

COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Third Floor Henrico, Virginia 23233

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Tentative Agenda of Drug Donation Workgroup Meeting August 11, 2022 9AM

TOPIC	PAGE
Call to Order: Dale St.Clair, PharmD, Chairman	

• Approval of Agenda

Welcome & Introductions

Call for Public Comment: The workgroup will receive public comment at this time. The workgroup will not receive comment on any regulation process of the Board for which a public comment period has closed or any pending disciplinary matters.

Background Materials:

SB 14	2
Relevant Law and Regulations	3-7
2011 Information provided from Board of Pharmacy to Del. Landes	8-13
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Discussion

Adjourn

Drug Donation Workgroup Members

- 1. Dale St.Clair, PharmD, Chairman, Board of Pharmacy Member
- 2. Kris Ratliff, DPh, Board of Pharmacy Member
- 3. Wendy Nash, PharmD, Board of Pharmacy Member
- 4. Joseph Jadallah, PharmD, Virginia Pharmacist Association
- 5. Natalie Nguyen, PharmD, Virginia Society of Health-Systems Pharmacists
- 6. Rachel Becker, Virginia Hospital and Healthcare Association
- 7. Michelle Taylor, Virginia Association of Free and Charitable Clinics
- 8. Alexis Page, PharmD, Virginia Department of Health

VIRGINIA ACTS OF ASSEMBLY -- 2022 RECONVENED SESSION

CHAPTER 703

An Act to direct the Board of Pharmacy to convene a work group related to increasing participation in the prescription drug donation program.

[S 14]

Approved April 27, 2022

Be it enacted by the General Assembly of Virginia:

1. § 1. That the Board of Pharmacy shall convene a work group of interested stakeholders, including the Virginia Pharmacists Association, the Virginia Society of Health-Systems Pharmacists, the Virginia Hospital and Healthcare Association, the Virginia Association of Free and Charitable Clinics, and the Virginia Department of Health, to evaluate any challenges and barriers to participation in the prescription drug donation program established pursuant to § 54.1-3411.1 of the Code of Virginia and ways to increase program participation, education, and outreach.

The work group shall report its findings to the Governor and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by December 1,

2022.

Relevant Law, July 1, 2022

§ 54.1-3411.1. Prohibition on returns, exchanges, or re-dispensing of drugs; exceptions.

- A. Drugs dispensed to persons pursuant to a prescription shall not be accepted for return or exchange for the purpose of re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises from which they were dispensed except:
- 1. In a hospital with an on-site hospital pharmacy wherein drugs may be returned to the pharmacy in accordance with practice standards;
- 2. In such cases where official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better, and such return or exchange is consistent with federal law; or
- 3. When a dispensed drug has not been out of the possession of a delivery agent of the pharmacy.
- B. The Board shall promulgate regulations to establish a prescription drug donation program for accepting unused previously dispensed prescription drugs that meet the criteria set forth in subdivision A 2, for the purpose of re-dispensing such drugs to indigent patients, either through hospitals or through clinics organized in whole or in part for the delivery of health care services to the indigent. Such program shall not authorize the donation of Schedule II-V controlled substances if so prohibited by federal law. No drugs shall be re-dispensed unless the integrity of the drug can be assured. Such program shall accept eligible prescription drugs from 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. Additionally, such program shall accept eligible prescription drugs from an agent pursuant to a power of attorney, a decedent's personal representative, a legal guardian of an incapacitated person, or a guardian ad litem donated on behalf of the represented individual.
- C. Unused prescription drugs dispensed for use by persons eligible for coverage under Title XIX or Title XXI of the Social Security Act, as amended, may be donated pursuant to this section unless such donation is prohibited.
- D. A pharmaceutical manufacturer shall not be liable for any claim or injury arising from the storage, donation, acceptance, transfer, or dispensing of any drug provided to a patient or any other activity undertaken in accordance with a drug distribution program established pursuant to this section.
- E. Nothing in this section shall be construed to create any new or additional liability, or to abrogate any liability that may exist, applicable to a pharmaceutical manufacturer for its products separately from the storage, donation, acceptance, transfer, or dispensing of any drug provided to a patient in accordance with a drug distribution program established pursuant to this section.

F. In the absence of bad faith or gross negligence, no person that donates, accepts, or dispenses unused prescription drugs in accordance with this section and Board regulations shall be subject to criminal or civil liability for matters arising from the donation, acceptance, or dispensing of such unused prescription drugs.

Relevant Regulations, February 16, 2022

18VAC110-20-740. Drug donation sites.

Any pharmacy with a current active pharmacy permit may apply on a form provided by the board for registration as a drug donation site. A registered drug donation site may receive eligible donated drugs, transfer such donated drugs to another registered drug donation site, or redispense the donated drugs in accordance with § 54.1-3411.1 of the Code of Virginia to patients of clinics organized in whole or in part for the delivery of health care services to the indigent. Drugs collected under the drug donation program may not be dispensed to any other patient, sold, or otherwise distributed except as authorized in 18VAC110-20-770 or 18VAC110-20-790.

18VAC110-20-750. Eligible drugs.

- A. Drugs may be accepted by a registered drug donation site only if the following criteria are met:
- 1. Official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium Class A or B container requirements, or better, as set forth in § 54.1-3411.1 A 2 of the Code of Virginia;
- 2. The drugs bear an expiration date that is not less than 90 days from the date the drug is donated; and
- 3. The drugs have not been adulterated or misbranded.
- B. The following drugs shall not be accepted by a drug donation site:
- 1. Schedule II-V controlled substances or any other drug if such return is inconsistent with federal law;

- 2. Drugs determined to be hazardous for donation based on (i) the pharmacist's professional judgment, experience or knowledge, or (ii) available reference materials;
- 3. Drugs that may only be dispensed to a patient registered with the drug manufacturer under a restricted distribution system; and
- 4. Drugs that have been previously compounded.

18VAC110-20-760. Procedures for collecting eligible donated drugs.

- A. A pharmacist or a pharmacy technician under the personal supervision of a pharmacist shall receive and conduct the initial screening for eligibility of donated drugs.
- B. At the time of accepting donated drugs, the drug donation site shall ensure that a donor form is completed. The drug donation site shall give a copy of the donor form to the person donating the drug at the time of the donation and shall maintain the original donor form. A donor form is not required for drugs donated by a patient residing in a long-term care facility or other facility where drugs are administered to that patient if the drugs are donated directly to the provider pharmacy for that facility and such provider pharmacy is registered as a drug donation site.
- C. A donor form shall include the following information:
- 1. A statement that the donor is the patient or patient's agent for whom the prescription drug was dispensed;
- 2. A statement that the donor intends to voluntarily donate the prescription drug for redispensing;
- 3. A statement attesting that the drugs have been properly stored at all times while in the possession of the patient according to official compendium storage requirements;
- 4. Contact information for the patient or patient's agent;
- 5. The date of donation;
- 6. A listing of the donated drugs to include name, strength, and quantity;
- 7. A statement that private health information will be protected:
- 8. The signature of the patient or patient's agent; and

- 9. The initials of the receiving pharmacist, or the initials of the receiving pharmacy technician and supervising pharmacist.
- D. Donated prescription drugs shall be stored within the prescription department, separate from other drug inventory.
- E. Prior to transferring any donated drugs or redispensing donated drugs, a pharmacist shall perform a final review of any donated drug for eligibility and shall ensure that all the donor's patient specific information has been removed from previous labeling or rendered unreadable.
- F. A drug donation site may not charge a fee for collecting donated drugs.

18VAC110-20-770. Procedure for transferring donated prescription drugs.

- A. A drug donation site may transfer eligible donated prescription drugs to another drug donation site for the purpose of redispensing.
- B. The transferring drug donation site shall provide a transfer record to the receiving drug donation site that includes the following:
- 1. The names and addresses of the transferring site and the receiving site;
- 2. The name, strength, and quantity of each donated drug being transferred; and
- 3. The date of transfer.
- C. The original transfer record shall be maintained by the transferring drug donation site.
- D. A copy of the transfer record shall be provided to the receiving drug donation site, the date of receipt shall be recorded on the copy, and it shall be maintained by the receiving drug donation site.

18VAC110-20-780. Procedure for dispensing donated prescription drugs.

- A. A drug donation site redispensing donated prescription drugs shall comply with applicable federal and state laws and regulations for dispensing prescription drugs.
- B. The pharmacy redispensing donated drugs shall not charge for cost of donated drugs, but may charge a dispensing or administrative fee for each such drug redispensed, consistent with the provisions of subdivision 10 of § 54.1-3301 of the Code of Virginia.

- C. Recipients of a redispensed donated drug shall sign a form prior to receiving the drug that includes a statement that the recipient understands that the drug received has been donated for the purpose of redispensing pursuant to § 54.1-3411.1 of the Code of Virginia. The drug donation site shall maintain this form.
- D. A drug donation site is under no obligation to obtain a prescription drug that is not in inventory at the time of a request for such drug.

18VAC110-20-790. Procedures for disposing of donated prescription drugs.

- A. A drug donation site in possession of donated prescription drugs ineligible for redispensing shall dispose of such drugs in compliance with 18VAC110-20-210.
- B. A drug donation site shall maintain records of disposal or transfer for disposal of donated prescription drugs separately from other pharmacy disposal records.

18VAC110-20-800. Records.

- A. All records required for drug donation programs shall be maintained chronologically for two years.
- B. Records and prescriptions related to donated drugs shall be maintained separately from other pharmacy records.
- C. Storage of records.
- 1. Transfer, dispensing, and disposal records may be stored in an electronic database or record.
- 2. Prescriptions and signed forms, as well as any other records, may be stored as an electronic image that provides an exact, clearly legible image of the document.
- 3. Records may be stored in secured storage, either on or offsite.
- D. All records in offsite storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

DONATION AND REDISPENSING OF PRESCRIPTION DRUGS

Representatives of VHHA, the Virginia Society of Health-System Pharmacists and the Virginia Board of Pharmacy met during 2011 to identify opportunities for donation and redispensing of unused prescription drugs.

The General Assembly created Virginia's "Prescription Drug Donation Program" in 2009, authorizing acceptance of certain unused previously dispensed prescription drugs for redispensing to indigent patients through hospitals or free clinics when applicable state and federal requirements are met (§54.1-3411.1).

Virginia's donation program is implemented by Board of Pharmacy regulations (18VAC110-20 - http://www.dhp.virginia.gov/Pharmacy/pharmacy_laws_regs.htm), issued in October 2010, but the program also is subject to the provisions of the federal Controlled Substances Act, which restricts the handling and transfer of "controlled substances" (21 USC §801 et seq.). Therefore, it is limited to donation of Schedule VI drugs only.

Donation is further limited by federal Medicare and Medicaid reimbursement policies, especially in long-term care facilities where unused drugs are more likely to be found.

Additional limitations include the potential expense for the collection site properly destroying any drugs deemed ineligible for donation and the potential liability assumed by the receiving pharmacist for determining the drug's eligibility for donation, including a determination that the drug is properly packaged, has been properly stored and is not adulterated or misbranded by the patient to whom the drug was originally dispensed.

While these practical considerations limit opportunities for donation of unused drugs, hospitals and other providers wishing to support programs serving indigent patients, such as free clinics, may choose to do so, and Virginia's Prescription Drug Donation Program is available to provide procedures for donation that assure the safety and efficacy of donation and redispensing of unused drugs.

Procedures for drug donation under Virginia's Prescription Drug Donation Program and applicable federal law, as well as reimbursement constraints, are described in more detail below.

STATE AND FEDERAL LAW GOVERNING DRUG DONATION AND REDISPENSING

Who May Operate a Drug Donation Program

Any pharmacy with an active permit may apply to the Board of Pharmacy for registration as a drug donation site, authorizing it to receive eligible donated drugs, transfer such donated drugs to another registered drug donation site or redispense the donated drugs to patients of clinics organized in whole or in part for the delivery of health care services to the indigent. There is no fee for registering as a donation site, but registration allows the Board of Pharmacy to assist consumers by identifying participating pharmacies on its web site.

Drugs Eligible for Donation

Registered drug donation sites may accept only those drugs:

- For which official compendium storage requirements are assured:
- That are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better;
- That bear an expiration date that is at least 90 days after the donation date; and
- That are not adulterated or misbranded.

Drug donation sites shall not accept:

- Schedule II-V controlled substances or any other drug if such return is inconsistent with federal law. The federal Controlled Substances Act prohibits the transfer of "controlled substances," which include those drugs listed in Schedules II-V of Virginia's Drug Control Act. Therefore, only those prescription drugs listed in Schedule VI of Virginia's Drug Control Act (§54.1-3455) are eligible for donation; these include:
 - 1. Any compound, mixture, or preparation containing any stimulant or depressant drug exempted from Schedules III, IV or V and designated by the Board of Pharmacy for inclusion in Schedule VI.
 - 2. Every drug <u>not</u> included in Schedules I, II, III, IV or V or a device that because of its toxicity or other potential for harm is not generally recognized among experts as safe for use except by or under the supervision of a practitioner licensed to prescribe or administer such drug or device.
 - 3. Any drug <u>not</u> included in Schedules I, II, III, IV or V and that is required by federal law to bear on its label prior to dispensing the symbol "Rx only" or which bears the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian" or any device which bears the legend "Caution:

Federal Law Restricts This Device To Sales By Or On The Order Of A [prescribing practitioner]."

- Drugs determined to be hazardous for donation based on the pharmacist's professional judgment, experience or knowledge or on available reference materials;
- Drugs that can be dispensed only to a patient registered with the drug manufacturer under a restricted distribution system; or
- Drugs that have been previously compounded.

Collection Procedures

Pharmacy staff must perform initial screening for eligibility of a drug for donation. Such screening may be performed by a pharmacist or by a pharmacy technician under the personal supervision of a pharmacist.

If the drug is acceptable for donation, the drug donation site must ensure that a donor form is completed; the donation site keeps the original and gives a copy to the donor. (A donor form is not required for donation of drugs by a LTC facility resident or other facility where drugs are administered to the patient if the drugs are donated directly to the provider pharmacy for such facility and such provider pharmacy is a registered drug donation site.)

The donor form shall include:

- Statement that the donor is the patient or the agent of the patient for whom the drug was dispensed;
- Statement that the donor intends to voluntarily donate the drug for redispensing;
- Statement attesting to the proper storage of the drug at all times while in the patient's possession according to official compendium storage requirements;
- Contact information for patient or his agent;
- Date of donation:
- List of donated drugs with name, strength and quantity of the drug;
- Statement that private health information will be protected;
- Signature of patient or his agent; and
- Initials of receiving pharmacist or receiving pharmacy technician and supervising pharmacist.

Donated drugs must be stored in the drug donation site's prescription department separately from other drug inventory.

Before transferring any donated drugs or redispensing donated drugs, the pharmacist must perform a final review of the drug for eligibility and must ensure that all the patient-specific and identifying donor information is removed from the drug or rendered unreadable.

Drug donation sites are prohibited from charging a fee for collecting donated drugs.

Transfer of Donated Drugs

A drug donation site may transfer eligible donated drugs to another registered drug donation site for redispensing.

The transferring site shall complete a transfer record that includes:

- Names and addresses of the transferring site and the receiving site;
- Name, strength and quantity of each transferred drug; and
- Date of transfer.

The transferring site shall maintain the original transfer record and provide a copy of the transfer record to the receiving site with the date of receipt recorded on the copy. The receiving site shall maintain the copy.

Dispensing Donated Drugs

Donated drugs must be redispensed in compliance with all applicable state and federal laws governing dispensing of any prescription drug. (See §54.1-3408 and §54.1-3408.01.)

Pharmacies redispensing donated drugs shall not charge for the cost of drugs but may charge a dispensing or administrative fee for each drug dispensed to offset the cost of dispensing, not to exceed the actual cost of dispensing. If the patient is unable to pay such fee, it must be waived (§54.1-3301)

Any recipient of a redispensed drug shall sign a form prior to receiving the drug stating that he understands that the drug has been donated for redispensing. The drug donation site must maintain this form.

Disposing of Donated Drugs

Drug donation sites that possess donated drugs that are ineligible for redispensing must dispose of the drugs in compliance with Board of Pharmacy disposal regulations (18VAC110-20-210), which require that the pharmacist in charge either:

- 1. Transfer the drugs to another person or entity authorized to possess or provide for proper disposal of such drugs; or
- 2. Destroy the drugs by burning in an incinerator, or other method approved by the Board of Pharmacy, in compliance with all applicable local, state, and federal laws and regulations.

The drug donation site must maintain records of disposal or transfer for disposal of donated drugs separately from its other drug disposal records.

Management of Records

All records required for drug donation programs must be kept separately from other pharmacy records and maintained chronologically for two years.

Records should be stored securely and may be stored on-site or off-site. They may be stored in an electronic database or record or as an electronic image that provides an exact legible image of the document. They must be retrievable and available for inspection or audit within 48 hours of request.

Donation of Drugs Dispensed for Medicaid and Medicare Patients

Virginia's Drug Donation Program specifically allows the donation of unused prescription drugs dispensed for use by Medicare and Medicaid beneficiaries "unless such donation is prohibited." (§54.1-3411.1 C).

In hospitals, a quantity of drug is generally not dispensed to a single patient. The drug is generally administered as a single dose, and therefore there is seldom any unwanted or leftover drug to return to the pharmacy. With respect to unused drugs in long-term care facilities, where drugs may be dispensed to residents in multi-day supplies, determining whether unused drugs may be donated is complicated. Federal law prohibits "restocking" – resale by a pharmacy of drugs returned by hospitals or nursing homes that have already been paid for by the program. Because of the procedures for dispensing drugs in long-term care facilities, the drugs may have been paid for by the program and belong to the resident. When a resident no longer needs them or dies, the drugs cannot be restocked and redispensed if Medicaid would then be billed a second time.

Determining whether such drugs may be donated requires some analysis of how they were initially dispensed and paid for.

- For skilled nursing residents covered under Medicare Part A, the drugs belong to the facility, and the facility can return unused drugs to the pharmacy for a credit. The pharmacy then can redispense them to other residents, so there is no donation opportunity.
- For Medicaid residents who are over 65, Part D governs, and the drugs are the property of the resident.
 - o If the resident leaves the nursing home, he can take the drugs with him, and in fact must do so because if he still needs them, Part D will not pay for them again if they were dispensed earlier at the nursing home.
 - o If the resident dies in the nursing home, Part D treats the pharmacy like a retail pharmacy; the NH may donate the drugs, dispose of them or return them to the pharmacy for disposal. If the nursing home returns them to the pharmacy, Part D does not allow a credit for the return.

• For self-pay residents (probably not a large number), unused drugs can be returned to the pharmacy and redispensed.

Even in those limited situations where unused drugs can be donated – primarily where Part D coverage is involved -- HIPAA requires long-term care facilities to destroy all pharmaceutical labels that contain individual information and re-label the medication prior to donation or redistribution. The labor cost of these tasks and the risk of mislabeling – and potential patient harm and provider liability – discourages donation by long-term care facilities.

The Patient Protection and Affordable Care Act requires that by 2013 only a 14-day supply of brand-name drugs be dispensed at a time to nursing home residents, which will further limit the supply of dispensed but unused drugs potentially available in these settings for donation.

Liability

Virginia's law authorizing the Prescription Drug Donation Program provides pharmaceutical manufacturers with immunity from liability for claims or injuries arising from the storage, donation, acceptance, transfer or dispensing of any drug provided to a patient or any other activity undertaken under a drug distribution program established under the law. However, the statute does not provide immunity for any other participants in a donation program, including pharmacists or other individuals or entities donating, receiving or redispensing donated drugs.

REFERENCES

VA. CODE §54.1-3411.1

Board of Pharmacy Regulations Governing the Practice of Pharmacy 18VAC110-20

Controlled Substances Act - 21 U.S.C. Chapter 13

Deficit Reduction Act of 2005 – 42 U.S.C. 1396b

Virginia Board of Pharmacy web site - http://www.dhp.virginia.gov/Pharmacy/news_pharmacist.htm



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REGISTRATION FOR A PHARMACY TO BE A COLLECTION SITE FOR DONATED DRUGS

Applicant—Please provide the information requested below. (Print or Type) Use full name not initials

Name of Pharmacy

Area Code and Telephone Number

Street Address

City

City

State

Zip Code

If a current pharmacy permit is held, indicate the permit number

0201
Expected start date for collection of donated items



Agencies | Governor

Search Virginia.Gov

DHP Home Page > Pharmacy > Collection Sites

Contact Us | Search DHP

Board Home
Board Members
Laws & Regulations
Forms and Applications
Pharmaceutical Processor-
Cannabis Oil
Renew Online
Update Your Information
License Lookup
Case Decisions
Meetings & Minutes
Newsletters & Presentations
Disciplinary Proceedings
Prescription Monitoring
Program
FAQ
Guidance Documents
File a Complaint
Inspections
Administrative Proceedings
Division
Staff Directory

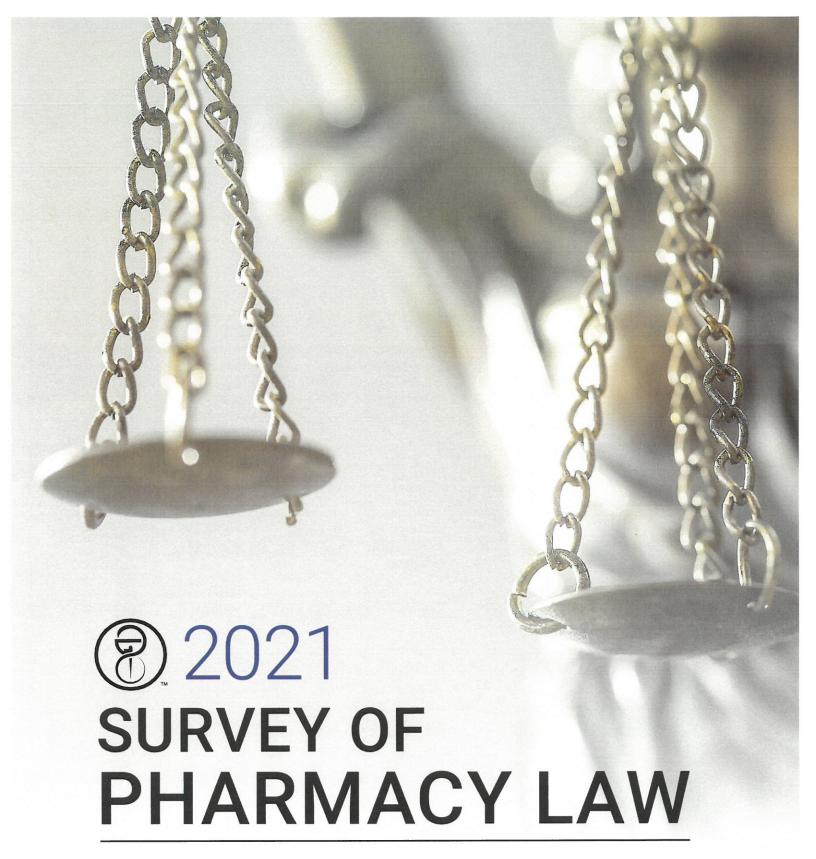
Virginia Board of Pharmacy Collection Sites for Donated Drugs

Pharmacies Registered to be a Collection Site for Donated Drugs

Facility Name	Address	Contact Info
Commonshare	2026A Dabney Rd Henrico, VA 23230	(804) 416-6255
Commonshare HDH	1602 Skipwith Rd, Suite 201 Henrico, VA 23229	(804) 416-6255
Community Pharmacy and Medical Supp	2900 Tyler Road, Suite 1890 Christiansburg, VA 24073	(540) 639-1647
Cross Over Health Center	108 Cowardin Avenue Richmond, VA 23224	(804) 233-5016
Free Clinic of Franklin County	1171 Franklin Street Rocky Mount, VA 24151	(540) 489-7500
Medical Center Pharmacy	2001 Crystal Spring Ave Suite 110 Roanoke VA 24014	(540) 853-0905
Mountain Care Center	8252 Riverside Drive Oakwood, VA 24631	(276) 498-5260
NovaScripts Central	6400 Arlington Blvd, Suite 120 Falls Church, VA 22042	(703) 532 - 0269
Sentara Rockingham Memorial Hospital Outpatient Pharmacy	2010 Health Campus Drive Harrisonburg, VA 22801	(540) 689-2400
Sinclair Health Clinic	301 N. Cameron Street Winchester, VA 22601	(540) 536-4012
Skyline Pharmacy & Clinic	5100 Leesburg Pike Alexandria VA 22302	(703) 417-9074
Timberlake Health & Wellness	20276 Timberlake Road Lynchburg, VA 24502	(434) 237-6337

Board of Pharmacy Email: <u>pharmbd@dhp.virginia.gov</u>

Caroline D. Juran, Executive Director R. Dale St. Clair, Jr., Chairman



Including all 50 states, DC, Guam, and Puerto Rico

State	Does State Allow Drug Repository/ Donation Program?	Does State Permit the Return and Reuse of Medications?	Does State Have Laws/ Regulations on the Disposal of Medications?	Does State Allow the Practice of Telepharmacy?
Alabama	Yes	No R4	Yes J4	No
Alaska	No	No	Yes S	Yes
Arizona	Yes	Yes DDD	No	Yes
Arkansas	Yes LL	Yes LL, S4	Yes	Yes U
California	Yes	Yes S5	Yes T5	Yes V5
Colorado	Yes	Yes	Yes Q5	Yes XX
Connecticut	Yes GG	Yes GG	Yes A4	Yes P
Delaware	No	Yes RR	Yes	Yes Y
District of Columbia	No	No	Yes B5	Yes
Florida	Yes	No	Yes	No A6
Georgia	Yes NN	Yes NN	Yes	No
Guam	No	Yes DDD	No	Yes
Hawaii	Yes B4	No	Yes †	No †
Idaho	Yes	Yes	Yes	Yes
Illinois	No	No L	Yes BB	Yes C
Indiana	Yes SS	Yes SS	Yes	Yes
lowa	Yes UU	UU	Yes TT	Yes
Kansas	Yes	Yes XX, AAA	Yes WW	No R5
Kentucky	Yes	KKK, LLL	Yes BB	No
Louisiana	Yes RRR	Yes U4	Yes	Yes
Maine	No	No	Yes	Yes
Maryland	Yes U	DDD	EEE	No
Massachusetts	No	No	Yes ZZ	Yes V
Michigan	Yes N, AA	Yes AA	Yes Per Admin. Rules	YY
Minnesota	Yes ZZZ, H4	AAA	Yes	Yes
Mississippi	Yes	Yes W4	Yes	No
Missouri	Yes CCC	Yes CC	Yes	V4
Montana	Yes GGG	Yes GGG	No	Yes
Nebraska	Yes HHH	Yes HH, HHH	Yes III	Yes
Nevada	Yes OOO	Yes OOO	No No	Yes
New Hampshire	Yes	Yes	Yes	Not addressed
New Jersey	No	No	No	
New Mexico	Yes	Yes FFF	Yes SSS	Not addressed
New York	Yes	Yes JJJ	Yes Z5	Yes
North Carolina	Yes	Yes F4	No No	No Yes YOO/
North Dakota	Yes	Yes KKK	Yes	Yes YYY
Ohio	Yes	Yes BBB	Yes K5	Yes
Oklahoma	No	Yes I4	Yes A4	Yes XX
Oregon	Yes T4	Yes NNN		No Yes 115
Pennsylvania	XX, ZZZ	Yes MMM	Yes	Yes U5
Puerto Rico	K	No	Yes	No
Rhode Island	Yes FFF	Yes FFF	Yes Yes	No
South Carolina	QQQ	QQQ	Yes	No
South Dakota	No	Yes JJJ		No
Tennessee	Yes		Yes ZZ, III	Yes
Texas	RRR	Yes VVV RRR	Yes	Yes W5
Jtah	Yes		Yes SSS	Yes
Vermont	No	Yes E4	No	Yes
	Yes	No Voc TTT	Yes	Yes
/irginia		Yes TTT	Yes UUU	No
Nashington Nest Virginia	No PPP	Yes PPP t	Yes WWW	Yes Q4
vesi virdinia	Yes FFF, YYY	Yes FFF, YYY	Yes	Yes
Visconsin	Yes	Yes	No	Yes

Colored text denotes change from 2020 edition. † Other comments noted in 2020 edition no longer apply.

Legend

- A Prescriber ownership of pharmacies is prohibited if prescribers are likely to benefit due to the prescriptions they write.
- B Limited to industrial accident prescriptions.
- C See ILCS 85/3(d)(9).
- Prescriber(s) may own no more than 10% total interest in a pharmacy.
- E Does not apply to HMO or self-funded Employee Retirement Income Security Act plans.
- F Department of Health & Human Services,
 Division of Public Health, Licensure Unit.
- G Prescriber ownership of pharmacy is not prohibited; however, benefits earned in connection to patient referral may violate rebating laws RCW 19.68.010.
- Referral to pharmacies in which the prescriber has ownership interest is prohibited.
- Required for automated medication systems.
- J In the Division of Facilities' Standards,
 Department of Health.
- K Not specifically released in the law.
- See Section 1330.750 of the Rules.
- M Self-referral prohibited; limits ownership.
- N Contact Board for specific requirements.
- No legislation but Board rules prohibit any activity that negates patient freedom of choice.
- P In hospital settings only.
- Q For durable medical equipment.
- R As of May 2, 2013, legislation was signed eliminating the pharmacist requirement for device/DME only pharmacies.
- S 12 AAC 52.560.
- T However, it shall be unlawful for one or more medical practitioners to have a proprietary or beneficial interest sufficient to permit them to exercise supervision or control over the pharmacist in his or her professional responsibilities or duties.
- U If board approved.
- Must comply with Board rules regarding centralized dispensing (MA – Must comply with Board policy regarding shared pharmacy services).
- W Encouraged, but not mandated at this time.
- Must have technician help if filling more than 15 prescriptions/hour on average.
- Y Consulting purpose only.
- Not specifically addressed; must follow laws and regulations governing all pharmacies.

- AA Statutory requirements for unused drug program, disposal, and cancer drug repository program in MCL 333.17775 to MCL 333.17780. (PA 329 of 2004 effective September 23, 2004).
- BB EPA and Occupational Safety and Health Administration guidelines are applicable to legend drugs; DEA guidelines apply for controlled substances.
- CC Under some circumstances.
- DD Board recommends that such programs be addressed in the pharmacy policy and procedure manual.
- EE Board may approve technician ratio variances.
- FF Refer to Board Rules, Chapter 2, Section 15
- GG Administered through the Department of Social Services.
- HH At the pharmacist's discretion, non-controlled substances may be returned from a LTCF for a credit and reuse if they have been in the control of the LTCF at all times, are in unit dose tamper-evident packaging, and the labels bear the expiration date or calculated expiration date and lot number. Similar provisions also exist for community health centers, correctional facilities, and jails.
- Amendments to rules and regulations allow for greater use of technology and unlicensed personnel.
- JJ Board has established policy on allowing pharmacist work breaks without closing the pharmacy.
- KK Meal break provisions. (AL Meal and break. See Board Rule 680-X-2.28 and Code of Alabama (1975) §34-23-70(a).)
- LL Charitable clinics may reuse unused nursing home medications under a specific permit and regulations. Certain medications defined by regulations sent to a LTCF or correctional facility and returned to the pharmacy within 72 hours may also be reused if the package has not been opened or partially used by the returning facility.
- MM However, Board has a 12-hour per day work limit.
- NN Per Board Rule 480-10-.17 and Chapter 480-50 and DPH Rule 511-5-12.
- OO Unless performing the practice of pharmacy.
- PP Under O.C.G.A. §26-4-110.1(b).
- QQ Pharmacists may not be required to work more than 12 continuous hours in a single workday.

Legend cont.

RR — Permit reuse and return in specific ca	ases.
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SS — Only under very limited conditions set forth in 856 IAC 1-21-1 and IC-25-26-13-25.

TT — Controlled substances only.

UU — Excluding controlled substances.

VV — Institutional setting compounding pharmacies.

WW — Licensed pharmacist shall destroy deteriorated, outdated, unused, or discontinued drugs and biologicals at nursing home in the presence of one witness who is an RN. KAR 28-39-156.

XX — Limited circumstances.

YY - MCL 333.16283 - MCL 333.16288.

 In hospitals/clinics, policy of Department of Public Health – Drug Control Program.

AAA — If returns from patient – no; returns from nursing home, assisted living facilities, and jails are available under certain circumstances.

BBB — See OAC 4729-5-14.

CCC — Handled by the Department of Health and Senior Services.

DDD — Return and reuse of medication is allowed only for items in manufacturer's sealed packages or unit-dose packages if pharmacist determines they have been properly stored and handled. (GU – In health care facility.)

EEE — Long-term care regulations allow for two nurses or pharmacist and nurse to view disposal of medication. Any pharmacy accepting medication from individuals for disposal is required to register with the Board under the Prescription Drug Repository Program and comply with federal law if collecting controlled dangerous substances for disposal. Regulations pending.

FFF — Allowed in limited circumstances (only if drugs are repackaged as required by current regulations; if ultimate user is a patient in a hospital, nursing home, or assisted living facility).

 GGG — Only applies to drugs in LTCF; may be donated to indigent clinics and cancer drug repositories.

HHH — For certain cancer and immunosuppressant drugs.

III — For controlled substances and drugs in LTCFs.

 JJJ — Return and reuse permitted only in certain facilities with approved systems for medication storage.

KKK — Restricted to LTCFs and repositories in which drugs are stored appropriately

and meet USP Class B packaging requirements or better.

LLL — Refer to 902 KAR 55:065. Although drug repository programs are not licensed, return and reuse of certain drugs are permitted if certain circumstances are met.

MMM — Only under very strict conditions.

NNN — Only in long-term care pharmacies and supervised living groups where drugs have remained in the control of health care provider and are packaged.

COO — Limited circumstances of certain institutional distribution and cancer drug donation program.

PPP — Voluntary drug donation and redistribution program. The law allows practitioners, pharmacists, medical facilities, drug manufacturers, drug wholesalers, patients or their representatives to donate specific drugs and supplies to participating pharmacies for redispensing. Drugs must meet specific conditions to be eligible to donate. Does not include controlled substances. No drug repository.

QQQ — State drug repository program is not permitted; however, return and reuse of medications are allowed with pharmacist's professional judgment.

RRR — Under very limited conditions; contact the Board for specific requirements.

NABPLAW Online Search Terms

Miscellaneous State Pharmacy Laws (type as indicated below)

- absence security
- · central fill
- · continuous quality improvement
- destruction disposal
- drug donation program
- drug repository
- "freedom of choice"
- pharmacy benefit manager
- pharmacist breaks
- pharmacist present security
- pharmacist workload
- practitioner pharmacy owner
- prohibited ownership
- return reuse
- self-inspection

Legend cont.

- SSS The board has rules regarding the destruction of drugs dispensed to patients in nursing homes, drugs returned to a pharmacy, and the disposal of stock prescription drugs.
- TTT Refer to 54.1-3411.1. Prohibition on Returns, Exchanges, or Re-dispensing of Drugs; Exceptions.
- UUU - If a pharmacist-in-charge wishes to dispose of unwanted drugs, he or she shall use one of the following procedures: (1) Transfer the drugs to another person or entity authorized to possess or provide for proper disposal of such drugs; or (2) Destroy the drugs by burning in an incinerator in compliance with all applicable local, state, and federal laws and regulations. If Schedule II through Schedule V drugs are to be destroyed, additional procedures apply. Disposal of drugs by authorized collectors is allowed following conditions found in Regulation 18VAC110-20-211.
- VVV TCA 63-10 Part 5.
- WWW Secure Drug Take Back Act passed in 2018 (ESHB 1047) mandates that the Department of Health establish a comprehensive drug take-back program that will be fully funded by the pharmaceutical industry.
- XXX OAR 855-041-1170.
- YYY Only remote medication order entry services for health care facility pharmacies.
- ZZZ Cancer drugs only.
 - A4 For controlled substances.
 - B4 The Department of Public Safety,
 Narcotics Enforcement Division, has a
 drug repository program for controlled
 substances. Return of prescription drugs
 dispensed or distributed by a pharmacy
 for administration to patients in an
 institutional facility allowed under certain
 conditions. The Department of Health
 (Chapter 328 C, HRS) allows for the
 donation of prescription drugs previously
 dispensed to patients in an institutional
 facility to be donated to needy persons.
 - C4 With Board-approved central fill designation on pharmacy drug outlet registration.
 - D4 Pharmacists may not be required to work more than 12 continuous hours in a single workday and are entitled to a 30-minute meal break and another 15-minute break if working more than six continuous hours.

- E4 A pharmacist may accept back and redistribute a drug that was dispensed for a patient in a nursing care facility, ICFMR, state prison, county jail, or state hospital and the drug was returned to the original dispensing pharmacist and is in a unit pack or in the manufacturer's sealed container.
- F4 In accordance with Rules at 21 NCAC 46.2513 and N.C.-GS 90-85.44(c).
- G4 Regulations pending.
- H4 The Minnesota Board of Pharmacy is creating a medication drug repository program through which donors may donate a drug or medical supply for use by an individual who meets certain eligibility criteria.
- See OK Rules 535, Chapter 12. Allowed unused drugs in LTCF to be dispensed in charitable pharmacies and mental health facilities.
- J4 See Code of Alabama 1975 34-23-6 and as mandated by DEA for controlled substances and 680-X-2-.42 for drug disposal receptacles.
- K4 Only as it pertains to prescription laws.
- Unless a drug outlet without an on-site pharmacist or prescriber, then monthly self-inspections are required.
- M4 For Alabama-licensed pharmacies only.
- N4 Centralized prescription processing;
 Chapter 2, Section 32(e)(iii)(E).
- O4 For pharmacies approved for central fill processes.
- P4 See §22-1915.11.
- Q4 Rules are specific to pharmacies storing, dispensing, and delivering drugs to patients without a pharmacist on site.
- R4 Allows return of drugs if for destruction.
- S4 Pharmacists serving long-term care facilities and/or correctional facilities may accept for return and reuse medications returned to the pharmacy within 72 hours that meet stipulations included in 04-00-0004.
- T4 Charitable pharmacy program. No controlled substances. OAR 855-044.
- U4 Return and reuse allowed only in hospital and correctional pharmacies.
- V4 Pharmacists can provide designated non-dispensing activities remotely or electronically, but cannot remotely supervise pharmacy technicians or perform final product/label verification.
- W4 Charitable pharmacies may reuse unused long-term care facility medications under a specific permit and regulations.

Legend cont.

- X4 No pharmacist shall work more than eight hours without a meal/rest break.
- Y4 Except that the Board regulates the practice of pharmacy into the state; for example if a PBM was conducting MTM into the state.
- Z4 See §1330.560(b)(1)(E)(vi).
- A5 Regulated by the Department of Insurance.
- \$22B-502: Safe Disposal of Unused
 Pharmaceuticals in Health Care Facilities.
- C5 For entities not licensed in Nebraska, if pharmacist practice impacts Nebraska patients, then pharmacist must hold a Nebraska pharmacist license.
- Must be registered with the Insurance Division in the Department of Consumer and Business Services.
- E5 §22-1501.1.
- F5 For initial pharmacy permit application only.
- G5 As a precursor to the inspection by a compliance officer for verification.
- H5 Yes, for in-state pharmacies. For outof-state pharmacies, only if home state inspection is two years or older.
- 15 Sterile compounding.
- J5 18VAC110-20-110(B) Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.
- K5 See Chapter 4729-8 of the Ohio Administrative Code.
- L5 Self-assessment form must be completed by July 1 of each odd-numbered year.
- M5 Reviewed with inspector upon annual inspection.
- N5 Compounders only (gap analysis).
- O5 In process.
- P5 Michigan Administrative Code R 338.477(5) requires applicants for new license or relocation to complete a selfinspection form.
- Q5 Colorado Department of Public Health and Environment.
- R5 Pharmaceutical Task Force has provided recommendations.
- S5 Limited and specific in statutes. See California Business and Professions Code 4046 and 4169.5 and California Health and Safety Code 150204.

- T5 The Board's prescription drug take-back program became effective on June 6, 2017. See California Code of Regulations Title 16, Article 9.1, including Sections 1776-1776.6.
- U5 Per Board approval, a pharmacy may obtain a remote processing designation on pharmacy registration (see OAR 855-041-3100 to 855-041-3130); per Board approval, a remote distribution facility registration allows supervision of technicians preparing drugs for clinic administration by means of live audiovisual connection (see OAR 855-041-5050 to 855-041-5055).
- V5 Remote dispensing site pharmacy is allowed in medically underserved areas (See CA BPC 4130, 4131, 4132, 4134, and 4135).
- W5 Only in federally qualified health centers.
- X5 See Minnesota Rule 6800.2160, Pharmacy Work Conditions.
- Y5 Requires pharmacies to perform and complete a self-inspection worksheet in March of each year. A new self-inspection form is also required within 30 days of a change in pharmacy's responsible manager.
- Z5 Drug Take Back Law will establish a statewide drug take back program for the safe disposal of drugs, effective 2019.
- A6 The specific practice of "telepharmacy" is not specifically addressed in statute or rule. Section 465.035, F.S., provides that it is lawful for a pharmacy to dispense medicinal drugs, including controlled substances authorized under subsection (2), based on reception of an electronic facsimile of the original prescription if certain conditions are met. Section 465.0235, F.S., also provides that a pharmacy may provide pharmacy services to a long-term care facility or hospice or a state correctional institution through the use of an automated pharmacy system that need not be located at the same location as the pharmacy.
- B6 Under review.
- C6 If PBMs conduct audits, they are subject to the requirements of Indiana Code 25-26-22.
- D6 May be dispensed by a pharmacy or medical equipment supplier. See §54.1-3435.2, §54.1-3435.02, and 18VAC110-20-680.
- E6 For telepharmacy locations only.

Legend cont.

- F6 Licensure required for Medical Device Manufacturers and Retailers in CA; license is issued by the CA Department of Public Health.
- G6 See §22-1911.2.
- H6 Licensed by the Department of State Health Services.
- 16 Board of pharmacy.
- J6 Under the jurisdiction of the Home Medical Equipment and Services Board, the Board of Orthotics, Prosthetics, and Pedorthics, and the Board of Pharmacy.
- K6 Set forth in 856 IAC 1-39.
- L6 Medical oxygen and medical devices.
- M6 Addressed in the Pharmacy Practice Act.
- N6 As of June 1, 2014, entities that dispense only prescription devices or prescription durable medical equipment are no longer required to obtain a pharmacy permit.

- O6 If the device or oxygen bears the federal legend, the Massachusetts regulations would treat them as Schedule VI controlled substances.
- P6 Same as federal regulations.
- Q6 State board of pharmacy.
- R6 Prohibits a wholesale distributor to sell a prescription device directly to ultimate consumer.
- S6 ORC 4752 and OAC 4729.11.
- T6 Department of Health regulates through the Drug, Device, and Cosmetic Program.
- U6 See BPC 4113.5 Community Pharmacies: Required Staffing.
- V6 Jurisdiction: State Department of Health.
- W6 State law and rules are silent; however, pharmacies have a duty to deliver lawfully prescribed medication in a timely manner within reasonable expectations for filling rule provides exceptions.



State Prescription Drug Repository **Programs**

10/1/2021



Patients Looking to Donate

If you are looking to dispose of a prescription drug product, drug repository programs will not meet your needs. If you wish to **donate** medicine, contact SIRUM, an organization specializing in assisting with drug donations and national drug donation laws. Please check with a local pharmacy, prescriber or contact your state Board of Pharmacy for more information.

Please note: NCSL provides material about state laws as general information, primarily for policymakers. No information in this report is intended as personal legal or medical advice; NCSL is not responsible for any such uses or application of material in this report. All program status descriptions are subject to change. States may have additional regulations or executive agency guidelines that clarify or modify the terms described below.

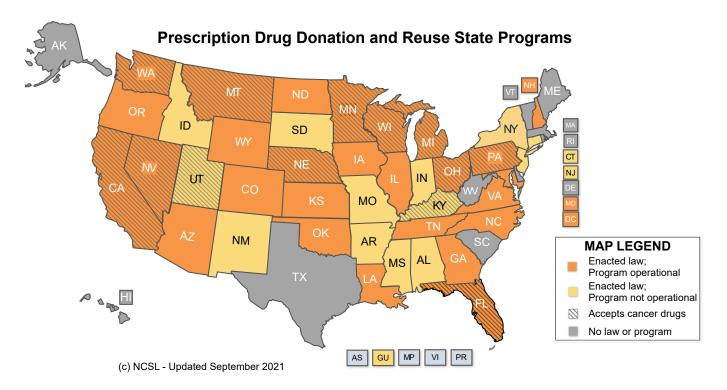
Overview

Unused medication worth billions of dollars in ends up in the trash every year. For example, research shows medication worth over \$3 billion is thrown out by hospitals every year, and an additional \$2 billion worth is discarded in long-term care facilities. Medication in these settings often goes unused because a patient's condition improves, they change doses, change care settings or die. Any unopened medicine not used by the patient must be disposed of. 023

Instead of disposing of the unused medicine, facilities in states with repository programs may donate it. By collecting unused prescription drugs and redistributing them to qualifying individuals, prescription drug donation and reuse programs, or drug repositories, aim to increase medication access, especially to underserved populations.

As of fall 2021, 40 states, Guam and Washington, D.C. passed legislation establishing prescription drug repository programs. Twenty-seven states and Washington D.C. have operational programs. Thirteen states plus Guam have laws enacted but no operational program. Operational programs are those with participating pharmacies, charitable clinics or hospitals approved by the state to collect and redistribute donated drugs. Twelve states—California, Florida, Kentucky, Michigan, Minnesota, Montana, Nebraska, Nevada, Ohio, Pennsylvania, Utah, Washington and Wisconsin—have more permissive programs related to cancer medications in addition to a general drug repository program.

Common obstacles to program success include: (1) requirements for participation may be overly burdensome, and may include limitations on types of entities that are eligible to donate and receive medications, (2) the potential increased administrative burden for participating agencies, (3) lack of financial resources and (4) a lack of public awareness of or participation in the program.



Examples of State Donation Programs

- Established in 2001, Iowa's SafeNetRx Program has served over 100,000 patients and redistributed more than \$45.7 million of medication and supplies.
- Wyoming's Medication Donation Program began in 2007 and has helped the state fill over 150,000 prescriptions worth over \$25 million.
- Since 2004, Oklahoma's Drug Recycling Program has filled over 250,000 prescriptions, worth at least \$27 million.

While only operational since 2017, according to SIRUM, Georgia's Donated Drug Repository Program
has filled over 450,000 prescriptions, worth over \$42 million.

Comparison of Provisions in Enacted Legislation

Most state programs have a number of common provisions such as:

- No acceptance or transfer of a controlled substance medication.
- Only professionally designated persons are allowed to donate—although some states do allow individuals patients to donate directly.
- All prescription drugs must be unopened and in sealed, tamper-evident packaging, though some exceptions exist for cancer drugs.
- Expired drugs are never accepted.
- Expiration dates must be visible, and drugs must not expire before use.
- Usually, donated drugs must be delivered to a specific type of medical facility or pharmacy. Some may require the donor to sign a form or waiver.
- All products must be checked by a pharmacist prior to being dispensed.
- Financial compensation or payment for donations is prohibited.
- Selling or reselling donated prescription drugs is illegal.
- Donations may be tax-deductible under certain conditions.
- Adulterated or misbranded medications are not accepted or transferred.
- Protection from liability is guaranteed for both donors and recipients.

Some differences across state programs include:

- Types of drugs accepted for redistribution (e.g. over-the-counter drugs, condition-specific drugs).
- Eligible donors, recipients and patients.
- Protocols for transferring and repackaging donated drugs.
- Maximum pharmacy dispensing fees.
- Agency oversight.
- Funding mechanisms.

2021 Operational State Laws and Programs

This table only examines drug reuse and repository laws—any drug take-back and disposal-only programs are not included in this report. For the details of each state law, please click the hyperlinked state statute, bill or visit the state's website.

State	Statute
Arizona	AZ Rev Stat § 32-1909
California	CA Health and Safety Code §§150200-150208
Colorado	CO Rev Stat § 12-42.5-133
Florida	FL Stat §499.029
	FL Admin. Code R. 61N-1.026
Georgia	O.C.G.A. § 31-8-301
Illinois	2021 enacted legislation
lowa	IA Code §§ 135M.1—7
	IA Code §§ 641 IAC 109.1
Kansas	Kansas Board of Pharmacy Laws and Regulations
	KS Stat §§ 65-1668 – 1675
	KS Stat § 65-1664
Louisiana	LA Rev Stat §§ 37:1226.2—3
Maryland	MD Health-Gen Code § 15–605
Michigan	MI Comp L § 333.17775
Minnesota	MN Stat § 151.555
Montana	MT Code §§ 37-71401—08
Nebraska	NE Code §§71-2422—2430
Nevada	NV Rev Stat §§ 453B.010—240
New Hampshire	NH Rev Stat § 318.58
North Carolina	NC Gen Stat § 90-85.44
	Board Of Pharmacy Rules, 21 NCAC 46.2513
North Dakota	ND Century Code § 43-15.2
Ohio	OH Rev Code § 3715.87
	OAC 4729:5-10
Oklahoma	OK Stat §§59-367.1—8
Oregon	OR Rev Stat §§ 689.770—830
Pennsylvania	49 PA Code §§ 27.501—506

State	Statute
Tennessee	Tenn. Code Ann. § 63-10-501—510
Virginia	VA Code § 54.1-3411.1
Washington	RCW § 69.70.020
Washington D.C.	§ 48–851.02
Wisconsin	WI Stat §§ 148.01—10
Wyoming	Wyo. Stat. § 35-7-1603

States with Laws but Non-operational Programs

State	Statute
Alabama	AL Admin Code 420-11-1.01—1.03
Arkansas	A.C.A. § 17-92-1103
Connecticut	CGS § 17b-363a
Guam	§§ 5101—5107
Idaho	ID Code § 54-1761
Indiana	IC§ 25-26-20 and IC § 25-26-23
Kentucky	KRS § 315.452 ; Formerly § 194A.452
Mississippi	MS § 43-13-501-9
Missouri	MO Rev Stat § 196.979
New Jersey	NJ Stat. § 24:6M
New Mexico	NM Stat § 26-1-3.2
	16.19.34 NMAC
New York	NY Public Health § 280-B
South Dakota	SD 20:51:13:02.0104
Utah	UT Code §§ 58-17b901—17b907

Other Information

NCSL Resources

- Prescription Drug Policy: A Bipartisan Remedy
- Prescription Drug Policy Database
- Prescription Drug Policy Resource Center

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