

**ASSEMBLY BILL 845 (LRB -3894)**

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. (FE)

2004

02-26. A. 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, McCormick and Staskunas; cosponsored by Senators Stepp, Roessler, Schultz, Robson, Chvala, Plale, Lassa, Kanavas, Carpenter, Zien, Welch, Coggs, Erpenbach, Brown, Wirch and A. Lasee.

02-16. A. Read first time and referred to committee on Health ..... 702

02-16. A. Fiscal estimate received.

02-17. A. Public hearing held.

02-17. A. Executive action taken.

02-17. A. Assembly amendment 1 offered by committee on Health (LRB a2226) ..... 704

02-19. A. Report Assembly Amendment 1 adoption recommended by committee on Health, Ayes 14, Noes 0 ..... 708

02-19. A. Report passage as amended recommended by committee on Health, Ayes 13, Noes 1 ..... 708

02-19. A. Referred to committee on Rules ..... 708

02-19. A. Placed on calendar 2-25-2004 by committee on Rules.

02-25. A. Representative Van Roy added as a coauthor ..... 742

02-25. A. Representative Steinbrink added as a coauthor.

02-25. A. Read a second time ..... 742

02-25. A. Assembly amendment 1 adopted ..... 742

02-25. A. Assembly amendment 2 offered by Representative Underheim (LRB a2350) ..... 742

02-25. A. Assembly amendment 2 withdrawn and returned to author ..... 742

02-25. A. Assembly amendment 3 offered by Representative Underheim (LRB a2381) ..... 742

02-25. A. Assembly amendment 3 withdrawn and returned to author ..... 742

02-25. A. Assembly amendment 4 offered by Representative Colon (LRB a2378) ..... 742

02-25. A. Assembly amendment 4 laid on table, Ayes 57, Noes 39 ..... 742

02-25. A. Assembly amendment 5 offered by Representative Colon (LRB a2379) ..... 742

02-25. A. Assembly amendment 5 laid on table, Ayes 57, Noes 37 ..... 742

02-25. A. Assembly amendment 6 offered by Representative Underheim (LRB a2399) ..... 742

02-25. A. Assembly amendment 1 to Assembly amendment 6 offered by Representative Underheim (LRB f136) ..... 742

02-25. A. Assembly amendment 1 to Assembly amendment 6 adopted ..... 742

02-25. A. Assembly amendment 6 adopted ..... 742

02-25. A. Assembly amendment 7 offered by Representative Colon (LRB a2382) ..... 742

02-25. A. Assembly amendment 7 laid on table, Ayes 54, Noes 40 ..... 742

02-25. A. Assembly amendment 8 offered by Representative Underheim (LRB a2403) ..... 743

02-25. A. Assembly amendment 8 withdrawn and returned to author ..... 743

02-25. A. Ordered to a third reading ..... 743

02-25. A. Rules suspended ..... 743

02-25. A. Read a third time and passed, Ayes 92, Noes 2 ..... 743

02-25. A. Ordered immediately messaged ..... 743

02-26. S. Received from Assembly.

02-26. S. Read first time and referred to committee on Senate Organization.

02-26. S. Withdrawn from committee on Senate Organization and taken up.

02-26. S. Read a second time.

02-26. S. Ordered to a third reading.

02-26. S. Rules suspended.

02-26. S. Read a third time and concurred in.

02-26. S. Senator Moore added as a cosponsor.

02-26. S. Ordered immediately messaged.

02-27. A. Received from Senate concurred in.

2003  
ENROLLED BILL

03en AB-845

ADOPTED DOCUMENTS:

Orig     Engr           SubAmdt       

03 -3894/2

Amendments to above (if none, write "NONE"): AA1, AAG as  
affected by AA1 thereof

Corrections - show date (if none, write "NONE"): ~~None~~ 2/27/04

Topic relay clause MINUS Rule etc

2/27/04      [Signature]  
Date                      Enrolling Drafter

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## 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.**

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### *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,

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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.

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*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

AAU ✓  
2-15

3-4 (AAI)

3-1 (AAI)

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.

AAI

3-6 (AAI)

3-15 (AAI)

3-16 (AAI)

3-18 (AAI)

3-22 (AAI)

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.

AAG

4-3 (AA)

4-5 (AAI)

3-21

AAG

4-10 (AAC)

4-15 (AAI)

4-19 (AAC)

4-18 (AAI)

4-20 (AAI)

4-25 (AAI)

ASSEMBLY BILL 845

7 5-3 (AA1)

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.~~

5-6 (AA1)

✓ 5-8 (AA1)

5-10 ✓  
AA1

**SECTION 2. Nonstatutory provisions.**

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

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.

(END)

**ASSEMBLY AMENDMENT 1,  
TO 2003 ASSEMBLY BILL 845**

February 17, 2004 - Offered by COMMITTEE ON HEALTH.

1 At the locations indicated, amend the bill as follows:

2 ✓ 1. Page 2, line 15: after "drug" insert "or supplies needed to administer a  
2-15 cancer drug".

4 ✓ 2. Page 3, line 1: after "drug" insert "or supplies needed to administer a cancer  
3-1 5 drug".

6 ✓ 3. Page 3, line 4: delete that line and substitute "cancer drug or supplies  
7 needed to administer a cancer drug under this subsection may distribute the cancer  
3-4 8 drug or supplies to another eligible".

9 ✓ 4. Page 3, line 6: on lines 6, 8, and 13, after "drug" insert "or supplies needed  
10 to administer a cancer drug".

11 ✓ 5. Page 3, line 15: delete "before the drug is" and substitute "or supplies needed  
3-6 12 to administer a cancer drug before the drug or supplies are".  
3-15

1 ✓6. Page 3, line 16: delete "is" and substitute "or supplies needed to administer  
3-16 a cancer drug are".

3 ✓7. Page 3, line 17: delete "is" and substitute "are".

4 ✓8. Page 3, line 18: delete "that is" and substitute "or supplies needed to  
5 administer a cancer drug that are".

6 ✓9. Page 3, line 22: on lines 22, 23, and 25, after "drug" insert "or supplies  
7 needed to administer a cancer drug".

8 ✓10. Page 4, line 3: after "drug" insert "or supplies needed to administer a  
9-3 cancer drug".

10 ✓11. Page 4, line 5: delete "by the manufacturer of the cancer drug" and  
11 substitute "or supplies needed to administer a cancer drug by the manufacturer of  
12 the cancer drug or the supplies".

13 ✓12. Page 4, line 10: on lines 10, 13, and 14, after "drugs" insert "or supplies  
14 needed to administer cancer drugs".

15 ✓13. Page 4, line 15: delete "is" and substitute "or supplies needed to  
16 administer a cancer drug are".

17 ✓14. Page 4, line 18: after "drugs" insert "or supplies needed to administer  
18 cancer drugs". 4-18

19 ✓15. Page 4, line 19: delete "is" and substitute "or supplies needed to  
20-19 administer a cancer drug are".

21 ✓16. Page 4, line 20: after "drugs" insert "or supplies needed to administer  
22-20 cancer drugs".

1 ✓ 17. Page 4, line 25: after "drug" insert "or supplies needed to administer a  
4-25 cancer drug".

3 ✓ 18. Page 5, line 3: on lines 3 and 5, after "drugs" insert "or supplies needed to  
5-3 administer cancer drugs".

5 ✓ 19. Page 5, line 6: delete that line and substitute:

6 "(f) A list of cancer drugs and supplies needed to administer cancer drugs,  
5-6 arranged by category or by individual cancer drug or supply,"

8 ✓ 20. Page 5, line 8: delete that line and substitute:

9 "(g) A list of cancer drugs and supplies needed to administer cancer drugs,  
5-8 arranged by category or by individual cancer drug or supply,"

11 ✓ 21. Page 5, line 10: delete "is" and substitute "or supplies needed to  
5-10 administer a cancer drug are".

13

(END)



State of Wisconsin  
2003-2004 LEGISLATURE

**CORRECTIONS IN:**

**ASSEMBLY AMENDMENT 6,  
TO 2003 ASSEMBLY BILL 845**

Prepared by the Legislative Reference Bureau  
(February 27, 2004)

1. Page 2, line 4: delete "par. (a)" and substitute "par. (b)".

(END)

**ASSEMBLY AMENDMENT 6,  
TO 2003 ASSEMBLY BILL 845**

February 25, 2004 - Offered by Representative UNDERHEIM.

1 At the locations indicated, amend the bill as follows:

2 1. Page 3, line 21: delete the material beginning with that line and ending with  
3 page 4, line 7, and substitute:

AA1 to AAG ✓

3-26

4 ~~“(6) (a) Unless the manufacturer of a cancer drug or supply exercises bad faith,~~  
5 the manufacturer is not subject to criminal or civil liability for injury, death, or loss  
6 to a person or property for matters related to the donation, acceptance, or dispensing  
7 of a cancer drug or supply manufactured by the manufacturer that is donated by any  
8 person under this section, including liability for failure to transfer or communicate  
9 product or consumer information or the expiration date of the donated cancer drug  
10 or supply.

11 (b) Except as provided in par. (c), any person, except the manufacturer of a  
12 cancer drug or supply, is immune from civil liability for injury to or the death of the  
13 individual to whom the cancer drug or supply is dispensed and may not be found

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3-21

(b) ✓ CCC

1 guilty of unprofessional conduct for his or her acts or omissions related to donating,  
2 accepting, distributing, or dispensing a cancer drug or supply under this section.

3 (c) The immunity or the prohibition on a finding of guilty of unprofessional  
4 conduct under par. ~~(a)~~ does not extend to donation, acceptance, distribution, or  
5 dispensation of a cancer drug by a person whose act or omission involves reckless,  
6 wanton, or intentional misconduct.

7

(END)

