





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 III** 

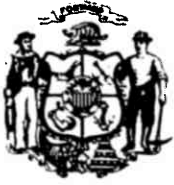
Appendix A  The drafting file for LRB 13-0576 (used to create 13-3348)
(Representative Nygren draft)

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 III

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.



soon
State of Wisconsin
2011 - 2012 LEGISLATURE



LRB-0330/P0

MPG&CMH:cjs:rs

stays

3

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

Insert

Regen.

SA ✓

1 AN ACT *to renumber and amend* 961.335 (1); *to amend* subchapter III (title)
2 of chapter 961 [precedes 961.31]; and *to create* 66.0437, 440.255, 450.01 (23)
3 (n), 450.01 (23) (o), 961.32 (2) (e), 961.335 (1) (c) 1. and 2. and 961.337 of the
4 statutes; **relating to:** the creation of drug disposal programs, regulation of
5 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:

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

7 **66.0437 Drug disposal programs.** (1) In this section, "political subdivision"
8 has the meaning given in s. 440.255 (1) (e).

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

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

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

2 **440.255 Drug disposal program. (1) DEFINITIONS.** In this section:

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

4 (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.~~

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

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

~~****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?~~

(15) (2) DEPARTMENT AUTHORIZATION TO OPERATE A DRUG DISPOSAL PROGRAM. (a) No
16 person may receive pharmaceutical items pursuant to a drug disposal program

Except as provided under sub. (3) 1

1 unless the department grants written authorization for that program under this
2 subsection ~~or the program is authorized under federal law~~

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

6 1. The person adopts written policies and procedures that comply with sub. (a). 5

7 The department shall review and either approve or disapprove in writing those
8 policies and procedures. The department ~~may~~ ^{shall} disapprove the policies and
9 procedures if the department determines that the policies and procedures do not
10 ~~meet~~ ^{violate} the requirements of this section or any other applicable federal or state law.
11 If the department disapproves the policies and procedures, the department shall
12 state the reasons for that disapproval in writing to the person. At any time, the
13 person may resubmit revised policies and procedures for the department's review
14 and approval under this subdivision.

15 2. If the drug disposal program will receive pharmaceutical items in any
16 manner other than the transfer of those pharmaceutical items in person to the
17 program by the ultimate user or by a person authorized under s. ~~961.337 (2m)~~, the
18 person demonstrates to the satisfaction of the department that those transfers will
19 comply with any federal or state law applicable to the transportation and delivery
20 of pharmaceutical items.

21 (c) A person may not revise policies and procedures approved by the
22 department under par. (b) 1. unless the department approves the revisions under
23 par. (b) 1.

24 ~~(d) The department may revoke an authorization granted under par. (b) if the~~
25 ~~department determines that the drug disposal program or the person operating the~~

Insert 3-2

and shall disapprove them otherwise 450.115(3)

SECTION 2

The political subdivision or the authorized person operates the drug disposal program within the boundaries of the political subdivision

1 drug disposal program is not in compliance with any provision of this section or other
2 applicable federal or state law.

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

A political subdivision may operate or

EXCEPT AS PROVIDED UNDER SUB. (4)

5 (3) AUTHORIZATION BY A POLITICAL SUBDIVISION TO OPERATE A DRUG DISPOSAL
6 PROGRAM. The governing body of a political subdivision may grant written

7 authorization for the operation of a drug disposal program on behalf of the political

8 subdivision if all of the following apply:

9 (a) The department authorizes the drug disposal program under sub. (2).

****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?

10 (b) The political subdivision ensures that the requirements under sub. (a) are
11 satisfied.

12 (c) The drug disposal program receives pharmaceutical items only by means
13 of delivery in person by an ultimate user or by a person authorized under s. 961.337

450.115

14 (2m) and only within the boundaries of the political subdivision

****NOTE: Based on the revised drafting instructions, the intent appears to be to restrict a drug disposal program authorized by a political subdivision that operates on behalf of the 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?

****NOTE: With respect to the in-person delivery of pharmaceutical items, is the restriction to ultimate users and persons authorized under s. 961.337 (2m) (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?

UNLESS the drug disposal program is authorized under federal law to

7-7-11 DRAFT

5
****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 DSPS authorization or any other provisions in the draft regarding the operation of drug disposal programs?

1 (b) OPERATION OF A DRUG DISPOSAL PROGRAM. (a) A person that operates a drug
2 disposal program shall establish and, ~~subject to sub. (2)(b) 1.~~ promptly update as
3 appropriate written policies and procedures that do all of the following:

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

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

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

16 4. If controlled substances or controlled substance analogs may be received
17 under the program, ensure compliance with any applicable provision under 21 USC
18 801 to 865 relating to controlled substances or controlled substance analogs, ensure
19 that delivery of any controlled substances complies with 21 USC 822 (g) and its
20 implementing regulations, and ensure that any required permissions have been
21 obtained from the federal drug enforcement administration.

22 (b) The policies and procedures for a proposed drug disposal program
23 ~~implemented or~~ authorized under sub. (3) and any changes to those policies and procedures must be

except a drug disposal program that is

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for the political subdivision, at the discretion of the political subdivision, the department of the political subdivision or the political subdivision shall review

including a drug disposal program that is authorized under federal law; SECTION 2

~~reviewed and approved in writing by legal counsel for the political subdivision. The political subdivision shall provide a copy of that approval to the department.~~

(c) The operation of a drug disposal program shall immediately cease if a law enforcement officer, as defined in s. 165.85 (2) (c), ^{a an} federal law enforcement officer, as defined in s. 175.40 (7) (a) 1., or ^{the department or other} federal or state agency notifies a ^{designated} contact person for the program ^{under par. (a) 2.} that the program is in violation of any federal or state law enforceable by the ^{agency or officer} agency or officer. That notification is not subject to judicial review. The operation of the program may be resumed only upon the program's receipt of written notice from the ^{agency or officer} agency or officer that the program is no longer in violation of the federal or state law.

6 (5) TRANSFER AND RECEIPT OF PHARMACEUTICAL ITEMS. (a) Notwithstanding ss. 450.03 (1) and 450.11 (7) (g) and (9) (b), a person that lawfully possesses a pharmaceutical item may transfer, and it is not a crime for such a person to transfer, the pharmaceutical item to a drug disposal program if the program ^{has been} authorized under sub. (2) or (3) ^{or under federal law} ^{use 3x}.

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

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 ^{has been} authorized under s. 440.255 (2) or (3) ^{is} or the possession or delivery of

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Insert 6-22

Insert 7-6

1 a pharmaceutical item, as defined in s. 440.255 (1) (d), within the scope of such a drug
2 disposal program.

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

prescription drug

4 450.01 (23) (o) The possession or delivery of a ~~controlled substance~~ or a
5 ~~controlled substance analog, as defined in s. 961.01 (4m),~~ within the scope of a
6 written authorization under s. ~~961.337 (2m).~~ 450.115 (3) ✓

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

9 CHAPTER 961

10 SUBCHAPTER III

11 REGULATION OF MANUFACTURE,

12 DISTRIBUTION AND DISPENSING,

13 AND POSSESSION OF CONTROLLED

14 SUBSTANCES

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

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16 961.32 (2) (e) A person actively engaged in the direct operation or
17 implementation of a drug disposal program that has been authorized under s.
18 440.255 (2) or (3). or under Federal law is

19 SECTION 7. 961.335 (1) of the statutes is renumbered 961.335 (1) (a) and
20 amended to read:

21 961.335 (1) (a) 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. Ne

of under federal law

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

(c) 3. ~~An individual may be who is~~ designated and authorized to receive the a permit under this section 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 additional permit issued under this section, possess and use a controlled substance, for the purposes authorized in the permit received for the department or unit.

SECTION 8. 961.335 (1) (c) 1. and 2. of the statutes are created to read:

961.335 (1) (c) 1. A person who is actively engaged in the direct operation or implementation of a drug disposal program that is authorized under s. 440.255 (2) or (3) may, without a permit issued under this section, obtain or possess a controlled substance for the purposes of operating and implementing the drug disposal program.

2. A person who is authorized under s. 961.337 (2m) to dispose of a controlled substance may, without a permit issued under this section, possess the controlled substance for the purpose of disposing of the controlled substance.

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

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

(a) "Guardian" means the person named by the court under ch. 880, 2003 stats., or ch. 48 or 54 that has 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

federal law

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to incorporate the broader "fiduciary" language, we should broaden the definition of "ward" accordingly. Please let me know how you would like to proceed.

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

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

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

170 H

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

9 (1) (a) The direct operation or implementation of a drug disposal program that has
10 been authorized under s. 440.255 (2) or (3) or under federal law

11 (2) (b) The transfer by the ultimate user or a person authorized under sub. (2m)
12 of a controlled substance or controlled substance analog to a drug disposal program
13 that has been authorized under s. 440.255 (2) or (3) and that accepts the controlled
14 substance or controlled substance analog or under federal law

B

15 (c) Subject to sub. (3), the possession of a controlled substance or controlled
16 substance analog under a written authorization described in sub. (2m).

17 (2m)(a) A guardian may grant written authorization to an adult who is related
18 to the guardian's ward by blood, marriage, or adoption within the 3rd degree of
19 kinship as computed under s. 990.001 (16), or to a domestic partner of the ward under
20 ch. 770, for the disposal of a controlled substance or controlled substance analog that
21 belongs to the ward.

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

22 (b) A personal representative or a trustee may grant written authorization to
23 an adult beneficiary, as defined in s. 701.20 (2) (b), of the estate or trust for the

1 disposal of a controlled substance or controlled substance analog that belongs to the
2 estate or trust.

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

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

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

12 (b) The authorization is in the physical possession of the person authorized to
13 dispose of the controlled substance or controlled substance analog and each
14 controlled substance or controlled substance analog described in the authorization
15 is, within 24 hours after the authorization is signed by the person granting the
16 authorization, transferred to a drug disposal program under s. 440.255 or otherwise
17 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.

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

****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?~~

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SECTION 10. Effective date.

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

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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.~~

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(END)

2011-2012 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-0330/P3ins.
MPG:.....

Supplemental Insert

1 INSERT 5-21A

2 (b) 1. The policies and procedures for a drug disposal program authorized under
3 sub. (2) and any changes to those policies and procedures are subject to review and
4 approval under sub. (2) (b) 1.

5 2. Legal counsel for the political subdivision, or, at the discretion of the political
6 subdivision, the department if the political subdivision's legal counsel is not an
7 employee of the political subdivision, shall review and either approve or disapprove
8 the policies and procedures for a drug disposal program implemented or authorized
9 under sub. (3) and any changes to those policies and procedures. Legal counsel, or
10 the department if appropriate, shall approve the policies and procedures or changes
11 if it determines that the policies and procedures or changes do not violate the
12 requirements of this section or any other applicable federal or state law, and shall
13 disapprove them otherwise. Any approval under this paragraph shall be in writing.
14 The political subdivision shall provide a copy of the approval and a copy of the policies
15 and procedures or changes to the policies and procedures to the department.

16 END INSERT 5-21A

17 INSERT 6-22

18 SECTION 1. 450.01 (21w) of the statutes is created to read:

19 450.01 (21w) "Ultimate user" means an individual who lawfully possesses a
20 prescription drug for that individual's own use or for the use of a member of that
21 individual's household or for administering to an animal owned by that individual
22 or by a member of that individual's household.

23 END INSERT 6-22

2011-2012 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-0330/P3ins
MPG&CMH:cjs:rs

1 INSERT 3-2

****NOTE: Consistent with the revised drafting instructions, an exception for programs "authorized under federal law" has been inserted throughout the draft, except where otherwise indicated in the drafting instructions (see s. 440.255 (5) (c) in this draft). ✓

2 END INSERT 3-2

3 INSERT 4-14 ✓

4 (4) MULTIJURISDICTIONAL DRUG DISPOSAL PROGRAM. A drug disposal program may
5 operate within more than one political subdivision if the department authorizes that
6 program under sub. (2), all political subdivisions within which the drug disposal
7 program operates authorize that program under sub. (3), or the program is
8 authorized under federal law. ✓

9 END INSERT 4-14

10 INSERT 5-21

****NOTE: Does it still make sense to include subd. 4. if, as requested in the revised drafting instructions, a program authorized under federal law is exempt from the requirement to provide policies and procedures to the Department of Safety and Professional Services (DSPS)? (See par. (5) (a) (intro.) above). Under 21 USC 822 (g), a person may only receive a controlled substance for disposal if that person is authorized under that federal law to dispose of controlled substances. Subd. 4. only applies to the receipt of controlled substances and controlled substance analogs (under 21 USC 813, a controlled substance analogue is treated as a controlled substance for purposes of federal law, including the disposal authorization). Note that subd. 1., above, requires a drug disposal program to disclose to DSPS the kinds of pharmaceutical items the program may receive, including whether the program may receive controlled substances and controlled substance analogues.

11 END INSERT 5-21 *the*

12 INSERT 7-6 *^*

13 SECTION 1. 450.115 of the statutes is created to read: ✓

14 **450.115 Drug disposal programs and authorizations. (1) In this section:**

15 (a) "Guardian" means the person named by the court under ch. 880, 2003 stats., ✓

16 or ch. 48 or 54 that has the duty and authority of guardianship. ✓✓

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

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

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

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

9 (a) The direct operation or implementation of a drug disposal program that is
10 authorized under s. 440.255 (2) or (3) or under federal law. ✓

11 (b) The transfer by the ultimate user or a person authorized under sub. (3) of
12 a prescription drug to a drug disposal program that is authorized under s. 440.255
13 (2) or (3) or under federal law and that accepts the prescription drug.

14 (c) Subject to sub. (4), the possession of a prescription drug under a written
15 authorization described in sub. (3).

16 (3) (a) A guardian may grant written authorization to an adult who is related
17 to the guardian's ward by blood, marriage, or adoption within the 3rd degree of
18 kinship as computed under s. 990.001 (16), or to a domestic partner of the ward under
19 ch. 770, for the disposal of a prescription drug that belongs to the ward. ✓

20 (b) A personal representative or a trustee may grant written authorization to
21 an adult beneficiary, as defined in s. 701.20 (2) (b), of the estate or trust for the
22 disposal of a prescription drug that belongs to the estate or trust. ✓

23 (c) An ultimate user who is a competent adult may grant written authorization
24 to that ultimate user's domestic partner under ch. 770 or to another adult who is ✓
25 related to that ultimate user by blood, marriage, or adoption within the 3rd degree ✓

1 of kinship as computed under s. 990.001 (16), for the disposal of a prescription drug ✓
2 that belongs to that ultimate user. ✓

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

5 (a) The authorization describes with reasonable specificity each prescription
6 drug that is to be disposed of.

7 (b) The authorization is in the physical possession of the person authorized to
8 dispose of the prescription drug and each prescription drug described in the
9 authorization is, within 24 hours after the authorization is signed by the person
10 granting the authorization, transferred to a drug disposal program under s. 440.255 ✓
11 or otherwise lawfully disposed of.

12 (c) The authorization and each prescription drug to be disposed of were ✓
13 obtained without consideration.

14 END INSERT 7-6

applicable

1

(b) The political subdivision ensures that the requirements under sub. (5) are

2 satisfied.

3 (c) The drug disposal program receives pharmaceutical items only by means
4 of delivery in person by an ultimate user or by a person authorized under s. 450.115
5 (3), unless the drug disposal program is authorized under federal law to receive
6 pharmaceutical items by other means.

7 (4) MULTIJURISDICTIONAL DRUG DISPOSAL PROGRAM. A drug disposal program may
8 operate within more than one political subdivision if the department authorizes that
9 program under sub. (2), all political subdivisions within which the drug disposal
10 program operates authorize that program under sub. (3), or the program is
11 authorized under federal law.

12 (5) OPERATION OF A DRUG DISPOSAL PROGRAM. (a) A person that operates a drug
13 disposal program, except a drug disposal program that is authorized under federal
14 law, shall establish and promptly update as appropriate written policies and
15 procedures that do all of the following:

16 1. Describe with specificity the manner in which the program operates,
17 including an identification of the kinds of pharmaceutical items that may be received
18 under the program, whether the program may receive controlled substances and
19 controlled substance analogs, whether pharmaceutical items will be transferred by
20 mail under the program, and the locations at which pharmaceutical items may be
21 transferred in person under the program.

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



PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

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4 and 961.337 of the statutes; **relating to:** the creation of drug disposal
5 programs, 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:

6 SECTION 1. 66.0437 of the statutes is created to read:
7 **66.0437 Drug disposal programs. (1)** In this section, “political subdivision”
8 has the meaning given in s. 440.255 (1) (e).
9 **(2)** A political subdivision may operate or authorize a person to operate a drug
10 disposal program as provided under s. 440.255 (3).

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

2 **440.255 Drug disposal program. (1) DEFINITIONS.** In this section:

3 (a) “Controlled substance” has the meaning given in s. 961.01 (4).

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

5 (c) “Drug disposal program” means a program to receive pharmaceutical items
6 and to recycle, destroy, or otherwise dispose of those items.

7 (d) “Pharmaceutical item” means a drug, as defined in s. 450.01 (10); a
8 prescription drug, as defined in s. 450.01 (20); a device, as defined in 450.01 (6); or
9 a hypodermic syringe, needle, or other object used for administering 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) DEPARTMENT AUTHORIZATION TO OPERATE A DRUG DISPOSAL PROGRAM.** (a) Except
16 as provided under sub. (3), no person may receive pharmaceutical items pursuant to
17 a drug disposal program unless the department grants written authorization for that
18 program under this subsection or the program is authorized under federal law.

****NOTE: Consistent with the revised drafting instructions, an exception for
programs “authorized under federal law” has been inserted throughout the draft, except
where otherwise indicated in the drafting instructions (see s. 440.255 (5) (c) in this draft).

19 (b) The department may, without a hearing, grant written authorization to a
20 person to operate a drug disposal program if all of the following conditions are
21 satisfied:

22 1. The person adopts written policies and procedures that comply with sub. (5).

23 The department shall review and either approve or disapprove in writing those

1 policies and procedures. The department shall approve the policies and procedures
2 if the department determines that the policies and procedures do not violate the
3 requirements of this section or any other applicable federal or state law, and shall
4 disapprove them otherwise. If the department disapproves the policies and
5 procedures, the department shall state the reasons for that disapproval in writing
6 to the person. At any time, the person may resubmit revised policies and procedures
7 for the department's review and approval under this subdivision.

8 2. If the drug disposal program will receive pharmaceutical items in any
9 manner other than the transfer of those pharmaceutical items in person to the
10 program by the ultimate user or by a person authorized under s. 450.115 (3), the
11 person demonstrates to the satisfaction of the department that those transfers will
12 comply with any federal or state law applicable to the transportation and delivery
13 of pharmaceutical items.

14 (c) A person may not revise policies and procedures approved by the
15 department under par. (b) 1. unless the department approves the revisions under
16 par. (b) 1.

17 (d) Any determination or action by the department under par. (b) or (c) is not
18 subject to judicial review.

19 **(3) AUTHORIZATION BY A POLITICAL SUBDIVISION TO OPERATE A DRUG DISPOSAL**
20 **PROGRAM.** A political subdivision may operate or the governing body of a political
21 subdivision may grant written authorization to operate a drug disposal program only
22 if all of the following apply:

23 (a) The political subdivision or the authorized person operates the drug
24 disposal program only within the boundaries of the political subdivision, except as
25 provided under sub. (4).

1 (b) The applicable requirements under sub. (5) are satisfied.

2 (c) The drug disposal program receives pharmaceutical items only by means
3 of delivery in person by an ultimate user or by a person authorized under s. 450.115
4 (3), unless the drug disposal program is authorized under federal law to receive
5 pharmaceutical items by other means.

6 (4) MULTIJURISDICTIONAL DRUG DISPOSAL PROGRAM. A drug disposal program may
7 operate within more than one political subdivision if the department authorizes that
8 program under sub. (2), all political subdivisions within which the drug disposal
9 program operates authorize that program under sub. (3), or the program is
10 authorized under federal law.

11 (5) OPERATION OF A DRUG DISPOSAL PROGRAM. (a) A person that operates a drug
12 disposal program, except a drug disposal program that is authorized under federal
13 law, shall establish and promptly update as appropriate written policies and
14 procedures that do all of the following:

15 1. Describe with specificity the manner in which the program operates,
16 including an identification of the kinds of pharmaceutical items that may be received
17 under the program, whether the program may receive controlled substances and
18 controlled substance analogs, whether pharmaceutical items will be transferred by
19 mail under the program, and the locations at which pharmaceutical items may be
20 transferred in person under the program.

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

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

4 4. If controlled substances or controlled substance analogs may be received
5 under the program, ensure compliance with any applicable provision under 21 USC
6 801 to 865 relating to controlled substances or controlled substance analogs, ensure
7 that delivery of any controlled substances complies with 21 USC 822 (g) and its
8 implementing regulations, and ensure that any required permissions have been
9 obtained from the federal drug enforcement administration.

****NOTE: Does it still make sense to include subd. 4. if, as requested in the revised drafting instructions, a program authorized under federal law is exempt from the requirement to provide policies and procedures to the Department of Safety and Professional Services (DSPS)? (See par. (5) (a) (intro.) above). Under 21 USC 822 (g), a person may only receive a controlled substance for disposal if that person is authorized under that federal law to dispose of controlled substances. Subd. 4. only applies to the receipt of controlled substances and controlled substance analogs (under 21 USC 813, a controlled substance analogue is treated as a controlled substance for purposes of federal law, including the disposal authorization). Note that subd. 1., above, requires a drug disposal program to disclose to DSPS the kinds of pharmaceutical items the program may receive, including whether the program may receive controlled substances and controlled substance analogues.

10 (b) 1. The policies and procedures for a drug disposal program authorized under
11 sub. (2) and any changes to those policies and procedures are subject to review and
12 approval under sub. (2) (b) 1.

13 2. Legal counsel for the political subdivision, or, at the discretion of the political
14 subdivision, the department if the political subdivision's legal counsel is not an
15 employee of the political subdivision, shall review and either approve or disapprove
16 the policies and procedures for a drug disposal program implemented or authorized
17 under sub. (3) and any changes to those policies and procedures. Legal counsel, or
18 the department if appropriate, shall approve the policies and procedures or changes
19 if it determines that the policies and procedures or changes do not violate the

1 requirements of this section or any other applicable federal or state law, and shall
2 disapprove them otherwise. Any approval under this subdivision shall be in writing.
3 The political subdivision shall provide a copy of the approval and a copy of the policies
4 and procedures or changes to the policies and procedures to the department.

5 (c) The operation of a drug disposal program, including a drug disposal program
6 that is authorized under federal law, shall immediately cease if a law enforcement
7 officer, as defined in s. 165.85 (2) (c), a federal law enforcement officer, as defined in
8 s. 175.40 (7) (a) 1., or the department or another federal or state agency notifies a
9 designated contact person for the program that the program is in violation of any
10 federal or state law enforceable by the officer, department, or other agency. That
11 notification is not subject to judicial review. The operation of the program may be
12 resumed only upon the program's receipt of written notice from the officer,
13 department, or other agency that the program is no longer in violation of the federal
14 or state law.

15 (6) TRANSFER AND RECEIPT OF PHARMACEUTICAL ITEMS. (a) Notwithstanding ss.
16 450.03 (1) and 450.11 (7) (g) and (9) (b), a person that lawfully possesses a
17 pharmaceutical item may transfer, and it is not a crime for such a person to transfer,
18 the pharmaceutical item to a drug disposal program if the program is authorized
19 under sub. (2) or (3) or under federal law.

20 (b) Notwithstanding s. 450.11 (7) (g) and (h) and (9) (b), a person may receive,
21 and it is not a crime for a person to possess, a pharmaceutical item pursuant to a drug
22 disposal program if the receipt is within the scope of the program and the program
23 is authorized under sub. (2) or (3) or under federal law or, if the receipt is not within
24 the scope of the program, the receipt is inadvertent and the program promptly

1 notifies an appropriate law enforcement officer of the receipt and complies with any
2 instructions the law enforcement officer provides.

3 **SECTION 3.** 450.01 (21w) of the statutes is created to read:

4 **450.01 (21w)** “Ultimate user” means an individual who lawfully possesses a
5 prescription drug for that individual’s own use or for the use of a member of that
6 individual’s household or for administering to an animal owned by that individual
7 or by a member of that individual’s household.

8 **SECTION 4.** 450.01 (23) (n) of the statutes is created to read:

9 **450.01 (23) (n)** The operation or implementation of a drug disposal program
10 that is authorized under s. 440.255 (2) or (3) or under federal law or the possession
11 or delivery of a pharmaceutical item, as defined in s. 440.255 (1) (d), within the scope
12 of such a drug disposal program.

13 **SECTION 5.** 450.01 (23) (o) of the statutes is created to read:

14 **450.01 (23) (o)** The possession or delivery of a prescription drug within the
15 scope of a written authorization under s. 450.115 (3).

16 **SECTION 6.** 450.115 of the statutes is created to read:

17 **450.115 Drug disposal programs and authorizations. (1)** In this section:

18 (a) “Guardian” means the person named by the court under ch. 880, 2003 stats.,
19 or ch. 48 or 54 that has the duty and authority of guardianship.

20 (b) “Personal representative” means an executor, administrator, or special
21 administrator of a decedent’s estate, a person legally authorized to perform
22 substantially the same functions, or a successor to any of those persons.

23 (c) “Trustee” means a person that holds in trust title to or power over property.
24 “Trustee” includes an original, added, or successor trustee.

25 (d) “Ward” means an ultimate user for whom a guardian has been appointed.

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

3 (a) The direct operation or implementation of a drug disposal program that is
4 authorized under s. 440.255 (2) or (3) or under federal law.

5 (b) The transfer by the ultimate user or a person authorized under sub. (3) of
6 a prescription drug to a drug disposal program that is authorized under s. 440.255
7 (2) or (3) or under federal law and that accepts the prescription drug.

8 (c) Subject to sub. (4), the possession of a prescription drug under a written
9 authorization described in sub. (3).

10 **(3)** (a) A guardian may grant written authorization to an adult who is related
11 to the guardian's ward by blood, marriage, or adoption within the 3rd degree of
12 kinship as computed under s. 990.001 (16), or to a domestic partner of the ward under
13 ch. 770, for the disposal of a prescription drug that belongs to the ward.

14 (b) A personal representative or a trustee may grant written authorization to
15 an adult beneficiary, as defined in s. 701.20 (2) (b), of the estate or trust for the
16 disposal of a prescription drug that belongs to the estate or trust.

17 (c) An ultimate user who is a competent adult may grant written authorization
18 to that ultimate user's domestic partner under ch. 770 or to another adult who is
19 related to that ultimate user by blood, marriage, or adoption within the 3rd degree
20 of kinship as computed under s. 990.001 (16), for the disposal of a prescription drug
21 that belongs to that ultimate user.

22 **(4)** A written authorization under sub. (3) is valid only to the extent permitted
23 under federal law and only if all of the following conditions are satisfied:

24 (a) The authorization describes with reasonable specificity each prescription
25 drug that is to be disposed of.

1 (b) The authorization is in the physical possession of the person authorized to
2 dispose of the prescription drug and each prescription drug described in the
3 authorization is, within 24 hours after the authorization is signed by the person
4 granting the authorization, transferred to a drug disposal program under s. 440.255
5 or otherwise lawfully disposed of.

6 (c) The authorization and each prescription drug to be disposed of were
7 obtained without consideration.

8 SECTION 7. 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 8. 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 is authorized under s. 440.255 (2)
19 or (3) or under federal law.

20 SECTION 9. 961.335 (1) of the statutes is renumbered 961.335 (1) (a) and
21 amended to read:

22 961.335 (1) (a) Upon application the controlled substances board may issue a
23 permit authorizing a person to manufacture, obtain, possess, use, administer, or
24 dispense a controlled substance for purposes of scientific research, instructional

1 activities, chemical analysis, or other special uses, without restriction because of
2 enumeration. No

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

5 ~~(c) 3. An individual may be who is designated and authorized to receive the a~~
6 ~~permit under this section for a college or university department, research unit, or~~
7 ~~similar administrative organizational unit, and students, laboratory technicians,~~
8 ~~research specialists, or chemical analysts under his or her supervision, may be~~
9 ~~permitted possession and use of controlled substances for these purposes, without~~
10 ~~obtaining an individual additional permit issued under this section, possess and use~~
11 ~~a controlled substance, for the purposes authorized in the permit received for the~~
12 ~~department or unit.~~

13 SECTION 10. 961.335 (1) (c) 1. and 2. of the statutes are created to read:

14 961.335 (1) (c) 1. A person who is actively engaged in the direct operation or
15 implementation of a drug disposal program that is authorized under s. 440.255 (2)
16 or (3) or under federal law may, without a permit issued under this section, obtain
17 or possess a controlled substance for the purposes of operating and implementing the
18 drug disposal program.

19 2. A person who is authorized under federal law to dispose of a controlled
20 substance may, without a permit issued under this section, possess the controlled
21 substance for the purpose of disposing of the controlled substance.

22 SECTION 11. 961.337 of the statutes is created to read:

23 961.337 Drug disposal programs. Nothing in this chapter, or rules
24 promulgated under this chapter, prohibits any of the following:

