State of Wisconsin

Date of enactment:
2025 Assembly Bill 969 Date of publication*:

2025 WISCONSIN ACT

AN ACT ***to repeal*** 255.056 (7); ***to renumber and amend*** 255.056 (1) (bg), 255.056 (3) (c) and 255.056 (3) (d); ***to amend*** 255.056 (1) (br), 255.056 (1) (e), 255.056 (2), 255.056 (2m) (intro.), 255.056 (2m) (b), 255.056 (3) (intro.), (a) and (b), 255.056 (4), 255.056 (5), 255.056 (6) (b) and 255.056 (6) (c); ***to repeal and recreate*** 255.056 (1) (d) and 255.056 (1) (f); ***to create*** 255.056 (1) (bd), 255.056 (1) (bg) 2. and 3., 255.056 (1) (bm), 255.056 (1) (br), 255.056 (1) (gc) and (gm), 255.056 (1) (m), 255.056 (2g) (b), 255.056 (2h) (b) and (c), 255.056 (3) (bm), 255.056 (3m) and 255.056 (8) to (20) of the statutes; **relating to:** the drug repository program.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 255.056 (1) (bd) of the statutes is created to read:

255.056 **(1)** (bd) "Donor" means any person authorized under state or federal law to possess a drug, including an individual member of the public; wholesaler or distributor; 3rd-party logistics provider; pharmacy; dispenser; clinic; surgical or health center; detention or rehabilitation center; jail; prison; laboratory; medical or pharmacy school; prescriber or other health care professional; long-term care facility or health care facility; government agency; drug manufacturer; repackager; relabeler; outsourcing facility; hospital operated by the federal department of veterans affairs; or person authorized to import a drug under section 801 or 804 of the federal Food, Drug, and Cosmetic Act, 21 USC 381 to 384, or a similar provision of federal law.

SECTION 1g. 255.056 (1) (bg) of the statutes is renumbered 255.056 (1) (bg) (intro.) and amended to read:

255.056 **(1)** (bg) (intro.) "Drug" ~~has the meaning given~~ means any of the following:

1. A drug, as defined in s. 450.01 (10).

SECTION 1r. 255.056 (1) (bg) 2. and 3. of the statutes are created to read:

255.056 **(1)** (bg) 2. A nonprescription drug product, as defined in s. 450.01 (13m).

3. A prescription drug.

SECTION 2. 255.056 (1) (bm) of the statutes is created to read:

255.056 **(1)** (bm) "Eligible patient" means an individual who is indigent, uninsured, underinsured, or enrolled in a public health benefits program. "Eligible patient" includes a patient who is not indigent, uninsured, underinsured, or enrolled in a public health benefits program if a need for a donated drug is not identified among patients who are indigent, uninsured, underinsured, or enrolled in a public health benefits program.

SECTION 3. 255.056 (1) (br) of the statutes is created to read:

255.056 **(1)** (br) "Health care professional" means a person who is licensed to practice as a physician, registered nurse, licensed practical nurse, advanced practice registered nurse, as defined in s. 154.01 (1g), optometrist, pharmacist, pharmacy technician, or any

* Section 991.11, WISCONSIN STATUTES: Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication."

other person who is authorized to dispense or administer drugs.

SECTION 4. 255.056 (1) (br) of the statutes, as created by 2025 Wisconsin Act .... (this act), is amended to read:

255.056 **(1)** (br) "Health care professional" means a person who is licensed to practice as a physician, registered nurse, licensed practical nurse, advanced practice registered nurse~~, as defined in s. 154.01 (1g),~~ licensed under s. 441.09, optometrist, pharmacist, pharmacy technician, or any other person who is authorized to dispense or administer drugs.

SECTION 5. 255.056 (1) (d) of the statutes is repealed and recreated to read:

255.056 **(1)** (d) "Pharmacist" means a person licensed by the board under s. 450.03 or 450.05 or licensed similarly in the state in which the person is located.

SECTION 6. 255.056 (1) (e) of the statutes is amended to read:

255.056 **(1)** (e) "Pharmacy" means a pharmacy that is licensed under s. 450.06 or licensed or permitted similarly in the state in which the pharmacy is located.

SECTION 7. 255.056 (1) (f) of the statutes is repealed and recreated to read:

255.056 **(1)** (f) "Practitioner" means any of the following:

1. A person licensed in this state to prescribe and administer drugs.

2. A person licensed in another state and authorized to prescribe and administer drugs in this state.

3. A person licensed to prescribe and administer drugs in the state in which they are located.

SECTION 8. 255.056 (1) (gc) and (gm) of the statutes are created to read:

255.056 **(1)** (gc) "Recipient" means a person that is licensed or permitted to possess a drug in the state in which the person is located, including a wholesaler or distributor, reverse distributor, repackager, hospital, pharmacy, medical facility, clinic, or prescriber office.

(gm) "Returns processor" has the meaning given in 21 USC 360eee (18) and includes a reverse distributor.

SECTION 9. 255.056 (1) (m) of the statutes is created to read:

255.056 **(1)** (m) "Tamper-evident packaging" means a packaging system the contents of which cannot be accessed without obvious destruction of the packaging system, including unit-dose, multiple-dose, immediate, secondary, and tertiary packaging.

SECTION 10. 255.056 (2) of the statutes is amended to read:

255.056 **(2)** The department shall establish and maintain a drug repository program, under which ~~any person~~ a donor may donate a drug or supplies, other than a drug specified under sub. (2m), and a recipient may receive a donated drug or supply for use by an ~~individual who meets eligibility criteria specified by rule by the department. Donation may be made on the premises of a medical facility or pharmacy that elects to participate in the program and meets requirements specified by rule by the department. The medical facility or pharmacy~~ eligible patient.

(2g) (a) A recipient may charge an ~~individual~~ eligible patient who receives a drug or supplies under ~~this subsection~~ sub. (2) a handling fee ~~that may not exceed the amount specified by rule by the department. A medical facility or pharmacy.~~

(2h) A recipient that receives a donated drug or supplies under ~~this subsection~~ sub. (2) may ~~distribute~~ do any of the following:

(a) Distribute the drug or supplies to another ~~eligible medical facility or pharmacy~~ recipient for use under the program under this section or to an entity participating in a drug donation program operated by another state.

SECTION 11. 255.056 (2g) (b) of the statutes is created to read:

255.056 **(2g)** (b) If the recipient is a for-profit entity, the handling fee under par. (a) may not exceed the recipient's cost of providing the drug or supplies, including the current and anticipated costs of educating eligible patients or donors, providing technical support to participating donors, shipping and handling, labor, storage, licensing, utilities, advertizing, technology, supplies, and equipment. No limitation other than the limitations described under this paragraph may be imposed upon the amount of a handling fee under par. (a).

SECTION 12. 255.056 (2h) (b) and (c) of the statutes are created to read:

255.056 **(2h)** (b) Repackage the donated drug or supply as necessary for storage, dispensing, administration, or transfers, in accordance with sub. (12).

(c) Replenish with the drug or supplies a drug or supplies of the same drug name and strength that was previously dispensed or administered to eligible patients.

SECTION 13. 255.056 (2m) (intro.) of the statutes is amended to read:

255.056 **(2m)** (intro.) None of the following drugs may be donated, accepted into inventory, distributed, or dispensed under this section:

SECTION 14. 255.056 (2m) (b) of the statutes is amended to read:

255.056 **(2m)** (b) A drug for which the U.S. food and drug administration ~~requires that a patient using the drug be enrolled in a registry as provided~~ has a risk eval-

uation and mitigation strategy that prohibits inventory transfers under 21 USC 355-1 ~~(f) (3) (F)~~.

SECTION 15. 255.056 (3) (intro.), (a) and (b) of the statutes are amended to read:

255.056 **(3)** (intro.) A drug or supplies may be accepted ~~and dispensed~~ into inventory under the program specified in sub. (2) only if all of the following requirements are met:

(a) The drug or supplies are in their ~~original,~~ unopened, ~~sealed, and~~ tamper-evident packaging ~~or,~~; if the drug or supplies are packaged in single-unit doses, the single-unit-dose packaging is unopened; or the drug or supplies have been repackaged as part of the program specified under sub. (2).

(b) In the case of a drug, the drug ~~bears an expiration date that is later than 90 days after the date that the drug was donated~~ is not expired.

SECTION 16. 255.056 (3) (bm) of the statutes is created to read:

255.056 **(3)** (bm) In the case of a drug that requires temperature control other than room temperature storage, the drug has a method recognized by the U.S. Pharmacopeia to detect improper temperature variations during transit.

SECTION 17. 255.056 (3) (c) of the statutes is renumbered 255.056 (3m) (e) and amended to read:

255.056 **(3m)** (e) The drug or supplies are not adulterated or misbranded, as determined by a ~~pharmacist employed by, or under contract with, the medical facility or pharmacy~~ health care professional, who shall inspect the drug or supplies before the drug or supplies are dispensed.

SECTION 18. 255.056 (3) (d) of the statutes is renumbered 255.056 (3m) (f) and amended to read:

255.056 **(3m)** (f) For a prescription drug or supplies used to administer a prescription drug, the drug or supplies are prescribed by a practitioner for use by an eligible ~~individual~~ patient and are dispensed by a pharmacist or practitioner with patient-specific written or electronic records maintained in accordance with rules promulgated by the pharmacy examining board.

SECTION 19. 255.056 (3m) of the statutes is created to read:

255.056 **(3m)** A recipient may administer or dispense a drug or supplies accepted into inventory under the program described in sub. (2) only if it meets all of the following requirements:

(a) If dispensed to a patient, the drug or supplies is repackaged into a new container or all previous patient information on the donated container has been redacted or removed.

(b) The drug or supplies is properly labeled in accordance with rules promulgated by the pharmacy examining board.

(c) For a prescription drug, the drug has an expiration or beyond use date that will not expire before the use by a patient based on the prescribing practitioner's directions for use.

(d) For a nonprescription drug, the drug has an expiration or beyond use date on the package's label.

SECTION 20. 255.056 (4) of the statutes is amended to read:

255.056 **(4)** No drug or supplies that are donated for use under this section may be resold, and donated drugs or supplies shall be considered nonsaleable. For purposes of this subsection, handling, dispensing, or usual and customary charges to an eligible patient, health plan, pharmacy benefit manager, pharmacy services administrative organization, government agency, or other entity do not constitute reselling.

SECTION 21. 255.056 (5) of the statutes is amended to read:

255.056 **(5)** Nothing in this section requires that a ~~medical facility, pharmacy, pharmacist, or practitioner~~ person participate in the program under this section.

SECTION 22. 255.056 (6) (b) of the statutes is amended to read:

255.056 **(6)** (b) Except as provided in par. (c), any person, except the manufacturer of a drug or supply, is immune from civil or criminal liability ~~for injury to or the death of the individual to whom the drug or supply is dispensed~~ and may not be found guilty of unprofessional conduct for his or her acts or omissions related to prescribing, administering, replenishing, repackaging, donating, accepting, distributing, or dispensing a drug or supply, or facilitating any of those actions, under this section.

SECTION 23. 255.056 (6) (c) of the statutes is amended to read:

255.056 **(6)** (c) The immunity or the prohibition on a finding of guilty of unprofessional conduct under par. (b) does not extend to prescription, administration, replenishment, repackaging, donation, acceptance, distribution, or dispensation of a drug or supply by a person whose act or omission involves reckless, wanton, or intentional misconduct.

SECTION 24. 255.056 (7) of the statutes is repealed.

SECTION 25. 255.056 (8) to (20) of the statutes are created to read:

255.056 **(8)** (a) Prior to the first donation of a drug or supplies from a person that has not previously donated to the recipient, a recipient must verify and record all of the following:

1. That the person meets the definition of "donor" provided in sub. (1) (bd).

2. The donor's name, phone number, and license number, if applicable.

3. That the donor will make donations of drugs or supplies only in accordance with sub. (2m).

4. If applicable, that the donor will remove or redact any patient names and prescription numbers on donated drugs or supplies or will otherwise maintain patient confidentiality by executing a confidentiality agreement with the recipient.

(b) No record about a donor, other than the records described under par. (a), may be required prior to or with a donation.

(9) A drug or supplies accepted under the program described in sub. (2) that does not meet the requirements of subs. (2m) and (3) shall be disposed by returning the drug or supplies to the donor, destroying the drug or supplies by an incinerator, licensed waste hauler, or other lawful method, or transferring the drug or supplies to a returns processor. A record of disposed drug or supplies shall consist of the disposal method described in this subsection, the date of disposal, and the name, strength, and quantity of each drug or supplies disposed. No record, other than the record described under this subsection, may be required for disposal of a drug or supplies.

(10) All donated drugs or supplies received under the program described in sub. (2) but not yet accepted into a recipient's inventory shall be kept in a separate, designated area. Prior to or upon accepting or transferring a donation into inventory, a recipient shall maintain a written or electronic inventory of the donation that consists of the name, strength, and quantity of each accepted drug or supplies, if applicable, and the name and phone number of the donor. A written or electronic inventory is not required if the 2 parties to the donation are under common ownership or control. No record of the acceptance or transfer of a donation, other than the written or electronic inventory described under this subsection, may be required.

(11) A recipient shall store and maintain drugs donated under the program described in sub. (2) physically or electronically separate from other inventory and in a secure and temperature-controlled environment that meets the drug manufacturer's recommendations and U.S. Pharmacopeial Convention standards.

(12) A recipient shall label repackaged drugs or supplies that were donated under the program described in sub. (2) with the drug name, strength, and expiration date. If a recipient repackages multiple packaged donated drugs or supplies with varied expiration dates together, the recipient shall use the earliest expiration date.

(13) To the extent permitted by other laws, a recipient may dispense or administer a donated prescription drug received under the program described in sub. (2) to an eligible patient.

(14) The donation, transfer, receipt, or facilitation of donations, transfers, and receipt of drugs pursuant to this section does not constitute wholesale distribution and does not require licensure as a wholesale distributor. A drug manufacturer, repackager, dispenser, or wholesaler other than a returns processor participating in the program described in sub. (2) shall comply with the requirements of 21 USC 360eee-1 to 360eee-4 relating to drug supply chain security.

(15) When performing any action associated with the program described under sub. (2) or otherwise processing donated drugs or supplies for tax, manufacture, or other credit, a recipient is considered to be acting as a returns processor and shall comply with all recordkeeping requirements for nonsaleable returns under federal law.

(16) All records required under this section shall be retained by a recipient in physical or electronic format, on or off the recipient's premises, for a period of 6 years. A recipient may contract with a donor or a 3rd party to create or maintain records on the recipient's behalf. Except as provided under this subsection, an identifier, such as a serial number or bar code, may be used in place of any information required for a record or label under this section if it allows for the information to be readily retrievable. Upon request by a state or federal regulator, the identifier used for a requested record shall be replaced with the original information. An identifier may not be used on patient labels when dispensing or administering a drug.

(17) For purposes of this section, a donation or other transfer of possession or control of drugs or supplies is not a change of ownership unless it is specified as such by the recipient. If a record of the donation's transaction information or history is required by a state or federal regulator, the record of the history shall begin with the donor of the drug or supplies, shall include all prior donations, and, if the drug or supplies was previously dispensed, shall include only drug or supplies information that is required to be included on the patient label in accordance with rules promulgated by the pharmacy examining board.

(18) An entity participating in a drug donation or repository program operated by another state may participate in the program described in sub. (2) and, in the case of a pharmacy, may dispense donated drugs and supplies to the residents of this state. The entity shall comply with all laws and administrative rules in this state, unless the laws or administrative rules differ or conflict with the laws or rules in the state in which the entity is located.

(19) (a) A recipient may dispense or administer a substitute for a donated, prescribed drug for any of the following:

1. A drug that is in stock and that is a therapeutically equivalent drug.

2. For a prescribed drug that is a biological product, an interchangeable biological product.

(b) A substitution under par. (a) may include any of the following:

1. Splitting a combination drug into 2 or more drugs.

2. Combining 2 or more drugs into a combination drug.

3. A different form of the prescribed drug, including an oral tablet or capsule.

(c) If a recipient dispenses or administers a substitute described in par. (a), the recipient shall inform the patient and the prescribing practitioner of the substitution, unless the recipient's substitution policy for the program described in sub. (2) is readily available on the recipient's website.

(20) A recipient operating primarily for the purpose of participating in the program described in sub. (2) is not required to possess a comprehensive or minimum supply of medicine.

SECTION 26. Effective dates. This act takes effect on the day after publication, except as follows:

(1) The amendment of s. 255.056 (1) (br) takes effect on September 1, 2026.