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Indiana Board of Pharmacy Adopts Interim Rule to Incorporate Updated Standards Adopted by the United States Pharmacopeia

STATEWIDE – The United States Pharmacopeia ("USP") recently announced several new operating standards for pharmacies. Specifically, USP adopted Chapter 795, related to non-sterile drug compounding; Chapter 797, related to sterile drug compounding; Chapter 800, related to responsibilities of personnel handling hazardous drugs; and Chapter 825, related to radiopharmaceuticals. These rules require incorporation into Indiana law before they may be enforced against Indiana pharmacies and pharmacy personnel.

On February 12, 2024, the Indiana Board of Pharmacy (the Board) adopted an interim rule to incorporate USP Chapters 795, 797, 800, and 825. A copy of the Board's draft interim rule is provided below. The interim rule will be filed with an effective date of **January 1, 2025**. Upon this effective date, the Board will begin enforcing compliance with USP Chapters 795, 797, 800, and 825. In the interim, the Board urges pharmacies and pharmacy practitioners to familiarize themselves with the updated standards of USP Chapters 795, 797, 800, and 825, and to comply with those provisions as soon as is practicable to do so.

As established in law, the Board's interim rule will be effective for not more than four hundred twenty-five (425) days after the interim rule is accepted for filing with the publisher of the Indiana Register. During the interim rule's effectiveness, the Board will complete the formal rulemaking process and adopt a final rule to formally adopt these standards within the Board's administrative rules under Title 856 of the Indiana Administrative Code (856 IAC). The Board and the Indiana Professional Licensing Agency (PLA) will provide additional updates concerning these actions as deemed necessary. For questions regarding the interim rule, please contact the Board's staff at PLA at pla4@pla.in.gov. More information regarding USP standards can be found at https://www.usp.org/.

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About the Indiana Professional Licensing Agency (IPLA):

The Indiana Professional Licensing Agency (IPLA) was established by the Indiana General Assembly in 2005, consolidating the Indiana Health Professions Bureau and the former Indiana Professional Licensing Agency into one centralized umbrella agency. The IPLA now issues licenses for forty (40) different professions and over two hundred (200) unique license types. 1 in 6 working Hoosiers are currently licensed by the IPLA. The IPLA supports approximately forty (40) of the State of Indiana's occupational licensing boards, commissions, and committees in administering their duties and business, and also provides inspection services for certain professions and businesses across the state of Indiana. The IPLA partners with several other Indiana state agencies in providing professional licensing services, by managing the State of Indiana's online professional licensing system – the Indiana Licensing Enterprise. The goal of the IPLA is to ensure Hoosiers have access to robust, safe, and reliable professional services by providing licensure to professionals in a fair and efficient manner.

TITLE 856 INDIANA BOARD OF PHARMACY

ARTICLE 1. PHARMACIES AND PHARMACISTS

Rule 20 Violations and Penalties

SECTION 1. A pharmacist licensed to practice pharmacy under IC 25-26-13-1 through 25-26-13-29, or a pharmacist extern or a pharmacist intern licensed under IC 25-26-13-10, as a part of the responsibility, to not knowingly violate the Indiana board of pharmacy's (board's) standards for the competent practice of pharmacy shall not do the following:

(1) Violate the Uniform Indiana Controlled Substances Act found at IC 35-48-1-1 through 35-48-4-14, as amended up to and including January 1, 1983, or any of the rules promulgated by the board under the authority of the Uniform Indiana Controlled Substances Act, which were effective by January 1, 1983, insofar as such violation would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.

(2) Violate the Indiana Legend Drug Act found at IC 16-6-8-1 through 16-6-8-9 [IC 16-6 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.], as amended up to and including January 1, 1983, insofar as such violation would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.

(3) Violate IC 16-1-30-1 through IC 16-1-30-19 [IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.], as amended to and including January 1, 1983, which deal with adulterated and misbranded drugs or devices, or any rules promulgated by the board under the authority of IC 16-1-30-1 through IC 16-1-30-19 [IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.], which were effective as of January 1, 1983, insofar as such violation would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.

(4) Violate 21 U.S.C. 801 through 21 U.S.C. 1191, as amended, up to January 1, 1983, which deal with drug abuse and any of the rules and regulations promulgated under the authority of said Title and Sections as of January 1, 1983, insofar as such violations would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.

(5) Violate the Federal Food, Drug, and Cosmetic Act, which is found at 21 U.S.C. 301 through 21 U.S.C. 392, as amended, up to January 1, 1983, or any rules or regulations promulgated under the authority of the said act as of January 1, 1983, insofar as such violation would pertain to the sale of drugs or devices in Indiana as defined by IC 25-26-13-2.

(6) Violate Executive Proclamations of the President of the United States, which were effective by January 1, 1983, which pertain to the sale of drugs or devices in Indiana as defined by IC 25-26-13-2.

(7) Sell, as defined in IC 25-26-13-2, controlled substances or legend drugs with or without prescription, where such sale or distribution is not in good faith and enables the person to whom the sale is made to supply or divert the controlled substances or legend drugs in an unlawful manner. The sale or distribution of controlled substances or legend drugs in unusually large amounts and within an unusually short period of time to the same individual is considered to be against the public welfare, health and safety and may be determined to be a sale or distribution not in good faith.

(8) Sell, as defined in IC 25-26-13-2, to the public any drugs, biologicals, medicinal substances, or devices when such pharmacist knows such drugs, biologicals, medicinal

substances, or devices to be forgeries or a counterfeit product or beyond the manufacturer's expiration date.
(9) Aid or abet in the practice of a pharmacy a person not having a license to practice as a pharmacist in Indiana.
(10) Practice pharmacy in such a manner as to amount to incompetency or negligence in the sale or dispensation of legend drugs as defined in the Indiana Legend Drug Act under IC 16-6-8-2 [IC 16-6 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.] or controlled substance as defined in the Uniform Controlled Substances Act of 1973, under IC 35-48-1-1.
(11) Violate the act regulating the practice of pharmacy in Indiana, which is codified at IC 25-26-13-1 through IC 25-26-13-29 as amended up to and including January 1, 1983, or any of the rules promulgated by the board under the authority of the said act, which were effective by January 1, 1983.
(12) Practice pharmacy in a manner not incompliance with Sections 795, 797, 800, and 825 of the US Pharmacopeia.