TITLE 856 INDIANA BOARD OF PHARMACY

Emergency Rule

Temporarily adds provisions concerning products containing ephedrine or pseudoephedrine.
Statutory authority: IC 25-26-13-4; IC 35-48-4-14.3

Effective July 13, 2016

SECTION1. The definitions in IC 25-26-13-2 and this document apply throughout this document.

SECTION 2. "Pharmacy technician" has the meaning set forth in IC 25-26-19-2.

SECTION 3. "Agency" means the Indiana professional licensing agency.

SECTION 4. "Relationship on record" means a relationship formed between an individual and a pharmacy, of which the pharmacy holds a profile in its system of the individual for prescription medication dispensed, or the individual previously purchased ephedrine or pseudoephedrine at that pharmacy location and is tracked in the National Precursor Log Exchange (NPLEx) system.

SECTION 5. "Conversion resistant" refers to describing a product containing ephedrine or pseudoephedrine that does not pose a significant risk of being used in the illicit manufacture of methamphetamine, as determined by the board pursuant to this article.

SECTION 6. "Extraction resistant" refers to describing a product containing ephedrine or pseudoephedrine that cannot be used in the illicit manufacture of methamphetamine, as determined by the U.S. Attorney General.

SECTION 7. If an individual has a relationship on record and intends to purchase a product containing ephedrine or pseudoephedrine, the pharmacist may use his or her professional discretion in determining whether there is a legitimate medical or pharmaceutical need for the product before dispensing. A pharmacist's professional determination to dispense a product containing ephedrine or pseudoephedrine shall be based on factors relevant to the individual's medical need or the appropriateness of purchasing the requested product, taking into account:

(1) the individual's relationship on record; or
(2) the pharmacist's screening of the individual's existing medical conditions and physical symptoms as appropriate for the treatment being considered. The screening may include a review of the individual's medical history, disease history, prescription history, physical symptoms, and relevant vital signs. Screenings performed by the pharmacist may be documented and maintained in the individual's pharmacy record.

However, if the pharmacist believes that the ephedrine or pseudoephedrine purchase will be used to illicitly manufacture methamphetamine, the pharmacist may refuse to dispense the ephedrine or pseudoephedrine product to the individual.

SECTION 8. (a) If an individual does not have a relationship on record and intends to purchase a product containing ephedrine or pseudoephedrine, the pharmacist may dispense the product only after making a professional determination that there is a legitimate medical or pharmaceutical need for the product. The pharmacist shall base the decision to dispense on factors

relevant to the individual's medical need or the appropriateness of purchasing the requested product, taking into account the pharmacist's screening of the individual's existing medical conditions and physical symptoms as appropriate for the treatment being considered. The screening may include a review of the individual's medical history, disease history, prescription history, physical symptoms, and relevant vital signs. Screenings performed by the pharmacist may be documented and maintained in the individual's pharmacy record. However, if the pharmacist believes that the ephedrine or pseudoephedrine purchase will be used to illicitly manufacture methamphetamine, the pharmacist may refuse to dispense the ephedrine or pseudoephedrine product to the individual.

(b) A pharmacist or pharmacy technician shall not refuse to dispense a product containing ephedrine or pseudoephedrine solely based on an individual not having a relationship on record.

SECTION 9. (a) The agency shall post on the board's website an application for drug manufacturers to apply for products containing ephedrine or pseudoephedrine to be considered conversion resistant.

(b) The application shall include, and the applicant shall fill out in its entirety, the following information:

(1) The business name of the drug manufacturer, point of contact at the business, and business address.
(2) The exact trade name of the product for which recognition as conversion resistant is sought.
(3) The complete quantitative and qualitative composition of the drug product.
(4) A brief statement of the facts that the applicant believes justify the granting of recognition as conversion resistant under this document.
(5) Certification by the applicant that the product may be lawfully marketed or distributed under the Federal Food, Drug, and Cosmetic Act.
(6) The identification of any information on the application that is considered by the applicant to be a trade secret or confidential and entitled to protection under state or federal laws restricting the public disclosure of such information by the agency and board.
(7) Empirical evidence demonstrating the product containing ephedrine or pseudoephedrine does not pose a significant risk of being used in the illicit manufacture of methamphetamine, including, but not limited, to underwriter laboratory analysis certifying the product can quantitatively yield low levels of ephedrine or pseudoephedrine when extracted or converted from the product.

(c) The board may require the applicant to submit additional documents or written statements of fact relevant to the application that the board deems necessary for determining if the application should be granted.

(d) Upon receiving a completed application, the board shall hear a presentation from the applicant within a reasonable period of time if a presentation is requested by the applicant.

(e) Before the board approves or disapproves an application under this SECTION, the board shall consult with the Indiana state police.

(f) Within a reasonable period of time after the receipt of a completed application and conclusion of an applicant's presentation, if applicable, under this Section, the board shall notify the applicant of approval or nonapproval of the application. If the application is not approved, an explanation shall be provided in writing from the board. The applicant may, however, amend the application to meet the requirements of subsections (b) and (c).

(g) The applicant may appeal the board's ruling, denying the application, through judicial review.

(h) The board may remove a conversion resistant product from the approved list if it is determined by the board that the product has become a significant risk in the illicit manufacture of

methamphetamine. A notice of revocation shall be sent by certified mail to the previously approved applicant, which will be effective upon receipt by such entity. The previously approved applicant receiving the revocation notice shall have the right to an appeal through judicial review.

SECTION 10. (a) A product containing ephedrine or pseudoephedrine shall be determined conversion resistant if an application is approved by the board.

(b) Upon approval of the board to list a product as conversion resistant, the board shall adopt an emergency rule to list the approved product under this document.

(c) Upon approval of the board to list a product as conversion resistant or the removal of a product previously approved, the agency shall notify, on behalf of the board, all licensed pharmacists, pharmacy technicians, and pharmacies and post the list of approved products publicly online.

SECTION 11. (a) Products containing ephedrine or pseudoephedrine shall be determined extraction resistant if the U.S. Attorney General approves an application submitted by a manufacturer of a scheduled listed chemical product, pursuant to 21 U.S.C. 830(e)(3) and 21 CFR 1310.16.

(b) Upon approval of the U.S. Attorney General to exempt a product as extraction resistant, the board shall adopt an emergency rule to list the approved product under this document.

(c) The board shall publicly post a list of all approved, extraction resistant products online.

(d) The board shall remove an extraction resistant product from the approved list if the U.S. Attorney General revokes an exemption pursuant to 21 U.S.C. 830(b).