

**2009 DRAFTING REQUEST**

**Assembly Amendment (AA-AB651)**

Received: **01/21/2010**

Received By: **rryan**

Wanted: **As time permits**

Identical to LRB:

For: **John Nygren (608) 266-2343**

By/Representing: **Matt Banaszynski**

This file may be shown to any legislator: **NO**

Drafter: **rryan**

May Contact:

Addl. Drafters:

Subject: **Health - miscellaneous**

Extra Copies:

Submit via email: **YES**

Requester's email: **Rep.Nygren@legis.wisconsin.gov**

Carbon copy (CC:) to:

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**Pre Topic:**

No specific pre topic given

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**Topic:**

Drug donation

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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>
/?	rryan 01/21/2010	jdye 01/21/2010		_____			
/1			rschluet 01/21/2010	_____	sbasford 01/21/2010	sbasford 01/21/2010	

FE Sent For:

<END>

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/?	rryan						
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FE Sent For:

<END>

## Ryan, Robin

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**From:** Duerst, Christina  
**Sent:** Wednesday, January 20, 2010 9:14 AM  
**To:** Ryan, Robin; Sundberg, Christopher  
**Subject:** FW: drafting request

**Importance:** High

**Attachments:** 09-15393.pdf

LRB-3878

I see Robin drafted 09-1539 and Chris drafted AB 651 so I wasn't sure which of you to send it to?

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**From:** Banaszynski, Matt  
**Sent:** Wednesday, January 20, 2010 9:07 AM  
**To:** LRB.Legal  
**Subject:** drafting request

To Whom It May Concern:

Could you please take the language included in the attached bill and draft it as an amendment to AB 651. We want to add the language contained in our bill to AB 651. Thank you and please feel free to contact me if you have any questions or concerns.

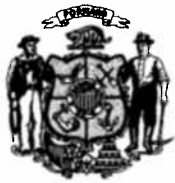


09-15393.pdf (35  
KB)

Respectfully,

*Matt Banaszynski*

Research Aide  
Office of State Representative John Nygren  
89th Assembly District  
Phone: 608-266-2343  
E-Mail: Matt.Banaszynski@legis.wisconsin.gov



State of Wisconsin  
2009 - 2010 LEGISLATURE

LRBa1334/3

RLR:...

Soon  
To 1/21/10

JL + NW

~~PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION~~

ASSEMBLY AMENDMENT,  
TO 2009 ASSEMBLY BILL 651

RMNR

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

2 1. Page 1, line 2: after "drugs" insert ", donating drugs, and dispensing  
3 donated drugs". ✓

4 2. Page 1, line 3: before that line insert: ✓

INS

5 3. Page 1, line 3: delete "SECTION 1" and substitute "SECTION 21".

6

(END)

21 ← B

*INS for a 1334/1*

**BILL**

civil liability to drug manufacturers and provides immunity from civil liability to other people participating in the program.

This bill provides that any drug, with certain exceptions, and supplies to administer drugs may be donated and dispensed under the drug repository program. The exceptions provide that controlled substances and drugs for which the U.S. Food and Drug Administration requires that a patient using the drug be enrolled in a registry may not be donated or dispensed under the program. The bill also changes the drug expiration date requirement for the program so that drugs with an expiration date that is at least 90 days after the date of donation may be donated and dispensed under the program. And, the bill provides that a practitioner, which is defined as a person licensed to prescribe and administer drugs, may dispense prescription drugs under the program.

*LPS - please freeze this insert*

*before inserting into URBA 1334*

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

*INS*

*1*

*1* SECTION *1* 255.056 (title) *1m. ← frzn* of the statutes is amended to read:

2 255.056 (title) ~~Cancer and chronic diseases drug~~ **Drug repository.**

3 SECTION *2* 255.056 (1) (a) *frzn* of the statutes is repealed.

4 SECTION *3* 255.056 (1) (am) *frzn* of the statutes is repealed.

5 SECTION *4* 255.056 (1) (bg) *frzn* of the statutes is created to read:

6 255.056 (1) (bg) "Drug" has the meaning given in s. 450.01 (10).

7 SECTION *5* 255.056 (1) (h) *frzn* of the statutes is amended to read:

8 255.056 (1) (h) "Supplies" means items that are necessary to administer a  
9 ~~cancer or chronic disease~~ drug.

10 SECTION *6* 255.056 (2) *frzn* of the statutes is amended to read:

11 255.056 (2) The department shall establish and maintain a ~~cancer and chronic~~  
12 ~~diseases drug repository~~ program, under which any person may donate a ~~cancer or~~  
13 ~~chronic disease drug~~ or supplies, other than a drug specified under sub. (2m), for use

14 by an individual who meets eligibility criteria specified by rule by the department.

15 Donation may be made on the premises of a medical facility or pharmacy that elects



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

9 SECTION 7. 255.056 (2m) of the statutes is created to read:

10 255.056 (2m) None of the following drugs may be donated, accepted,  
11 distributed, or dispensed under this section:

12 (a) A controlled substance, as defined in s. 961.01 (4).

13 (b) A drug for which the U.S. food and drug administration requires that a  
14 patient using the drug be enrolled in a registry as provided under 21 USC 355-1 (f)  
15 (3) (F).

16 SECTION 8. 255.056 (3) of the statutes is amended to read:

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

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

23 (b) ~~The cancer or chronic disease~~ In the case of a drug, the drug bears an  
24 expiration date that is later than ~~6 months~~ 90 days after the date that the drug was  
25 donated.



INSERT  
CONT

**BILL**

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

5 (d) ~~The cancer or chronic disease~~ For a prescription drug or supplies used to  
6 administer a prescription drug, the drug or supplies are prescribed by a practitioner  
7 for use by an eligible individual and are dispensed by a pharmacist or practitioner.

8 SECTION <sup>frzn</sup>9. 255.056 (4) <sup>✓</sup> of the statutes is amended to read:

9 255.056 (4) No ~~cancer or chronic disease~~ drug or supplies that are donated for  
10 use under this section may be resold.

11 SECTION <sup>frzn</sup>10. 255.056 (6) <sup>✓</sup> of the statutes is amended to read:

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

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



INSERT  
CONT

**BILL**

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

5 **SECTION 11.** <sup>frzn</sup> 255.056 (7) (a) (intro.) <sup>x</sup> of the statutes is amended to read:

6 255.056 (7) (a) (intro.) Requirements for medical facilities and pharmacies to  
7 accept and dispense donated ~~cancer or chronic disease~~ drugs or supplies under this  
8 section, including all of the following:

9 **SECTION 12.** <sup>frzn</sup> 255.056 (7) (a) 2. <sup>x</sup> of the statutes is amended to read:

10 255.056 (7) (a) 2. Standards and procedures for accepting, safely storing, and  
11 dispensing donated ~~cancer or chronic disease~~ drugs or supplies.

12 **SECTION 13.** <sup>frzn</sup> 255.056 (7) (a) 3. <sup>x</sup> of the statutes is amended to read:

13 255.056 (7) (a) 3. Standards and procedures for inspecting donated ~~cancer or~~  
14 ~~chronic disease~~ drugs or supplies to determine if the drug or supplies are in their  
15 original, unopened, sealed, and tamper-evident ~~unit-dose~~ packaging or, if packaged  
16 in single-unit doses, the single-unit-dose packaging is unopened.

17 **SECTION 14.** <sup>frzn</sup> 255.056 (7) (a) 4. <sup>x</sup> of the statutes is amended to read:

18 255.056 (7) (a) 4. Standards and procedures for inspecting donated ~~cancer or~~  
19 ~~chronic disease~~ drugs or supplies to determine that the drug or supplies are not  
20 adulterated or misbranded.

21 **SECTION 15.** <sup>frzn</sup> 255.056 (7) (b) <sup>x</sup> of the statutes is amended to read:

22 255.056 (7) (b) Eligibility criteria for individuals to receive donated ~~cancer or~~  
23 ~~chronic disease~~ drugs or supplies dispensed under the program. The standards shall  
24 prioritize dispensation to individuals who are uninsured or indigent, but will permit  
25 dispensation to others if an uninsured or indigent individual is unavailable.



INSERT  
CONT

**BILL**

1 SECTION 16. 255.056 (7) (c) of the statutes is amended to read:

2 255.056 (7) (c) A means, such as an identification card, by which an individual  
3 who is eligible to receive a donated ~~cancer or chronic disease~~ drug or supplies may  
4 indicate that eligibility.

5 SECTION 17. 255.056 (7) (d) of the statutes is amended to read:

6 255.056 (7) (d) Necessary forms for administration of the ~~cancer and chronic~~  
7 ~~diseases~~ drug repository program, including forms for use by persons that donate,  
8 accept, distribute, or dispense ~~cancer or chronic disease~~ drugs or supplies under the  
9 program.

10 SECTION 18. 255.056 (7) (e) of the statutes is amended to read:

11 255.056 (7) (e) The maximum handling fee that a medical facility or pharmacy  
12 may charge for accepting, distributing, or dispensing donated ~~cancer or chronic~~  
13 ~~disease~~ drugs or supplies The fee under this paragraph may not be less than 300  
14 percent of the dispensing fee permitted to be charged for prescription drugs for which  
15 coverage is provided under s. 49.46 (2) (b) 6. h.

16 SECTION 19. 255.056 (7) (f) of the statutes is repealed.

17 SECTION 20. 255.056 (7) (g) of the statutes is amended to read:

18 255.056 (7) (g) A list of ~~cancer or chronic disease~~ drugs and supplies, arranged  
19 by category or by individual drug or supply, that the ~~cancer and chronic diseases~~ drug  
20 repository program will not accept for dispensing. The list shall include a statement  
21 that specifies the reason that the drug or supplies are ineligible for donation.

22

END INS

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↑↑