

American Society of Clinical Oncology**Position Statement on Drug Repository Programs****Revised on October 21, 2022****INTRODUCTION**

In 2020, ASCO released a position statement on drug repository programs in support of our commitment to addressing barriers to accessing cancer care. Since the release of this statement, ASCO has continued to review and monitor legislation and programs on drug repository programs. After discussion with other stakeholders and observing changes to the current policy landscape, ASCO offers an updated position statement to reflect the current environment surrounding drug repository programs.

Since release of ASCO's position statement, there has been a shift in thinking regarding donation in closed vs. open distribution systems. 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. When a drug repository program includes drugs donated in an open distribution system, the drug has left the supply chain and was dispensed to a patient.

While the Society acknowledges there may be increased risk allowing donations outside a closed system, key stakeholders have determined that the risk is worth bearing, given the cost and access challenges for many patients with cancer. We take note of a shift in position announced by the National Boards of Pharmacy (NABP) allowing donation in open systems.¹ Given all these factors, together with the fact that more than \$2.8B dollars of medications are discarded each year, ASCO is updating its position to align with that of the NABP.² For any drug donation, pharmacists should use their professional judgement to determine the drug's integrity and appropriateness for returning to the distribution system.

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 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.³ ASCO also identified waste as a concern in a 2018 Position Statement on Pharmacy Benefit Managers and their Role in Cancer Care.⁴ 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."

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 \$50 billion in 2017 to \$75 billion in 2021; and expected to continue trending upwards.⁵ Cancer drugs often are specialty drugs, which frequently are administered as injections or infusions, often requiring special handling and administration. They tend to be substantially more expensive than more commonly used traditional drugs.⁶⁻⁷ 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.⁸ 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.⁹⁻¹⁰

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.¹⁰⁻¹² A small share of the most expensive drugs (8.8%) 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. 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.¹³ Drug abandonment such as this can have a serious effect on patient health, leading to hospitalizations, extensive health care costs, and even death.¹³⁻¹⁵

The abandonment rate for brand-name drugs accounts for 40% of all abandoned claims for new patients, in contrast to new patient abandonment rates for generics which are three times lower.¹⁵⁻¹⁶ One recent study found that distributing essential medicines at no charge led to increased adherence to treatment and some improvement in health outcomes.¹⁷

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.¹⁸ 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. 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.¹⁹⁻²⁰ 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.²¹ 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. 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

Drug 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 2021 survey conducted by the National Conference of State Legislatures, a total of 40 states, Guam, and Washington, D.C. have passed legislation establishing prescription drug repository programs.²² Twenty-seven states and Washington D.C. have operational programs while thirteen of these state programs including Guam 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, 10 states have no law or program.²²

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 12 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.

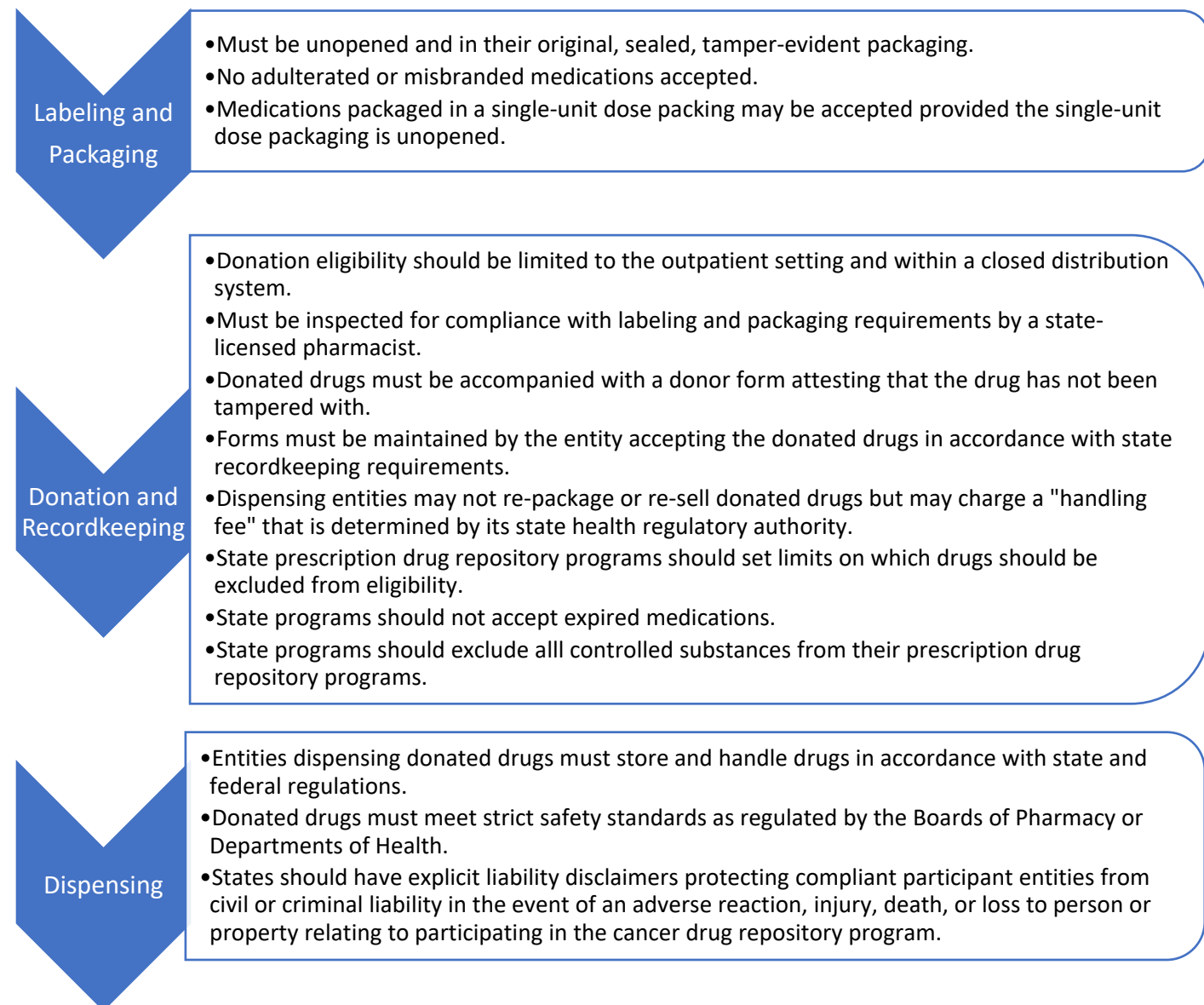
Most drug repository programs exclude controlled substances, expired drugs, and drugs that show any signs of tampering, misbranding, deterioration, compromised integrity, or adulteration. They typically require that all drugs be inspected by a pharmacist, a pharmacy contracted delivery service, or an 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.

The National Association of Boards of Pharmacy (NABP) endorses the return and reuse of medications based on a pharmacist's professional judgment to ensure that any returned and/or donated medication is an unadulterated product.¹ 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.²³ ASCO supports the protections recommended by the AMA and NABP and in this respect, support drug repository programs for oral medications.

While each state's prescription drug repository program is unique, these programs tend to incorporate the following common provisions:²²



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 (launched in 2007) reported that as of 2021, \$54M worth of drugs were donated to over 117,000 patients in need at little to no cost.²⁴

Since 2007, Wyoming's program has filled over 150,000 prescriptions worth over \$25M, with nearly 10,000 prescription medications donated in 2019 alone.²⁵ In Oklahoma, 269,724 prescriptions were filled through its drug recycling program valued at over \$28.1M through May, 2012.²⁶

ASCO'S POSITION ON DRUG REPOSITORY PROGRAMS

In 2017, ASCO published a Position Statement on Addressing the Affordability of Cancer Care Drugs.³ 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."

ASCO is committed to helping patients access the right treatment at the right time. However, we also recognize certain treatments, notably infused therapy, routinely involve highly specialized handling, storage, and administration of chemotherapy agents that, if not handled safely, could expose both patients and clinicians to hazardous conditions. **As such, we support drug repository programs solely for oral medications.** Several states have passed legislation on donated and reused drugs provided they are maintained within a closed system. Although the FDA does not endorse the donation and reuse of drugs that have left the closed distribution system, the NABP and AMA support an open distribution system as they are registered and regulated under the jurisdiction of the respective Boards of Pharmacy. 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). In that regard, ASCO believes that state or federal legislation regarding drug repositories who provide access to drugs outside of the closed distribution system should 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 minimum standards for medication and reuse with the guidance of their respective state boards of pharmacy.**
- **Drug repository programs that allow medications used in the treatment of cancer should solely be limited to oral medications due to safety concerns involving the specialized handling, storage, and administration of chemotherapy agents.**
- **State legislation should clarify that the return and reuse of prescription drugs should include any person or practice setting.**

- States should expand access to drug repository programs to include controlled drugs for appropriate pain management for cancer patients and survivors.
 - Patients should be fully informed that medications were previously dispensed and receive appropriate notification that they are receiving a donated prescription drug pursuant to a repository program's qualifications for acceptable medications for reuse.
 - 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.
 - State governments should ensure that any charges made by third-party payers should be reserved prior to reuse.
- State laws should ensure that donated drugs are prohibited from reentering the commercial supply chain.

Questions? Contact policy@asco.org

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