



State of Wisconsin

LEGISLATIVE REFERENCE BUREAU

RESEARCH APPENDIX -
PLEASE DO NOT REMOVE FROM DRAFTING FILE

Date Transfer Requested: 10/04/2013 (Per: CMH)

☞ **Appendix B ... segment I** ↙

Appendix A ☞ The drafting file for LRB 13-0576 (used to create 13-3348)
(Representative Nygren draft)

Appendix B ☞ The drafting file for LRB 11-0330 (used to create 13-0576)
(DOJ draft)

has been transferred to the drafting file for

2013 LRB-3348

(Representative Nygren draft)



State of Wisconsin

LEGISLATIVE REFERENCE BUREAU

Appendix A ... segment I

LRB BILL HISTORY RESEARCH APPENDIX

The drafting file for

2011 LRB-0330 (For: DOJ)

has been transferred to the drafting file for

2013 LRB-0576 (For: DOJ)



RESEARCH APPENDIX - **PLEASE KEEP WITH THE DRAFTING FILE**

Date Transfer Requested: 01/08/2013

(Per: MPG)

The attached draft was incorporated into the new draft listed above. For research purposes the attached materials were added, as a appendix, to the new drafting file. If introduced this section will be scanned and added, as a separate appendix, to the electronic drafting file folder.

2011 DRAFTING REQUEST

Bill

Received: 11/05/2010

Received By: **chanaman**

Wanted: **As time permits**

Companion to LRB:

For: **Justice**

By/Representing: **Mark Rinehart**

May Contact:

Drafter: **chanaman**

Subject: **Occupational Reg. - misc
Health - miscellaneous**

Addl. Drafters: **mgallagh**

Extra Copies:

Submit via email: **YES**

Requester's email: **rinehartmw@doj.state.wi.us**

Carbon copy (CC:) to: **michael.gallagher@legis.wisconsin.gov**

Pre Topic:

No specific pre topic given

Topic:

Drug disposal 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>
/?	csundber 12/23/2010 tdodge 12/27/2010 chanaman 12/27/2010	kfollett 01/10/2011		_____			
/P1	mgallagh 12/06/2011 chanaman	csicilia 01/09/2012	mduchek 01/10/2011	_____	lparisi 01/10/2011		

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
	12/23/2011			_____			
/P2	mgallagh 07/13/2012 chanaman 08/03/2012	csicilia 08/14/2012	rschluet 01/09/2012	_____ _____ _____	sbasford 01/09/2012		
/P3	mgallagh 08/14/2012		phenry 08/14/2012 phenry 08/14/2012	_____ _____ _____	roose 08/14/2012		

FE Sent For:

<END>

2011 DRAFTING REQUEST

Bill

Received: 11/05/2010

Received By: chanaman

Wanted: As time permits

Companion to LRB:

For: Justice

By/Representing: Mark Rinehart

May Contact:

Drafter: chanaman

Subject: Occupational Reg. - misc
Health - miscellaneous

Addl. Drafters: mgallagh

Extra Copies:

Submit via email: YES

Requester's email: rinehartmw@doj.state.wi.us

Carbon copy (CC:) to:

Pre Topic:

No specific pre topic given

Topic:

Drug disposal 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>
/?	csundber 12/23/2010 tdodge 12/27/2010 chanaman 12/27/2010	kfollett 01/10/2011	8/14 ph	<u> </u> <u> </u> <u> </u> <u> </u>			
/P1	mgallagh 12/06/2011 chanaman	csicilia 01/09/2012	mduchek 01/10/2011	<u> </u> <u> </u> <u> </u>	lparisi 01/10/2011		

Vers. Drafted Reviewed Typed Proofed Submitted Jacketed Required

12/23/2011

/P2

P3 gjs
8/14
12

rschluet _____
01/09/2012 _____

sbasford _____
01/09/2012 _____

FE Sent For:

<END>

2011 DRAFTING REQUEST

Bill

Received: 11/05/2010

Received By: csundber

Wanted: As time permits

Companion to LRB:

For: Justice

By/Representing: Mark Rinehart

May Contact:

Drafter: csundber

Subject: Occupational Reg. - misc
Health - miscellaneous

Addl. Drafters: chanaman

Extra Copies:

Submit via email: YES

Requester's email: rinehartmw@doj.state.wi.us

Carbon copy (CC:) to: christopher.sundberg@legis.wisconsin.gov

Pre Topic:

No specific pre topic given

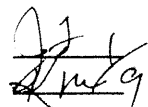
Topic:

Drug disposal 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>
/?	csundber 12/23/2010	kfollett 01/10/2011	RS 1/9				
	tdodge 12/27/2010						
	chanaman 12/27/2010	p2 js 1/5 12					
/P1			mduchek 01/10/2011		lparisi 01/10/2011		



FE Sent For:

<END>

2011 DRAFTING REQUEST

Bill

Received: 11/05/2010

Received By: **csundber**

Wanted: **As time permits**

Companion to LRB:

For: **Justice**

By/Representing: **Mark Rinehart**

May Contact:

Drafter: **csundber**

Subject: **Occupational Reg. - misc
Health - miscellaneous**

Addl. Drafters: **chanaman**

Extra Copies:

Submit via email: **YES**

Requester's email: **rinehartmw@doj.state.wi.us**

Carbon copy (CC:) to: **christopher.sundberg@legis.wisconsin.gov**

Pre Topic:

No specific pre topic given


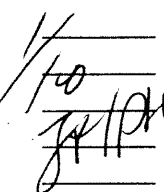
Topic:

Drug disposal 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>
1/?	csundber 12/23/2010 tdodge 12/27/2010 chanaman	1R1Kf 1/10					

FE Sent For:

<END>

2011 DRAFTING REQUEST

Bill

Received: 11/05/2010

Received By: **csundber**

Wanted: **As time permits**

Companion to LRB:

For: **Justice**

By/Representing: **Mark Rinehart**

May Contact:

Drafter: **csundber**

Subject: **Occupational Reg. - misc
Health - miscellaneous**

Addl. Drafters: **tdodge**

Extra Copies:

Submit via email: **YES**

Requester's email: **rinehartmw@doj.state.wi.us**

Carbon copy (CC:) to: **christopher.sundberg@legis.wisconsin.gov**

Pre Topic:

No specific pre topic given

Topic:

Drug disposal 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>
--------------	----------------	-----------------	--------------	----------------	------------------	-----------------	-----------------

/?	csundber			_____			

FE Sent For:

<END>

Sundberg, Christopher

From: Hanaman, Cathlene
Sent: Friday, November 05, 2010 9:03 AM
To: Sundberg, Christopher
Cc: Dodge, Tamara
Subject: FW: 2011 drafting request
Attachments: lrbseconddraftcomments-drugdisposalstatutoryrevisions.doc

Chris:

I gave this to Tami, but then I bothered to open it to see that you were on too. And then I realized that Robin was on due to the crime-y parts. Sorry, Tami.

Let me know if you want me to enter it.

-Cathlene

From: Rinehart, Mark W. [mailto:RinehartMW@DOJ.STATE.WI.US]
Sent: Friday, November 05, 2010 8:54 AM
To: Hanaman, Cathlene
Subject: 2011 drafting request

Hello Cathlene,

Last spring and summer, Robin Ryan worked on a draft (LRB-3692/P2) for us regarding prescription drug disposal programs. I don't know if this is also your area of drafting, but attached is a memo from one of our attorneys with a few changes to 3692/P2. We'd like to have these changes incorporated into a 2011 Session draft.

Thank you.

Mark Rinehart
Legislative Liaison
DOJ

CORRESPONDENCE/MEMORANDUM

DEPARTMENT OF JUSTICE

Date:

To: Legislative Reference Bureau

From: Kevin C. Potter, Administrator
Legal Services Division
Department of Justice

Subject: *Comments on 2009 LRB-3692/P/2--June 14, 2010 Second Preliminary Draft of Drug Disposal Statutory Revisions*

This memorandum responds to your memorandum of June 14, 2010 enclosing a second preliminary draft of proposed legislation to facilitate the operation of community drug disposal programs.

With respect to the items contained in the second preliminary draft, we have the following suggestions, which we believe are also responsive to the points raised in your memorandum:

Change the new Wis. Stat. § 440.255(2) in the preliminary draft to read:

(2) The department may grant written authorization to a person or political subdivision to operate a drug disposal program if all of the following conditions are satisfied:

(a) The person or political subdivision adopts written procedures for receiving and recycling, disposing of, or destroying pharmaceutical items. The written procedures must ensure compliance with the provisions of chs. 450 and 961, any applicable provision relating to controlled substances under 21 USC 801 to 871, any applicable provision relating to medical waste, solid waste, or hazardous waste under s. 299.51 or chs. 287, 289, or 291, and any other applicable federal or state law.

(b) The ultimate user of a pharmaceutical item transfers the item to the political subdivision or person operating the program in person.

(c) If controlled substances are accepted under the program,

1. Delivery of the controlled substances complies with 21 USC 822(g) and any applicable regulations promulgated thereunder; or

2. The Federal Drug Enforcement Administration grants permission for or approves the receipt, recycling, disposal, or destruction of the controlled substances.

Create a new Wis. Stat. § 440.255(3) to read:

(3) The governing body of a political subdivision may grant written authorization for the operation of a local drug disposal program that meets the requirements of subd. (2)(a)-(c) if all pharmaceutical items are received by the program within the boundaries of the political subdivision. The political subdivision may operate the local program. The governing body must first obtain and review written verification from a law enforcement officer that the operation of the program will not violate chs. 450 and 961, any applicable provision relating to controlled substances under 21 USC 801 to 871, any applicable provision relating to medical waste, solid waste, or hazardous waste under s. 299.51 or chs. 287, 289, or 291, or any other applicable federal or state law. Departmental authorization is not required if authorization to operate a local drug disposal program is obtained under this subsection.

Renumber Wis. Stat. § 440.255(3) in the preliminary draft to Wis. Stat. § 440.255(4).

We also are concerned that the limited revisions to Wis. Stat. ch. 450 in the second preliminary draft may not sufficiently address all of the criminal penalties currently imposed under that chapter. For example, Wis. Stat. § 450.11(7)(g) provides: "Except as authorized by this chapter, no person may possess, with intent to . . . deliver, a prescription drug." Wisconsin Stat. § 450.11(7)(h) provides: "No person may possess a prescription drug unless the prescription drug is obtained in compliance with this section." Wisconsin Stat. § 450.11(9)(b) further provides: "Any person who delivers, or who possesses with intent to . . . deliver, a prescription drug in violation of this section is guilty of a Class H felony." The preliminary draft contains no express exclusion or exemption to these provisions for persons operating drug disposal programs or for participants in drug disposal programs.

+ 450.03 (1)(d) - practice of pharm.
450.14 - highly toxic subst.

We had previously suggested creation of a new Wis. Stat. § 450.19. It could read:

Drug Disposal Authorization. (1) Nothing in this chapter, or the rules promulgated under this chapter, prohibits:

(a) The operation of a drug disposal program in compliance with state and federal law if the program is authorized under Wis. Stat. § 440.255(2) or (3).

(b) In person transfer of a pharmaceutical item by an ultimate user to a drug disposal program that is authorized under Wis. Stat. § 440.255(2) or (3) and that accepts the item as part of the program.

We recognize that there are other approaches that may accommodate this concern.

KCP:FTC:cla

creeronft\dojmemos\rbseconddraftcomments-drugdisposalstatutoryrevisions.doc



In 12/28

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

PAF

neg. cat

1 **AN ACT to amend** subchapter III (title) of chapter 961 [precedes 961.31] and
2 961.335 (1); and **to create** 66.0437, 440.255, 450.01 (23) (n), 961.32 (2) (e) and
3 961.337 of the statutes; **relating to:** the creation of drug disposal programs,
4 regulation of controlled substances, and the practice of pharmacy.

Analysis by the Legislative Reference Bureau

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

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

5 SECTION 1. 66.0437 of the statutes is created to read:
6 **66.0437 Drug disposal programs.** A political subdivision may operate, or
7 authorize a person to operate, a drug disposal program as provided under s. 440.255.

8 SECTION 2. 440.255 of the statutes is created to read:
9 **440.255 Drug disposal program.** (1) In this section:

10 (a) "Controlled substance" has the meaning given in s. 961.01 (4).

(3)

1 (b) "Drug disposal program" means a program to receive from an ultimate user
2 pharmaceutical items that the ultimate user does not want and to recycle, dispose
3 of, or destroy the pharmaceutical items.

4 (c) "Law enforcement officer" means a law enforcement officer, as defined in s.
5 165.85 (2) (c), or a federal law enforcement officer, as defined in s. 175.40 (7) (a) 1.

6 (d) "Pharmaceutical item" means a drug, as defined in s. 450.01 (10);
7 prescription drug, as defined in s. 450.01 (20); device, as defined in 450.01 (6); or a
8 hypodermic syringe, needle, or other object used for injecting a drug.

9 (e) "Political subdivision" means a city, village, town, or county.

10 (f) "Ultimate user" means an individual who lawfully possesses a
11 pharmaceutical item for that individual's own use or for the use of a member of that
12 individual's household or for administering to an animal owned by that individual
13 or by a member of that individual's household.

14 (2) *The department may grant written authorization to a person or to*
~~A political subdivision may operate, or authorize a person to operate,~~ a drug
15 disposal program if all of the following conditions are satisfied:

16 (a) The *person or* political subdivision ~~or person~~ adopts written procedures for receiving
17 and recycling, disposing of, or destroying pharmaceutical items. INS
2-17

18 (b) The ultimate user of a pharmaceutical item transfers the item to the
19 political subdivision or person operating the program in person.

20 (c) With respect to a controlled substance, the federal Drug Enforcement
21 Administration grants permission for receipt, recycling, disposal, or destruction of
22 the controlled substance consistent with 21 CFR 1307.21.

23 (d) A law enforcement officer verifies in writing that operation of the program
24 does not violate any provision relating to controlled substances under 21 USC 801

INS
2-19

1 to 971, any provision relating to medical waste, solid waste, or hazardous waste
2 under s. 299.51 or chs. 287, 289, or 291, or any other applicable federal or state law.

3 (e) One of the following applies:

4 1. If the program is operated by a political subdivision, the governing body of
5 the political subdivision, after reviewing a written verification under par. (d),
6 approves the program.

7 2. If the program is operated by a person other than a political subdivision one
8 of the following applies:

9 a. The program is approved by a federal government agency or official.

10 b. The program is approved by the governing body of the political subdivision
11 in which pharmaceutical items will be received from ultimate users, or by the
12 department of regulation and licensing, after the governing body or the department,
13 whichever is applicable, reviews a written verification under par. (d).

14 (3) A political subdivision or person shall discontinue operation of a drug
15 disposal program if ⁽⁵⁾ an entity that may approve the drug disposal program under sub.

16 (2) (e), notifies the political subdivision or person that operation of the program
17 violates federal or state law. INS 3-16

18 SECTION 3. 450.01 (23) (n) of the statutes is created to read:

19 450.01 (23) (n) The operation or implementation of a drug disposal program
20 that satisfies the conditions under s. 440.255 or the possession, delivery, distribution,
21 transfer, receipt, or return of a pharmaceutical item, as defined in s. 440.255 (1) (d),
22 within the scope of such a drug disposal program. ^{(2) or (3)}

23 SECTION 4. Subchapter III (title) of chapter 961 [precedes 961.31] of the
24 statutes is amended to read:

25 **CHAPTER 961**

has
has been authorized

15
13

SUBCHAPTER III

REGULATION OF MANUFACTURE,
DISTRIBUTION AND, DISPENSING,
AND POSSESSION OF CONTROLLED
SUBSTANCES

SECTION 5. 961.32 (2) (e) of the statutes is created to read:

961.32 (2) (e) A person actively engaged in the direct operation or implementation of a drug disposal program that satisfies the conditions under s. 440.255 (2) or (3) ^{has been authorized}

SECTION 6. 961.335 (1) of the statutes is amended to read:

961.335 (1) Upon application the controlled substances board may issue a permit authorizing a person to manufacture, obtain, possess, use, administer or dispense a controlled substance for purposes of scientific research, instructional activities, chemical analysis or other special uses, without restriction because of enumeration. No person shall engage in any such activity without a permit issued under this section, except that no permit is required for a person actively engaged in the direct operation or implementation of a drug disposal program that satisfies the conditions under s. 440.255 ^{(2) or (3)} and except that an individual may be designated and authorized to receive the permit for a college or university department, research unit or similar administrative organizational unit and students, laboratory technicians, research specialists or chemical analysts under his or her supervision may be permitted possession and use of controlled substances for these purposes without obtaining an individual permit.

SECTION 7. 961.337 of the statutes is created to read:

has been authorized

**2011-2012 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRB-0330/P1ins
CTS:.....

Insert 2-17:

The procedures shall ensure compliance with chs. 450 and 961; with any applicable provision under 21 USC 801 to 870 relating to controlled substances; with any applicable provision under chs. 287, 289, and 291 and s. 299.51 relating to medical waste, solid waste, or hazardous waste; and with any other applicable federal or state law.

Insert 2-19:

(c) If controlled substances are accepted under the program, all of the following are true:

1. Delivery of the controlled substances complies with 21 USC 822 (g) and with any applicable regulations promulgated under 21 USC 822 (g).

2. The federal drug enforcement administration grants permission for, or approves, the receipt, recycling, disposal, or destruction of the controlled substances.

(3) The governing body of a political subdivision may grant written authorization for the operation of a local drug disposal program that meets the requirements of sub. (2) (a) to (c), if all of the following apply:

(a) The governing body has obtained and reviewed written verification from a law enforcement officer that the operation of the program will not violate any applicable provision of ch. 450 or 961, any applicable provision under 21 USC 801 to 870 relating to controlled substances, with any applicable provision under chs. 287, 289, and 291 and s. 299.51 relating to medical waste, solid waste, or hazardous waste, and under any other applicable federal or state law.

1 (b) The receipt of pharmaceutical items under the program occurs within the
2 boundaries of the political subdivision.

3 **Insert 3-13:**

4 (4) (a) Notwithstanding ss. 450.03 (1) (d) and 450.11 (7) (g) and (h) and (9) (b),
5 a person may transfer a pharmaceutical item to a drug disposal program if the
6 program has been authorized under sub. (2) or (3).

7

(b) Notwithstanding s. 450.11 (7) (g) and (h) and (9) (b), a person may receive
8 a pharmaceutical item pursuant to a drug disposal program if the receipt is within
9 the scope of the program and the program has been authorized under sub. (2) or (3).

10 **Insert 3-16:**

11 a federal agency or official, law enforcement officer, or the department



Proper Disposal of Prescription Drugs

Office of National Drug Control Policy | October 2014

Federal Guidelines:

- ✚ Do not flush prescription drugs down the toilet or drain unless the label or accompanying patient information specifically instructs you to do so. For information on drugs that should be flushed visit the [FDA's website](#).
- ✚ To dispose of prescription drugs not labeled to be flushed, you may be able to take advantage of community drug take-back programs or other programs, such as household hazardous waste collection events, that collect drugs at a central location for proper disposal. Call your city or county government's household trash and recycling service and ask if a drug take-back program is available in your community.
- ✚ If a drug take-back or collection program is not available:
 1. Take your prescription drugs out of their original containers.
 2. Mix drugs with an undesirable substance, such as cat litter or used coffee grounds.
 3. Put the mixture into a disposable container with a lid, such as an empty margarine tub, or into a sealable bag.
 4. Conceal or remove any personal information, including Rx number, on the empty containers by covering it with black permanent marker or duct tape, or by scratching it off.
 5. Place the sealed container with the mixture, and the empty drug containers, in the trash.

Office of National Drug Control Policy
750 17th St. N.W., Washington, D.C. 20503
p (202) 395-6618 f (202) 395-6730





» **Featured Program**

Drug Disposal: A Legislative Update

Numerous bills relating directly to drug disposal have been introduced in Congress and state houses across the country.



State Legislation Introduced in 2009

Maine, Minnesota, Oregon, and Florida have legislation pending that would require drug manufacturers to operate and pay for statewide systems to collect, transport, and dispose of leftover pharmaceuticals from the public and certain facilities. A similar bill in Washington was not voted on in time to advance during this legislative session. Links to, and the status of, these states' bill are below:

FLORIDA: [An Act Relating to the Pharmaceutical Take-back Program Pilot Project](#) was sent to the House Committee on Health Care Regulation Policy in early March 2009. On the Senate side, [An Act Relating to Pharmaceutical Take-back Programs](#) was introduced in March 2009.

MAINE: [An Act to Support Collection and Proper Disposal of Unwanted Drugs](#) was printed in March 2009 but has not yet been scheduled for hearing before the Maine Committee on Health and Human Services.

MINNESOTA: [The Safe Drug Disposal Act](#) was referred to the House Committee on Environmental Policy and Oversight in early March 2009.

OREGON: The [Oregon Drug Take Back Bill](#), relating to pharmaceutical take-back, appropriating funds, and declaring an emergency was introduced to the Senate Human Services Committee in February 2009.

WASHINGTON: [The Secure Medicine Return Act](#) passed out of the policy, fiscal and Rules committees in the House, and was on the short list to be voted on the Floor. Unfortunately, the clock ran out before a vote could be taken. So it is done for this legislative session.

In California, [SB 26](#) would require the state's Board of Pharmacy to work with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste. This bill was sent to the Senate Committee on Business, Professions and Economic Development in early February 2009.

Federal Legislation Introduced in 2009

At the federal level, two bills have been introduced in the House of Representatives to amend the Controlled Substances Act. Both bills have been referred to the House Committee on Energy and Commerce and the House Committee on the Judiciary. HR 1191, the Safe Drug Disposal Act of 2009 introduced by Congressman Inslee (D-WA) with Congressman Moran (D-VA), would provide for disposal of controlled substances by ultimate users and care takers through state take-back disposal programs. It would also amend the Federal Food, Drug, and Cosmetic Act to prohibit recommendations on drug labels for disposal by flushing, and for other purposes. The Secure and Responsible Drug Disposal Act of 2009, HR 1359, was introduced by Congressman Stupak (D-MI) with Congressman Smith (R-TX) to provide for the disposal of controlled substances in specific instances.

The Water Quality Investment Act, HR 1262, passed the House of Representatives and was referred to the Senate Committee on Environment and Public Works on March 16, 2009. This bill includes provisions requiring federal agencies to study the presence of pharmaceuticals and personal care products in the waters of the United States (Section 6001), and for the EPA to convene a task force to develop drug disposal recommendations for consumers and healthcare institutions (Section 7001).

UNITED STATES CODE SERVICE
Copyright © 2011 Matthew Bender & Company, Inc.
a member of the LexisNexis Group (TM)
All rights reserved.

*** CURRENT THROUGH PL 112-24, APPROVED 7/26/2011 ***

TITLE 21. FOOD AND DRUGS
CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL
CONTROL AND ENFORCEMENT
REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED
SUBSTANCES

Go to the United States Code Service Archive Directory

21 USCS § 822

§ 822. Persons required to register

(a) Period of registration.

(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

(b) Authorized activities. Persons registered by the Attorney General under this title to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this title.

(c) Exceptions. The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this title:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 102(25).

(d) Waiver. The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e) Separate registration. A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(f) Inspection. The Attorney General is authorized to inspect the establishment of a registrant or applicant for

21 USCS § 822

registration in accordance with the rules and regulations promulgated by him.

(g) Delivery of controlled substances by ultimate users for disposal.

(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this title may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if--

(A) the person receiving the controlled substance is authorized under this title to engage in such activity; and

(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

(2) In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

(3) The Attorney General may, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at such long-term care facilities in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

(4) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.

HISTORY:

(Oct. 27, 1970, P.L. 91-513, Title II, Part C, § 302, 84 Stat. 1253; Oct. 12, 1984, P.L. 98-473, Title II, Ch V, Part B, § 510, 98 Stat. 2072; Dec. 17, 1993, P.L. 103-200, § 3(b), 107 Stat. 2336.)

(As amended Oct. 12, 2010, P.L. 111-273, § 3(a), 124 Stat. 2859.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

References in text:

"This title", referred to in this section, is Title II of Act Oct. 27, 1970, P.L. 91-513, 84 Stat. 1242, which appears generally as *21 USCS §§ 801 et seq.* For full classification of such Title, consult USCS Tables volumes.

The term "list I chemical", referred to in this section, is defined in *21 USCS § 802(34)*.

"Section 102(25)", referred to in this section, is § 102(25) of Act Oct. 27, 1970, P.L. 91-513. This section was redesignated § 102(26) of such Act by Act Oct. 12, 1984, P.L. 91-513, and was further redesignated § 102(27) of the 1970 Act by Act Oct. 27, 1986, P.L. 99-570. Such section appears as *21 USCS § 802(27)*.

Effective date of section:

Act Oct. 27, 1970, P.L. 91-513, Title II, Part G, § 704(a), 84 Stat. 1284, which appears as *21 USCS § 801* note, provided that this section is effective on the first day of the seventh calendar month that begins after the day immediately preceding enactment on Oct. 27, 1970.

Amendments:

1984. Act Oct. 12, 1984 substituted subsec. (a) for one which read: "Every person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance, shall obtain annually a registration issued by the Attorney General in accordance with the rules

21 USCS § 822

and regulations promulgated by him."

1993. Act Dec. 17, 1993 (effective on the date that is 120 days after enactment, as provided by § 11 of such Act, which appears as 21 USCS § 802 note), in subsec. (a)(1), inserted "or list I chemical" wherever appearing; in subsec. (b), inserted "or list I chemicals" and "or chemicals"; in subsec. (c), inserted "or list I chemical" wherever appearing; and, in subsec. (e), inserted "or list I chemicals".

2010. Act Oct. 12, 2010, added subsec. (g).

Other provisions:

Provisional registration. Act Oct. 27, 1970, P.L. 91-513, Title II, Part G, § 703, 84 Stat. 1283, provided:

"(a)

(1) Any person who--

(A) is engaged in manufacturing, distributing, or dispensing any controlled substance on the day before the effective date of section 302 [see 21 USCS § 801 note], and

"(B) is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act [21 USCS § 360] or under section 4722 of the Internal Revenue Code of 1954 [26 USCS § 4722],

Shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 303 [21 USCS § 823] for the manufacture, distribution, or dispensing (as the case may be) of controlled substances.

"(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 [21 USCS § 360] or under such section 4722 [26 USCS § 4722] (as the case may be) shall be his registration number for purposes of section 303 of this title [21 USCS § 823].

"(b) The provisions of section 304 [21 USCS § 824], relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

"(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until--

"(1) the date on which such person has registered with the Attorney General under section 303 [21 USCS § 823] or has had his registration denied under such section, or

"(2) such date as may be prescribed by the Attorney General for registration of manufacturers, distributors, or dispensers, as the case may be, whichever occurs first."

Secure and Responsible Drug Disposal Act of 2010; congressional findings. Act Oct. 12, 2010, P.L. 111-273, § 2, 124 Stat. 2858, provides:

"Congress finds the following:

"(1) The nonmedical use of prescription drugs is a growing problem in the United States, particularly among teenagers.

"(2) According to the Department of Justice's 2009 National Prescription Drug Threat Assessment--

"(A) the number of deaths and treatment admissions for controlled prescription drugs (CPDs) has increased significantly in recent years;

"(B) unintentional overdose deaths involving prescription opioids, for example, increased 114 percent from 2001 to 2005, and the number of treatment admissions for prescription opioids increased 74 percent from 2002 to 2006; and

"(C) violent crime and property crime associated with abuse and diversion of CPDs has increased in all regions of the United States over the past 5 years.

"(3) According to the Office of National Drug Control Policy's 2008 Report 'Prescription for Danger', prescription drug abuse is especially on the rise for teens--

"(A) one-third of all new abusers of prescription drugs in 2006 were 12- to 17-year-olds;

21 USCS § 822

"(B) teens abuse prescription drugs more than any illicit drug except marijuana--more than cocaine, heroin, and methamphetamine combined; and

"(C) responsible adults are in a unique position to reduce teen access to prescription drugs because the drugs often are found in the home.

"(4)

(A) Many State and local law enforcement agencies have established drug disposal programs (often called 'take-back' programs) to facilitate the collection and destruction of unused, unwanted, or expired medications. These programs help get outdated or unused medications off household shelves and out of the reach of children and teenagers.

"(B) However, take-back programs often cannot dispose of the most dangerous pharmaceutical drugs--controlled substance medications--because Federal law does not permit take-back programs to accept controlled substances unless they get specific permission from the Drug Enforcement Administration and arrange for full-time law enforcement officers to receive the controlled substances directly from the member of the public who seeks to dispose of them.

"(C) Individuals seeking to reduce the amount of unwanted controlled substances in their household consequently have few disposal options beyond discarding or flushing the substances, which may not be appropriate means of disposing of the substances. Drug take-back programs are also a convenient and effective means for individuals in various communities to reduce the introduction of some potentially harmful substances into the environment, particularly into water.

"(D) Long-term care facilities face a distinct set of obstacles to the safe disposal of controlled substances due to the increased volume of controlled substances they handle.

"(5) This Act gives the Attorney General authority to promulgate new regulations, within the framework of the Controlled Substances Act, that will allow patients to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion.

"(6) The goal of this Act is to encourage the Attorney General to set controlled substance diversion prevention parameters that will allow public and private entities to develop a variety of methods of collection and disposal of controlled substances, including some pharmaceuticals, in a secure, convenient, and responsible manner. This will also serve to reduce instances of diversion and introduction of some potentially harmful substances into the environment."

Gallagher, Michael

From: Rinehart, Mark W. [RinehartMW@DOJ.STATE.WI.US]
Sent: Tuesday, August 09, 2011 9:42 AM
To: Gallagher, Michael
Subject: RE: drug disposal draft
Attachments: drugdisposal-latemarch2011statutorysuggestions.pdf

Thank you.

From: Gallagher, Michael [mailto:Michael.Gallagher@legis.wisconsin.gov]
Sent: Tuesday, August 09, 2011 9:16 AM
To: Rinehart, Mark W.
Cc: Hanaman, Cathlene; Kuczenski, Tracy
Subject: RE: drug disposal draft

Mark: I will take a look at the file. I'll be drafting this, so you can send the attachment referenced in the e-mails to me.

Thanks.

Mike

Michael P. Gallagher
Legislative Attorney
Legislative Reference Bureau
(608) 267-7511
michael.gallagher@legis.wisconsin.gov

From: Hanaman, Cathlene
Sent: Tuesday, August 09, 2011 8:23 AM
To: Rinehart, Mark W - DOJ; Kuczenski, Tracy; Gallagher, Michael
Subject: RE: drug disposal draft

Mark:

Tracy Kuczenski and Mike Gallagher are doing Occupational Regulation so I have forwarded this email to them.

Thanks,
Cathlene

From: Rinehart, Mark W. [mailto:RinehartMW@DOJ.STATE.WI.US]
Sent: Monday, August 08, 2011 3:45 PM
To: Hanaman, Cathlene
Subject: FW: drug disposal draft

I just realized Christopher Sundberg is no longer with the LRB. Would you please let me know who has taken over his responsibilities? Thank you.

From: Rinehart, Mark W.

Sent: Monday, August 08, 2011 3:34 PM
To: Sundberg, Christopher
Subject: FW: drug disposal draft

Hello Christopher,

I believe the attached changes were proposed in response to 2011 LRB-0330/P2. Have you had a chance to incorporate them into another draft? Thanks.

Mark Rinehart
Legislative Liaison
DOJ

From: Creeron, F. Thomas
Sent: Monday, April 18, 2011 2:39 PM
To: Sundberg, Christopher
Cc: Potter, Kevin; Rinehart, Mark W.; Tarver, Sandra L.
Subject: RE: drug disposal draft

Kevin Potter has asked me to forward to you the most recent version of DOJ's suggested statutory revisions.

From: Rinehart, Mark W.
Sent: Tuesday, December 07, 2010 8:33 AM
To: Sundberg, Christopher
Cc: Creeron, F. Thomas; Potter, Kevin
Subject: RE: drug disposal draft

You can direct your questions to Assistant Attorney General Tom Creeron. Thanks.

From: Sundberg, Christopher [<mailto:Christopher.Sundberg@legis.wisconsin.gov>]
Sent: Monday, December 06, 2010 4:19 PM
To: Rinehart, Mark W.
Subject: drug disposal draft

Who should I contact with questions about the redraft instructions?

Christopher Sundberg
Legislative Attorney
Legislative Reference Bureau
(608) 266-9739
christopher.sundberg@legis.wi.gov

AN ACT *to amend* subchapter III (title) of chapter 961 [precedes 961.31] and 961.335 (1); and *to create* 66.0437, 440.255, 450.01(23)(n) and (o), 961.32(2)(e) and 961.337 of the statutes; **relating to:** the operation and implementation of drug disposal programs, regulation of controlled substances, and the practice of pharmacy.

SECTION 1. 66.0437 of the statutes is created to read:

66.0437 Local Drug disposal programs. A political subdivision may establish and operate a local drug disposal program or authorize a person to establish and operate a local drug disposal program for or on behalf of the political subdivision, as provided in s. 440.255(3) and (4).

SECTION 2. 440.255 of the statutes is created to read:

440.255 Drug disposal programs. (1) In this section:

- (a) “Beneficiary” has the meaning given in s. 701.20(2)(b).
- (b) “Controlled substance” has the meaning given in s. 961.01(4).
- (c) “Controlled substance analog” has the meaning given in s. 961.01(4m).
- (d) “Disposer” means a person who is in lawful possession of unwanted pharmaceutical items and is actively engaged in the process of transferring those items to a drug disposal program. A “disposer” may be a person who is actively engaged in the process of transferring unwanted pharmaceutical items to a drug disposal program while in physical possession of a valid written authorization, as provided in sub. (2).
- (e) “Drug disposal program” means a program to receive unwanted pharmaceutical items from disposers and to lawfully recycle, dispose of, or destroy those items.
- (f) “Guardian” means a fiduciary that exercises lawful control over nontransferable pharmaceutical items for the person or estate of a ward.

(g) "Law enforcement officer" means a law enforcement officer, as defined in s. 165.85(2)(c), or a federal law enforcement officer, as defined in s. 175.40(7)(a)1.

(h) "Local drug disposal program" means a drug disposal program that receives unwanted pharmaceutical items from disposers in person within the boundaries of the political subdivision that operates or that has authorized the establishment and operation of the program.

(i) "Nontransferable pharmaceutical item" means a pharmaceutical item that cannot lawfully be transferred to the possession of another person, other than to dispose of the item, under the laws of this state.

(j) "Personal representative" means an executor, administrator, successor personal representative, special administrator, or a person exercising similar legal authority that possesses title to or control over nontransferable pharmaceutical items that were in the possession of a decedent.

(k) "Pharmaceutical item" means a drug, as defined in s. 450.01(10); prescription drug, as defined in s. 450.01(20); device, as defined in 450.01(6); or a hypodermic syringe, needle, or other object used for injecting a drug.

(l) "Political subdivision" means a city, village, town, or county.

(m) "Trustee" means a person holding in trust title to or holding in trust control over nontransferable pharmaceutical items. "Trustee" includes an original, added, or successor trustee.

(n) "Ward" means an individual for whom a guardian has been appointed.

(2) Written Authorization To Dispose. A guardian, personal representative, trustee, or adult individual in lawful possession or lawful control of unwanted nontransferable pharmaceutical items may grant written authorization to dispose of the items, as follows:

(a) A guardian may grant written authorization to an adult related to a ward by blood, marriage, or adoption within the 3rd degree of kinship as computed under s. 990.001(16), or to a domestic partner of the ward under ch. 770.

(b) A personal representative or a trustee may grant written authorization to an adult beneficiary of the estate or trust.

(c) An adult individual may grant written authorization to a domestic partner under ch. 770 or to an adult related by blood, marriage, or adoption within the 3rd degree of kinship as computed under s. 990.001(16).

(d) A written authorization is valid only on the day that it is both signed and dated.

(e) A written authorization must describe the unwanted nontransferable pharmaceutical items to be disposed of with reasonable certainty.

(f) A written authorization is valid only to dispose of the items designated.

(g) A written authorization is valid only if the authorization and the items to be disposed of were obtained without consideration.

(h) A written authorization is valid only if it is in the physical possession of the person authorized to dispose of the items.

(i) A written authorization to dispose of a prescription drug, controlled substance, or controlled substance analog is valid only to the extent permitted by federal law.

(3) Departmental Permission To Operate A Drug Disposal Program. The department may grant written permission without a hearing to a person or to a political

subdivision to establish and operate a drug disposal program. The department may not grant written permission for a drug disposal program to receive pharmaceutical items by any method other than in person transfer unless the program demonstrates to the satisfaction of the department that disposers will be in compliance with applicable postal statutes and regulations and any other federal and state statutes and regulations that may be applicable to the shipment of the pharmaceutical items. The grant, denial, or withdrawal of written permission by the department to operate a drug disposal program is not subject to judicial review.

(4) Establishment And Operation Of Local Drug Disposal Programs.

(a) The governing body of a political subdivision may establish and operate a local drug disposal program.

(b) The law enforcement agency of a political subdivision may, without a hearing, establish and operate a local drug disposal program.

(c) The governing body of a political subdivision may grant written permission to a person or persons to establish and operate one or more local drug disposal programs for or on behalf of the political subdivision.

(d) The governing body of a political subdivision may designate an employee to grant written permission, without a hearing, to a person or persons to establish and operate one or more local drug disposal programs for or on behalf of the political subdivision.

(e) The political subdivision shall promptly notify the department of all local drug disposal programs that are operated or permitted under this subsection.

(f) The grant, denial, or withdrawal of written permission by a political subdivision to operate a local drug disposal program is not subject to judicial review.

(5) Drug Disposal Program Requirements. A drug disposal program must comply with all of the following requirements:

(a) The program must be authorized or operated under sub. (2) or (3).

(b) The program must establish and promptly update written procedures for receiving and recycling, disposing of, and/or destroying pharmaceutical items. The written procedures must at all times accurately describe the manner in which the program operates. The procedures must contain the name, address, telephone number, and twenty-four hour contact information for one or more persons in Wisconsin who are responsible for the operation of the program and identify the times, dates, locations, and kinds of pharmaceutical items that will be received from disposers. The procedures shall ensure compliance with chs. 450 and 961; with any applicable provision under chs. 287, 289, and 291 and s. 299.51 relating to medical waste, solid waste, or hazardous waste; and with any other applicable federal or state law. If controlled substances are accepted or may be received under the program, the procedures must ensure compliance with any applicable provision under 21 USC 801 to 870 relating to controlled substances; that delivery of any controlled substances complies with 21 USC 822(g) and its implementing regulations; and that all required permissions have been obtained from the federal drug enforcement administration.

(c) The department, prior to or in conjunction with granting written permission under sub. (2), shall review and approve in writing the procedures described in sub. (b). Any proposed changes in written procedures subsequent to the receipt of written permission from the department under sub. (2) shall be promptly furnished to the department. The department may disapprove the proposed changes if they do not demonstrate or assure that the requirements of sub. (b) are met.

(d) Prior to granting written permission under sub. (3), the written procedures described in sub. (b) must be reviewed and approved in writing by legal counsel for the political subdivision. A copy of the written approval and the procedures approved shall be furnished to the department. Any proposed changes in written procedures subsequent to the receipt of written permission under sub. (3) shall be furnished to legal counsel for the political subdivision for review and also to the department. Legal counsel for the political subdivision may disapprove the changes in writing if they do not demonstrate or assure that the requirements of sub. (b) are met. A copy of any written disapproval shall be furnished to the department.

(e) Any political subdivision or law enforcement agency that is operating a local drug disposal program on the effective date of this legislation must comply with the requirements of subs. (3)(e) and (4)(b) and (d) within ninety days after the effective date.

(f) A drug disposal program shall immediately cease operation if a law enforcement officer or a federal or state agency notifies a person in Wisconsin who is responsible for the operation of the program that the program is in violation of any federal or state law enforceable by the agency or official. The operation of the program may be resumed upon receipt of written notification from the agency or official that the program is no longer in violation of the federal or state law enforceable by the officer or agency. Notifications under this subsection are not subject to judicial review.

(6) (a) Nothing in this chapter or rules promulgated under this chapter prohibits:

(i) the operation or implementation of a drug disposal program that is in compliance with sub. (4) in accordance with the approved written procedures of the program.

(ii) The inadvertent receipt of an unwanted pharmaceutical item by a drug disposal program contrary to its approved written procedures, provided that the program immediately contacts an appropriate law enforcement officer and promptly complies with the law enforcement officer's instructions for disposing of the unwanted pharmaceutical item.

(b) Notwithstanding s. 450.11(7)(g) and (h) and (9)(b), a person implementing or operating a drug disposal program that is in compliance with sub. (4) may receive an unwanted pharmaceutical item in accordance with the approved written procedures of the program.

(c) Notwithstanding ss. 450.03(1)(d) and 450.11(7)(g) and (h) and (9)(b), a disposer may transfer an unwanted pharmaceutical item to a drug disposal program that is in compliance with sub. (4) in accordance with the approved written procedures of the program.

SECTION 3. 450.01(23)(n) of the statutes is created to read:

450.01(23)(n) The operation or implementation of a drug disposal program that is in compliance with s. 440.255(4) in accordance with the approved written procedures of the program and ss. 440.255(6)(a)(ii) and 961.337(2).

SECTION 4. 450.01(23)(o) of the statutes is created to read:

450.01(23)(n) The transfer of an unwanted pharmaceutical item by a disposer, as defined in s. 440.255(1)(d), to a drug disposal program that is in compliance with s. 440.255(4) in accordance with the approved written procedures of the program.

SECTION 5. Subchapter III (title) of chapter 961 [precedes 961.31] of the statutes is amended to read:

CHAPTER 961
SUBCHAPTER III
REGULATION OF MANUFACTURE,
DISTRIBUTION AND, DISPENSING,
AND POSSESSION OF CONTROLLED
SUBSTANCES

SECTION 6. 961.32(2)(e) of the statutes is created to read:

961.32(2)(e) A person operating or implementing a drug disposal program that is in compliance with s. 440.255(4) in accordance with the approved written procedures of the program.

SECTION 7. 961.335(1) of the statutes is amended to read:

961.335(1) Upon application the controlled substances board may issue a permit authorizing a person to manufacture, obtain, possess, use, administer, or dispense a controlled substance for purposes of scientific research, instructional activities, chemical analysis, or other special uses, without restriction because of enumeration. No person shall engage in any such activity without a permit issued under this section, except that no permit is required for a person operating or implementing a drug disposal program that is in compliance with s. 440.255(4) in accordance with the approved written procedures of the program and except that an individual may be designated and authorized to receive the permit for a college or university department, research unit, or similar administrative organizational unit and students, laboratory technicians, research specialists, or chemical analysts under his or her supervision may be permitted

possession and use of controlled substances for these purposes without obtaining an individual permit.

SECTION 8. 961.337 of the statutes is created to read:

961.337 Drug disposal programs. Nothing in this chapter, or rules promulgated under this chapter, prohibits any of the following:

(1) The operation or implementation of a drug disposal program that is in compliance with s. 440.255(4) in accordance with the approved written procedures of the program.

(2) The inadvertent receipt of an unwanted controlled substance or an unwanted controlled substance analog by a drug disposal program contrary to its approved written procedures, provided that the program immediately contacts an appropriate law enforcement officer and promptly complies with the law enforcement officer's instructions for disposing of the unwanted controlled substance or unwanted controlled substance analog.

(3) The in person physical transfer by a disposer, as defined in s. 440.255(1)(d), of an unwanted controlled substance or an unwanted controlled substance analog to a drug disposal program that is in compliance with s. 440.255(4) in accordance with the approved written procedures of that program to the extent permitted by federal law.

dojmemos\drugdisposal-latemarch2011statutoryuggestions.doc