2005 ASSEMBLY BILL 197

1	AN ACT <i>to amend</i> 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 <i>to create</i> 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

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

- 7 **SECTION 1.** 255.056 (title) of the statutes, as affected by 2003 Wisconsin Acts
- 8 175 and 327, is amended to read:

9 **255.056** (title) **Cancer** <u>and chronic diseases</u> drug repository.

- **SECTION 2.** 255.056 (1) (a) of the statutes, as affected by 2003 Wisconsin Acts
- 11 175 and 327, is amended to read:

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1	255.056 (1) (a) "Cancer <u>or chronic disease</u> drug" means a prescription drug that
2	is used to treat any of the following:
3	1. Cancer or chronic disease or side effects of cancer or chronic disease.
4	2. The side effects of any prescription drug that is used to treat cancer or side
5	effects of cancer <u>under subd. 1</u> .
6	SECTION 3. 255.056 (1) (am) of the statutes is created to read:
7	255.056 (1) (am) "Chronic disease" means any disease, illness, impairment, or
8	other physical condition, other than cancer, that requires health care and treatment
9	over a prolonged period and, although amenable to treatment, frequently progresses
10	to increasing disability or death.
11	SECTION 4. 255.056 (1) (h) of the statutes is created to read:
12	255.056 (1) (h) "Supplies" means items that are necessary to administer a
13	cancer or chronic disease drug.
14	SECTION 5. 255.056 (2) of the statutes, as affected by 2003 Wisconsin Acts 175
15	and 327, is amended to read:
16	255.056 (2) The department shall establish and maintain a cancer <u>and chronic</u>
17	<u>diseases</u> drug repository program, under which any person may donate a cancer <u>or</u>
18	<u>chronic disease</u> drug or supplies needed to administer a cancer drug for use by an
19	individual who meets eligibility criteria specified by rule by the department.
20	Donation may be made on the premises of a medical facility or pharmacy that elects
21	to participate in the program and meets requirements specified by rule by the
22	department. The medical facility or pharmacy may charge an individual who
23	receives a cancer <u>or chronic disease</u> drug or supplies needed to administer a cancer
24	drug under this subsection a handling fee that may not exceed the amount specified
25	by rule by the department. A medical facility or pharmacy that receives a donated

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cancer <u>or chronic disease</u> drug or supplies needed to administer a cancer drug under
 this subsection may distribute the cancer <u>or chronic disease</u> drug or supplies to
 another eligible medical facility or pharmacy for use under the program under this
 section.

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

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

(c) The cancer <u>or chronic disease</u> drug or supplies needed to administer a cancer
drug is <u>are</u> 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 <u>or chronic disease</u> 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:

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1	255.056 (4) No cancer <u>or chronic disease</u> drug or supplies needed to administer
2	a cancer drug that are donated for use under this section may be resold.
3	SECTION 8. 255.056 (6) of the statutes, as affected by 2003 Wisconsin Acts 175
4	and 327, is amended to read:
5	255.056 (6) (a) Unless the manufacturer of a drug or supply exercises bad faith,
6	the manufacturer is not subject to criminal or civil liability for injury, death, or loss
7	to a person or property for matters related to the donation, acceptance, or dispensing
8	of a cancer <u>or chronic disease</u> drug or supply manufactured by the manufacturer that
9	is donated by any person under this section, including liability for failure to transfer
10	or communicate product or consumer information or the expiration date of the
11	donated cancer <u>or chronic disease</u> drug or supply.
12	(b) Except as provided in par. (c), any person, except the manufacturer of a drug
13	or supply, is immune from civil liability for injury to or the death of the individual
14	to whom the cancer <u>or chronic disease</u> drug or supply is dispensed and may not be
15	found guilty of unprofessional conduct for his or her acts or omissions related to
16	donating, accepting, distributing, or dispensing a cancer <u>or chronic disease</u> drug or

17 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 <u>or chronic disease</u> drug <u>or supply</u> by a person whose act or
omission involves reckless, wanton, or intentional misconduct.

22 **SECTION 9.** 255.056 (7) (a) (intro.) and 2. to 4., (b), (c), (d), (e), (f) and (g) of the 23 statutes, as affected by 2003 Wisconsin Acts 175 and 327, are amended to read:

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1	255.056 (7) (a) (intro.) Requirements for medical facilities and pharmacies to
2	accept and dispense donated cancer <u>or chronic disease</u> drugs or supplies needed to
3	administer cancer drugs under this section, including all of the following:
4	2. Standards and procedures for accepting, safely storing, and dispensing
5	donated cancer or chronic disease drugs or supplies needed to administer cancer
6	drugs.
7	3. Standards and procedures for inspecting donated cancer or chronic disease
8	drugs or supplies needed to administer cancer drugs to determine if the cancer drug
9	or supplies needed to administer a cancer drug are in its <u>their</u> original, unopened,
10	sealed, and tamper–evident unit dose packaging or, if packaged in single–unit doses,
11	the single–unit–dose packaging is unopened.
12	4. Standards and procedures for inspecting donated cancer or chronic disease
13	drugs or supplies needed to administer cancer drugs to determine that the cancer
14	drug or supplies needed to administer a cancer drug are not adulterated or
15	misbranded.
16	(b) Eligibility criteria for individuals to receive donated cancer or chronic
17	disease drugs or supplies needed to administer cancer drugs dispensed under the
18	program. The standards shall prioritize dispensation to individuals who are
19	uninsured or indigent, but will permit dispensation to others if an uninsured or
20	indigent individual is unavailable.
91	(a) A means such as an identification cand by which an individual who is

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

(d) Necessary forms for administration of the cancer <u>and chronic diseases</u> drug
 repository program, including forms for use by persons that donate, accept,

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- distribute, or dispense cancer <u>or chronic disease</u> drugs or supplies needed to
 administer cancer drugs under the program.
- 3 (e) The maximum handling fee that a medical facility or pharmacy may charge
 4 for accepting, distributing, or dispensing donated cancer <u>or chronic disease</u> drugs or
 5 supplies needed to administer cancer drugs. <u>The fee under this paragraph may not</u>
 6 <u>be less than 300 percent of the dispensing fee permitted to be charged for prescription</u>
 7 <u>drugs for which coverage is provided under s. 49.46 (2) (b) 6. h.</u>
- 8 (f) A list of cancer <u>or chronic disease</u> drugs and supplies needed to administer
 9 cancer drugs, arranged by category or by individual cancer drug or supply, that the
 10 cancer <u>and chronic diseases</u> drug repository program will accept for dispensing.
- (g) A list of cancer <u>or chronic disease</u> drugs and supplies needed to administer
 cancer drugs, arranged by category or by individual cancer drug or supply, that the
 cancer <u>and chronic diseases</u> 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.
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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.

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SECTION 11. Effective date.

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

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