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## **TITLE 856 INDIANA BOARD OF PHARMACY**

### **Proposed Rule** LSA Document #05-140

#### **DIGEST**

Adds 856 IAC 1-40 to implement rules based on Senate Enrolled Act 590 (P.L.204-2005) to establish definitions, standards and requirements for electronic transmissions of prescriptions, including addressing the privacy protection for the practitioner and the practitioner's patient, the security of the electronic transmission, a process for approving electronic data intermediaries for the electronic transmission of prescriptions, use of the practitioner's United States Drug Enforcement Administration registration number and protection of the practitioner from identity theft or fraudulent use of the practitioner's prescribing authority. Effective 30 days after filing with the Secretary of State.

#### **IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses**

##### **Estimated Number of Small Businesses Subject to This Rule:**

The Indiana Board of Pharmacy ("Board") estimates that some small businesses will be directly affected by this rule. The Board has the authority to promulgate rules in accordance with the requirements of SEA 590 (P.L.204-2005). The proposed rule is being promulgated to establish standards for the approval of electronic data intermediaries and to set standards for the secure transmission of electronic prescriptions.

##### **Estimated Average Annual Administrative Costs That Small Businesses Will Incur:**

The Board estimates that there will be no annual reporting, record keeping, or administrative costs incurred by small businesses to comply with this rule.

##### **Estimated Total Annual Economic Impact on Small Businesses:**

The Board estimates that there will be no annual economic impact on small businesses as a result of compliance with this rule.

- Justification of Requirements or Costs on Small Businesses Where Rule Is Not Expressly Required by Law: There are no compliance costs that need to be justified for this proposed rule.
- Supporting Data, Studies, or Analyses: The Board has not relied on any studies in reaching these estimates.

##### **Regulatory Flexibility Analysis of Alternative Methods:**

Due to the fact that the new proposed rule found in this proposed rule were mandated by P.L.204-2005 (SEA 590-2005), the Board has not analyzed alternatives to this proposed rule.

- Explanation of Preliminary Determination: The General Assembly required the Board to enact and add these rules, and thus the Board did not explore alternative measures.
- Supporting Data, Studies, or Analyses: The Board did not rely on any studies in its decision not to employ alternatives to rulemaking.

#### **856 IAC 1-40**

SECTION 1. 856 IAC 1-40 IS ADDED TO READ AS FOLLOWS:

##### **Rule 40. Electronic Prescribing**

##### **856 IAC 1-40-1 "Board" defined**

**Authority:** IC 25-26-13-4

**Affected:** IC 25-26-13-2

**Sec. 1. "Board" has the meaning set forth in IC 25-26-13-2. (*Indiana Board of Pharmacy; 856 IAC 1-40-1*)**

##### **856 IAC 1-40-2 "Electronically transmitted" or "electronic transmission" defined**

**Authority:** IC 25-26-13-4

**Affected:** IC 16-18-2-106.4; IC 25-26-13-2

**Sec. 2. “Electronically transmitted” or “electronic transmission” has the meaning set forth in IC 16-18-2-106.4 and IC 25-26-13-2. (Indiana Board of Pharmacy; 856 IAC 1-40-2)**

**856 IAC 1-40-3 “Electronic data intermediary” or “EDI” defined**

**Authority: IC 25-26-13-4**

**Affected: IC 25-26-13-2**

**Sec. 3. “Electronic data intermediary” or “EDI” has the meaning set forth in IC 25-26-13-2. (Indiana Board of Pharmacy; 856 IAC 1-40-3)**

**856 IAC 1-40-4 “Practitioner” defined**

**Authority: IC 25-26-13-4**

**Affected: IC 25-26-13-2**

**Sec. 4. “Practitioner” has the meaning set forth in IC 25-26-13-2. (Indiana Board of Pharmacy; 856 IAC 1-40-4)**

**856 IAC 1-40-5 “Prescription” defined**

**Authority: IC 25-26-13-4**

**Affected: IC 25-26-13-2**

**Sec. 5. “Prescription” has the meaning set forth in IC 25-26-13-2. (Indiana Board of Pharmacy; 856 IAC 1-40-5)**

**856 IAC 1-40-6 Equipment**

**Authority: IC 25-26-13-4**

**Affected: IC 25-26-13**

**Sec. 6. All electronic equipment for receipt of prescription drug orders communicated by way of electronic transmission shall be maintained so as to ensure against the following:**

**(1) Unauthorized access.**

**(2) Changes to the prescription.**

*(Indiana Pharmacy Board; 856 IAC 1-40-6)*

**856 IAC 1-40-7 Electronic transmission**

**Authority: IC 25-26-13-4**

**Affected: IC 25-26-13**

**Sec. 7. Each electronic data intermediary shall ensure that the prescription electronically transmitted to the pharmacy:**

**(1) contains:**

**(A) no alterations to the:**

**(i) prescription;**

**(ii) order entry;**

**(iii) drug selection; or**

**(iv) intended drug selection;**

**by any electronic data intermediary;**

**(B) the exact information the prescription contained when originated by the authorized practitioner; and**

**(C) a unique identifier for the practitioner, such as:**

**(i) a National Practitioner Identifier (NPI);**

**(ii) a Drug Enforcement Administration registration number;**

**(iii) a state-issued practitioner license number; or**

**(iv) another board-approved identifier; and**

**(2) shall not interfere with the patient’s freedom to choose a pharmacy.**

*(Indiana Board of Pharmacy; 856 IAC 1-40-7)*

**856 IAC 1-40-8 Electronic data intermediary requirements**

**Authority: IC 25-26-13-4**

**Affected: IC 25-26-13**

**Sec. 8. An applicant for approval as an electronic data intermediary shall do the following:**

- (1) File an application provided by the board.**
- (2) Submit information regarding how the EDI shall do the following:**
  - (A) Guarantee the security of the following:**
    - (i) The prescription.**
    - (ii) The practitioner's identity and privacy.**
    - (iii) The patient's identity, privacy, and confidentiality.**
  - (B) Validate the authorized practitioner's licensure status.**
- (3) Appear before the board, if requested.**

*(Indiana Board of Pharmacy; 856 IAC 1-40-8)*

**856 IAC 1-40-9 Electronic data intermediary standards**

**Authority: IC 25-26-13-4**

**Affected: IC 25-26-13**

**Sec. 9. Each electronic data intermediary shall do the following:**

- (1) Maintain policies and procedures regarding the security of the following:**
  - (A) The prescription.**
  - (B) The practitioner's identity and privacy.**
  - (C) The patient's identity, privacy, and confidentiality.**
- (2) Validate positive identification of the practitioner.**

*(Indiana Board of Pharmacy; 856 IAC 1-40-9)*

**856 IAC 1-40-10 Electronic prescription prohibitions**

**Authority: IC 25-26-13-4**

**Affected: IC 25-26-13**

**Sec. 10. An electronic prescription does not include a prescription that is as follows:**

- (1) Transmitted via:**
  - (A) electronic mail, without the use of an electronic data intermediary; or**
  - (B) facsimile.**
- (2) Printed from a computer or electronic device.**

*(Indiana Board of Pharmacy; 856 IAC 1-40-10)*

***Notice of Public Hearing***

*Under IC 4-22-2-24, notice is hereby given that on November 14, 2005 at 10:00 a.m., at the Indiana Government Center-South, 402 West Washington Street, Room W064, Indianapolis, Indiana the Indiana Board of Pharmacy will hold a public hearing on a proposed new rule to implement rules based on Senate Enrolled Act 590 (P.L.204-2005) to establish definitions, standards and requirements for electronic transmissions of prescriptions, including addressing the privacy protection for the practitioner and the practitioner's patient, the security of the electronic transmission, a process for approving electronic data intermediaries for the electronic transmission of prescriptions, use of the practitioner's United States Drug Enforcement Administration registration number and protection of the practitioner from identity theft or fraudulent use of the practitioner's prescribing authority.*

*The Indiana Board of Pharmacy has the authority to promulgate rules in accordance with the requirements of SEA 590 (P.L.204-2005). The proposed rule is being promulgated to establish standards for the approval of electronic data intermediaries and to set standards for the secure transmission of electronic prescriptions. This proposed rule will have no cost on the regulated entities.*

*Copies of these rules are now on file at the Indiana Government Center-South, 402 West Washington Street, Room W072 and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.*

Frances L. Kelly  
Executive Director  
Indiana Professional Licensing Agency

