



State of Wisconsin
2005 - 2006 LEGISLATURE

LRB-0239/PE P2

DAK:ach

D-NOTE

11/10

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

Regen

to include prescription drugs and supplies for chronic diseases

1 AN ACT to amend 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.), 2., 3., 4., (b), (c), (d), (e), (f) and (g);
3 and to create 255.056 (1) (am) of the statutes; relating to: including
4 prescription drugs and supplies for other chronic diseases in the cancer drug
5 repository program and requiring the exercise of rule-making authority.

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a later version.

INSERT ANAL

use twice

as affected by 2003 Wisconsin Acts 175 and 327,

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

6 SECTION 1. 255.056 (title) of the statutes is amended to read:

7 255.056 (title) Cancer and other chronic disease drug repository.

8 SECTION 2. 255.056 (1) (a) of the statutes is amended to read:

9 255.056 (1) (a) "Cancer drug or other chronic disease drug or supplies" means

10 a prescription drug that is used to treat any of the following:

RESTORE TO PLAIN TEXT

RESTORE TO PLAIN TEXT

- 1. Cancer ~~A prescription drug that is used to treat cancer or ~~other~~ chronic disease or side effects of cancer or ~~other~~ chronic disease.~~
- 2. ~~The A prescription drug that is used to treat the side effects of any prescription drug that is used to treat cancer or side effects of cancer under subd. 1.~~
- 3. ~~Supplies needed to administer a prescription drug under subd. 1 or 2.~~

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, ^{as affected by 2003 Wisconsin Acts 175 and 327,} frequently progresses to increasing disability or death.

INSERT 2-10

SECTION 4. 255.056 (2) of the statutes is amended to read:

255.056 (2) The department shall establish and maintain a cancer and ~~other~~ ~~chronic disease~~ drug repository program, under which any person may donate a cancer or ~~other~~ 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 ~~other~~ 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 ~~other~~ chronic disease drug or supplies needed to administer a cancer drug under this subsection may distribute the cancer or ~~other~~ chronic disease drug or supplies to another eligible medical facility or pharmacy for use under the program under this section.

use 4 times

RESTORE TO PLAIN
TEXT

or chronic
disease

use 4
times

1 SECTION ~~5~~ 255.056 (3) of the statutes is amended to read:

2 255.056 (3) A cancer or ~~other~~ chronic disease drug or supplies needed to
3 administer a cancer drug may be accepted and dispensed under the program
4 specified in sub. (2) only if all of the following requirements are met:

5 (a) The ~~cancer~~ drug or supplies needed to administer a cancer drug is are in its
6 their original, unopened, sealed, and tamper-evident unit dose packaging or, if
7 packaged in single-unit doses, the single-unit-dose packaging is unopened.

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

10 (c) The ~~cancer~~ drug or supplies needed to administer a cancer drug is are not
11 adulterated or misbranded, as determined by a pharmacist employed by, or under
12 contract with, the medical facility or pharmacy, who shall inspect the drug or
13 supplies needed to administer a cancer drug before the drug or supplies are
14 dispensed.

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

use twice
, as affected by 2003 Wisconsin Acts 175
and 327,

18 SECTION ~~6~~ 255.056 (4) of the statutes is amended to read:

19 255.056 (4) No cancer or ~~other~~ chronic disease drug or supplies needed to
20 administer a cancer drug that are donated for use under this section may be resold.

21 SECTION ~~7~~ 255.056 (6) of the statutes is amended to read:

22 255.056 (6) (a) Unless the manufacturer of a drug or supply exercises bad faith,
23 the manufacturer is not subject to criminal or civil liability for injury, death, or loss
24 to a person or property for matters related to the donation, acceptance, or dispensing

25 of a cancer or ~~other~~ chronic disease drug or supply manufactured by the

1 manufacturer that is donated by any person under this section, including liability
2 for failure to transfer or communicate product or consumer information or the
3 expiration date of the donated cancer or other chronic disease drug or supply.

4 (b) Except as provided in par. (c), any person, except the manufacturer of a drug
5 or supply, is immune from civil liability for injury to or the death of the individual
6 to whom the cancer or other chronic disease drug or supply is dispensed and may not
7 be found guilty of unprofessional conduct for his or her acts or omissions related to
8 donating, accepting, distributing, or dispensing a cancer or other chronic disease
9 drug or supply under this section.

10 (c) The immunity or the prohibition on a finding of guilty of unprofessional
11 conduct under par. (b) does not extend to donation, acceptance, distribution, or
12 dispensation of a cancer or other chronic disease drug or supply by a person whose
13 act or omission involves reckless, wanton, or intentional misconduct.

14 *as affected by 2003 Wisconsin Acts 175 and 327, to*
SECTION 8. 255.056 (7) (a) (intro.), 2. ~~11~~ 4., (b), (c), (d), (e), (f) and (g) of the
15 statutes are amended to read:

16 255.056 (7) (a) (intro.) Requirements for medical facilities and pharmacies to
17 accept and dispense donated cancer or other chronic disease drugs or supplies ~~needed~~
18 ~~to administer cancer drugs~~ under this section, including all of the following:

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

22 3. Standards and procedures for inspecting donated cancer or other chronic
23 disease drugs or supplies ~~needed to administer cancer drugs~~ to determine if the
24 cancer drug or supplies ~~needed to administer a cancer drug~~ are in its their original,

1 unopened, sealed, and tamper-evident unit dose packaging or, if packaged in
2 single-unit doses, the single-unit-dose packaging is unopened.

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

7 (b) Eligibility criteria for individuals to receive donated cancer or ~~other~~ chronic
8 disease drugs or supplies needed to administer cancer drugs dispensed under the
9 program. The standards shall prioritize dispensation to individuals who are
10 uninsured or indigent, but will permit dispensation to others if an uninsured or
11 indigent individual is unavailable.

12 (c) A means, such as an identification card, by which an individual who is
13 eligible to receive a donated cancer or ~~other~~ chronic disease drug or supplies needed
14 to administer a cancer drug may indicate that eligibility.

15 (d) Necessary forms for administration of the cancer or ~~other~~ chronic disease ^{and}
16 drug repository program, including forms for use by persons that donate, accept,
17 distribute, or dispense cancer ^{or chronic disease} drugs or supplies needed to administer cancer drugs
18 under the program.

19 (e) The maximum handling fee that a medical facility or pharmacy may charge
20 for accepting, distributing, or dispensing donated cancer or ~~other~~ chronic disease
21 drugs or supplies needed to administer cancer drugs.

22 (f) A list of cancer or ~~other~~ chronic disease drugs and supplies needed to
23 administer cancer drugs, arranged by category or by individual cancer drug or
24 supply, that the cancer ^S and ~~other~~ chronic disease drug repository program will accept *
25 for dispensing.

1 (g) A list of cancer ~~or other~~ chronic disease drugs and supplies needed to
2 administer ~~cancer~~ drugs, arranged by category or by individual ~~cancer~~ drug or
3 supply, that the cancer ~~and other~~ chronic disease^{S/} drug repository program will not
4 accept for dispensing. The list shall include a statement that specifies the reason
5 that the ~~cancer~~ drug or supplies needed to administer a ~~cancer~~ drug are ineligible for
6 donation.

7 ~~SECTION 9~~ [#] **Effective dates.** This act takes effect on July 1, 2005, or on the day
8 after publication, whichever is later. ✓

9 (END)

D-NOTE

UPS: should be: (DHFS) rules

INSERT ANAL

Under current law, under the cancer drug repository program, any person may donate an unused prescription drug for use to treat cancer, the side effects of cancer, or the side effects of any prescription drug that has been used to treat cancer or the side effects of cancer. The cancer drug or supplies needed to administer it may be donated on the premises of a medical facility or pharmacy that meets requirements in ~~DHFS~~ rules. Persons receiving the donated drugs for use must meet eligibility criteria in rules promulgated by ~~the Department of Health and Family Services (DHFS)~~. No donated cancer drugs or supplies may be resold. Manufacturers that do not exercise bad faith have immunity from civil and criminal liability for matters related to the donation, acceptance, and dispensing of donated cancer drugs and supplies. Other persons who do not act recklessly, wantonly, or with intentional misconduct with respect to donating, accepting, distributing, or dispensing cancer drugs or supplies are immune from civil liability and findings of unprofessional conduct.

MOVE

X

The bill, effective July 1, 2005, expands the cancer drug repository program to include prescription drugs and supplies for chronic diseases, as defined in the bill.

For further information see the *state and local* fiscal estimate, which will be printed as an appendix to this bill.

INSERT 2-10

- 1 SECTION ~~1~~ 255.056 (1) (h) of the statutes is created to read:
- 2 255.056 (1) (h) "Supplies" means items that are necessary to administer a
- 3 cancer or chronic disease drug.
- 4

**DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRB-0239/P2dn
DAK: *keb*

Date

To Representative Vukmir:

This bill has an effective date of July 1, 2005, and requires that (DHFS) promulgate rules to implement the bill's addition to the cancer drug repository program. The effective date may be too early to provide sufficient time for the rule-making process to take place. One solution might be to delay the effective date until January 1, 2006, and require DHFS to submit proposed rules to the Legislative Council rules clearinghouse by *four* 4 or 5 months after enactment of the bill as an act (s. 227.11 (2) (d), stats., authorizes an agency to promulgate rules implementing or interpreting a statute before the statute takes effect, although the rules may not take effect before the statute does). A second solution might be to provide DHFS with emergency rule-making authority without requiring a finding of emergency and permit the emergency rules to remain in effect (they are limited to 150 days, or an additional 120 days if an extension is granted) until permanent rules become effective.

the Department of Health and Family Services

X
XX
X

Please do not hesitate to call if you have questions about or would like changes made to this bill.

Debora A. Kennedy
Managing Attorney
Phone: (608) 266-0137
E-mail: debora.kennedy@legis.state.wi.us

**DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRB-0239/P2dn
DAK:kjf:rs

November 5, 2004

To Representative Vukmir:

This bill has an effective date of July 1, 2005, and requires that the Department of Health and Family Services (DHFS) promulgate rules to implement the bill's addition to the cancer drug repository program. The effective date may be too early to provide sufficient time for the rule-making process to take place. One solution might be to delay the effective date until January 1, 2006, and require DHFS to submit proposed rules to the Legislative Council rules clearinghouse by four or five months after enactment of the bill as an act (s. 227.11 (2) (d), stats., authorizes an agency to promulgate rules implementing or interpreting a statute before the statute takes effect, although the rules may not take effect before the statute does). A second solution might be to provide DHFS with emergency rule-making authority without requiring a finding of emergency and permit the emergency rules to remain in effect (they are limited to 150 days, or an additional 120 days if an extension is granted) until permanent rules become effective.

Please do not hesitate to call if you have questions about or would like changes made to this bill.

Debora A. Kennedy
Managing Attorney
Phone: (608) 266-0137
E-mail: debora.kennedy@legis.state.wi.us

0239

1/21/05 From Deau, Rep Vukmir's aide -
Make draft same as -1516



~~PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION~~

Regen

1 AN ACT to amend 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.), 2., to 4., (b), (c), (d), (e), (f) and (g);
3 and to create 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

Under current law, under the cancer drug repository program, any person may donate an unused prescription drug for use to treat cancer, the side effects of cancer, or the side effects of any prescription drug that has been used to treat cancer or the side effects of cancer. The cancer drug or supplies needed to administer it may be donated on the premises of a medical facility or pharmacy that meets requirements in the Department of Health and Family Services (DHFS) rules. Persons receiving the donated drugs for use must meet eligibility criteria in rules promulgated by DHFS. No donated cancer drugs or supplies may be resold. Manufacturers that do not exercise bad faith have immunity from civil and criminal liability for matters related to the donation, acceptance, and dispensing of donated cancer drugs and supplies. Other persons who do not act recklessly, wantonly or with intentional misconduct with respect to donating, accepting, distributing, or dispensing cancer drugs or supplies are immune from civil liability and findings of unprofessional conduct.

January

2006

INSERT ANAL

The bill, effective ~~July 1, 2005~~, expands the cancer drug repository program to include prescription drugs and supplies for chronic diseases, as defined in the bill.

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

3 **255.056** (title) **Cancer and chronic diseases drug repository.**

4 **SECTION 2.** 255.056 (1) (a) of the statutes, as affected by 2003 Wisconsin Acts
5 175 and 327, is amended to read:

6 255.056 (1) (a) “Cancer or chronic disease drug” means a prescription drug that
7 is used to treat any of the following:

- 8 1. Cancer or chronic disease or side effects of cancer or chronic disease.
- 9 2. The side effects of any prescription drug ~~that is used to treat cancer or side~~
10 ~~effects of cancer under subd. 1.~~

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

12 255.056 (1) (am) “Chronic disease” means any disease, illness, impairment, or
13 other physical condition, other than cancer, that requires health care and treatment
14 over a prolonged period and, although amenable to treatment, frequently progresses
15 to increasing disability or death.

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

17 255.056 (1) (h) “Supplies” means items that are necessary to administer a
18 cancer or chronic disease drug.

19 **SECTION 5.** 255.056 (2) of the statutes, as affected by 2003 Wisconsin Acts 175
20 and 327, is amended to read:

1 255.056 (2) The department shall establish and maintain a cancer and chronic
2 diseases drug repository program, under which any person may donate a cancer or
3 chronic disease drug or supplies ~~needed to administer a cancer drug~~ for use by an
4 individual who meets eligibility criteria specified by rule by the department.
5 Donation may be made on the premises of a medical facility or pharmacy that elects
6 to participate in the program and meets requirements specified by rule by the
7 department. The medical facility or pharmacy may charge an individual who
8 receives a cancer or chronic disease drug or supplies ~~needed to administer a cancer~~
9 ~~drug~~ under this subsection a handling fee that may not exceed the amount specified
10 by rule by the department. A medical facility or pharmacy that receives a donated
11 cancer or chronic disease drug or supplies ~~needed to administer a cancer drug~~ under
12 this subsection may distribute the cancer or chronic disease drug or supplies to
13 another eligible medical facility or pharmacy for use under the program under this
14 section.

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

17 255.056 (3) A cancer or chronic disease drug or supplies ~~needed to administer~~
18 ~~a cancer drug~~ may be accepted and dispensed under the program specified in sub. (2)
19 only if all of the following requirements are met:

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

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

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

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

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

11 255.056 (4) No cancer or chronic disease drug or supplies needed to administer
12 a cancer drug that are donated for use under this section may be resold.

13 SECTION 8. 255.056 (6) of the statutes, as affected by 2003 Wisconsin Acts 175
14 and 327, is amended to read:

15 255.056 (6) (a) Unless the manufacturer of a drug or supply exercises bad faith,
16 the manufacturer is not subject to criminal or civil liability for injury, death, or loss
17 to a person or property for matters related to the donation, acceptance, or dispensing
18 of a cancer or chronic disease drug or supply manufactured by the manufacturer that
19 is donated by any person under this section, including liability for failure to transfer
20 or communicate product or consumer information or the expiration date of the
21 donated cancer or chronic disease drug or supply.

22 (b) Except as provided in par. (c), any person, except the manufacturer of a drug
23 or supply, is immune from civil liability for injury to or the death of the individual
24 to whom the cancer or chronic disease drug or supply is dispensed and may not be
25 found guilty of unprofessional conduct for his or her acts or omissions related to

1 donating, accepting, distributing, or dispensing a cancer or chronic disease drug or
2 supply under this section.

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

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

9 255.056 (7) (a) (intro.) Requirements for medical facilities and pharmacies to
10 accept and dispense donated cancer or chronic disease drugs or supplies needed to
11 ~~administer cancer drugs~~ under this section, including all of the following:

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

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

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

24 (b) Eligibility criteria for individuals to receive donated cancer or chronic
25 disease drugs or supplies needed to ~~administer cancer drugs~~ dispensed under the

1 program. The standards shall prioritize dispensation to individuals who are
2 uninsured or indigent, but will permit dispensation to others if an uninsured or
3 indigent individual is unavailable.

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

7 (d) Necessary forms for administration of the cancer and chronic diseases drug
8 repository program, including forms for use by persons that donate, accept,
9 distribute, or dispense cancer or chronic disease drugs or supplies needed to
10 ~~administer cancer drugs~~ under the program.

11 (e) The maximum handling fee that a medical facility or pharmacy may charge
12 for accepting, distributing, or dispensing donated cancer or chronic disease drugs or
13 supplies needed to ~~administer cancer drugs~~.

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

17 (g) A list of cancer or chronic disease drugs and supplies needed to ~~administer~~
18 ~~cancer drugs~~, arranged by category or by individual ~~cancer~~ drug or supply, that the
19 cancer and chronic diseases drug repository program will not accept for dispensing.
20 The list shall include a statement that specifies the reason that the ~~cancer~~ drug or
21 supplies needed to ~~administer a cancer drug~~ are ineligible for donation.

22 **SECTION 10. Effective dates.** This act takes effect on ~~July 1, 2005~~, or on the
23 day after publication, whichever is later.

24 (END)

January 1, 2006

2005-2006 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-0239/lins
DAK:kjf:rs

No #

INSERT ANAL

The bill requires DHFS to submit proposed rules concerning these changes to the Legislative Council staff by the date that is four months after publication of the bill as an act.

INSERT 6-21

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5
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7

~~#~~
SECTION 1. 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.

Kennedy, Debora

From: Stegall, Jennifer
Sent: Thursday, February 24, 2005 4:12 PM
To: Kennedy, Debora
Subject: modification to drug repository bill



Language-DispensingFee.pdf

Debora,

Here is the change I mentioned earlier. Please let me know if you have any questions/concerns.

Thanks,
Jennifer

*Note: Dean Cody gave permission for this change,
for 05-0239 2/24/05 D.A.K.*

The following language, which would be added to s. 255.056(7)(e), would accomplish what we just discussed--

"The maximum handling fee established by rule may not be less than 350% of the dispensing fee permitted to be charged for prescription drugs for which coverage is provided under s. 49.46(2)(b)6.h."



2005 BILL

Regen

1 AN ACT to amend 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 to create 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

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BILL

INSERT ANAL

The bill, effective January 1, 2006, expands the cancer drug repository program to include prescription drugs and supplies for chronic diseases, as defined in the bill. The bill requires DHFS to submit proposed rules concerning these changes to the Legislative Council staff by the date that is four months after publication of the bill as an act.

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

3 **255.056 (title) Cancer and chronic diseases drug repository.**

4 **SECTION 2.** 255.056 (1) (a) of the statutes, as affected by 2003 Wisconsin Acts
5 175 and 327, is amended to read:

6 255.056 (1) (a) “Cancer or chronic disease drug” means a prescription drug that
7 is used to treat any of the following:

- 8 1. Cancer or chronic disease or side effects of cancer or chronic disease.
9 2. The side effects of any prescription drug ~~that is used to treat cancer or side~~
10 ~~effects of cancer~~ under subd. 1.

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12 255.056 (1) (am) “Chronic disease” means any disease, illness, impairment, or
13 other physical condition, other than cancer, that requires health care and treatment
14 over a prolonged period and, although amenable to treatment, frequently progresses
15 to increasing disability or death.

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

17 255.056 (1) (h) “Supplies” means items that are necessary to administer a
18 cancer or chronic disease drug.

BILL

1 **SECTION 5.** 255.056 (2) of the statutes, as affected by 2003 Wisconsin Acts 175
2 and 327, is amended to read:

3 255.056 (2) The department shall establish and maintain a cancer and chronic
4 diseases drug repository program, under which any person may donate a cancer or
5 chronic disease drug or supplies needed to administer a cancer drug for use by an
6 individual who meets eligibility criteria specified by rule by the department.
7 Donation may be made on the premises of a medical facility or pharmacy that elects
8 to participate in the program and meets requirements specified by rule by the
9 department. The medical facility or pharmacy may charge an individual who
10 receives a cancer or chronic disease drug or supplies needed to administer a cancer
11 drug under this subsection a handling fee that may not exceed the amount specified
12 by rule by the department. A medical facility or pharmacy that receives a donated
13 cancer or chronic disease drug or supplies needed to administer a cancer drug under
14 this subsection may distribute the cancer or chronic disease drug or supplies to
15 another eligible medical facility or pharmacy for use under the program under this
16 section.

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

19 255.056 (3) A cancer or chronic disease drug or supplies needed to administer
20 a cancer drug may be accepted and dispensed under the program specified in sub. (2)
21 only if all of the following requirements are met:

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

BILL**SECTION 6**

1 (b) The cancer or chronic disease drug bears an expiration date that is later
2 than 6 months after the date that the drug was donated.

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

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

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

13 255.056 (4) No cancer or chronic disease drug or supplies ~~needed to administer~~
14 ~~a cancer drug~~ that are donated for use under this section may be resold.

15 **SECTION 8.** 255.056 (6) of the statutes, as affected by 2003 Wisconsin Acts 175
16 and 327, is amended to read:

17 255.056 (6) (a) Unless the manufacturer of a drug or supply exercises bad faith,
18 the manufacturer is not subject to criminal or civil liability for injury, death, or loss
19 to a person or property for matters related to the donation, acceptance, or dispensing
20 of a cancer or chronic disease drug or supply manufactured by the manufacturer that
21 is donated by any person under this section, including liability for failure to transfer
22 or communicate product or consumer information or the expiration date of the
23 donated cancer or chronic disease drug or supply.

24 (b) Except as provided in par. (c), any person, except the manufacturer of a drug
25 or supply, is immune from civil liability for injury to or the death of the individual

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1 to whom the cancer or chronic disease drug or supply is dispensed and may not be
2 found guilty of unprofessional conduct for his or her acts or omissions related to
3 donating, accepting, distributing, or dispensing a cancer or chronic disease drug or
4 supply under this section.

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

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

11 255.056 (7) (a) (intro.) Requirements for medical facilities and pharmacies to
12 accept and dispense donated cancer or chronic disease drugs or supplies ~~needed to~~
13 ~~administer cancer drugs~~ under this section, including all of the following:

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

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

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

BILL**SECTION 9**

1 (b) Eligibility criteria for individuals to receive donated cancer or chronic
2 disease drugs or supplies ~~needed to administer cancer drugs~~ dispensed under the
3 program. The standards shall prioritize dispensation to individuals who are
4 uninsured or indigent, but will permit dispensation to others if an uninsured or
5 indigent individual is unavailable.

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

9 (d) Necessary forms for administration of the cancer and chronic diseases drug
10 repository program, including forms for use by persons that donate, accept,
11 distribute, or dispense cancer or chronic disease drugs or supplies ~~needed to~~
12 ~~administer cancer drugs~~ under the program.

13 (e) The maximum handling fee that a medical facility or pharmacy may charge
14 for accepting, distributing, or dispensing donated cancer or chronic disease drugs or
15 supplies ~~needed to administer cancer drugs.~~ INSERT 6-15

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

19 (g) A list of cancer or chronic disease drugs and supplies ~~needed to administer~~
20 ~~cancer drugs~~, arranged by category or by individual ~~cancer~~ drug or supply, that the
21 cancer and chronic diseases drug repository program will not accept for dispensing.
22 The list shall include a statement that specifies the reason that the ~~cancer~~ drug or
23 supplies ~~needed to administer a cancer drug~~ are ineligible for donation.

SECTION 10. Nonstatutory provisions.

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1 (1) CANCER AND CHRONIC DISEASES DRUG REPOSITORY PROGRAM; RULES. The
 2 department of health and family services shall submit in proposed form the rules
 3 required under section 255.056 (7) (a) (intro.) and 2. to 4., (b), (c), (d), (e), (f), and (g)
 4 of the statutes, as affected by this act, to the legislative council staff under section
 5 227.15 (1) of the statutes no later than the first day of the 5th month beginning after
 6 the effective date of this subsection.

Change
Component
action: NS: effdate
text: NS: effdate

SECTION 11. Effective dates. This act takes effect on January 1, 2006, or on

8 the day after publication, whichever is later.

9 (END)

2005-2006 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-1516/2ins
DAK:kjf:rs

0239

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no # The bill modifies one of the rules that DHFS must promulgate, to specify that the maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated cancer or chronic disease drugs may not be less than 350 percent of the dispensing fee permitted to be charged for prescription drugs under Medical Assistance.

INSERT 6-15

- no #* 1 The fee under this paragraph may not be less than 350 percent of the dispensing
2 fee permitted to be charged for prescription drugs for which coverage is provided
3 under s. 49.46 (2) (b) 6. h.

Emery, Lynn

From: Cady, Dean
Sent: Monday, February 28, 2005 12:33 PM
To: LRB.Legal
Subject: Draft review: LRB 05-0239/2 Topic: Expand cancer drug repository program

It has been requested by <Cady, Dean> that the following draft be jacketed for the ASSEMBLY:

Draft review: LRB 05-0239/2 Topic: Expand cancer drug repository program