

**2003 DRAFTING REQUEST**

**Bill**

Received: 12/16/2003

Received By: dkennedy

Wanted: As time permits

Identical to LRB:

For: Gregg Underheim (608) 266-2254

By/Representing: Randy Thorson

This file may be shown to any legislator: NO

Drafter: dkennedy

May Contact:

Addl. Drafters:

Subject: Health - miscellaneous

Extra Copies:

Submit via email: YES

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

Carbon copy (CC:) to:

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**Pre Topic:**

No specific pre topic given

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**Topic:**

Cancer drug donation repository

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**Instructions:**

See Attached

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**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>
/?	dkennedy 01/30/2004	kfollett 01/30/2004		_____			S&L
/1			rschluet 01/30/2004	_____	lemery 01/30/2004		S&L
/2	dkennedy	kfollett	pgreensl	_____	mbarman	lemery	S&L

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
	02/03/2004	02/03/2004	02/03/2004	_____	02/03/2004	02/04/2004	
		kfollett		_____			
		02/03/2004		_____			

FE Sent For:

<END>

02-13-2004  
("1/2")

Requested  
By Randy Thorson

Rush  
=

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	02/03/2004	02/03/2004 kfollett 02/03/2004	02/03/2004	_____	02/03/2004		
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/?	dkennedy 01/30/2004	kfollett 01/30/2004					S&L
/1		12/16/03 2/3/04 kjf	rschluet 01/30/2004 2/3/04 ps		lemery 01/30/2004		S&L

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**<END>**

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~~Cancer~~ drug donation repository


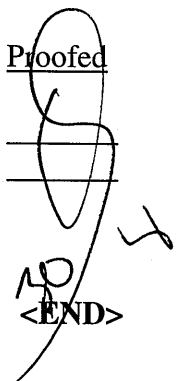
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/?	dkennedy	1/1 kjf 1/30					

FE Sent For:

NO  
<END>

## Kennedy, Debora

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**From:** Thorson, Randy  
**Sent:** Monday, December 15, 2003 3:00 PM  
**To:** Kennedy, Debora  
**Subject:** FW: Bill Drafting Request for Rep. Underheim

-----Original Message-----

**From:** Cannon, Peter (Legislature)  
**Sent:** Monday, December 15, 2003 2:22 PM  
**To:** Thorson, Randy  
**Subject:**

Here's a link to the Ohio law

[http://www.legislature.state.oh.us/bills.cfm?ID=124\\_HB\\_221](http://www.legislature.state.oh.us/bills.cfm?ID=124_HB_221)

and here's a Nebraska version signed earlier this year. Below is a link to the slip law and a newspaper story.

[http://www.unicam.state.ne.us/legal/SLIP\\_LB756.pdf](http://www.unicam.state.ne.us/legal/SLIP_LB756.pdf)

Johanns signs three bills into law

McDonald's cancer drug donation bill goes into effect in September

By Scott Bauer

The Associated Press

Publication Date: [04/16/03 <http://theindependent.com/stories/041603/>](http://theindependent.com/stories/041603/)

LINCOLN -- Gov. Mike Johanns signed into law Wednesday bills that will create a cancer drug repository, increase penalties for child pornography and allow wrongful death lawsuits against anyone who kills an unborn child.

Nebraska becomes the second state to establish a repository for cancer drugs under the bill (LB756) introduced by Sen. Vickie McDonald of Rockville.

Under the program, drugs in their original, unsealed packages could be accepted and they could not be resold, but they could be distributed at the discretion of participating offices, including doctors, pharmacies, hospitals and health clinics.

McDonald, whose husband state Sen. Rick McDonald died of cancer in 2001, held up a packet of unused anti-nausea drugs worth \$850 she recently found in her house.

"You don't know how good it makes me feel to donate to the cancer drug repository," she said. "I will be the first one to donate."

McDonald said she will refer to the law as the MAC Act. Mac was the nickname of her husband. McDonald said it also will stand for "Mission Against Cancer."



The program will become effective Sept. 15.

Ohio was the first state to establish a cancer drug repository.

Under another bill (LB294) signed Wednesday by Johanns, anyone who kills an unborn child could be subject to a wrongful-death lawsuit.

Bill sponsor Sen. Mike Foley of Lincoln said the bill is the civil law counterpart of Nebraska's fetal-homicide law.

"We now, belatedly, have fixed a broken law," Foley said.

The bill was supported by the family of Vicki Soto, a North Platte woman who was 8 1/2 months pregnant when she was killed in 2001. She was carrying a full-term baby boy when she had her throat slashed and legs severed below the knees in December 2001.

Other families whose unborn children were killed also supported the measure and attended the bill signing.

Under the third bill (LB111) signed by Johanns, penalties for possessing child pornography will increase effective immediately.

The crime will now be a felony instead of a misdemeanor. The punishment can now be as high as up to five years in prison and a \$10,000 fine. The current penalty is no more than six months in jail and a \$1,000 fine.

Click here to return to story:

[http://www.theindependent.com/stories/041603/new\\_johanns16.shtml](http://www.theindependent.com/stories/041603/new_johanns16.shtml)

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Let me know what else I can do.

Pete

Peter Cannon  
Senior Legislative Analyst  
LRB  
6-5446

## AN ACT

To enact sections 3715.87, 3715.871, 3715.872, and 3715.873 of the Revised Code to establish under the direction of the State Board of Pharmacy a drug repository program to accept and dispense donated prescription drugs.

*Be it enacted by the General Assembly of the State of Ohio:*

SECTION 1. That sections 3715.87, 3715.871, 3715.872, and 3715.873 of the Revised Code be enacted to read as follows:

Sec. 3715.87. (A) As used in this section and in sections 3715.871, 3715.872, and 3715.873 of the Revised Code:

(1) "Hospital" has the same meaning as in section 3727.01 of the Revised Code.

(2) "Nonprofit clinic" means a charitable nonprofit corporation organized and operated pursuant to Chapter 1702. of the Revised Code, or any charitable organization not organized and not operated for profit, that provides health care services to indigent and uninsured persons as defined in section 2305.234 of the Revised Code. "Nonprofit clinic" does not include a hospital as defined in section 3727.01 of the Revised Code, a facility licensed under Chapter 3721. of the Revised Code, or a facility that is operated for profit.

(3) "Prescription drug" means any drug to which the following applies:

(a) Under the "Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend, "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription.

(b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.

(B) The state board of pharmacy shall establish a drug repository program to accept and dispense prescription drugs donated for the purpose of being dispensed to individuals who are residents of this state and meet

eligibility standards established in rules adopted by the board under section 3715.873 of the Revised Code. Only drugs in their original sealed and tamper-evident unit dose packaging may be accepted and dispensed. The packaging must be unopened, except that drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed. Drugs donated by individuals bearing an expiration date that is less than six months from the date the drug is donated shall not be accepted or dispensed. A drug shall not be accepted or dispensed if there is reason to believe that it is adulterated as described in section 3715.63 of the Revised Code. Subject to the limitation specified in this division, unused drugs dispensed for purposes of the medicaid program may be accepted and dispensed under the drug repository program.

Sec. 3715.871. (A) Any person, including a drug manufacturer or any health care facility as defined in section 1337.11 of the Revised Code, may donate prescription drugs to the drug repository program. The drugs must be donated at a pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program and meets criteria for participation in the program established in rules adopted by the state board of pharmacy under section 3715.873 of the Revised Code. Participation in the program by pharmacies, hospitals, and nonprofit clinics is voluntary. Nothing in this or any other section of the Revised Code requires a pharmacy, hospital, or nonprofit clinic to participate in the program.

(B) A pharmacy, hospital, or nonprofit clinic eligible to participate in the program shall dispense drugs donated under this section to individuals who are residents of this state and meet the eligibility standards established in rules adopted by the board under section 3715.873 of the Revised Code or to other government entities and nonprofit private entities to be dispensed to individuals who meet the eligibility standards. A drug may be dispensed only pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs, as defined in section 4729.01 of the Revised Code. A pharmacy, hospital, or nonprofit clinic that accepts donated drugs shall comply with all applicable federal laws and laws of this state dealing with storage and distribution of dangerous drugs and shall inspect all drugs prior to dispensing them to determine that they are not adulterated. The pharmacy, hospital, or nonprofit clinic may charge individuals receiving donated drugs a handling fee established in accordance with rules adopted by the board under section 3715.873 of the Revised Code. Drugs donated to the repository may not be resold.

*Page missing*

Sub. H. B. No. 221

3

7.

means any of the following who provide medical, dental, or other health-related diagnosis, care, or treatment:

(1) Individuals authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;

(2) Registered nurses and licensed practical nurses licensed under Chapter 4723. of the Revised Code;

(3) Physician assistants authorized to practice under Chapter 4730. of the Revised Code;

(4) Dentists and dental hygienists licensed under Chapter 4715. of the Revised Code;

(5) Optometrists licensed under Chapter 4725. of the Revised Code;

(6) Pharmacists licensed under Chapter 4729. of the Revised Code.

(B) The state board of pharmacy; the director of health; any person, including a drug manufacturer, or government entity that donates drugs to the repository program; any pharmacy, hospital, nonprofit clinic, or health care professional that accepts or dispenses drugs under the program; and any pharmacy, hospital, or nonprofit clinic that employs a health care professional who accepts or dispenses drugs under the program shall not, in the absence of bad faith, be subject to any of the following for matters related to donating, accepting, or dispensing drugs under the program: criminal prosecution; liability in tort or other civil action for injury, death, or loss to person or property; or professional disciplinary action.

A drug manufacturer shall not, in the absence of bad faith, be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a drug manufactured by the drug manufacturer that is donated by any person under the program, including but not limited to liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

Sec. 3715.873. In consultation with the director of health, the state board of pharmacy shall adopt rules governing the drug repository program that establish all of the following:

(A) Eligibility criteria for pharmacies, hospitals, and nonprofit clinics to receive and dispense donated drugs under the program;

(B) Standards and procedures for accepting, safely storing, and dispensing donated drugs;

(C) Standards and procedures for inspecting donated drugs to determine that the original unit dose packaging is sealed and tamper-evident and that the drugs are unadulterated, safe, and suitable for dispensing;

(D) Eligibility standards based on economic need for individuals to receive drugs;

(E) A means, such as an identification card, by which an individual who is eligible to receive donated drugs may demonstrate eligibility to the pharmacy, hospital, or nonprofit clinic dispensing the drugs;

(F) A form that an individual receiving a drug from the repository must sign before receiving the drug to confirm that the individual understands the immunity provisions of the program;

(G) A formula to determine the amount of a handling fee that pharmacies, hospitals, and nonprofit clinics may charge to drug recipients to cover restocking and dispensing costs;

(H) In addition, for drugs donated to the repository by individuals:

(1) A list of drugs, arranged either by category or by individual drug, that the repository will accept from individuals;

(2) A list of drugs, arranged either by category or by individual drug, that the repository will not accept from individuals. The list must include a statement as to why the drug is ineligible for donation.

(3) A form each donor must sign stating that the donor is the owner of the drugs and intends to voluntarily donate them to the repository.

(I) In addition, for drugs donated to the repository by health care facilities:

(1) A list of drugs, arranged either by category or by individual drug, that the repository will accept from health care facilities;

(2) A list of drugs, arranged either by category or by individual drug, that the repository will not accept from health care facilities. The list must include a statement as to why the drug is ineligible for donation.

(J) Any other standards and procedures the board considers appropriate.

The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

SECTION 2. Sections 3715.87, 3715.871, and 3715.872 of the Revised Code as enacted by this act shall take effect one year after the effective date of this section.

SECTION 3. The State Board of Pharmacy shall adopt the rules required by section 3715.873 of the Revised Code not later than nine months after the effective date of this section.

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*Speaker* \_\_\_\_\_ *of the House of Representatives.*

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*President* \_\_\_\_\_ *of the Senate.*

Passed \_\_\_\_\_, 20\_\_\_\_

Approved \_\_\_\_\_, 20\_\_\_\_

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*Governor.*

Sub. H. B. No. 221

6

The section numbering of law of a general and permanent nature is complete and in conformity with the Revised Code.

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*Director, Legislative Service Commission.*

Filed in the office of the Secretary of State at Columbus, Ohio, on the  
\_\_\_\_ day of \_\_\_\_\_, A. D. 20\_\_\_\_.

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*Secretary of State.*

File No. \_\_\_\_\_ Effective Date \_\_\_\_\_

## LEGISLATIVE BILL 756

Approved by the Governor April 16, 2003

Introduced by McDonald, 41; Aguilar, 35; Baker, 44; Bourne, 8; Burling, 33; Byars, 30; Combs, 32; Connealy, 16; Cudaback, 36; Cunningham, 40; Erdman, 47; Hudkins, 21; Jensen, 20; Johnson, 37; Jones, 43; Kremer, 34; Kruse, 13; Mines, 18; Mossey, 3; Dw. Pedersen, 39; D. Pederson, 42; Preister, 5; Price, 26; Redield, 12; Schimek, 27; Smith, 48; Stuhr, 24; Stuthman, 22; Synowiecki, 7; Thompson, 14; Tyson, 19; Vrtiska, 1; Wehrbein, 2; Foley, 29; Maxwell, 9

AN ACT relating to health; to adopt the Cancer Drug Repository Program Act; and to provide an operative date.

Be it enacted by the people of the State of Nebraska,

Section 1. Sections 1 to 8 of this act shall be known and may be cited as the Cancer Drug Repository Program Act.

Sec. 2. For purposes of the Cancer Drug Repository Program Act:

(1) Cancer drug means a prescription drug used to treat (a) cancer or its side effects or (b) the side effects of a prescription drug used to treat cancer or its side effects;

(2) Department means the Department of Health and Human Services Regulation and Licensure;

(3) Health care facility has the definition found in section 71-413;

(4) Health clinic has the definition found in section 71-416;

(5) Hospital has the definition found in section 71-419;

(6) Pharmacy has the definition found in section 71-425;

(7) Physician's office means the office of a person licensed to practice medicine and surgery or osteopathic medicine and surgery;

(8) Prescribing practitioner means a health care practitioner licensed under the Uniform Licensing Law who is authorized to prescribe cancer drugs; and

(9) Prescription drug has the definition found in section 71-1,142.

Sec. 3. The department shall establish a cancer drug repository program for accepting donated cancer drugs and dispensing such drugs to Nebraska residents. Participation in the program shall be voluntary.

Sec. 4. Any person or entity, including, but not limited to, a cancer drug manufacturer or health care facility, may donate cancer drugs to the cancer drug repository program. Cancer drugs may be donated at a physician's office, pharmacy, hospital, or health clinic that elects to participate in the program and meets criteria established by the department for such participation.

Sec. 5. (1) A cancer drug shall only be accepted or dispensed under the cancer drug repository program if such drug is in its original, unopened, sealed, and tamper-evident unit dose packaging, except that a cancer drug packaged in single unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened.

(2) A cancer drug shall not be accepted or dispensed under the cancer drug repository program if (a) such drug bears an expiration date that is earlier than six months after the date the drug was donated or (b) such drug is adulterated or misbranded as described in section 71-2401 or 71-2402.

(3) Subject to limitations provided in this section, unused cancer drugs dispensed under the medical assistance program established in section 68-1018 may be accepted and dispensed under the cancer drug repository program.

Sec. 6. (1) A physician's office, pharmacy, hospital, or health clinic that accepts donated cancer drugs under the cancer drug repository program shall comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of such drugs and shall inspect all such drugs prior to dispensing to determine if they are adulterated or misbranded as described in section 71-2401 or 71-2402. Such drugs shall only be dispensed pursuant to a prescription issued by a prescribing practitioner. Such drugs may be distributed to another participating physician's office, pharmacy, hospital, or health clinic for dispensing.

(2) A physician's office, pharmacy, hospital, or health clinic may charge a handling fee for distributing or dispensing cancer drugs under the cancer drug repository program. Such fee shall be established in rules and regulations adopted and promulgated by the department. Cancer drugs donated

450.09 (7m)  
(c)



under the program shall not be resold.

Sec. 7. (1) Any person or entity, including a cancer drug manufacturer, which exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs under the Cancer Drug Repository Program Act or rules and regulations adopted and promulgated under the act shall be immune from civil or criminal liability or professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

(2) Notwithstanding subsection (1) of this section, the donation of a cancer drug by a cancer drug manufacturer does not absolve the manufacturer of any criminal or civil liability that would have existed but for the donation, nor shall such donation increase the liability of such cancer drug manufacturer that would have existed but for the donation.

Sec. 8. The department, upon the recommendation of the Board of Pharmacy, shall adopt and promulgate rules and regulations to carry out the Cancer Drug Repository Program Act. Initial rules and regulations under the act shall be adopted and promulgated no later than ninety days after the operative date of this act. Such rules and regulations shall include, but not be limited to:

(1) Eligibility criteria and other standards and procedures for physician's offices, pharmacies, hospitals, and health clinics that accept and distribute or dispense donated cancer drugs;

(2) Necessary forms for administration of the cancer drug repository program, including, but not limited to, forms for use by persons or entities that donate, accept, distribute, or dispense cancer drugs under the program;

(3) The maximum handling fee that may be charged by physician's offices, pharmacies, hospitals, or health clinics that accept and distribute or dispense donated cancer drugs; and

(4) (a) Categories of cancer drugs that the cancer drug repository program will accept for dispensing and (b) categories of cancer drugs that the program will not accept for dispensing and the reason that such drugs will not be accepted.

Sec. 9. This act becomes operative on September 15, 2003.

4/21/04

Note missing page  
Ohio stat

Questions to ask Randy:

1. To cover all drugs (Ohio) or just cancer-related drugs (Neb)?

1/22  
Ans:  
Cancer  
related  
only

~~Ans:  
all  
drugs~~

DAFS

2. Who should prom rules? <sup>Ohio</sup> Pharm Bd.? <sup>Neb?</sup> DAFS?

3. Exp date? Emergency rules?

4. Eligibility criteria?  
Indigent + uninsured (Ohio) - rule  
No criteria (Neb)

~~No  
criteria~~

Wants flexible distribution -  
most indigent or uninsured first,  
then persons not needy



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**HB 221**

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and Associated  
Reports](#)

[As Passed by Senate](#)

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Committee](#)

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[HELP - Field  
Definitions for this  
Page](#)

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**(124th General Assembly)  
(Substitute House Bill Number 221)**

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***Be it enacted by the General Assembly of the State of Ohio:***

**SECTION 1.** That sections 3715.87, 3715.871, 3715.872, and 3715.873 of the Revised Code be enacted to read as follows:

**Sec. 3715.87.** (A) As used in this section and in sections 3715.871, 3715.872, and 3715.873 of the Revised Code:

(1) "Hospital" has the same meaning as in section 3727.01 of the Revised Code.

(2) "Nonprofit clinic" means a charitable nonprofit corporation organized and operated pursuant to Chapter 1702. of the Revised Code, or any charitable organization not organized and not operated for profit, that provides health care services to indigent and uninsured persons as defined in section 2305.234 of the Revised Code. "Nonprofit clinic" does not include a hospital as defined in section 3727.01 of the Revised Code, a facility licensed under Chapter 3721. of the Revised Code, or a facility that is operated for profit.

(3) "Prescription drug" means any drug to which the following applies:

(a) Under the "Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend, "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription.

(b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.

(B) The state board of pharmacy shall establish a drug repository program to accept and dispense prescription drugs donated for the purpose of being dispensed to individuals who are residents of this state and meet eligibility standards established in rules adopted by the board under section 3715.873 of the Revised Code. Only drugs in their original sealed and tamper-evident unit dose packaging may be accepted and dispensed. The packaging must be unopened, except that drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed. Drugs donated by individuals bearing an expiration date that is less than six months from the date the drug is donated shall not be accepted or dispensed. A drug shall not be accepted or dispensed if there is reason to believe that it is adulterated as described in section 3715.63 of the Revised Code. Subject to the limitation specified in this division, unused drugs dispensed for purposes of the medicaid program may be accepted and dispensed under the drug repository program.

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participation in the program established in rules adopted by the state board of pharmacy under section 3715.873 of the Revised Code. Participation in the program by pharmacies, hospitals, and nonprofit clinics is voluntary. Nothing in this or any other section of the Revised Code requires a pharmacy, hospital, or nonprofit clinic to participate in the program.

(B) A pharmacy, hospital, or nonprofit clinic eligible to participate in the program shall dispense drugs donated under this section to individuals who are residents of this state and meet the eligibility standards established in rules adopted by the board under section 3715.873 of the Revised Code or to other government entities and nonprofit private entities to be dispensed to individuals who meet the eligibility standards. A drug may be dispensed only pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs, as defined in section 4729.01 of the Revised Code. A pharmacy, hospital, or nonprofit clinic that accepts donated drugs shall comply with all applicable federal laws and laws of this state dealing with storage and distribution of dangerous drugs and shall inspect all drugs prior to dispensing them to determine that they are not adulterated. The pharmacy, hospital, or nonprofit clinic may charge individuals receiving donated drugs a handling fee established in accordance with rules adopted by the board under section 3715.873 of the Revised Code. Drugs donated to the repository may not be resold.

**Sec. 3715.872.** (A) As used in this section, "health care professional" means any of the following who provide medical, dental, or other health-related diagnosis, care, or treatment:

(1) Individuals authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;

(2) Registered nurses and licensed practical nurses licensed under Chapter 4723. of the Revised Code;

(3) Physician assistants authorized to practice under Chapter 4730. of the Revised Code;

(4) Dentists and dental hygienists licensed under Chapter 4715. of the Revised Code;

(5) Optometrists licensed under Chapter 4725. of the Revised Code;

(6) Pharmacists licensed under Chapter 4729. of the Revised Code.

(B) The state board of pharmacy; the director of health; any person, including a drug manufacturer, or government entity that donates drugs to the repository program; any pharmacy, hospital, nonprofit clinic, or health care professional that accepts or dispenses drugs under the program; and any pharmacy, hospital, or nonprofit clinic that employs a health care professional who accepts or dispenses drugs under the program shall not, in the absence of bad faith, be subject to any of the following for matters related to donating, accepting, or dispensing drugs under the program: criminal prosecution; liability in tort or other civil action for injury, death, or loss to person or property; or professional disciplinary action.

A drug manufacturer shall not, in the absence of bad faith, be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a drug manufactured by the drug manufacturer that is donated by any person under the program, including but not limited to liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

**Sec. 3715.873.** In consultation with the director of health, the state board of pharmacy shall adopt rules governing the drug repository program that establish all of the following:

(A) Eligibility criteria for pharmacies, hospitals, and nonprofit clinics to receive and dispense donated drugs under the program;

(B) Standards and procedures for accepting, safely storing, and dispensing donated drugs;

(C) Standards and procedures for inspecting donated drugs to determine that the original unit dose packaging is sealed and tamper-evident and that the drugs are unadulterated, safe, and suitable for dispensing;

(D) Eligibility standards based on economic need for individuals to receive drugs;

(E) A means, such as an identification card, by which an individual who is eligible to receive donated drugs may demonstrate eligibility to the pharmacy, hospital, or nonprofit clinic dispensing the drugs;

(F) A form that an individual receiving a drug from the repository must

sign before receiving the drug to confirm that the individual understands the immunity provisions of the program;

(G) A formula to determine the amount of a handling fee that pharmacies, hospitals, and nonprofit clinics may charge to drug recipients to cover restocking and dispensing costs;

(H) In addition, for drugs donated to the repository by individuals:

(1) A list of drugs, arranged either by category or by individual drug, that the repository will accept from individuals;

(2) A list of drugs, arranged either by category or by individual drug, that the repository will not accept from individuals. The list must include a statement as to why the drug is ineligible for donation.

(3) A form each donor must sign stating that the donor is the owner of the drugs and intends to voluntarily donate them to the repository.

(I) In addition, for drugs donated to the repository by health care facilities:

(1) A list of drugs, arranged either by category or by individual drug, that the repository will accept from health care facilities;

(2) A list of drugs, arranged either by category or by individual drug, that the repository will not accept from health care facilities. The list must include a statement as to why the drug is ineligible for donation.

(J) Any other standards and procedures the board considers appropriate.

The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

**SECTION 2.** Sections 3715.87, 3715.871, and 3715.872 of the Revised Code as enacted by this act shall take effect one year after the effective date of this section.

**SECTION 3.** The State Board of Pharmacy shall adopt the rules required by section 3715.873 of the Revised Code not later than nine months after the effective date of this section.

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MONDAY  
State of Wisconsin  
2003 - 2004 LEGISLATURE

LRB-3894/1

DAK: [Signature]

D-NOTE

~~PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION~~

Gen

- 1 AN ACT ...; **relating to:** establishing a cancer drug repository program and  
2 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 clinic, pharmacy, or hospital that elects to participate in the program and meets requirements specified by rule by DHFS. The medical clinic, pharmacy, or hospital may distribute the cancer drug to another participating medical clinic, pharmacy, or hospital, or may dispense the cancer drug. If dispensing the cancer drug, the medical clinic, pharmacy, or hospital 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 clinics, pharmacies, and hospitals, 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 clinic, pharmacy, or hospital may charge for



accepting, 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<sup>✓</sup> 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<sup>✓</sup> (7).

9           (c) "Hospital" has the meaning given in s. 50.33<sup>✓</sup> (2).

10          (d) "Medical clinic" includes a rural health clinic, as defined in s. 50.50<sup>✓</sup> (10).

11          (e) "Pharmacist" has the meaning given in s. 450.01<sup>✓</sup> (15).

12          (f) "Pharmacy" means a pharmacy that is licensed under s. 450.06<sup>✓</sup>.

13          (g) "Practitioner" has the meaning given in s. 450.01<sup>✓</sup> (17).

14          (h) "Prescription drug" has the meaning given in s. 450.01<sup>✓</sup> (20).

15          (2) The department<sup>✓</sup> shall establish and maintain a cancer drug repository  
16 program, under which any person may donate a cancer drug for use by an individual  
17 who meets eligibility criteria specified by rule by the department. Donation may be  
18 made on the premises of a medical clinic, pharmacy, or hospital that elects to

1 participate in the program and meets requirements specified by rule by the  
2 department. The medical clinic, pharmacy, or hospital may charge an individual who  
3 receives a cancer drug under this subsection a handling fee that may not exceed the  
4 amount specified by rule by the department. A medical clinic, pharmacy, or hospital  
5 that receives a donated cancer drug under this subsection may distribute the cancer  
6 drug to another eligible medical clinic, pharmacy, or hospital for use under the  
7 program under this section.

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

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

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

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

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

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

21 (5) Nothing in this section requires that a medical clinic, pharmacy, hospital,  
22 pharmacist, or practitioner participate in the program under this section.

23 (6) (a) Except as provided in par. (b), any person, including the manufacturer  
24 of a cancer drug, is immune from civil liability for injury to or the death of the  
25 individual to whom the cancer drug is dispensed and may not be found guilty of

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

3 (b) The immunity or the prohibition on a finding of guilty of unprofessional  
4 conduct under par. (a) <sup>✓</sup> 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 (c) The donation of a cancer drug by the manufacturer of the cancer drug may  
8 not increase any liability of the manufacturer that would have existed but for the  
9 donation.

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

11 (a) Requirements for medical clinics, pharmacies, and hospitals to accept and  
12 dispense donated cancer drugs under this section, including all of the following:

13 1. Eligibility criteria.

14 2. Standards and procedures for accepting, safely storing, and dispensing  
15 donated cancer drugs.

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

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

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

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

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

6 (e) The maximum handling fee that a medical clinic, pharmacy, or hospital may  
7 charge for accepting, distributing, or dispensing donated cancer drugs.

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

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

14 **SECTION 2. Nonstatutory provisions.**

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

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

22 (1) The treatment of section 255.055<sup>✓</sup> of the statutes takes effect on July 1, 2005.

23 (END)

D NOTE

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

LRB-3894/dn  
DAK: [Signature]

*Date*

To Representative Underheim:

1. Please note that I required DHFS to submit rules to the Legislative Council staff by the first day of the ninth month after enactment; this should speed up the rule-making process so that the act can take effect on July 1, 2005, as I have specified.
2. The statutes contain no specific definition of "medical clinic." These entities are not regulated as such by DHFS. Do you want any greater specification than I have made in the definition under s. 255.055 (1)(d)? (Ohio, for instance, specifies that the clinic be nonprofit.)
3. Please review the standard under s. 255.055 (7) (b). Does this capture your intent?
4. The immunity from liability provisions contained in s. 255.05 (6) differ somewhat from those of both Ohio and Nebraska; I consulted Robert Nelson, the attorney who drafts in courts and procedures, in drafting them to conform to Wisconsin law. Please review.

Please don't hesitate to call if you have a question or need any changes to the draft.

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-3894/1dn  
DAK:kjfrs

January 30, 2004

To Representative Underheim:

1. Please note that I required DHFS to submit rules to the Legislative Council staff by the first day of the ninth month after enactment; this should speed up the rule-making process so that the act can take effect on July 1, 2005, as I have specified.
2. The statutes contain no specific definition of "medical clinic"; these entities are not regulated as such by DHFS. Do you want any greater specification than I have made in the definition under s. 255.055 (1) (d)? (Ohio, for instance, specifies that the clinic be nonprofit.)
3. Please review the standard under s. 255.055 (7) (b). Does this capture your intent?
4. The immunity from liability provisions contained in s. 255.05 (6) differ somewhat from those of both Ohio and Nebraska; I consulted Robert Nelson, the attorney who drafts in courts and procedures, in drafting them to conform to Wisconsin law. Please review.

Please don't hesitate to call if you have a question or need any changes to the draft.

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

## Kennedy, Debora

---

**From:** Rep.Underheim  
**Sent:** Tuesday, February 03, 2004 9:25 AM  
**To:** Kennedy, Debora  
**Subject:** LRB 3894/1

Debora,

Here is the language for the changes to LRB 3894

Randy

Randy:

The medical facilities definition is 943.145(1)  
Thanks!  
Michelle

Michelle I. Mettner  
Broydrick & Associates  
44 E. Mifflin, Suite 404  
Madison, WI 53703  
(608) 255-0566 (office)  
(608) 255-4612 (fax)  
(608) 692-8541 (cell)

>  
>  
> Randy-  
> Just two changes if possible -  
>  
> One related to the question raised by the drafter about the medical clinic  
> definition - can we use the word medical facility instead (b/c it includes  
> doctors offices, etc)  
>  
> Second one is on page 2 - line 17: instead of the use of the word any  
> person may donate a cancer drug - can the wording be any person or health  
> care facility may donate?  
>  
> Will stop by later. Do you think we can get the final draft today??  
>  
> Thanks!  
> Alison

> Alison & Michelle,  
>  
> Here you go, let me know if you have any answers to the drafters note, or  
> further instructions for her.  
>  
> Randy Thorson  
> Research Assistant to  
> Gregg Underheim  
> State Representative  
> 54th Assembly District  
>  
> <<03-38941dn.pdf>> <<03-38941.pdf>>

## TELEPHONE DRAFTING INSTRUCTIONS

Drafting instructions received by Debora Kennedy.

DATE:

2/3/04

CONVERSATION  
WITH:

Randy

OF:

Wieckert's office

TELEPHONE NO:

REGARDING LRB #  
OR DRAFT TOPIC:

2894/1

INSTRUCTIONS:

Redraft

① Change "medical clinic" to  
"medical facility" - def in 943.145(1)  
(includes hospitals, so will take out)

② Add re "hc facility" to p. 2, l. 16 -

DAR: unnecessary, bc. of def of "person"  
in ch. 990; Randy: ok





BY WEDNESDAY, if possible

State of Wisconsin  
2003 - 2004 LEGISLATURE

LRB-3894/E 2  
DAK:kjf

2003 BILL

Regen

Facility or

Facility (as defined in the bill) or

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 ~~office~~, pharmacy, ~~or hospital~~ that elects to participate in the program and meets requirements specified by rule by DHFS. The medical ~~office~~, pharmacy, ~~or hospital~~ may distribute the cancer drug to another participating medical ~~office~~, pharmacy, ~~or hospital~~, or may dispense the cancer drug. If dispensing the cancer drug, the medical ~~office~~, pharmacy, ~~or hospital~~ 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 ~~offices~~, pharmacies, ~~and hospitals~~, 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 ~~office~~, pharmacy, ~~or hospital~~ may charge for

Facilities and

**BILL**

accepting, 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) "Hospital" has the meaning given in s. 50.33 (2).~~

10 ~~(d) "Medical ~~area~~" includes a rural health clinic, as defined in s. 50.30 (10).~~

11 (d) "Pharmacist" has the meaning given in s. 450.01 (15).

12 (e) "Pharmacy" means a pharmacy that is licensed under s. 450.06.

13 (f) "Practitioner" has the meaning given in s. 450.01 (17).

14 (g) "Prescription drug" has the meaning given in s. 450.01 (20).

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

facility

has the meaning given in s. 943.145 (1)

facility or

**BILL**

facility or

1 participate in the program and meets requirements specified by rule by the  
 2 department. The medical ~~pharmacy~~ ~~pharmacy~~ ~~hospital~~ may charge an individual who  
 3 receives a cancer drug under this subsection a handling fee that may not exceed the  
 4 amount specified by rule by the department. A medical ~~pharmacy~~ ~~pharmacy~~ ~~hospital~~  
 5 that receives a donated cancer drug under this subsection may distribute the cancer  
 6 drug to another eligible medical ~~pharmacy~~ ~~pharmacy~~ ~~hospital~~ for use under the  
 7 program under this section.

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

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

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

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

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

facility

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

21 (5) Nothing in this section requires that a medical ~~pharmacy~~ ~~pharmacy~~ ~~hospital~~  
 22 pharmacist, or practitioner participate in the program under this section.

23 (6) (a) Except as provided in par. (b), any person, including the manufacturer  
 24 of a cancer drug, is immune from civil liability for injury to or the death of the  
 25 individual to whom the cancer drug is dispensed and may not be found guilty of

**BILL**

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

3 (b) 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 (c) The donation of a cancer drug by the manufacturer of the cancer drug may  
8 not increase any liability of the manufacturer that would have existed but for the  
9 donation.

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

11 (a) Requirements for medical ~~clinics~~ pharmacies ~~and hospitals~~ to accept and  
12 dispense donated cancer drugs under this section, including all of the following:

- 13 1. Eligibility criteria.
- 14 2. Standards and procedures for accepting, safely storing, and dispensing  
15 donated cancer drugs.
- 16 3. Standards and procedures for inspecting donated cancer drugs to determine  
17 if the cancer drug is in its original, unopened, sealed, and tamper-evident unit dose  
18 packaging or, if packaged in single-unit doses, the single-unit-dose packaging is  
19 unopened.
- 20 4. Standards and procedures for inspecting donated cancer drugs to determine  
21 that the cancer drug is not adulterated or misbranded.

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

**BILL**

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

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

6 (e) The maximum handling fee that a medical ~~pharmacy~~ <sup>facility or</sup> pharmacy ~~or institution~~ may  
7 charge for accepting, distributing, or dispensing donated cancer drugs.

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

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

**SECTION 2. Nonstatutory provisions.**

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

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

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

23 (END)

**Basford, Sarah**

---

**From:** Thorson, Randy  
**Sent:** Wednesday, February 04, 2004 12:16 PM  
**To:** LRB.Legal  
**Subject:** Draft review: LRB 03-3894/2 Topic: Cancer drug donation repository

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

Draft review: LRB 03-3894/2 Topic: Cancer drug donation repository