

2003 ASSEMBLY BILL 845

February 16, 2004 – Introduced by Representatives UNDERHEIM, KRAWCZYK, PETTIS, M. LEHMAN, JOHNSRUD, KERKMAN, VRUWINK, KREIBICH, MONTGOMERY, MILLER, VUKMIR, GUNDERSON, HAHN, HEBL, GIELOW, HINES, PLOUFF, HUBER, WIECKERT, HUEBSCH, HUNDERTMARK, BIES, TOWNSEND, NASS, TRAVIS and MCCORMICK, cosponsored by Senators STEPP, ROESSLER, SCHULTZ, ROBSON, CHVALA, PLALE, LASSA, KANAVAS, CARPENTER, ZIEN, WELCH, COGGS, ERPENBACH, BROWN, WIRCH and A. LASEE. Referred to Committee on Health.

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

Analysis by the Legislative Reference Bureau

This bill requires the Department of Health and Family Services (DHFS) to establish, effective July 1, 2005, and maintain a cancer drug repository program, under which any person may donate a cancer drug, as defined in the bill, that may be prescribed for use by an individual who meets eligibility criteria specified by rule by DHFS. Under the bill, cancer drugs may be donated to a medical facility (as defined in the bill) or pharmacy that elects to participate in the program and meets requirements specified by rule by DHFS. The medical facility or pharmacy may distribute the cancer drug to another participating medical facility or pharmacy, or may dispense the cancer drug. If dispensing the cancer drug, the medical facility or pharmacy must follow standards and procedures specified by rule by DHFS for inspecting the drug to determine that the packaging is unopened and that the drug is not adulterated or misbranded. No donated cancer drug may be accepted unless it bears an expiration date that is later than six months after the date that the drug is donated, and no donated cancer drug may be resold. The donated cancer drug must be prescribed by a practitioner for the eligible individual and dispensed by a pharmacist. DHFS is required, under the bill, to promulgate numerous rules, including requirements of participation by medical facilities and pharmacies, eligibility criteria for individuals to receive donated cancer drugs that require dispensation be prioritized for persons who are indigent or uninsured, and a maximum handling fee that a medical facility or pharmacy may charge for accepting,

ASSEMBLY BILL 845

distributing, or dispensing donated cancer drugs. Lastly, the bill provides immunity from civil liability for injury to or the death of the individual to whom the drug is dispensed, and prohibits a finding of unprofessional conduct, for acts or omissions related to donating, accepting, distributing, or dispensing a cancer drug that do not involve reckless, wanton, or intentional misconduct.

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.** 255.055 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).

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

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

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

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

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

14 **(2)** The department shall establish and maintain a cancer drug repository
15 program, under which any person may donate a cancer drug for use by an individual
16 who meets eligibility criteria specified by rule by the department. Donation may be
17 made on the premises of a medical facility or pharmacy that elects to participate in
18 the program and meets requirements specified by rule by the department. The

ASSEMBLY BILL 845

1 medical facility or pharmacy may charge an individual who receives a cancer drug
2 under this subsection a handling fee that may not exceed the amount specified by
3 rule by the department. A medical facility or pharmacy that receives a donated
4 cancer drug under this subsection may distribute the cancer drug to another eligible
5 medical facility or pharmacy for use under the program under this section.

6 **(3)** A cancer drug may be accepted and dispensed under the program specified
7 in sub. (2) only if all of the following requirements are met:

8 (a) The cancer drug is in its original, unopened, sealed, and tamper-evident
9 unit dose packaging or, if packaged in single-unit doses, the single-unit-dose
10 packaging is unopened.

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

13 (c) The cancer drug is not adulterated or misbranded, as determined by a
14 pharmacist employed by, or under contract with, the medical facility or pharmacy,
15 who shall inspect the drug before the drug is dispensed.

16 (d) The cancer drug is prescribed by a practitioner for use by an eligible
17 individual and is dispensed by a pharmacist.

18 **(4)** No cancer drug that is donated for use under this section may be resold.

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

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

ASSEMBLY BILL 845

1 (b) The immunity or the prohibition on a finding of guilty of unprofessional
2 conduct under par. (a) 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 (c) The donation of a cancer drug by the manufacturer of the cancer drug may
6 not increase any liability of the manufacturer that would have existed but for the
7 donation.

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

9 (a) Requirements for medical facilities and pharmacies to accept and dispense
10 donated cancer drugs under this section, including all of the following:

11 1. Eligibility criteria.

12 2. Standards and procedures for accepting, safely storing, and dispensing
13 donated cancer drugs.

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

18 4. Standards and procedures for inspecting donated cancer drugs to determine
19 that the cancer drug is not adulterated or misbranded.

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

24 (c) A means, such as an identification card, by which an individual who is
25 eligible to receive a donated cancer drug may indicate that eligibility.

ASSEMBLY BILL 845

1 (d) Necessary forms for administration of the cancer drug repository program,
2 including forms for use by persons that donate, accept, distribute, or dispense cancer
3 drugs under the program.

4 (e) The maximum handling fee that a medical facility or pharmacy may charge
5 for accepting, distributing, or dispensing donated cancer drugs.

6 (f) A list of cancer drugs, arranged by category or by individual cancer drug,
7 that the cancer drug repository program will accept for dispensing.

8 (g) A list of cancer drugs, arranged by category or by individual cancer drug,
9 that the cancer drug repository program will not accept for dispensing. The list shall
10 include a statement that specifies the reason that the cancer drug is ineligible for
11 donation.

SECTION 2. Nonstatutory provisions.

12 (1) RULES. The department of health and family services shall submit in
13 proposed form the rules required under section 255.055 (7) of the statutes, as created
14 by this act, to the legislative council staff under section 227.15 (1) of the statutes no
15 later than the first day of the 9th month beginning after the effective date of this
16 subsection.
17

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

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

21 (END)