Rep. Laura Faver Dias

Filed: 4/8/2025

AMENDMENT TO HOUSE BILL 2346

AMENDMENT NO. _____. Amend House Bill 2346 by replacing everything after the enacting clause with the following:

"Section 5. The Illinois Drug Reuse Opportunity Program Act is amended by changing Sections 5, 45, and 55 and by adding Section 70 as follows:

(410 ILCS 715/5)

Sec. 5. Definitions. In this Act:

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through V of 21 CFR 1308.

"Department" means the Illinois Department of Public Health.

"Dispense" has the same meaning as defined in Section 3 of the Pharmacy Practice Act.

"Donor" means any person, including an individual member of the public, or any entity legally authorized to possess

medicine, including, but not limited to, a wholesaler or distributor, third party logistic provider, pharmacy, dispenser, clinic, surgical or health center, detention and rehabilitation center, jail, prison laboratory, medical or pharmacy school, prescriber or other health care professional, long-term care facility, or healthcare facility. "Donor" includes government agencies and entities that are federally authorized to possess medicine, including, but not limited to, drug manufacturers, repackagers, relabelers, outsourcing facilities, health care facilities operated by the U.S. Department of Veterans Affairs, and prisons.

"Drug" means a prescription drug, over-the-counter drug, or supplies needed to administer a prescription or over-the-counter drug.

"Eligible patient" means an individual:

(1) with a prescription for the drug, if a prescription is required to dispense the drug, or who reports symptoms treated by the drug if the drug is over-the-counter; and

(2) who is registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements, if the registration is required to dispense the drug.

"Manufacturer" has the same meaning as defined in Section 15 of the Wholesale Drug Distribution Licensing Act.

"Pharmacist" means an individual licensed to engage in the

practice of pharmacy under the Pharmacy Practice Act or licensed to engage in the practice of pharmacy in another state.

"Practitioner" means a person licensed in this State to dispense or administer drugs or who is licensed in another state as a person authorized to dispense or administer drugs.

"Prescription drug" means any prescribed drug that may be legally dispensed by a pharmacy. "Prescription drug" does not include a drug for the treatment of cancer that can only be dispensed to a patient registered with the drug manufacturer in accordance with the federal Food and Drug Administration's requirements.

"Priority patient" means an eligible patient who is an Illinois resident and who is indigent, uninsured, underinsured, or enrolled in a public health benefits program.

"Recipient" means any person or entity legally authorized to possess medicine with a license or permit in the state in which the person or entity is located, including, but not limited to, a wholesaler or distributor, reverse distributor, repackager, hospital, pharmacy, or clinic.

"Returns processor" has the same meaning as defined in paragraph (18) of 21 U.S.C. 360eee. "Returns processor" includes, but is not limited to, a reverse distributor.

"Unopened tamper-evident packaging" has the same meaning as defined in the United States Pharmacopeia (USP) General Chapter 659, Packaging and Storage Requirements, including,

but not limited to, unopened unit-dose, multiple-dose, immediate, secondary, and tertiary packaging.

(Source: P.A. 102-389, eff. 1-1-22.)

(410 ILCS 715/45)

Sec. 45. Recordkeeping requirements. When performing any action associated with a program under this Act or otherwise processing a donated drug for tax, manufacturer, or other credit, a recipient shall be considered to be acting as a returns processor and shall comply with all recordkeeping requirements for nonsalable ~~nonsaleable~~ returns under federal law. Records maintained under this Act may be accessed by the Department upon request.

(Source: P.A. 102-389, eff. 1-1-22.)

(410 ILCS 715/55)

Sec. 55. Retention of records. All records required under this Act shall be retained in physical or electronic format and on or off the recipient's premises for a period of 6 years. Donors or recipients may contract with one another or a third party to create or maintain records on each other's behalf. An identifier, such as a serial number or bar code, may be used in place of any or all information required by a record or label pursuant to this Act if it allows for such information to be readily retrievable. Upon request by a State or federal regulatory agency, the identifier used for requested records

shall be replaced with the original information. An identifier shall not be used on patient labels when dispensing or administering a drug. Records maintained under this Act may be accessed by the Department upon request.

(Source: P.A. 102-389, eff. 1-1-22.)

(410 ILCS 715/70 new)

Sec. 70. Program support provided by the Department.

(a) The Department shall:

(1) develop, maintain, and publish on its website information regarding the names and locations of pharmacies participating in the Illinois Drug Reuse Opportunity Program;

(2) educate pharmacies in the State about the Illinois Drug Reuse Opportunity Program and how to participate in it voluntarily;

(3) develop and publish educational materials to allow program participants and the Department to inform the general public about the purposes and benefits of the program; and

(4) collect information from participants and publish the information in an annual report to the General Assembly by December 31 of each calendar year, beginning December 31, 2026.

(b) Pharmacy participants are required to notify the Department of their participation in any program under this

Act and report any data required in a format established by the Department.".