangerous drug that is used to treat cancer or its side effects; or an orally administered dangerous drug that is used to treat the side effects of a dangerous drug used to treat cancer. Orally administered cancer drugs do not include controlled substances or drugs that require refrigeration, freezing, or storage at a special temperature.

Oklahoma	N	Oklahoma residents who are medically indigent	Drugs may be transferred from residential care homes, nursing facilities, assisted living centers, public intermediate care facilities for people with mental retardation (ICF/MR) or pharmaceutical manufacturers	Any pharmacies operated by a county, pharmacy operated by a city-county health department or a pharmacy under contract with a city-county health department, a pharmacy operated by the Department of Mental Health and Substance Abuse Services or a charitable clinic for the purpose of distributing the unused prescription medications.	Unused prescription drugs other than prescription drugs defined as controlled dangerous substances.
Tennessee Drug Donation Repository Program	N	Tennessee residents who are indigent	Nursing homes or hospice services programs	Charitable clinic pharmacies	Prescription drugs in its original sealed and tamper-evident packaging, which includes unit dose packaging created by a licensed pharmacy. However, a prescription drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit-dose packaging is undisturbed.
Texas	N	Uninsured and underinsured humans	Health facility, assisted living facility, hospice, hospital, physician, and pharmacies	Charitable medical clinic, charitable	Unused prescription drugs.

Prescription Drug Donation Program				pharmacy, physicians, and penal institutions	
Virginia No formal name	N	Indigent patients	Hospital with an on-site hospital pharmacy, manufacturers, pharmacies	individuals, including those residing in nursing homes, assisted living facilities, or intermediate care facilities established for individuals with intellectual disability (ICF/IID), licensed hospitals, or any facility operated by the Department of Behavioral Health and Developmental Services	Prescription drugs.
Wisconsin Drug Donation Program – Repository	Y	Residents who have a valid prescription, have cancer, and do not have the means to pay for the medication	Any person or entity	Medical facilities or pharmacies that elects to participate in the program and meets requirements specified by rule by the department. State prison pharmacies.	Prescription drugs, cancer drugs or supplies. Includes supplies for other chronic diseases.
Wyoming Wyoming Medication Donation Program	N	Wyoming residents; those without prescription insurance, low income or on Wyoming Medicaid	Any person or entity, including but not limited to a drug manufacturer, physician or health care facility	Any physician's office, a pharmacy or health care facility that elects to participate in the program and meets criteria established by the Department of Public Health	Prescription drugs.

Table 2 – States (including Guam and Washington, DC) with No Active Drug Repository Program

States may have enacted law allowing for a drug repository program but no infrastructure to create a drug repository.

This information is accurate as of 12/1/2019. Interested parties should review their respective state Department of Health or Board of Pharmacy for updates. States highlighted in blue indicate legislation that includes cancer-related drug repository.

State	Enacted Law? (Y/N)	Does State Board of Pharmacy Allow a Drug Repository Program?	Notes
Alabama	Y	N	Signed into law in 2002.
Alaska	N	Y	Bills have been introduced regarding drug repository programs, but not enacted.
Arkansas	Y	Y	Signed into law in 2005.
Colorado	N	N	Repealed in 2018.
Connecticut	Y	Y	Signed into law in 2000.
Delaware	N	Y	Bills have been introduced regarding drug repository programs, but not enacted.
Guam	Y	Y	Signed into law in 2004.
Hawaii	N	N	Repealed in 2010.
Idaho	Y	Y	Signed into law in 2009.
Illinois	N	Y	Bill undergoing review in 2018.
Indiana	Y	Y	Signed into law in 2004.
Kentucky	Y	Y	Signed into law in 2005.
Maine	N	N	In 2017, Legislature proposed bill to require the Board of Pharmacy to create rules establishing a redispensing process; however, it failed.
Massachusetts	N	N	Law repealed in 2012.
Minnesota	Y	Y	Signed into law in 2007.
Mississippi	Y	Y	Signed into law in 2017.
Missouri	Y	Y	Signed into law in 2004.
Nevada	Y	Y	Signed into law in 2003.
New Jersey	N	Y	No laws enacted.
New Mexico	Y	Y	Signed into law in 2011.
New York	N	Y	2015-2016 legislative session passed law directing the commissioner to create regulations for the reuse and redistribution of prescriptions.

North Carolina	Y	Y	Signed into law in 2009.
Oregon	Y	Y	Signed into law in 2009.
Pennsylvania	Y	Y	Signed into law in 2008.
Rhode Island	N	N	Repealed in 2013.
South Carolina	N	N	Bills have been introduced regarding drug repository programs, but not enacted.
South Dakota	N	N	Signed into law in 2014.
Utah	Y	Y	Signed into law in 2005.
Vermont	N	N	Repealed in 2018.
Washington	Y	Y	Signed into law in 2013.
Washington, D.C.	N	N	Bills have been introduced regarding drug repository programs, but not enacted.
West Virginia	N	Y	Bills have been introduced regarding drug repository programs, but not enacted.

¹ American Society of Clinical Oncology – Position Statement on Addressing the Affordability of Cancer Drugs. November 2017. Journal of Oncology Practice. <https://ascopubs.org/doi/full/10.1200/JOP.2017.027359>

² American Society of Clinical Oncology – Position Statement on the Role of Pharmacy Benefit Managers in Cancer Care. August 2018. <https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2018%20ASCO%20PBM%20Statement.pdf>

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