

Drug Prescription Donation: Senate Bill 37 Revised

Specific Amendments

Broaden Eligible Donors and Increase Patient Access to Unused Drugs

Currently, individuals may only donate their unused drugs to a clinic or participating practitioner that originally prescribed the prescription drug. This restriction on drugs eligible for donation severely limits the pool of eligible drugs and limits patient access.

- We recommend allowing any individual or any entity to donate those unused drugs they were legally authorized to possess. The success of most repository programs and the top three (GA, IA, and WY) are due to the ability to receive medicine from a wide pool of eligible donors.
- Following many other states, this will increase available drugs for donation and help reduce prescription drug waste. The acceptance and inspection requirements set forth will verify such donated drugs are safe to be accepted into inventory.

Specifically, we recommend these entities not be limited to in NM. Many entities around the country including manufacturers, wholesalers, pharmacies, and long-term care facilities do not have an eligible in-state repository to donate their unopened, unexpired drugs. In addition, drug repositories around the country occasionally have an oversupply of certain drugs that can be distributed to another drug repository.

Expand Eligible Recipient Entities

The current program limits the types of entities that may accept and dispense unused donated drugs to the clinic or practitioner that originally prescribed the prescription drug. This restriction on recipient entities severely limits the range of potential patients benefiting from this program. Most donation program participants are charitable pharmacies and/or free clinics with some charitable distributors assisting with logistics. State donation programs aim to increase medication access, especially to underserved populations, including those patients ordinarily served by charitable pharmacies and free clinics. Notably, none of the successful operational state donation programs impose such recipient entity limitations.

- Expand list of eligible recipient entities that may accept and dispense unused donated drugs.
- Permit any entity legally authorized to possess medicine with a license or permit in good standing in the state in which it is located, including but not limited to a wholesaler or distributor, reverse distributor, repackager, hospital, pharmacy, clinic, or prescriber office.
- Many states have drug repository programs with charitable pharmacies that may be interested in participating in the program. We believe that these out-of-state pharmacies would be interested in dispensing eligible drugs to residents.

Expiration Date

To be eligible for donation, drugs must have an expiration date of six months or greater listed on the packaging.

- We believe a six-month limitation on expiration dates will diminish the donation inventory stock of otherwise eligible drugs.
- Successful operational programs (GA, IA, OH & WY) do not impose strict expiration date restrictions, other than being unexpired prior to donation. Any medications that may be expired will not reach a patient, as the program requires drugs to be inspected by a healthcare professional prior to being dispensed.
- We recommend a drug may only be dispensed if it will not expire before the completion by the eligible patient based on the prescribing health care professional's directions for use. Allowing health care professionals to use their professional judgment will maintain the same level of safety while increasing the stock of donated drugs available to those eligible patients in need.

Reduce Recordkeeping Burden

We have seen many repository programs fail due to overly burdensome content requirements on forms, we suggest limited, specific requirements per form that we believe are sufficient for efficiency and safety.

For example, New Mexico's current program requires a participating clinic or practitioner to collect a signed form by the donor verifying the donor is voluntarily donating the drug, the donated prescription drug has been properly stored-not stored at temperature extremes nor hazardous conditions and protected from light and humidity, the container has not been tampered with, and the drug has not been adulterated or misbranded. The form also includes requires at least the following:

1. Date the drug was donated
 2. Name, address, and telephone number of donor
 3. Name, strength, and quantity of the drug
 4. Manufacturer and lot number (if applicable) of drug
 5. The expiration date of drug
 6. Name, date and signature of the practitioner or pharmacist who is accepting and inspecting the donated drugs
- We suggest the forms provided by the Board of Pharmacy be identified as examples and that recipient entities be allowed to develop their own records that capture the same information either physically or electronically online with regulatory requirements.
 - We believe this will reduce the paperwork burden while maintaining the same level of accountability and transparency.
 - In addition, because we have seen many donation programs fail due to overly burdensome content requirements on forms, we suggest limited, specific requirements per form that we believe are sufficient for efficiency and safety. For example, we strongly recommend removing lot number, expiration date and signature requirements to the existing form and allowing for NDC to supplement for manufacturer.

- Another example is that repository programs will often utilize a mail order and/or home delivery option for some patients, in which a physical acceptance form may impose heavy burdens. Patients served by drug donation programs often lack access to a computer and printer to mail back a physical form.

Handling Fees

Program rules limit a handling fee to \$20.

- We strongly support flexibility and recommend against a cap because a primary issue with donation programs today is financial viability. Donation programs that lack adequate sources of funding, especially those without state funding, are often unsuccessful or become nonoperational.
- This approach provides the flexibility needed to address the concerns listed above and does not include a cap, which does not account for the high cost of handling some drugs (e.g. temperature-sensitive drugs). Allowing participants to charge a reasonable handling fee is necessary to support the continued financial viability—and success—of donation programs. We believe an ideal model is the Georgia donation program handling fee rule 511-5-12-.07, which ties the fees charged to the “reasonable costs of participating in the program.”

Transfer of Donated Drugs in and out of state

- Current program lacks provisions regarding transfers of donated medication between participating entities.
- Most active state repository programs - even very successful ones - have a portion of donated drugs that they cannot use. Rather than waiting for these drugs to expire and not help anyone, it would be nice to be able to supply these drugs to repository programs in other states.

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