



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 II** 

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 II

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.



TODAY
State of Wisconsin
2011 - 2012 LEGISLATURE



LRB-0330/P1

CTS&CMH:kj:md

As early as possible (per request)

MPG \$

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

SA

Gen 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:

insert 1-4

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 ~~(3).~~
9 SECTION 2. 440.255 of the statutes is created to read:
10 440.255 Drug disposal program. (1) In this section:

SECTION 2

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

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

5 (c) "Law enforcement officer" means a law enforcement officer, as defined in s.
6 165.85 (2) (c), or a federal law enforcement officer, as defined in s. 175.40 (7) (a) 1.

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

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

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

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

18 (a) The person or political subdivision adopts written procedures for receiving
19 and recycling, disposing of, or destroying pharmaceutical items. The procedures
20 shall ensure compliance with chs. 450 and 961; with any applicable provision under
21 21 USC 801 to 870 relating to controlled substances; with any applicable provision
22 under chs. 287, 289, and 291 and s. 299.51 relating to medical waste, solid waste, or
23 hazardous waste; and with any other applicable federal or state law.

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

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

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

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

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

10 (a) The governing body has obtained and reviewed written verification from a
11 law enforcement officer that the operation of the program will not violate any
12 applicable provision of ch. 450 or 961, any applicable provision under 21 USC 801 to
13 870 relating to controlled substances, with any applicable provision under chs. 287,
14 289, and 291 and s. 299.51 relating to medical waste, solid waste, or hazardous
15 waste, and under any other applicable federal or state law.

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

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

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

24 (5) A political subdivision or person shall discontinue operation of a drug
25 disposal program if a federal agency or official, law enforcement officer, or the

1 department notifies the political subdivision or person that operation of the program
2 violates federal or state law.

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

4 450.01 (23) (n) The operation or implementation of a drug disposal program
5 that has been authorized under s. 440.255 (2) or (3) or the possession, delivery,
6 distribution, transfer, receipt, or return of a pharmaceutical item, as defined in s.
7 440.255 (1) (d), within the scope of such a drug disposal program.

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

10 CHAPTER 961

11 SUBCHAPTER III

12 REGULATION OF MANUFACTURE,

13 DISTRIBUTION AND DISPENSING,

14 AND POSSESSION OF CONTROLLED

15 SUBSTANCES

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

17 961.32 (2) (e) A person actively engaged in the direct operation or
18 implementation of a drug disposal program that has been authorized under s.
19 440.255 (2) or (3).

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

21 961.335 (1) Upon application the controlled substances board may issue a
22 permit authorizing a person to manufacture, obtain, possess, use, administer or
23 dispense a controlled substance for purposes of scientific research, instructional
24 activities, chemical analysis or other special uses, without restriction because of
25 enumeration. No person shall engage in any such activity without a permit issued

~~or for a person who possesses a controlled substance for the purpose of disposing of that controlled substance under an authorization under 961.337(2)(c)~~

SECTION 6

1 under this section, except that no permit is required for a person actively engaged
2 in the direct operation or implementation of a drug disposal program that has been
3 authorized under s. 440.255 (2) or (3), and except that an individual may be
4 designated and authorized to receive the permit for a college or university
5 department, research unit or similar administrative organizational unit and
6 students, laboratory technicians, research specialists or chemical analysts under his
7 or her supervision may be permitted possession and use of controlled substances for
8 these purposes without obtaining an individual permit.

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

10 ~~961.337 Drug disposal programs.~~ Nothing in this chapter, or rules
11 promulgated under this chapter, prohibits any of the following:

12 (1) ~~The direct operation or implementation of a drug disposal program that has~~
13 ~~been authorized under s. 440.255 (2) or (3).~~

14 (2) ~~The physical transfer by the ultimate user, as defined in s. 440.255 (1) (f),~~
15 ~~of a prescription controlled substance or controlled substance analog that the~~
16 ~~ultimate user does not want to a drug disposal program that has been authorized~~
17 ~~under s. 440.255 (2) or (3) and that accepts the prescription controlled substance or~~
18 ~~controlled substance analog.~~

19 (END)

2011-2012 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-0330/P2ins.
MPG/CMH:.....

SA

1 INSERT 1-4

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

3 **66.0437 Drug disposal programs.** (1) In this section, "political subdivision"
4 has the meaning given in s. 440.255 (1) (e).

5 (2) A political subdivision may operate or authorize a person to operate on its
6 behalf a drug disposal program as provided under s. 440.255 (3) or (4).

***NOTE: The authority to operate a program includes the authority to establish the program. Therefore, I have not included the language "establish and operate."

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

8 **440.255 Drug disposal program.** (1) DEFINITIONS. In this section:

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

10 (b) "Controlled substance analog" has the meaning given in s. 961.01 (4m).

***NOTE: I did not include a definition of "disposer" because that term is not used anywhere in the draft. Instead, where appropriate, the draft refers to a person who lawfully possesses a pharmaceutical item and transfers the item to another person. Is this change okay? See also the note under "Paragraph (f)", "ultimate user," below.

11 (c) "Drug disposal program" means a program to receive pharmaceutical items
12 and to recycle, destroy, or otherwise dispose of those items.

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

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

17 (2) DEPARTMENT AUTHORIZATION TO OPERATE A DRUG DISPOSAL PROGRAM. (a) No

18 (drug disposal program) person may receive pharmaceutical items unless the department
19 grants written authorization for the program under this subsection.

INSERT MPB 1-16

that

pursuant to a drug disposal program

1 (b) The department may, without a hearing, grant written authorization to a
2 person, including a political subdivision, to operate a drug disposal program if all of
3 the following conditions are satisfied:

4 1. The person adopts written policies and procedures that comply with sub. (4).
5 The department shall review and either approve or disapprove in writing those
6 policies and procedures. The department may disapprove the policies and
7 procedures if the department determines that the policies and procedures do not
8 meet the requirements of this section or any other applicable federal or state law.
9 If the department disapproves the policies and procedures, the department shall
10 state the reasons for that disapproval in writing to the person. At any time, the
11 person may resubmit revised policies and procedures for the department's review
12 and approval under this subdivision.

13 2. If the drug disposal program will receive pharmaceutical items in any
14 manner other than the direct physical transfer of those pharmaceutical items in
15 person to the program, the person demonstrates to the satisfaction of the department
16 that those transfers will comply with ^{any} federal ^{or} state laws applicable to the mailing
17 of pharmaceutical items. transportation and delivery

18 (c) Any changes to policies and procedures already approved by the authority
19 under par. (b) 1. are subject to approval by the department in the same manner
20 provided under par (b) 1. Insert MPB 2-17

21 (d) The department may revoke an authorization granted under par. (b) if the
22 department determines that the drug disposal program or the person operating the
23 drug disposal program is not in compliance with any provision of this section or other
24 applicable federal or state law.

by the ultimate user or by a person authorized under

1 (e) Any determination or action by the department under par. (b), (c), or (d) is
2 not subject to judicial review.

3 (3) AUTHORIZATION BY A POLITICAL SUBDIVISION TO OPERATE A DRUG DISPOSAL
4 PROGRAM. (a) The governing body of a political subdivision may grant written
5 authorization for the operation of a drug disposal program on behalf of the political
6 subdivision if all of the following apply:

7 1. The department authorizes the drug disposal program under sub. (2). ✓

(a)

****NOTE: While not included in the revised drafting instructions, I included this requirement because the revised drafting instructions require an authorization granted by the Department of Safety and Professional Services (DPS) before a political subdivision may itself operate a drug disposal program. That requirement implies that a political subdivision should only be able to authorize another person to operate a drug disposal program on behalf of the political subdivision if that program is itself authorized by DPS. Otherwise, the draft would create a situation in which a political subdivision may only operate a drug disposal program if the program is authorized by DPS but may authorize another person to operate a drug disposal program for the political subdivision without authorization from DPS. Please let me know if this change is inconsistent with your intent?

b)

8 2. The political subdivision ensures that the requirements under sub. (4) are
9 satisfied.

(10)

10 3. The drug disposal program receives pharmaceutical items only in person
11 within the boundaries of the political subdivision.

by means of delivery

****NOTE: Based on the revised drafting instructions, the intent appears to be to restrict a drug disposal program authorized by a political subdivision to receiving pharmaceutical items only in person within the boundaries of the political subdivision. However, this restriction does not apply to a program operated by the political subdivision itself or to a program operated by any other person that DPS authorizes who does not operate a program on behalf of a political subdivision. Is that consistent with your intent?

(c)

Insect
MPG 3-11

****NOTE: Also, is it your intent to exempt a drug disposal program operated by the law enforcement agency of a political subdivision from the requirement of DPS authorization or any other provisions in the draft regarding the operation of drug disposal programs?

(12)

12 (4) OPERATION OF A DRUG DISPOSAL PROGRAM. (a) A drug disposal program shall
13 establish and promptly update as appropriate written policies and procedures that
14 do all of the following:

Person that operates a

subject to sub. (2)(b)1.

by an ultimate user or by a person authorized under
(611 227 (a)) and only

1 1. Describe with specificity the manner in which the program operates,
 2 including an identification of the kinds of pharmaceutical items that may be received
 3 under the program, including controlled substances and controlled substance
 4 analogs, whether pharmaceutical items will be transferred by mail under the
 5 program, and the locations at which pharmaceutical items may be transferred in
 6 person under the program.

7 2. List the name, address, telephone number, and 24-hour contact information
 8 for one or more persons in this state who are responsible for the operation of the
 9 program.

10 3. Ensure compliance with chs. 450 and 961; with any applicable provision
 11 under chs. 287, 289, and 291 and s. 299.51 relating to medical waste, solid waste, or
 12 hazardous waste; and with any other applicable federal or state law ←

13 4. If controlled substances or controlled substance analogs may be received
 14 under the program, ensure compliance with any applicable provision under 21 USC
 15 801 to ⁸⁶⁵870 relating to controlled substances or controlled substance analogs, ensure
 16 that delivery of any controlled substances complies with 21 USC 822 (g) and its
 17 implementing regulations, and ensure that any required permissions have been
 18 obtained from the federal drug enforcement administration.

19 (b) In the case of a political subdivision, the policies and procedures for a
 20 proposed drug disposal program authorized under sub. (2) or (3) and any changes to
 21 those policies and procedures must be reviewed and approved in writing by legal
 22 counsel for the political subdivision. The political subdivision shall provide a copy
 23 of that approval to the department.

24 (c) A drug disposal program shall immediately cease operation if a law
 25 enforcement officer, as defined in s. 165.85 (2) (c), federal law enforcement officer, as

The operation of

STEP
↓

Transfer and receipt of pharmaceutical items

for such a pers

1 defined in s. 175.40 (7) (a) 1., or federal or state agency notifies a contact person for
2 the program under par. (a) 2. that the program is in violation of any federal or state
3 law enforceable by the agency or official. That notification is not subject to judicial
4 review. The operation of the program may be resumed only upon the program's
5 receipt of written notice from the agency or official that the program is no longer in
6 violation of the federal or state law.

officer

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

and it is not a crime to transfer

11 (b) Notwithstanding s. 450.11 (7) (g) and (h) and (9) (b), a person may receive
12 a pharmaceutical item pursuant to a drug disposal program if the receipt is within
13 the scope of the program and the program has been authorized under sub. (2) or (3)
14 or if the receipt is not within the scope of the program, the receipt is inadvertent and
15 the program promptly notifies an appropriate law enforcement officer of the receipt
16 and complies with any instructions the law enforcement officer provides.

and it is not a crime to receive possession

for a person

17 END INSERT 1-4

18 INSERT 4-7

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

20 450.01 (23) (o) The possession or delivery of a controlled substance or a
21 controlled substance analog, as defined in s. 961.01 (4m), within the scope of a
22 written authorization under s. 961.337 (2) (c).

(2m)

23 END INSERT 4-7

24 INSERT 5-8

25 SECTION 4. 961.337 of the statutes is created to read:

ch. 880, 2003 stats. or

1 **961.337 Drug disposal programs and authorizations.** (1) In this section:

2 (a) "Guardian" means the person named by the court under ch. 48 or 54 or ch.

3 880, 2003 stats. ^{that has} having the duty and authority of guardianship.

****NOTE: The proposed definition of "ward" in the revised drafting instructions references the "appointment" of a guardian. Therefore, I have used a definition for "guardian" that references appointment under the appropriate statutes. If you still wish to incorporate the broader "fiduciary" language, we should broaden the definition of "ward" accordingly. Please let me know how you would like to proceed.

4 (b) "Personal representative" means an executor, administrator, or special
5 administrator of a decedent's estate, a person legally authorized to perform
6 substantially the same functions, or a successor to any of those persons.

7 (c) "Trustee" means a person that holds in trust title to or power over property.
8 "Trustee" includes an original, added, or successor trustee.

9 (d) "Ward" means an ultimate user for whom a guardian has been appointed.

10 (2) Nothing in this chapter, or rules promulgated under this chapter, prohibits
11 any of the following:

12 (a) The direct operation or implementation of a drug disposal program that has
13 been authorized under s. 440.255 (2) or (3). Sub. (2m)

14 (b) The physical transfer by the ultimate user or a person authorized under par.

15 (c) of a prescription controlled substance or controlled substance analog to a drug
16 disposal program that has been authorized under s. 440.255 (2) or (3) and that
17 accepts the prescription controlled substance or controlled substance analog.

18 (c) ^{Subject to sub. (3)} The possession of a controlled substance or controlled substance analog
19 under a written authorization to dispose of that controlled substance or controlled
20 substance analog only as follows: described in sub. (2m)

21 1. A guardian may grant written authorization to an adult who is related to the
22 guardian's ward by blood, marriage, or adoption within the 3rd degree of kinship as

(2m)(a)

1 computed under s. 990.001 (16), or to a domestic partner of the ward under ch. 770,
2 for the disposal of a controlled substance or controlled substance analog that belongs
3 to the ward.

****NOTE: "Adult" is defined in s. 990.01 (3).

4 (b) 2. A personal representative or a trustee may grant written authorization to
5 an adult beneficiary, as defined in s. 701.20 (2) (b), of the estate or trust for the
6 disposal of a controlled substance or controlled substance analog that belongs to the
7 estate or trust.

a competent

8 (c) 3. An ultimate user who is an adult may grant written authorization to that
9 ultimate user's domestic partner under ch. 770 or to another adult who is related to
10 that ultimate user by blood, marriage, or adoption within the 3rd degree of kinship
11 as computed under s. 990.001 (16), for the disposal of a controlled substance or
12 controlled substance analog that belongs to that ultimate user.

(2m)

13 (3) A written authorization under sub. (2) (c) is valid only to the extent
14 permitted under federal law and only if all of the following conditions are satisfied:

15 (a) The authorization describes with reasonable specificity each controlled
16 substance or controlled substance analog that is to be disposed of.

17 (b) The authorization is in the physical possession of the person authorized to
18 dispose of the controlled substance or controlled substance analog and each
19 controlled substance or controlled substance analog described in the authorization
20 is, within 24 hours after the authorization is signed by the person granting the
21 authorization, transferred to a drug disposal program under s. 440.255 or otherwise
22 lawfully disposed of.

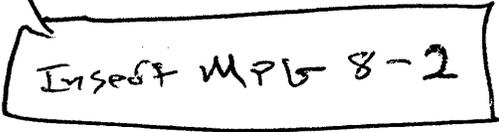
****NOTE: I included the 24-hour requirement for the sake of clarity. The "signed and dated" language in the revised drafting instructions could create ambiguity.

1 (c) The authorization and each controlled substance or controlled substance
2 analog to be disposed of were obtained without consideration.

3 **SECTION 5. Effective date.**

4 (1) This act takes effect on the first day of the 4th month beginning after
5 publication.

****NOTE: The draft includes a 90-day delayed effective date to give some time for existing drug disposal programs to comply with the draft's requirements. Is that consistent with your intent? Please let me know if, instead, you want to "grandfather-in" current drug disposal programs by exempting those programs from specific requirements in the draft.



Insert MPB 8-2

2011-2012 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-0330/2insch
CMH:.....

1 Insert 5-8 pink

2 SECTION 1. 961.335 (1) of the statutes is renumbered 961.335 (1) (a) (intro.) and
3 amended to read:

4 961.335 (1) (a) (intro.) Upon application the controlled substances board may
5 issue a permit authorizing a person to manufacture, obtain, possess, use, administer,
6 or dispense a controlled substance for purposes of scientific research, instructional
7 activities, chemical analysis, or other special uses, without restriction because of
8 enumeration. No

9 (b) Except as provide in par. (c), no person shall may engage in any such activity
10 described under par. (a) without a permit issued under this section, except that an

11 (c) 3. With regard to possession and use of a controlled substance, an individual
12 may be who is designated and authorized to receive ^a the permit _{under this section} for a college or
13 university department, research unit, or similar administrative organizational unit,

14 and students, laboratory technicians, research specialists, or chemical analysts
15 under his or her supervision ^{plan} may be permitted possession and use of controlled

16 substances ^{plan} for these ^{additional} purposes ^{plan} without obtaining an individual ^{plan} permit
17 designated and authorized ^{issued under this section} ^{possess}

History: 1971 c. 219; 1975 c. 110, 199; 1977 c. 26; 1995 a. 448 s. 2(2); Stats. 1995, 961.335.

18 SECTION 2. 961.335 (1) (c) ~~1~~ 1. and 2. of the statutes are created to read:

19 961.335 (1) (c) The following persons do not need a permit to engage in an
20 activity described under par. (a):

21 1. A person who is actively engaged in the direct operation or implementation
22 of a drug disposal program that is authorized under s. 440.255 (2) or (3) for the
23 purposes of operating and implementing the drug disposal program.

may, without a permit issued under this section, obtain or possess a controlled

permit
received
for the
department
or
unit

1 2. With regard to possession of a controlled substance, ^A a person who is
2 authorized under s. 961.337 (2) (c) to dispose of ~~the~~ controlled substance for the
3 purpose of disposing of the controlled substance.

(2m)

may ↑ without a
permit issued under
this section ↑
possess the
controlled
substance

2011-2012 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-0330/P2mpgin
MPG:.....

1 **NOTE: THIS IS AN INSERT TO THE INSERT LABELED -0330/P2ins.**

2 INSERT MPG 1-16

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

✓ ✓
****NOTE: Although the definition and use of the term "ultimate user" was omitted from the revised drafting instructions, I retained the definition in order to clarify the intent for an "in-person" delivery of a pharmaceutical item to a drug disposal program (see s. 440.255 (2) (b) 2. and (3) (c) in the draft). Use of the term "disposer" as defined in the revised drafting instructions would not provide the same clarity with respect to in-person delivery because that term could apply to a postal carrier, for example, and the apparent intent under the revised drafting instructions is to exclude delivery by a postal carrier from in-person delivery for purposes of the draft. Are these changes consistent with the intent?

7 END INSERT MPG 1-16

8 INSERT MPG 2-17

✓
✓
9 (c) A person may not revise policies and procedures approved by the
10 department under par. (b) 1. unless the department approves the revisions under
11 par. (b) 1.

12 END INSERT MPG 2-17

13 INSERT MPG 3-11

****NOTE: With respect to the in-person delivery of pharmaceutical items, is the restriction to ultimate users and persons authorized under s. 961.337 (m) (in the draft) consistent with your intent? Should the limitation only apply to controlled substances and controlled substance analogs as opposed to all pharmaceutical items of any kind?

14 END INSERT MPG 3-11

15 INSERT MPG 8-2

****NOTE: Under the revised drafting instructions, the authorizations apply to any "nontransferable pharmaceutical item," which the instructions define as "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." The authorizations

themselves determine at least in part to whom and how such items may be transferred. It seems to make sense to apply the authorizations to the transfer of controlled substances for the purpose of disposal. Is that consistent with the intent? Please let me know if you want to limit the authorizations to only certain controlled substances.

****NOTE: Also, in light of the application of the authorizations to the disposal of controlled substances, the provisions in the revised drafting instructions regarding disposal authorizations seem to fit more logically in chapter 961, which regulates the possession and delivery of controlled substances. Are these changes consistent with the intent?

1

END INSERT MPG 8-2

CORRESPONDENCE/MEMORANDUM

DEPARTMENT OF JUSTICE

Date: June 15, 2012

To: Cathlene M. Hanaman
Deputy Chief
Legislative Reference Bureau

Michael P. Gallagher
Legislative Attorney
Legislative Reference Bureau

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

Subject: *Comments on 2011-2012 LRB-0330/P/2--January 9, 2012 Third Preliminary Draft of Drug Disposal Statutory Revisions*

This memorandum comments upon and responds to the questions contained in the third preliminary draft of proposed legislation to facilitate the lawful operation of community drug disposal programs under both state and federal law.

Please revise the draft along the following lines:

General Instructions:

First: Provide that a political subdivision (1) is authorized to establish its own drug disposal program, (2) may authorize a person or entity to operate a drug disposal program on behalf of the political subdivision, and (3) may authorize a person or entity to operate a drug disposal program within the boundaries of the political subdivision. In all three circumstances, (a) the written procedures of the drug disposal program must be reviewed by legal counsel for the political subdivision; (b) the program must require in-person delivery; and (c) the political subdivision must provide the Department of Safety and Professional Services ("DSPS") with a copy of the approval and a copy of the procedures that were approved. Provide that the political subdivision's legal counsel must approve changes to program procedures and must provide a copy of the approval and the changes that were approved to DSPS. ✓

Second: Add a provision stating that a political subdivision whose legal counsel is not an employee of the political subdivision may request a DSPS attorney to approve the program's written procedures or changes to those procedures. ✓

Third: Provide that DSPS may approve a drug disposal program that operates within the boundaries of more than one political subdivision if the program so requests. A multi-jurisdictional program should have the option to seek local approval(s), approval from DSPS, or some combination of the two. ✓

Fourth: Provide that any program that will receive pharmaceutical items other than by in-person transfer must be approved by DSPS and cannot be approved by a political subdivision. ✓

Fifth: Provide that a program that is authorized by an officer or agency of the federal government may, but is not required to, obtain approval from DSPS or a political subdivision for any period that the federal authorization is in effect. ✓

Sixth: Grant DSPS explicit authority to order a state or locally approved drug disposal program to cease operating and to permit the program to resume operating. ✓

Seventh: Ensure that state law criminal prohibitions upon possession, distribution, and delivery do not apply to (1) persons operating either state or locally authorized drug disposal programs or federally authorized drug disposal programs; or (2) lawful participants in those programs. We have identified at least the following state law criminal statutes for which exemptions may need to be created or retained in the draft: Wisconsin Stat. §§ 450.01(5) (definition of "deliver" or "delivery"); 450.01(7) (definition of "distribute"); 450.01(23) (definition of "wholesale distribution"); 450.071(1) (prohibiting wholesale distribution without a license); 450.074(3)(i) (prohibiting sale or transfer of prescription drugs that are unfit for distribution); 450.074(3)(k) (prohibiting adulteration of prescription drugs); 450.074(3)(l) (prohibiting receipt of prescription drugs that are unfit for distribution); 450.11(7)(g) (prohibiting possession of prescription drugs with intent to manufacture or deliver); 450.11(7)(h) (prohibiting possession of prescription drugs); 450.11(9)(b) (making delivery or possession of prescription drugs with intent to deliver or manufacture a Class H felony); 961.41 (prohibiting distribution or delivery of controlled substances or controlled substance analogs); and 961.41(1m) (prohibiting possession with intent to manufacture, distribute, or deliver controlled substances or controlled substance analogs). ✓

Specific Instructions, Comments, and Responses to Notes.

Section 1: Please revise this section in accordance with the first general instruction. The note on page two is acceptable.

Section 2: This section should be revised in accordance with the general instructions.

In response to the notes on page two, the deletion of the term "disposer" and the insertion of the term "ultimate user" are both acceptable.

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The first note on page four is incorrect. DSPS approval should not be required if the approval of a political subdivision has been obtained. The subsection immediately preceding that note should therefore be deleted.

The second note on page four is correct insofar as it indicates that a drug disposal program authorized by a political subdivision may only accept in-person delivery. The political subdivision should not be prohibited from approving a program that accepts other than in-person delivery if other delivery methods have been federally authorized. The remainder of the note is addressed in the general instructions.

The third note on page four is correct insofar as it states that programs approved by political subdivisions are limited to in-person delivery of pharmaceutical items. The political subdivision should not be prohibited from approving a program that accepts other than in-person delivery if other delivery methods have been federally authorized. With respect to the written authorization limitation, please see the comments to Section 9.

In response to the note at the top of page five, drug disposal programs operated by law enforcement agencies of political subdivisions should not be exempted from the provisions of the draft, unless the programs are federally authorized. DSPS approval should not be required for such programs if the program procedures have been approved by legal counsel for the political subdivision.

On pages five and six, the introductory clause at the beginning of subsection 450.255(4) should include an exception for federally authorized programs. That exception should not apply to subsection 450.255(4)(c) on page six. ?

On page six, the possession and transfer exemptions in subsection 450.255(5)(a) should also apply to federally authorized programs. The introductory portion of subsection 450.255(5)(b) should apply to possession and receipt by federally authorized programs.

Section 3: The exemption from distribution in subsection 450.01(23)(n) should also apply to federally authorized programs.

Section 4: Change subsection 450.01(23)(o) to make it applicable to prescription drugs, *other than controlled substances and controlled substance analogs*. Please see our response to Section 9.

Section 5: No suggestions or comments.

Section 6: The exemption in subsection 961.32(2)(e) should also extend to persons engaged in the operation of federally authorized programs. ✓

Section 7: No suggestions or comments. ✓

Section 8: The "obtain" and "possess" exemptions in subsection 961.335(1)(c)1. should extend to persons engaged in the operation of federally authorized programs. ✓

In subsection 961.335(1)(c)2. substitute "federal law" for "s. 961.337(2m)." ✓

Section 9: Retain what are now subsections 961.337(2) (intro.), (2)(a), and (2)(b) in chapter 961.

Extend what is now subsection 961.337(2)(a) to include federally authorized programs.

Extend what is now subsection 961.337(2)(b) to include federally authorized programs. In that subsection, substitute "to do so under federal law" for "under sub. (2m)." ✓

Move what are now subsections 961.337(1), (2)(c), (2m), and (3) to chapter 450 and make them applicable to prescription drugs, *other than controlled substances and controlled substance analogs.* }

In the chapter 450 provision, change "authorization" to "permission" in what is now subsection 961.337(2m)(a). Make the permission provisions in chapter 450 applicable to prescription drugs, *other than controlled substances and controlled substance analogs.* In chapter 450, include a provision imposing a criminal penalty for fraudulent written permissions.

In response to the note on page eight, the definition of "guardian" should be extended to any person who is a legal guardian by operation of law, regardless of whether the appointment was made pursuant to a Wisconsin statute.

In the chapter 450 provision, substitute "prescription drugs" for "each controlled substance or controlled substance analog" in what is now subsection 961.337(3)(a). Provide that the chapter 450 written permission must describe "prescription drugs" (not "each prescription drug") with reasonable specificity.

In the chapter 450 provision, substitute "prescription drugs" for "each controlled substance or controlled substance analog" and for "controlled substance or controlled substance analog" in what is now subsection 961.337(3)(b). Change the "24 hours" requirement in that subsection to "five business days."

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In the chapter 450 provision, substitute "prescription drugs" for "each controlled substance or controlled substance analog" and for "controlled substance or controlled substance analog" in what is now subsection 961.337(3)(c).

Section 10: The note in subsection 10 is correct. There should be no grandfather clause, but federally authorized programs are not required to comply with the requirements in the draft. ✖

KCP:FTC:cla