



January 21, 2011

SENATE BILL No. 177

DIGEST OF SB 177 (Updated January 19, 2011 1:35 pm - DI 104)

Citations Affected: IC 11-10; IC 11-12; IC 16-28; IC 25-26.

Synopsis: Unused medication. Allows a county jail or a department of correction facility to return: (1) certain unused medication to the pharmacy that dispensed the medication; and (2) unused medical devices or medical supplies that are used for prescription drug therapy and that meet specified requirements. Allows a pharmacist or pharmacy that enters into an agreement to accept the return of unused medication, unused medical devices, or unused medical supplies to negotiate a fee for processing the return.

Effective: July 1, 2011.

Miller, Breaux

January 5, 2011, read first time and referred to Committee on Health and Provider Services.
January 20, 2011, amended, reported favorably — Do Pass.

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SB 177—LS 6699/DI 107+



January 21, 2011

First Regular Session 117th General Assembly (2011)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2010 Regular Session of the General Assembly.

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SENATE BILL No. 177

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

- 1 SECTION 1. IC 11-10-3-4 IS AMENDED TO READ AS
2 FOLLOWS [EFFECTIVE JULY 1, 2011]: Sec. 4. (a) The department
3 shall establish directives governing:
4 (1) medical care to be provided to committed individuals,
5 including treatment for mental retardation, alcoholism, and drug
6 addiction;
7 (2) administration of medical facilities and health centers
8 operated by the department;
9 (3) medical equipment, supplies, and devices to be available for
10 medical care;
11 (4) provision of special diets to committed individuals;
12 (5) acquisition, storage, handling, distribution, and dispensing of
13 all medication and drugs;
14 (6) **the return of unused medications that meet the**
15 **requirements of IC 25-26-13-25(j)(1) through**
16 **IC 25-26-13-25(j)(6) to the pharmacy that dispensed the**
17 **medication;**

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- 1 ~~(6)~~ (7) training programs and first aid emergency care for
- 2 committed individuals and department personnel;
- 3 ~~(7)~~ (8) medical records of committed individuals; and
- 4 ~~(8)~~ (9) professional staffing requirements for medical care.

5 (b) The state department of health shall make an annual inspection
6 of every health facility, health center, or hospital operated by the
7 department and report to the commissioner whether that facility, center,
8 or hospital meets the requirements established by the state department
9 of health. Any noncompliance with those requirements must be stated
10 in writing to the commissioner, with a copy to the governor.

11 (c) For purposes of IC 4-22-2, the term "directive" as used in this
12 section relates solely to internal policy and procedure not having the
13 force of law.

- 14 **(d) For purposes of subsection (a)(6), the department:**
- 15 **(1) shall return medication that belonged to a Medicaid**
- 16 **recipient; and**
- 17 **(2) may return other unused medication;**
- 18 **to the pharmacy that dispensed the medication if the unused**
- 19 **medication meets the requirements of IC 25-26-13-25(j)(1) through**
- 20 **IC 25-26-13-25(j)(6).**

21 (e) The department may establish directives concerning the
22 return of unused medical devices or medical supplies that are used
23 for prescription drug therapy and that meet the requirements of
24 IC 25-26-13-25(k).

- 25 **(f) A pharmacist or pharmacy that enters into an agreement**
- 26 **with the department to accept the return of:**
- 27 **(1) unused medications that meet the requirements of**
- 28 **IC 25-26-13-25(j)(1) through IC 25-26-13-25(j)(6); or**
- 29 **(2) unused medical devices or medical supplies that are used**
- 30 **for prescription drug therapy and that meet the requirements**
- 31 **of IC 25-26-13-25(k);**

32 **may negotiate with the department a fee for processing the returns.**

33 SECTION 2. IC 11-12-5-8 IS ADDED TO THE INDIANA CODE
34 AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
35 1, 2011]: **Sec. 8. (a) This section applies to the return of:**

- 36 **(1) unused medications that meet the requirements of**
- 37 **IC 25-26-13-25(j)(1) through IC 25-26-13-25(j)(6); and**
- 38 **(2) unused medical devices or medical supplies that are used**
- 39 **for prescription drug therapy and that meet the requirements**
- 40 **of IC 25-26-13-25(k).**

- 41 **(b) The county sheriff:**
- 42 **(1) shall return medication that belonged to a Medicaid**

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1 **recipient; and**
 2 **(2) may return other unused medication;**
 3 **to the pharmacy that dispensed the medication if the unused**
 4 **medication meets the requirements of IC 25-26-13-25(j)(1) through**
 5 **IC 25-26-13-25(j)(6).**

6 **(c) The county sheriff may return unused medical devices or**
 7 **medical supplies that are used for prescription drug therapy and**
 8 **that meet the requirements of IC 25-26-13-25(k) to a pharmacy or**
 9 **pharmacist.**

10 **(d) A pharmacist or pharmacy that enters into an agreement**
 11 **with the county sheriff to accept the return of:**

12 **(1) unused medications that meet the requirements of**
 13 **IC 25-26-13-25(j)(1) through IC 25-26-13-25(j)(6); or**

14 **(2) unused medical devices or medical supplies that are used**
 15 **for prescription drug therapy and that meet the requirements**
 16 **of IC 25-26-13-25(k);**

17 **may negotiate with the county sheriff a fee for processing the**
 18 **returns.**

19 SECTION 3. IC 16-28-11-4, AS AMENDED BY P.L.204-2005,
 20 SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
 21 JULY 1, 2011]: Sec. 4. A health facility, **county jail under**
 22 **IC 11-12-5-8, or department of correction facility under**
 23 **IC 11-10-3-4** that possesses unused medication that meets the
 24 requirements of IC 25-26-13-25(j)(1) through IC 25-26-13-25(j)(6):

25 (1) shall return medication that belonged to a Medicaid recipient;
 26 and

27 (2) may return other unused medication;
 28 to the pharmacy that dispensed the medication.

29 SECTION 4. IC 25-26-13-25, AS AMENDED BY P.L.204-2005,
 30 SECTION 16, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
 31 JULY 1, 2011]: Sec. 25. (a) All original prescriptions, whether in
 32 written or electronic format, shall be numbered and maintained in
 33 numerical and chronological order, or in a manner approved by the
 34 board and accessible for at least two (2) years in the pharmacy. A
 35 prescription transmitted from a practitioner by means of
 36 communication other than writing must immediately be reduced to
 37 writing or recorded in an electronic format by the pharmacist. The files
 38 shall be open for inspection to any member of the board or its duly
 39 authorized agent or representative.

40 (b) A prescription may be electronically transmitted from the
 41 practitioner by computer or another electronic device to a pharmacy
 42 that is licensed under this article or any other state or territory. An

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1 electronic data intermediary that is approved by the board:

2 (1) may transmit the prescription information between the

3 prescribing practitioner and the pharmacy;

4 (2) may archive copies of the electronic information related to the

5 transmissions as necessary for auditing and security purposes; and

6 (3) must maintain patient privacy and confidentiality of all

7 archived information as required by applicable state and federal

8 laws.

9 (c) Except as provided in subsection (d), a prescription for any drug,

10 the label of which bears either the legend, "Caution: Federal law

11 prohibits dispensing without prescription" or "Rx Only", may not be

12 refilled without written, electronically transmitted, or oral authorization

13 of a licensed practitioner.

14 (d) A prescription for any drug, the label of which bears either the

15 legend, "Caution: Federal law prohibits dispensing without

16 prescription" or "Rx Only", may be refilled by a pharmacist one (1)

17 time without the written, electronically transmitted, or oral

18 authorization of a licensed practitioner if all of the following conditions

19 are met:

20 (1) The pharmacist has made every reasonable effort to contact

21 the original prescribing practitioner or the practitioner's designee

22 for consultation and authorization of the prescription refill.

23 (2) The pharmacist believes that, under the circumstances, failure

24 to provide a refill would be seriously detrimental to the patient's

25 health.

26 (3) The original prescription authorized a refill but a refill would

27 otherwise be invalid for either of the following reasons:

28 (A) All of the authorized refills have been dispensed.

29 (B) The prescription has expired under subsection (g).

30 (4) The prescription for which the patient requests the refill was:

31 (A) originally filled at the pharmacy where the request for a

32 refill is received and the prescription has not been transferred

33 for refills to another pharmacy at any time; or

34 (B) filled at or transferred to another location of the same

35 pharmacy or its affiliate owned by the same parent corporation

36 if the pharmacy filling the prescription has full access to

37 prescription and patient profile information that is

38 simultaneously and continuously updated on the parent

39 corporation's information system.

40 (5) The drug is prescribed for continuous and uninterrupted use

41 and the pharmacist determines that the drug is being taken

42 properly in accordance with IC 25-26-16.

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(6) The pharmacist shall document the following information regarding the refill:

(A) The information required for any refill dispensed under subsection (e).

(B) The dates and times that the pharmacist attempted to contact the prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(C) The fact that the pharmacist dispensed the refill without the authorization of a licensed practitioner.

(7) The pharmacist notifies the original prescribing practitioner of the refill and the reason for the refill by the practitioner's next business day after the refill has been made by the pharmacist.

(8) Any pharmacist initiated refill under this subsection may not be for more than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day. However, a pharmacist may dispense a drug in an amount greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day if:

(A) the drug is packaged in a form that requires the pharmacist to dispense the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day; or

(B) the pharmacist documents in the patient's record the amount of the drug dispensed and a compelling reason for dispensing the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day.

(9) Not more than one (1) pharmacist initiated refill is dispensed under this subsection for a single prescription.

(10) The drug prescribed is not a controlled substance.

A pharmacist may not refill a prescription under this subsection if the practitioner has designated on the prescription form the words "No Emergency Refill".

(e) When refilling a prescription, the refill record shall include:

(1) the date of the refill;

(2) the quantity dispensed if other than the original quantity; and

(3) the dispenser's identity on:

(A) the original prescription form; or

(B) another board approved, uniformly maintained, readily retrievable record.

(f) The original prescription form or the other board approved

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1 record described in subsection (e) must indicate by the number of the
 2 original prescription the following information:
 3 (1) The name and dosage form of the drug.
 4 (2) The date of each refill.
 5 (3) The quantity dispensed.
 6 (4) The identity of the pharmacist who dispensed the refill.
 7 (5) The total number of refills for that prescription.
 8 (g) A prescription is valid for not more than one (1) year after the
 9 original date of issue.
 10 (h) A pharmacist may not knowingly dispense a prescription after
 11 the demise of the practitioner, unless in the pharmacist's professional
 12 judgment it is in the best interest of the patient's health.
 13 (i) A pharmacist may not knowingly dispense a prescription after
 14 the demise of the patient.
 15 (j) A pharmacist or a pharmacy shall not resell, reuse, or redistribute
 16 a medication that is returned to the pharmacy after being dispensed
 17 unless the medication:
 18 (1) was dispensed to ~~a patient~~ **an individual**:
 19 (A) residing in an institutional facility (as defined in 856
 20 IAC 1-28.1-1(6)); ~~or~~
 21 (B) in a hospice program under IC 16-25; **or**
 22 **(C) in a county jail or department of correction facility**;
 23 (2) was properly stored and securely maintained according to
 24 sound pharmacy practices;
 25 (3) is returned unopened and:
 26 (A) was dispensed in the manufacturer's original:
 27 (i) bulk, multiple dose container with an unbroken tamper
 28 resistant seal; or
 29 (ii) unit dose package; or
 30 (B) was packaged by the dispensing pharmacy in a:
 31 (i) multiple dose blister container; or
 32 (ii) unit dose package;
 33 (4) was dispensed by the same pharmacy as the pharmacy
 34 accepting the return;
 35 (5) is not expired; and
 36 (6) is not a controlled substance (as defined in IC 35-48-1-9),
 37 unless the pharmacy holds a Type II permit (as described in
 38 section 17 of this chapter).
 39 **(k) A pharmacist or a pharmacy shall not resell, reuse, or**
 40 **redistribute medical devices or medical supplies used for**
 41 **prescription drug therapy that have been returned to the**
 42 **pharmacy after being dispensed unless the medical devices or**

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1 **medical supplies:**
2 (1) were dispensed to an individual in a county jail or
3 department of correction facility;
4 (2) are not expired; and
5 (3) are returned unopened and in the original sealed
6 packaging.
7 ~~(l)~~ (l) A pharmacist may use the pharmacist's professional judgment
8 as to whether to accept medication for return under this section.
9 ~~(m)~~ (m) A pharmacist who violates subsection (d) commits a Class
10 A infraction.

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COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 177, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 1, between the enacting clause and line 1, begin a new paragraph and insert:

"SECTION 1. IC 11-10-3-4 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2011]: Sec. 4. (a) The department shall establish directives governing:

- (1) medical care to be provided to committed individuals, including treatment for mental retardation, alcoholism, and drug addiction;
- (2) administration of medical facilities and health centers operated by the department;
- (3) medical equipment, supplies, and devices to be available for medical care;
- (4) provision of special diets to committed individuals;
- (5) acquisition, storage, handling, distribution, and dispensing of all medication and drugs;
- (6) the return of unused medications that meet the requirements of IC 25-26-13-25(j)(1) through IC 25-26-13-25(j)(6) to the pharmacy that dispensed the medication;**
- ~~(6)~~ (7) training programs and first aid emergency care for committed individuals and department personnel;
- ~~(7)~~ **(8) medical records of committed individuals; and**
- ~~(8)~~ **(9) professional staffing requirements for medical care.**

(b) The state department of health shall make an annual inspection of every health facility, health center, or hospital operated by the department and report to the commissioner whether that facility, center, or hospital meets the requirements established by the state department of health. Any noncompliance with those requirements must be stated in writing to the commissioner, with a copy to the governor.

(c) For purposes of IC 4-22-2, the term "directive" as used in this section relates solely to internal policy and procedure not having the force of law.

(d) For purposes of subsection (a)(6), the department:

- (1) shall return medication that belonged to a Medicaid recipient; and**
- (2) may return other unused medication;**

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to the pharmacy that dispensed the medication if the unused medication meets the requirements of IC 25-26-13-25(j)(1) through IC 25-26-13-25(j)(6).

(e) The department may establish directives concerning the return of unused medical devices or medical supplies that are used for prescription drug therapy and that meet the requirements of IC 25-26-13-25(k).

(f) A pharmacist or pharmacy that enters into an agreement with the department to accept the return of:

- (1) unused medications that meet the requirements of IC 25-26-13-25(j)(1) through IC 25-26-13-25(j)(6); or
- (2) unused medical devices or medical supplies that are used for prescription drug therapy and that meet the requirements of IC 25-26-13-25(k);

may negotiate with the department a fee for processing the returns.

SECTION 2. IC 11-12-5-8 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2011]: Sec. 8. (a) This section applies to the return of:

- (1) unused medications that meet the requirements of IC 25-26-13-25(j)(1) through IC 25-26-13-25(j)(6); and
- (2) unused medical devices or medical supplies that are used for prescription drug therapy and that meet the requirements of IC 25-26-13-25(k).

(b) The county sheriff:

- (1) shall return medication that belonged to a Medicaid recipient; and
- (2) may return other unused medication;

to the pharmacy that dispensed the medication if the unused medication meets the requirements of IC 25-26-13-25(j)(1) through IC 25-26-13-25(j)(6).

(c) The county sheriff may return unused medical devices or medical supplies that are used for prescription drug therapy and that meet the requirements of IC 25-26-13-25(k) to a pharmacy or pharmacist.

(d) A pharmacist or pharmacy that enters into an agreement with the county sheriff to accept the return of:

- (1) unused medications that meet the requirements of IC 25-26-13-25(j)(1) through IC 25-26-13-25(j)(6); or
- (2) unused medical devices or medical supplies that are used for prescription drug therapy and that meet the requirements of IC 25-26-13-25(k);

may negotiate with the county sheriff a fee for processing the

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returns."

Page 1, line 3, delete "jail," and insert "**jail under IC 11-12-5-8**,"

Page 1, line 4, after "facility" insert "**under IC 11-10-3-4**".

Page 1, after line 9, begin a new paragraph and insert:

"SECTION 4. IC 25-26-13-25, AS AMENDED BY P.L.204-2005, SECTION 16, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2011]: Sec. 25. (a) All original prescriptions, whether in written or electronic format, shall be numbered and maintained in numerical and chronological order, or in a manner approved by the board and accessible for at least two (2) years in the pharmacy. A prescription transmitted from a practitioner by means of communication other than writing must immediately be reduced to writing or recorded in an electronic format by the pharmacist. The files shall be open for inspection to any member of the board or its duly authorized agent or representative.

(b) A prescription may be electronically transmitted from the practitioner by computer or another electronic device to a pharmacy that is licensed under this article or any other state or territory. An electronic data intermediary that is approved by the board:

- (1) may transmit the prescription information between the prescribing practitioner and the pharmacy;
- (2) may archive copies of the electronic information related to the transmissions as necessary for auditing and security purposes; and
- (3) must maintain patient privacy and confidentiality of all archived information as required by applicable state and federal laws.

(c) Except as provided in subsection (d), a prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may not be refilled without written, electronically transmitted, or oral authorization of a licensed practitioner.

(d) A prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may be refilled by a pharmacist one (1) time without the written, electronically transmitted, or oral authorization of a licensed practitioner if all of the following conditions are met:

- (1) The pharmacist has made every reasonable effort to contact the original prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.
- (2) The pharmacist believes that, under the circumstances, failure to provide a refill would be seriously detrimental to the patient's

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(3) The original prescription authorized a refill but a refill would otherwise be invalid for either of the following reasons:

(A) All of the authorized refills have been dispensed.

(B) The prescription has expired under subsection (g).

(4) The prescription for which the patient requests the refill was:

(A) originally filled at the pharmacy where the request for a refill is received and the prescription has not been transferred for refills to another pharmacy at any time; or

(B) filled at or transferred to another location of the same pharmacy or its affiliate owned by the same parent corporation if the pharmacy filling the prescription has full access to prescription and patient profile information that is simultaneously and continuously updated on the parent corporation's information system.

(5) The drug is prescribed for continuous and uninterrupted use and the pharmacist determines that the drug is being taken properly in accordance with IC 25-26-16.

(6) The pharmacist shall document the following information regarding the refill:

(A) The information required for any refill dispensed under subsection (e).

(B) The dates and times that the pharmacist attempted to contact the prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(C) The fact that the pharmacist dispensed the refill without the authorization of a licensed practitioner.

(7) The pharmacist notifies the original prescribing practitioner of the refill and the reason for the refill by the practitioner's next business day after the refill has been made by the pharmacist.

(8) Any pharmacist initiated refill under this subsection may not be for more than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day. However, a pharmacist may dispense a drug in an amount greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day if:

(A) the drug is packaged in a form that requires the pharmacist to dispense the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day; or

(B) the pharmacist documents in the patient's record the

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amount of the drug dispensed and a compelling reason for dispensing the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day.

(9) Not more than one (1) pharmacist initiated refill is dispensed under this subsection for a single prescription.

(10) The drug prescribed is not a controlled substance.

A pharmacist may not refill a prescription under this subsection if the practitioner has designated on the prescription form the words "No Emergency Refill".

(e) When refilling a prescription, the refill record shall include:

- (1) the date of the refill;
- (2) the quantity dispensed if other than the original quantity; and
- (3) the dispenser's identity on:
 - (A) the original prescription form; or
 - (B) another board approved, uniformly maintained, readily retrievable record.

(f) The original prescription form or the other board approved record described in subsection (e) must indicate by the number of the original prescription the following information:

- (1) The name and dosage form of the drug.
- (2) The date of each refill.
- (3) The quantity dispensed.
- (4) The identity of the pharmacist who dispensed the refill.
- (5) The total number of refills for that prescription.

(g) A prescription is valid for not more than one (1) year after the original date of issue.

(h) A pharmacist may not knowingly dispense a prescription after the demise of the practitioner, unless in the pharmacist's professional judgment it is in the best interest of the patient's health.

(i) A pharmacist may not knowingly dispense a prescription after the demise of the patient.

(j) A pharmacist or a pharmacy shall not resell, reuse, or redistribute a medication that is returned to the pharmacy after being dispensed unless the medication:

- (1) was dispensed to ~~a patient~~; **an individual:**
 - (A) residing in an institutional facility (as defined in 856 IAC 1-28.1-1(6)); ~~or~~
 - (B) in a hospice program under IC 16-25; **or**
 - (C) **in a county jail or department of correction facility;**
- (2) was properly stored and securely maintained according to sound pharmacy practices;

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- (3) is returned unopened and:
 - (A) was dispensed in the manufacturer's original:
 - (i) bulk, multiple dose container with an unbroken tamper resistant seal; or
 - (ii) unit dose package; or
 - (B) was packaged by the dispensing pharmacy in a:
 - (i) multiple dose blister container; or
 - (ii) unit dose package;
- (4) was dispensed by the same pharmacy as the pharmacy accepting the return;
- (5) is not expired; and
- (6) is not a controlled substance (as defined in IC 35-48-1-9), unless the pharmacy holds a Type II permit (as described in section 17 of this chapter).

(k) A pharmacist or a pharmacy shall not resell, reuse, or redistribute medical devices or medical supplies used for prescription drug therapy that have been returned to the pharmacy after being dispensed unless the medical devices or medical supplies:

- (1) were dispensed to an individual in a county jail or department of correction facility;**
- (2) are not expired; and**
- (3) are returned unopened and in the original sealed packaging.**

~~(l)~~ **(l)** A pharmacist may use the pharmacist's professional judgment as to whether to accept medication for return under this section.

~~(m)~~ **(m)** A pharmacist who violates subsection (d) commits a Class A infraction."

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 177 as introduced.)

MILLER, Chairperson

Committee Vote: Yeas 9, Nays 0.

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