

2005 Assembly Bill 197

Date of enactment: **July 5, 2005**
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AN ACT *to amend* 255.056 (title), 255.056 (1) (a), 255.056 (2), 255.056 (3), 255.056 (4), 255.056 (6) and 255.056 (7) (a) (intro.) and 2. to 4., (b), (c), (d), (e), (f) and (g); and *to create* 255.056 (1) (am) and 255.056 (1) (h) of the statutes; **relating to:** expanding the cancer drug repository program to include prescription drugs and supplies for chronic disease and requiring the exercise of rule-making authority.

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

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

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

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

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

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

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

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

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

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

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

SECTION 5. 255.056 (2) of the statutes, as affected by 2003 Wisconsin Acts 175 and 327, 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 ~~needed to administer a cancer drug~~ 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 ~~needed to administer a cancer drug~~ 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 ~~needed to administer a cancer drug~~ under this subsection may distribute the cancer or chronic disease drug or supplies to another eligible medi-

* Section 991.11, WISCONSIN STATUTES 2003-04 : 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].

cal facility or pharmacy for use under the program under this section.

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

255.056 (3) A cancer or chronic disease drug or supplies ~~needed to administer a cancer drug~~ 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 ~~needed to administer a cancer drug~~ is are in its 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 drug bears an expiration date that is later than 6 months after the date that the drug was donated.

(c) The cancer or chronic disease drug or supplies ~~needed to administer a cancer drug~~ is 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 ~~needed to administer a cancer drug~~ before the drug or supplies are dispensed.

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

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

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

SECTION 8. 255.056 (6) of the statutes, as affected by 2003 Wisconsin Acts 175 and 327, 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 per-

son whose act or omission involves reckless, wanton, or intentional misconduct.

SECTION 9. 255.056 (7) (a) (intro.) and 2. to 4., (b), (c), (d), (e), (f) and (g) of the statutes, as affected by 2003 Wisconsin Acts 175 and 327, are 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 ~~needed to administer cancer drugs~~ under this section, including all of the following:

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

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

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

(b) Eligibility criteria for individuals to receive donated cancer or chronic disease drugs or supplies ~~needed to administer cancer drugs~~ 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.

(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 ~~needed to administer a cancer drug~~ may indicate that eligibility.

(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 ~~needed to administer cancer drugs~~ under the program.

(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 ~~needed to administer cancer drugs~~. 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.

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

(g) A list of cancer or chronic disease drugs and supplies ~~needed to administer cancer drugs~~, arranged by

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category or by individual ~~cancer~~ 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 ~~cancer~~ drug or supplies ~~needed to administer a cancer drug~~ are ineligible for donation.

SECTION 10. Nonstatutory provisions.

(1) CANCER AND CHRONIC DISEASES DRUG REPOSITORY PROGRAM; RULES. The department of health and family

services shall submit in proposed form the rules required under section 255.056 (7) (a) (intro.) and 2. to 4., (b), (c), (d), (e), (f), and (g) of the statutes, as affected by this act, to the legislative council staff under section 227.15 (1) of the statutes no later than the first day of the 5th month beginning after the effective date of this subsection.

SECTION 11. Effective date.

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