



## Common Sense Initiative

**Mike DeWine**, Governor  
**Jon Husted**, Lt. Governor

**Joseph Baker**, Director

### MEMORANDUM

**TO:** Kylynne Johnson, State of Ohio Board of Pharmacy

**FROM:** Michael Bender, Business Advocate

**DATE:** March 7, 2023

**RE:** **CSI Review – Drug Repository Program (OAC 4729:5-10-01, 4729:5-10-02, 4729:5-10-03, 4729:5-10-04, 4729:5-10-05, 4729:5-10-06, 4729:5-10-07, and 4729:5-3-09)**

On behalf of Lt. Governor Jon Husted, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Board as provided for in ORC 107.54.

#### Analysis

This rule package consists of two new rules, six amended rules, and two rescinded rules proposed by the State of Ohio Board of Pharmacy (Board). This rule package was submitted to the CSI Office on January 10, 2023, and the public comment period was held open through January 24, 2023. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on January 10, 2023.

Ohio Administrative Code (OAC) 4729:5-10-01 sets forth definitions pertaining to Ohio's drug repository program. The rule is amended to revise the definition of "original sealed and tamper-evident unit dose packaging" and to add definitions for the terms "charitable pharmacy" and "underinsured." OAC 4729:5-10-02 contains eligibility requirements for pharmacies, hospitals, or nonprofit clinics that choose to operate a drug repository program. The rule is amended to add notification requirements and to update the rule title. OAC 4729:5-10-03 describes who is allowed to donate drugs to entities participating in the drug repository program. The rule is amended to clarify language and to allow charitable pharmacies, hospitals, and non-profit clinics to accept drugs from end-users. OAC 4729:5-10-04, originally submitted as an amended rule, is rescinded and replaced by a new rule with the same number to clarify language, add drug storage requirements, prohibit

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certain drugs from being donated, and update the rule title. OAC 4729:5-10-04, the proposed new rule, describes which drugs are eligible for donation to a drug repository program. OAC 4729:5-10-05 establishes who is eligible to receive drugs from a drug repository program. The rule is amended to clarify that individuals residing in Ohio and individuals who are uninsured or underinsured are eligible. OAC 4729:5-10-06 contains form and recordkeeping requirements for drug repository programs. The rule is amended to add clarifying language, update the information that must be included on donor forms, add a requirement for donor and recipient forms to be maintained by the repository program for at least three years, establish documentation requirements for prescribers distributing donated repository program drugs and pharmacies dispensing donated repository program drugs, and update the rule title. OAC 4729:510-07 is rescinded and replaced by a new rule with the same number to allow for occasional sales at wholesale of drugs donated or given to a drug repository program under certain conditions. OAC 4729:5-10-07, the proposed new rule, authorizes pharmacies, hospitals, and nonprofit clinics to charge a handling fee of up to twenty dollars to a recipient of a donated drug in order to cover restocking and dispensing costs. OAC 4729:5-3-09 regulates occasional wholesale sales of commercially manufactured dangerous drugs. The rule is amended to authorize occasional sales by drug repository programs.

During early stakeholder outreach, the Board distributed the rules to representatives of each charitable pharmacy located in Ohio as well as to SIRUM, a national organization that advocates for drug repository programs. Based on feedback provided to the Board, the rules were changed to allow charitable pharmacies to collect samples as part of the repository program, consolidate the recordkeeping and forms rules to avoid duplication, permit donations from entities outside of Ohio and sales between repository programs across state lines, permit repositories to handle all record generation to avoid burden on the donor, make the eligibility requirements as broad as possible to maximize the number of patients served, simplify the patient confidentiality provisions by making it the responsibility of the repository program to remove all confidential patient information prior to dispensing/personally furnishing, and clarify that donated drugs may be comingled with stock after they have been inspected and approved in accordance with the rule. During the CSI public comment period, the Board received comments from individuals associated with Cincinnati Children's Hospital Medical Center (Cincinnati Children's), the Board, Beacon Charitable Pharmacy (Beacon), Charitable Healthcare Network (CHN), SIRUM, the Cleveland Clinic, and The Ohio State University, James Cancer Hospital and Solove Research Institute (The James). Comments focused on issues such as orally administered cancer drugs, the expiration date of donated drugs, the facilitation of donated drugs, billing donated drugs to patient insurance, drug safety, donor forms, donations from patients in institutional facilities, the donation of drugs in their original, sealed containers, charitable pharmacies, transfer within health systems, and verifying individuals donating drugs on another's behalf.

The commenters from Cincinnati Children's and The James advocated for the removal of language

that appeared to prohibit orally administered cancer drugs from being donated to a program and which seemed to contradict other language allowing for the donation of such drugs. The Board agreed and struck this language from the rules, further revising the rules to improve clarity. The employee of the Board that submitted comments offered suggestions which were accepted by the Board to make clarifications regarding the expiration date of donated drugs and the name of an entity that owns drugs that must be included on the donor form. The Board did not incorporate suggestions from the employee regarding the facilitation of donated drugs, persons participating in non-profit outpatient programs wishing to donate unused drugs, and not billing donated drugs to patient insurance. The individual from Beacon asked for clarification on what compounding medications could be accepted as orally administered cancer drugs. The Board pointed to the definition of “orally administered cancer drug” provided in the rules and stated that drugs could be accepted as long as programs make the rational connection to the treatment of cancer. The Beacon commenter also asked how a program should treat the arrival of insulin that is dropped off at room temperature. The Board replied that it is up to the repository to review the drug for safety and efficacy.

SIRUM and the individual from Beacon requested more flexibility with respect to the donor form that must be completed. The Board updated the rules to allow repositories to utilize electronic or physical forms, noting that the rules as proposed already authorized repositories to use their own forms. SIRUM suggested removing a requirement to have institutional facilities donate drugs. The Board assured that this was permissive, not a requirement. SIRUM and CHN both requested clarifications to ensure that drugs in their original, sealed containers could be donated. The Board incorporated this suggestion into the rules. The Cleveland Clinic asked the Board to remove references to “charitable” pharmacies with respect to transfers. The Board replied that the authorization provided in law only applied to charitable pharmacies, hospitals, and nonprofit clinics. The Cleveland Clinic also asked the Board to remove the requirement to record the address when drugs are transferred within the same health system. The Board revised the rules to allow hospitals to use a preexisting recordkeeping process in lieu of the recordkeeping requirements in the rules. Lastly, the commenter from The James asked how charitable pharmacies would verify that an individual is the executor, administrator, or trustee of the estate of a deceased patient. The Board responded by revising the rules to require that the donor attest that any executor, administrator, or trustee would be acting on their behalf.

The business community impacted by the rules includes pharmacies, hospitals, and non-profit clinics that opt to participate in drug repository programs. The adverse impacts created by the rules include notification requirements, restrictions on drugs that can be donated and accepted, drug storage requirements, form requirements, and administrative discipline for a terminal distributor of dangerous drugs that violates the rules, which may include reprimand, suspension or revocation of a license, and/or a monetary fine. The Board notes that operation of a drug repository program is optional. The Board states that the adverse impacts to business are justified to protect and promote

public safety by ensuring uniform standards for the operation of drug repositories.

### **Recommendations**

Based on the information above, the CSI Office has no recommendations on this rule package.

### **Conclusion**

The CSI Office concludes that the Board should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.