
SENATE BILL No. 511

DIGEST OF INTRODUCED BILL

Citations Affected: IC 25-26-13.

Synopsis: Electronically transmitted prescriptions. Specifies conditions that an electronically transmitted prescription and an electronic data transmission device must meet. Prohibits advertising and messaging systems from being included in an electronic data transmission device except for certain information concerning formularies that may be provided. Requires a person to maintain electronic equipment that receives the transmission of an electronic prescription in a manner that ensures against unauthorized access to the information. Requires a pharmacy to maintain records containing a customer's health information in a manner that prevents a person not covered by a confidentiality agreement from having access to the information.

Effective: July 1, 2011.

Mishler

January 18, 2011, read first time and referred to Committee on Health and Provider Services.

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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. 511



A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

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

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

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

16 (1) may transmit the prescription information between the
17 prescribing practitioner and the pharmacy **in a manner that**



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prevents another person from having access to the prescription;

(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 health.
- (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

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1 regarding the refill:

2 (A) The information required for any refill dispensed under

3 subsection (e).

4 (B) The dates and times that the pharmacist attempted to

5 contact the prescribing practitioner or the practitioner's

6 designee for consultation and authorization of the prescription

7 refill.

8 (C) The fact that the pharmacist dispensed the refill without

9 the authorization of a licensed practitioner.

10 (7) The pharmacist notifies the original prescribing practitioner

11 of the refill and the reason for the refill by the practitioner's next

12 business day after the refill has been made by the pharmacist.

13 (8) Any pharmacist initiated refill under this subsection may not

14 be for more than the minimum amount necessary to supply the

15 patient through the prescribing practitioner's next business day.

16 However, a pharmacist may dispense a drug in an amount greater

17 than the minimum amount necessary to supply the patient through

18 the prescribing practitioner's next business day if:

19 (A) the drug is packaged in a form that requires the pharmacist

20 to dispense the drug in a quantity greater than the minimum

21 amount necessary to supply the patient through the prescribing

22 practitioner's next business day; or

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

24 amount of the drug dispensed and a compelling reason for

25 dispensing the drug in a quantity greater than the minimum

26 amount necessary to supply the patient through the prescribing

27 practitioner's next business day.

28 (9) Not more than one (1) pharmacist initiated refill is dispensed

29 under this subsection for a single prescription.

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

31 A pharmacist may not refill a prescription under this subsection if the

32 practitioner has designated on the prescription form the words "No

33 Emergency Refill".

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

35 (1) the date of the refill;

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

37 (3) the dispenser's identity on:

38 (A) the original prescription form; or

39 (B) another board approved, uniformly maintained, readily

40 retrievable record.

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

42 record described in subsection (e) must indicate by the number of the

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

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infraction.

SECTION 2. IC 25-26-13-25.5, AS ADDED BY P.L.204-2005, SECTION 17, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2011]: Sec. 25.5. (a) A prescription may be transmitted electronically from a practitioner to a pharmacy only through the use of an electronic data intermediary **that:**

- (1) is approved by the board; and
- (2) meets the requirements in section 25 of this chapter.

(b) An electronically transmitted prescription must meet the following requirements:

- (1) Be transmitted by an authorized practitioner or practitioner's designee.
- (2) Include the following:
 - (A) A means to contact the transmitter for oral or written verification of the contents of the prescription.
 - (B) The date and time of the transmitted prescription.
 - (C) The name of the pharmacy intended to receive the transmission.

An electronically transmitted prescription that meets the requirements of this section is considered to be the original prescription.

(c) An electronic data transmission device used to electronically transmit a prescription to a pharmacy or pharmacist must allow any legal prescription drug order to be entered into the device without interference or limitations before the prescription may be transmitted. Interference or limitations that are prohibited include programs or systems that do the following:

- (1) Limit the medications that may be chosen for the prescription.
 - (2) Display multiple messages.
 - (3) Except as provided in subsection (d), include advertisements or messages that:
 - (A) endorse;
 - (B) offer incentives for;
 - (C) attempt to influence; or
 - (D) encourage;
- the use of a specific pharmacy or prescription of a specific drug or device at the point of care.

(d) An electronic data transmission device may provide information concerning formulary for a policy of accident and sickness insurance or health maintenance organization if either the device or the information meets the following:

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(1) Includes a list of all the outpatient prescription drugs or area pharmacies.

(2) Does not attempt to influence the prescribing practitioner or patient in choosing a prescription drug or pharmacy.

(3) Allows the prescribing practitioner to receive prior authorization or another method to allow approval immediately for a prescribing practitioner to prescribe a drug not included in the formulary or use a pharmacy not usually authorized by the insurance company or health maintenance organization.

(4) Is limited to providing information to the prescribing practitioner or the practitioner's designee that meets the following:

- (A) Is consistent with the drug label.**
- (B) Is substantially supported by scientific evidence.**
- (C) Is fact based, accurate, and up to date.**
- (D) Provides an objective description of the risks and benefits of the drug.**
- (E) Provides support for better clinical decision making, including alerts to adverse events and formulary information.**
- (F) Is consistent with the federal Food and Drug Administration regulations concerning the advertisement of pharmaceutical products.**
- (G) Does not attempt to selectively persuade a practitioner to prescribe a specific brand drug.**

The provision of information under this subsection may not affect a patient's right to appeal.

(e) A person shall maintain electronic equipment that receives the transmission of an electronic prescription in a manner that ensures against unauthorized access to the information.

(f) A pharmacy shall maintain records containing a customer's health information in a manner that prevents a person not covered by a confidentiality agreement from having access to the information.

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