

2003 ASSEMBLY BILL 845

AN ACT *to create* 255.055 of the statutes; **relating to:** establishing a cancer drug repository program and requiring the exercise of rule-making authority.

Analysis by the Legislative Reference Bureau

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

- 1 **SECTION 1.** 255.055 of the statutes is created to read:
- 2 **255.055 Cancer drug repository. (1) DEFINITIONS.** In this section:
- 3 (a) “Cancer drug” means a prescription drug that is used to treat any of the
- 4 following:
- 5 1. Cancer or side effects of cancer.
- 6 2. The side effects of any prescription drug that is used to treat cancer or side
- 7 effects of cancer.
- 8 (b) “Dispense” has the meaning given in s. 450.01 (7).

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1 (c) “Medical facility” has the meaning given in s. 943.145 (1).

2 (d) “Pharmacist” has the meaning given in s. 450.01 (15).

3 (e) “Pharmacy” means a pharmacy that is licensed under s. 450.06.

4 (f) “Practitioner” has the meaning given in s. 450.01 (17).

5 (g) “Prescription drug” has the meaning given in s. 450.01 (20).

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

18 **(3)** A cancer drug or supplies needed to administer a cancer drug may be
19 accepted and dispensed under the program specified in sub. (2) only if all of the
20 following requirements are met:

21 (a) The cancer drug or supplies needed to administer a cancer drug is in its
22 original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged
23 in single-unit doses, the single-unit-dose packaging is unopened.

24 (b) The cancer drug bears an expiration date that is later than 6 months after
25 the date that the drug was donated.

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

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

9 **(4)** No cancer drug or supplies needed to administer a cancer drug that are
10 donated for use under this section may be resold.

11 **(5)** Nothing in this section requires that a medical facility, pharmacy,
12 pharmacist, or practitioner participate in the program under this section.

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

20 (b) Except as provided in par. (c), any person, except the manufacturer of a drug
21 or supply, is immune from civil liability for injury to or the death of the individual
22 to whom the cancer drug or supply is dispensed and may not be found guilty of
23 unprofessional conduct for his or her acts or omissions related to donating, accepting,
24 distributing, or dispensing a cancer drug or 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 drug by a person whose act or omission involves reckless,
4 wanton, or intentional misconduct.

5 (7) The department shall promulgate all of the following as rules:

6 (a) Requirements for medical facilities and pharmacies to accept and dispense
7 donated cancer drugs or supplies needed to administer cancer drugs under this
8 section, including all of the following:

9 1. Eligibility criteria.

10 2. Standards and procedures for accepting, safely storing, and dispensing
11 donated cancer drugs or supplies needed to administer cancer drugs.

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

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

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

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1 (c) A means, such as an identification card, by which an individual who is
2 eligible to receive a donated cancer drug or supplies needed to administer a cancer
3 drug may indicate that eligibility.

4 (d) Necessary forms for administration of the cancer drug repository program,
5 including forms for use by persons that donate, accept, distribute, or dispense cancer
6 drugs or supplies needed to administer cancer drugs under the program.

7 (e) The maximum handling fee that a medical facility or pharmacy may charge
8 for accepting, distributing, or dispensing donated cancer drugs or supplies needed
9 to administer cancer drugs.

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

13 (g) A list of cancer drugs and supplies needed to administer cancer drugs,
14 arranged by category or by individual cancer drug or supply, that the cancer drug
15 repository program will not accept for dispensing. The list shall include a statement
16 that specifies the reason that the cancer drug or supplies needed to administer a
17 cancer drug are ineligible for donation.

SECTION 2. Nonstatutory provisions.

18 (1) RULES. The department of health and family services shall submit in
19 proposed form the rules required under section 255.055 (7) of the statutes, as created
20 by this act, to the legislative council staff under section 227.15 (1) of the statutes no
21 later than the first day of the 9th month beginning after the effective date of this
22 subsection.
23

24 **SECTION 3. Effective dates.** This act takes effect on the day after publication,
25 except as follows:

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SECTION 3

1 (1) The treatment of section 255.055 of the statutes takes effect on July 1, 2005.

2 (END)