

State of Wisconsin



2009 Senate Bill 455

Date of enactment: **March 3, 2010**
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2009 WISCONSIN ACT 142

AN ACT *to repeal* 255.056 (1) (a), 255.056 (1) (am) and 255.056 (7) (f); *to amend* 255.056 (title), 255.056 (1) (h), 255.056 (2), 255.056 (3), 255.056 (4), 255.056 (6), 255.056 (7) (a) (intro.), 255.056 (7) (a) 2., 255.056 (7) (a) 3., 255.056 (7) (a) 4., 255.056 (7) (b), 255.056 (7) (c), 255.056 (7) (d), 255.056 (7) (e), 255.056 (7) (g) and 450.01 (23) (k); and *to create* 255.056 (1) (bg) and 255.056 (2m) of the statutes; **relating to**: the wholesale distribution of prescription drugs, donating drugs, and dispensing donated drugs.

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

SECTION 1m. 255.056 (title) of the statutes is amended to read:

255.056 (title) ~~Cancer and chronic diseases drug~~ Drug repository.

SECTION 2. 255.056 (1) (a) of the statutes is repealed.

SECTION 3. 255.056 (1) (am) of the statutes is repealed.

SECTION 4. 255.056 (1) (bg) of the statutes is created to read:

255.056 (1) (bg) "Drug" has the meaning given in s. 450.01 (10).

SECTION 5. 255.056 (1) (h) of the statutes is amended to read:

255.056 (1) (h) "Supplies" means items that are necessary to administer a ~~cancer or chronic disease~~ drug.

SECTION 6. 255.056 (2) of the statutes is amended to read:

255.056 (2) The department shall establish and maintain a ~~cancer and chronic diseases~~ drug repository program, under which any person may donate a ~~cancer or chronic disease~~ drug or supplies, other than a drug specified under sub. (2m), 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 may charge an individual who receives a ~~cancer or chronic disease~~ drug or supplies under this subsection a handling fee that may not exceed the amount specified by rule by the department. A medical facility or pharmacy that receives a donated ~~cancer or chronic disease~~ drug or supplies under this subsection may distribute the ~~cancer or chronic disease~~ drug or supplies to another eligible medical facility or pharmacy for use under the program under this section.

SECTION 7. 255.056 (2m) of the statutes is created to read:

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

(a) A controlled substance, as defined in s. 961.01 (4).

(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 under [21 USC 355-1](#) (f) (3) (F).

* Section 991.11, WISCONSIN STATUTES 2007-08 : 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 as designated" by the secretary of state [the date of publication may not be more than 10 working days after the date of enactment].

SECTION 8. 255.056 (3) of the statutes is amended to read:

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

(a) The ~~cancer or chronic disease~~ drug or supplies are in their original, unopened, sealed, and tamper-evident ~~unit dose~~ packaging or, if packaged in single-unit doses, the single-unit-dose packaging is unopened.

(b) The ~~cancer or chronic disease~~ In the case of a drug, the drug bears an expiration date that is later than ~~6 months~~ 90 days after the date that the drug was donated.

(c) The ~~cancer or chronic disease~~ drug or supplies are not adulterated or misbranded, as determined by a pharmacist employed by, or under contract with, the medical facility or pharmacy, who shall inspect the drug or supplies before the drug or supplies are dispensed.

(d) ~~The cancer or chronic disease~~ 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 and are dispensed by a pharmacist ~~or practitioner~~.

SECTION 9. 255.056 (4) of the statutes is amended to read:

255.056 (4) No ~~cancer or chronic disease~~ drug or supplies that are donated for use under this section may be resold.

SECTION 10. 255.056 (6) of the statutes is amended to read:

255.056 (6) (a) Unless the manufacturer of a drug or supply exercises bad faith, the manufacturer is not subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a ~~cancer or chronic disease~~ drug or supply manufactured by the manufacturer that is donated by any person under this section, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated ~~cancer or chronic disease~~ drug or supply.

(b) Except as provided in par. (c), any person, except the manufacturer of a drug or supply, is immune from civil liability for injury to or the death of the individual to whom the ~~cancer or chronic disease~~ drug or supply is dispensed and may not be found guilty of unprofessional conduct for his or her acts or omissions related to donating, accepting, distributing, or dispensing a ~~cancer or chronic disease~~ drug or supply under this section.

(c) The immunity or the prohibition on a finding of guilty of unprofessional conduct under par. (b) does not extend to donation, acceptance, distribution, or dispensation of a ~~cancer or chronic disease~~ drug or supply by a person whose act or omission involves reckless, wanton, or intentional misconduct.

SECTION 11. 255.056 (7) (a) (intro.) of the statutes is amended to read:

255.056 (7) (a) (intro.) Requirements for medical facilities and pharmacies to accept and dispense donated ~~cancer or chronic disease~~ drugs or supplies under this section, including all of the following:

SECTION 12. 255.056 (7) (a) 2. of the statutes is amended to read:

255.056 (7) (a) 2. Standards and procedures for accepting, safely storing, and dispensing donated ~~cancer or chronic disease~~ drugs or supplies.

SECTION 13. 255.056 (7) (a) 3. of the statutes is amended to read:

255.056 (7) (a) 3. Standards and procedures for inspecting donated ~~cancer or chronic disease~~ drugs or supplies to determine if the drug or supplies are in their original, unopened, sealed, and tamper-evident ~~unit dose~~ packaging or, if packaged in single-unit doses, the single-unit-dose packaging is unopened.

SECTION 14. 255.056 (7) (a) 4. of the statutes is amended to read:

255.056 (7) (a) 4. Standards and procedures for inspecting donated ~~cancer or chronic disease~~ drugs or supplies to determine that the drug or supplies are not adulterated or misbranded.

SECTION 15. 255.056 (7) (b) of the statutes is amended to read:

255.056 (7) (b) Eligibility criteria for individuals to receive donated ~~cancer or chronic disease~~ drugs or supplies dispensed under the program. The standards shall prioritize dispensation to individuals who are uninsured or indigent, but will permit dispensation to others if an uninsured or indigent individual is unavailable.

SECTION 16. 255.056 (7) (c) of the statutes is amended to read:

255.056 (7) (c) A means, such as an identification card, by which an individual who is eligible to receive a donated ~~cancer or chronic disease~~ drug or supplies may indicate that eligibility.

SECTION 17. 255.056 (7) (d) of the statutes is amended to read:

255.056 (7) (d) Necessary forms for administration of the ~~cancer and chronic diseases~~ drug repository program, including forms for use by persons that donate, accept, distribute, or dispense ~~cancer or chronic disease~~ drugs or supplies under the program.

SECTION 18. 255.056 (7) (e) of the statutes is amended to read:

255.056 (7) (e) The maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated ~~cancer or chronic disease~~ drugs or supplies The fee under this paragraph may not be less than 300 percent of the dispensing fee permitted to be charged for prescription drugs for which coverage is provided under s. 49.46 (2) (b) 6. h.

SECTION 19. 255.056 (7) (f) of the statutes is repealed.

2009 Senate Bill 455

2009 Wisconsin Act 142

SECTION 20. 255.056 (7) (g) of the statutes is amended to read:

255.056 (7) (g) A list of ~~cancer or chronic disease~~ drugs and supplies, arranged by category or by individual drug or supply, that the ~~cancer and chronic diseases~~ drug repository program will not accept for dispensing. The

list shall include a statement that specifies the reason that the drug or supplies are ineligible for donation.

SECTION 21m. 450.01 (23) (k) of the statutes is amended to read:

450.01 (23) (k) The donation or distribution of a prescription drug under s. 255.056 or under [21 CFR 203.39](#).
