

2005 ASSEMBLY BILL 197

March 10, 2005 – Introduced by Representatives VUKMIR, UNDERHEIM, GARD, BENEDICT, VRUWINK, MONTGOMERY, PETTIS, JESKEWITZ, LEHMAN, M. WILLIAMS, ALBERS, HUNDERTMARK, SEIDEL, STRACHOTA, BIES, GRONEMUS, GUNDERSON, HAHN, HINES, KERKMAN, MURSAU, NASS, OTT, PETROWSKI and VRAKAS, cosponsored by Senators ROESSLER, STEPP, BROWN, KANAVAS, COWLES, KEDZIE, A. LASEE, LAZICH and WIRCH. Referred to Committee on Health.

1 **AN ACT to amend** 255.056 (title), 255.056 (1) (a), 255.056 (2), 255.056 (3), 255.056
2 (4), 255.056 (6) and 255.056 (7) (a) (intro.) and 2. to 4., (b), (c), (d), (e), (f) and (g);
3 and **to create** 255.056 (1) (am) and 255.056 (1) (h) of the statutes; **relating to:**
4 expanding the cancer drug repository program to include prescription drugs
5 and supplies for chronic disease and requiring the exercise of rule-making
6 authority.

Analysis by the Legislative Reference Bureau

Under current law, under the cancer drug repository program, any person may donate an unused prescription drug for use to treat cancer, the side effects of cancer, or the side effects of any prescription drug that has been used to treat cancer or the side effects of cancer. The cancer drug or supplies needed to administer it may be donated on the premises of a medical facility or pharmacy that meets requirements in the Department of Health and Family Services (DHFS) rules. Persons receiving the donated drugs for use must meet eligibility criteria in rules promulgated by DHFS. No donated cancer drugs or supplies may be resold. Manufacturers that do not exercise bad faith have immunity from civil and criminal liability for matters related to the donation, acceptance, and dispensing of donated cancer drugs and supplies. Other persons who do not act recklessly, wantonly or with intentional misconduct with respect to donating, accepting, distributing, or dispensing cancer drugs or supplies are immune from civil liability and findings of unprofessional conduct.

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The bill, effective January 1, 2006, expands the cancer drug repository program to include prescription drugs and supplies for chronic diseases, as defined in the bill. The bill modifies one of the rules that DHFS must promulgate, to specify that the maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated cancer or chronic disease drugs may not be less than 350 percent of the dispensing fee permitted to be charged for prescription drugs under Medical Assistance. The bill requires DHFS to submit proposed rules concerning these changes to the Legislative Council staff by the date that is four months after publication of the bill as an act.

For further information see the *state and local* fiscal estimate, which will be printed as an appendix to this bill.

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, as affected by 2003 Wisconsin Acts
2 175 and 327, is amended to read:

3 **255.056 (title) Cancer and chronic diseases drug repository.**

4 **SECTION 2.** 255.056 (1) (a) of the statutes, as affected by 2003 Wisconsin Acts
5 175 and 327, is amended to read:

6 255.056 (1) (a) “Cancer or chronic disease drug” means a prescription drug that
7 is used to treat any of the following:

8 1. Cancer or chronic disease or side effects of cancer or chronic disease.

9 2. The side effects of any prescription drug that is used to treat cancer or side
10 effects of cancer under subd. 1.

11 **SECTION 3.** 255.056 (1) (am) of the statutes is created to read:

12 255.056 (1) (am) “Chronic disease” means any disease, illness, impairment, or
13 other physical condition, other than cancer, that requires health care and treatment
14 over a prolonged period and, although amenable to treatment, frequently progresses
15 to increasing disability or death.

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

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

3 **SECTION 5.** 255.056 (2) of the statutes, as affected by 2003 Wisconsin Acts 175
4 and 327, is amended to read:

5 255.056 (2) The department shall establish and maintain a cancer and chronic
6 diseases drug repository program, under which any person may donate a cancer or
7 chronic disease drug or supplies needed to administer a cancer drug for use by an
8 individual who meets eligibility criteria specified by rule by the department.
9 Donation may be made on the premises of a medical facility or pharmacy that elects
10 to participate in the program and meets requirements specified by rule by the
11 department. The medical facility or pharmacy may charge an individual who
12 receives a cancer or chronic disease drug or supplies needed to administer a cancer
13 drug under this subsection a handling fee that may not exceed the amount specified
14 by rule by the department. A medical facility or pharmacy that receives a donated
15 cancer or chronic disease drug or supplies needed to administer a cancer drug under
16 this subsection may distribute the cancer or chronic disease drug or supplies to
17 another eligible medical facility or pharmacy for use under the program under this
18 section.

19 **SECTION 6.** 255.056 (3) of the statutes, as affected by 2003 Wisconsin Acts 175
20 and 327, is amended to read:

21 255.056 (3) A cancer or chronic disease drug or supplies needed to administer
22 a cancer drug may be accepted and dispensed under the program specified in sub. (2)
23 only if all of the following requirements are met:

24 (a) The cancer or chronic disease drug or supplies needed to administer a cancer
25 drug is are in its their original, unopened, sealed, and tamper-evident unit dose

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1 packaging or, if packaged in single-unit doses, the single-unit-dose packaging is
2 unopened.

3 (b) The cancer or chronic disease drug bears an expiration date that is later
4 than 6 months after the date that the drug was donated.

5 (c) The cancer or chronic disease drug or supplies ~~needed to administer a cancer~~
6 ~~drug is~~ are not adulterated or misbranded, as determined by a pharmacist employed
7 by, or under contract with, the medical facility or pharmacy, who shall inspect the
8 drug or supplies ~~needed to administer a cancer drug~~ before the drug or supplies are
9 dispensed.

10 (d) The cancer or chronic disease drug or supplies ~~needed to administer a cancer~~
11 ~~drug~~ are prescribed by a practitioner for use by an eligible individual and are
12 dispensed by a pharmacist.

13 **SECTION 7.** 255.056 (4) of the statutes, as affected by 2003 Wisconsin Acts 175
14 and 327, is amended to read:

15 255.056 (4) No cancer or chronic disease drug or supplies ~~needed to administer~~
16 ~~a cancer drug~~ that are donated for use under this section may be resold.

17 **SECTION 8.** 255.056 (6) of the statutes, as affected by 2003 Wisconsin Acts 175
18 and 327, is amended to read:

19 255.056 (6) (a) Unless the manufacturer of a drug or supply exercises bad faith,
20 the manufacturer is not subject to criminal or civil liability for injury, death, or loss
21 to a person or property for matters related to the donation, acceptance, or dispensing
22 of a cancer or chronic disease drug or supply manufactured by the manufacturer that
23 is donated by any person under this section, including liability for failure to transfer
24 or communicate product or consumer information or the expiration date of the
25 donated cancer or chronic disease drug or supply.

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

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

11 **SECTION 9.** 255.056 (7) (a) (intro.) and 2. to 4., (b), (c), (d), (e), (f) and (g) of the
12 statutes, as affected by 2003 Wisconsin Acts 175 and 327, are amended to read:

13 255.056 (7) (a) (intro.) Requirements for medical facilities and pharmacies to
14 accept and dispense donated cancer or chronic disease drugs or supplies ~~needed to~~
15 ~~administer cancer drugs~~ under this section, including all of the following:

16 2. Standards and procedures for accepting, safely storing, and dispensing
17 donated cancer or chronic disease drugs or supplies ~~needed to administer cancer~~
18 ~~drugs~~.

19 3. Standards and procedures for inspecting donated cancer or chronic disease
20 drugs or supplies ~~needed to administer cancer drugs~~ to determine if the cancer drug
21 or supplies ~~needed to administer a cancer drug~~ are in its their original, unopened,
22 sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses,
23 the single-unit-dose packaging is unopened.

24 4. Standards and procedures for inspecting donated cancer or chronic disease
25 drugs or supplies ~~needed to administer cancer drugs~~ to determine that the cancer

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1 drug or supplies ~~needed to administer a cancer drug~~ are not adulterated or
2 misbranded.

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

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

11 (d) Necessary forms for administration of the cancer and chronic diseases drug
12 repository program, including forms for use by persons that donate, accept,
13 distribute, or dispense cancer or chronic disease drugs or supplies ~~needed to~~
14 ~~administer cancer drugs~~ under the program.

15 (e) The maximum handling fee that a medical facility or pharmacy may charge
16 for accepting, distributing, or dispensing donated cancer or chronic disease drugs or
17 supplies ~~needed to administer cancer drugs~~. The fee under this paragraph may not
18 be less than 350 percent of the dispensing fee permitted to be charged for prescription
19 drugs for which coverage is provided under s. 49.46 (2) (b) 6. h.

20 (f) A list of cancer or chronic disease drugs and supplies ~~needed to administer~~
21 ~~cancer drugs~~, arranged by category or by individual cancer drug or supply, that the
22 cancer and chronic diseases drug repository program will accept for dispensing.

23 (g) A list of cancer or chronic disease drugs and supplies ~~needed to administer~~
24 ~~cancer drugs~~, arranged by category or by individual cancer drug or supply, that the
25 cancer and chronic diseases drug repository program will not accept for dispensing.

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1 The list shall include a statement that specifies the reason that the cancer drug or
2 supplies needed to administer a cancer drug are ineligible for donation.

3 **SECTION 10. Nonstatutory provisions.**

4 (1) CANCER AND CHRONIC DISEASES DRUG REPOSITORY PROGRAM; RULES. The
5 department of health and family services shall submit in proposed form the rules
6 required under section 255.056 (7) (a) (intro.) and 2. to 4., (b), (c), (d), (e), (f), and (g)
7 of the statutes, as affected by this act, to the legislative council staff under section
8 227.15 (1) of the statutes no later than the first day of the 5th month beginning after
9 the effective date of this subsection.

10 **SECTION 11. Effective date.**

11 (1) This act takes effect on January 1, 2006, or on the day after publication,
12 whichever is later.

13 (END)