



2009 ASSEMBLY BILL 272

May 19, 2009 - Introduced by Representatives NYGREN, VAN ROY, SUDER, MONTGOMERY, BALLWEG, BENEDICT, BIES, BLACK, FRISKE, GOTTLIEB, GRIGSBY, GUNDERSON, KAUFERT, KERKMAN, KNODL, MOLEPSKE JR., NASS, A. OTT, PETERSEN, PETROWSKI, POPE-ROBERTS, RIPP, SHERMAN, SMITH, SOLETSKI, SPANBAUER, STRACHOTA, TAUCHEN, TOWNSEND, TURNER and VOS, cosponsored by Senators ROBSON, LASSA, LEHMAN, VINEHOUT, TAYLOR, DARLING, SCHULTZ, RISSER, OLSEN, MILLER, HARSDORF, HANSEN, COWLES, CARPENTER and WIRCH. Referred to Committee on Public Health.

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

Analysis by the Legislative Reference Bureau

Under current law, the Department of Health Services administers a drug repository program under which people may donate certain drugs and supplies to a medical facility or pharmacy and the medical facility or pharmacy may dispense the drugs and supplies or distribute them to another medical facility or pharmacy for dispensing. Only drugs for the treatment of cancer or a chronic disease, or supplies used to administer such drugs, may be accepted and dispensed under the program. Program requirements include that drugs and supplies are in their original, unopened packaging; that the drugs or supplies are inspected by a pharmacist; that the expiration date of the drugs is at least six months after the donation date; and that the drugs or supplies are prescribed for a person and dispensed by a pharmacist. Uninsured or indigent people have priority in obtaining drugs and supplies under the program. A medical facility or pharmacy may charge a handling fee for the drugs, but may not resell them. Finally, current law provides immunity from criminal and

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civil liability to drug manufacturers and provides immunity from civil liability to other people participating in the program.

This bill provides that any drug, with certain exceptions, and supplies to administer drugs may be donated and dispensed under the drug repository program. The exceptions provide that controlled substances and drugs for which the U.S. Food and Drug Administration requires that a patient using the drug be enrolled in a registry may not be donated or dispensed under the program. The bill also changes the drug expiration date requirement for the program so that drugs with an expiration date that is at least 90 days after the date of donation may be donated and dispensed under the program. And, the bill provides that a practitioner, which is defined as a person licensed to prescribe and administer drugs, may dispense prescription drugs under the program.

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

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

2 **255.056** (title) ~~Cancer and chronic diseases drug~~ **Drug repository.**

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

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

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

6 255.056 (1) (bg) “Drug” has the meaning given in s. 450.01 (10).

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

8 255.056 (1) (h) “Supplies” means items that are necessary to administer a
9 ~~cancer or chronic disease~~ drug.

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

11 255.056 (2) The department shall establish and maintain a ~~cancer and chronic~~
12 ~~diseases~~ drug repository program, under which any person may donate a ~~cancer or~~
13 ~~chronic disease~~ drug or supplies, other than a drug specified under sub. (2m), for use
14 by an individual who meets eligibility criteria specified by rule by the department.
15 Donation may be made on the premises of a medical facility or pharmacy that elects

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1 to participate in the program and meets requirements specified by rule by the
2 department. The medical facility or pharmacy may charge an individual who
3 receives a ~~cancer or chronic disease~~ drug or supplies under this subsection a handling
4 fee that may not exceed the amount specified by rule by the department. A medical
5 facility or pharmacy that receives a donated ~~cancer or chronic disease~~ drug or
6 supplies under this subsection may distribute the ~~cancer or chronic disease~~ drug or
7 supplies to another eligible medical facility or pharmacy for use under the program
8 under this section.

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

10 255.056 **(2m)** None of the following drugs may be donated, accepted,
11 distributed, or dispensed under this section:

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

13 (b) A drug for which the U.S. food and drug administration requires that a
14 patient using the drug be enrolled in a registry as provided under 21 USC 355-1 (f)
15 (3) (F).

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

17 255.056 **(3)** A ~~cancer or chronic disease~~ drug or supplies may be accepted and
18 dispensed under the program specified in sub. (2) only if all of the following
19 requirements are met:

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

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

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

5 (d) ~~The cancer or chronic disease~~ For a prescription drug or supplies used to
6 administer a prescription drug, the drug or supplies are prescribed by a practitioner
7 for use by an eligible individual and are dispensed by a pharmacist or practitioner.

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

9 255.056 (4) No ~~cancer or chronic disease~~ drug or supplies that are donated for
10 use under this section may be resold.

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

12 255.056 (6) (a) Unless the manufacturer of a drug or supply exercises bad faith,
13 the manufacturer is not subject to criminal or civil liability for injury, death, or loss
14 to a person or property for matters related to the donation, acceptance, or dispensing
15 of a ~~cancer or chronic disease~~ drug or supply manufactured by the manufacturer that
16 is donated by any person under this section, including liability for failure to transfer
17 or communicate product or consumer information or the expiration date of the
18 donated ~~cancer or chronic disease~~ drug or supply.

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

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

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

6 255.056 (7) (a) (intro.) Requirements for medical facilities and pharmacies to
7 accept and dispense donated ~~cancer or chronic disease~~ drugs or supplies under this
8 section, including all of the following:

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

10 255.056 (7) (a) 2. Standards and procedures for accepting, safely storing, and
11 dispensing donated ~~cancer or chronic disease~~ drugs or supplies.

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

13 255.056 (7) (a) 3. Standards and procedures for inspecting donated ~~cancer or~~
14 ~~chronic disease~~ drugs or supplies to determine if the drug or supplies are in their
15 original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged
16 in single-unit doses, the single-unit-dose packaging is unopened.

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

18 255.056 (7) (a) 4. Standards and procedures for inspecting donated ~~cancer or~~
19 ~~chronic disease~~ drugs or supplies to determine that the drug or supplies are not
20 adulterated or misbranded.

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

22 255.056 (7) (b) Eligibility criteria for individuals to receive donated ~~cancer or~~
23 ~~chronic disease~~ drugs or supplies dispensed under the program. The standards shall
24 prioritize dispensation to individuals who are uninsured or indigent, but will permit
25 dispensation to others if an uninsured or indigent individual is unavailable.

