

2005 DRAFTING REQUEST

Bill

Received: 09/21/2004

Received By: btradewe

Wanted: As time permits

Identical to LRB:

For: Leah Vukmir (608) 266-9180

By/Representing: Dean Cady

This file may be shown to any legislator: NO

Drafter: dkennedy

May Contact: Dick Sweet,
Laura Rose,
Sen. Roessler's office

Addl. Drafters:

Subject: Health - miscellaneous

Extra Copies:

Submit via email: YES

Requester's email: Rep.Vukmir@legis.state.wi.us

Carbon copy (CC:) to:

Pre Topic:

No specific pre topic given

Topic:

Expand cancer drug repository program

Instructions:

See Attached

Drafting History:

| <u>Vers.</u> | <u>Drafted</u> | <u>Reviewed</u> | <u>Typed</u> | <u>Proofed</u> | <u>Submitted</u> | <u>Jacketed</u> | <u>Required</u> |
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| /1 | dkennedy 01/21/2005 | kfollett 01/22/2005 | rschluet 01/24/2005 | _____ | lnorthro 01/24/2005 | | S&L |
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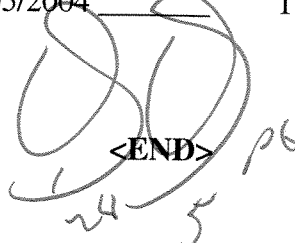
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Tradewell, Becky

From: Cady, Dean
Sent: Tuesday, September 21, 2004 2:04 PM
To: Tradewell, Becky
Cc: Stegall, Jennifer
Subject: Preliminary Draft Request

Hi Becky, this is dean from Representative Vukmir's office. As we discussed this afternoon, attached please find the Draft of the Cancer Repository expansion that was prepared by Leg Council for Senator Roessler & Representative Vukmir. In addition, I have attached the Memo from Dick Sweet to Senator Roessler & Representative Vukmir regarding the draft. Representative Vukmir & Senator Roessler would like a Preliminary draft of a bill expanding the Cancer Repository using the Leg Council draft as a template.

If you could please pass this on to Debora that would be brilliant, thank you. Should you (I understand that you will not be the drafter) or Debora have any questions feel free to contact Dick Sweet, Laura Rose, Jennifer in Senator Roessler's office or me.

cheers,
dean



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WISCONSIN LEGISLATIVE COUNCIL

Terry C. Anderson, Director
Laura D. Rose, Deputy Director

TO: SENATOR CAROL ROESSLER AND REPRESENTATIVE LEAH VUKMIR

FROM: Richard Sweet, Senior Staff Attorney

RE: WLC: 0001/1 (Drug Repository)

DATE: July 12, 2004

Attached is a bill draft prepared at your request--WLC: 0001/1, relating to including prescription drugs and supplies for other chronic diseases in the cancer drug repository program and requiring the exercise of rule-making authority.

The draft modifies the current cancer drug repository program to include drugs for other chronic diseases and supplies needed to administer those drugs. The term "chronic disease" is defined by using the definition in current s. 255.01 (1), Stats., but does not include the words "is reversible and" since, as was discussed at our June 24, 2004 meeting, certain diseases that might commonly be considered to be chronic diseases are reversible.

The current statute on the cancer drug repository defines the term "cancer drug." The draft expands this to define the term "cancer or other chronic disease drug or supplies." By including the term "supplies" in the definition to mean supplies that are needed to administer such a drug, it is not necessary to repeat the phrase "needed to administer a cancer drug" throughout the statute, as is done in the current statute.

In addition, the draft corrects what appears to be an error in the current statute that deals with immunity from liability for persons other than drug manufacturers. The immunity provision refers to drugs or supplies. However, the exception to that immunity, which allows liability to be imposed for reckless, wanton, or intentional misconduct, refers only to drugs. The draft adds supplies to that exception.

Feel free to contact me if I can be of further assistance.

RNS:jal

Attachment

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 prescription
4 drugs and supplies for other chronic diseases in the cancer drug repository program
5 and requiring the exercise of rule-making authority.

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

11 1. Cancer A prescription drug that is used to treat cancer or other chronic disease or side
12 effects of cancer or other chronic disease.

13 2. The A prescription drug that is used to treat the side effects of any prescription drug
14 that is used to treat cancer or side effects of cancer under subd. 1.

15 3. Supplies needed to administer a prescription drug under subd. 1. or 2.

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

17 255.056 (1) (am) “Chronic disease” means any disease, illness, impairment, or other
18 physical condition that requires health care and treatment over a prolonged period and,
19 although amenable to treatment, frequently progresses to increasing disability or death.

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

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

13 **SECTION 5.** 255.056 (3) of the statutes is amended to read:

14 255.056 (3) A cancer or other chronic disease drug or supplies ~~needed to administer a~~
15 ~~cancer drug~~ may be accepted and dispensed under the program specified in sub. (2) only if all
16 of the following requirements are met:

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

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

22 (c) The ~~cancer drug~~ drug or supplies ~~needed to administer a cancer drug~~ ~~is~~ are not adulterated
23 or misbranded, as determined by a pharmacist employed by, or under contract with, the

1 medical facility or pharmacy, who shall inspect the drug or supplies ~~needed to administer a~~
2 ~~cancer drug~~ before the drug or supplies are dispensed.

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

5 **SECTION 6.** 255.056 (4) of the statutes is amended to read:

6 255.056 (4) No cancer or other chronic disease drug or supplies ~~needed to administer~~
7 ~~a cancer drug~~ that are donated for use under this section may be resold.

8 **SECTION 7.** 255.056 (6) of the statutes is amended to read:

9 255.056 (6) (a) Unless the manufacturer of a drug or supply exercises bad faith, the
10 manufacturer is not subject to criminal or civil liability for injury, death, or loss to a person
11 or property for matters related to the donation, acceptance, or dispensing of a cancer or other
12 chronic disease drug or supply manufactured by the manufacturer that is donated by any
13 person under this section, including liability for failure to transfer or communicate product or
14 consumer information or the expiration date of the donated cancer or other chronic disease
15 drug or supply.

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

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

1 **SECTION 8.** 255.056 (7) (a) (intro.), 2., 3., 4., (b), (c), (d), (e), (f) and (g) of the statutes
2 are amended to read:

3 255.056 (7) (a) (intro.) Requirements for medical facilities and pharmacies to accept
4 and dispense donated cancer or other chronic disease drugs or supplies needed to administer
5 ~~cancer drugs~~ under this section, including all of the following:

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

8 3. Standards and procedures for inspecting donated cancer or other chronic disease
9 drugs or supplies ~~needed to administer cancer drugs~~ to determine if the ~~cancer~~ drug or supplies
10 ~~needed to administer a cancer drug~~ are in its their original, unopened, sealed, and
11 tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit-dose
12 packaging is unopened.

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

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

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

1 (d) Necessary forms for administration of the cancer or other chronic disease drug
2 repository program, including forms for use by persons that donate, accept, distribute, or
3 dispense cancer drugs or supplies ~~needed to administer cancer drugs~~ under the program.

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

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

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

15 **SECTION 9. Effective date.** This act takes effect on July 1, 2005, or on the day after
16 publication, whichever is later.

17 (END)

Debra -

9/21

Dean from Rep. Utker's office called with this request. They want a 1P draft for now. When it's been finalized, they will want a companion draft for Sen. Besder.

Becky