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Final Analysis

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Primary Sponsors: Reps. Roemer and Jordan

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SUMMARY

Drug repository program

- Revises the State Board of Pharmacy's Drug Repository Program, including by allowing charitable pharmacies, hospitals, and nonprofit clinics to accept or distribute donated drugs that are not in their original sealed and tamper-evident unit dose packaging.
- Excludes from the program any drug for which the federal Food and Drug Administration, as a risk evaluation and mitigation strategy, requires that the patient be registered with the drug's manufacturer.
- Authorizes participating charitable pharmacies, hospitals, and nonprofit clinics to make occasional sales of donated drugs at wholesale.
- Exempts participating charitable pharmacies from the licensure and renewal fees that otherwise must be paid to operate as a pharmacy.
- Extends the authority to distribute drugs under the program to licensed health professionals authorized to prescribe drugs.
- Eliminates the requirement that the Board consult with the Director of Health when adopting rules.

Adding drug delivery devices to prescriptions

- Authorizes a pharmacist to modify a drug's prescription to also include a drug delivery device if the pharmacist considers the device necessary for administering the drug.
- Specifies that the modified prescription is a valid prescription for the device for purposes of reimbursement under a health benefit plan.

Access to overdose reversal drugs

- Generally expands access to overdose reversal drugs, such as naloxone, including by authorizing access for all persons and government entities to purchase, possess,

distribute, dispense, personally furnish, sell, or otherwise obtain or provide an overdose reversal drug and any instrument or device to administer it.

- Consolidates, but largely maintains, other more specific overdose reversal drug provisions, including those related to maintaining supplies, the authority of various health care providers, and immunities from liability.
- Permits physician assistants and advanced practice registered nurses to authorize a pharmacist or pharmacy intern to dispense overdose reversal drugs without a prescription pursuant to a protocol.
- Expressly authorizes an individual, when not otherwise authorized to administer drugs under Ohio law, to administer an overdose reversal drug if the individual is in a position to assist another who is apparently experiencing an opioid-related overdose.

Pediatric transition care programs

- Eliminates licensure for pediatric respite care programs that provide only pediatric transition care, and instead requires registration for those programs.
- Defines "pediatric transition care program" as a program that arranges for health care and related services, including skilled nursing care, in a private home setting for up to 15 children who have been diagnosed with life-threatening diseases and conditions.
- Requires the Director of Health to adopt rules relating to the registration of pediatric transition care programs, including establishing fees for initial registration, registration renewal, and inspections.

Awareness designations

- Designates the fourth Wednesday of February as "Hypertrophic Cardiomyopathy Awareness Day."
- Designates March as "Bleeding Disorders Awareness Month."

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DETAILED ANALYSIS

DRUG REPOSITORY PROGRAM

The act modifies the laws governing the State Board of Pharmacy's Drug Repository Program, a program for the collection and redistribution of drugs donated or given by pharmacies, drug manufacturers, health care facilities, and others to Ohio residents who meet eligibility standards established by the Board in rules.[1]

[1] R.C. 3715.87 to 3715.873.

Charitable pharmacies, hospitals, and nonprofit clinics

Accepting and distributing donations of unsealed drugs

Generally, the Drug Repository Program continues to be limited to drugs that are in their original sealed and tamper-evident unit dose packaging. The act, however, authorizes drugs that do not meet this packaging standard to be accepted and distributed if done so by a charitable pharmacy, hospital, or nonprofit clinic. This authority is subject to rules that are to be adopted by the Board. The act continues to exclude controlled substances.

The act specifies that the authority being granted to a charitable pharmacy, hospital, or nonprofit clinic extends to both (1) orally administered cancer drugs and (2) drugs that may require storage at a special temperature. For other participating pharmacies, the act retains a limitation that permits unsealed drugs to be accepted and distributed only if they are orally administered cancer drugs that do not require refrigeration, freezing, or storage at a special temperature.[2]

Occasional sales of donated drugs at wholesale

The act authorizes charitable pharmacies, hospitals, and nonprofit clinics to make occasional sales of donated drugs at wholesale. This acts as an exemption to the general prohibition against reselling drugs that are donated or given to the Drug Repository Program.[3]

Definitions regarding eligible distributors

In identifying the entities being granted the authority described above, the act does the following:

- Defines "charitable pharmacy" as a pharmacy that holds a terminal distributor license issued by the Board, is not a hospital, and is exempt from federal taxation.[4]
- Expands the definition of "nonprofit clinic" by including those that provide health care services to underinsured persons, as defined in Board rules, in addition to serving indigent and uninsured persons as specified in continuing law.[5]

Exclusion of REMS drugs

The act excludes from the Drug Repository Program any drug that the Board has determined, by rule, to be subject to federal safety requirements known as "REMS." Such a drug is one for which the federal Food and Drug Administration (FDA) requires the patient, as a risk evaluation and mitigation strategy (REMS), to be registered with the drug's manufacturer.[6]

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[2] R.C. 3715.87.

[3] R.C. 3715.871 and 3715.873.

[4] R.C. 3715.87(A); see also R.C. 3719.811, not in the act.

[5] R.C. 3715.87.

[6] R.C. 3715.87(C)(2)(b) and 3715.873(J).

As described by the FDA, REMS is a drug safety program for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.[7]

Distribution by prescribers

The act authorizes a drug to be distributed under the Drug Repository Program to an eligible individual through a licensed health professional authorized to prescribe drugs, often referred to as a prescriber. This form of prescriber-based distribution, known as "personally furnishing" a drug, is in addition to distribution by being dispensed by a pharmacist pursuant to a prescription, as permitted under law maintained by the act. The act expressly includes personally furnishing drugs as one of the activities covered by the program's immunity from civil liability.[8]

Facilitating donations

The act permits any person or government entity to facilitate the continuing authority of others to make a donation or gift of drugs to the Drug Repository Program. Accordingly, the program's immunities from civil liability and criminal prosecution are extended to these facilitators.[9]

Rules on ineligible drugs and use of donation forms

The act eliminates provisions that required the Board to adopt rules establishing separate lists of drugs that the Drug Repository Program can and cannot accept as donations, with distinctions based on whether the donor is an individual or a health care facility. In place of separate lists, the act requires rules to be adopted establishing a single list that addresses only the drugs or drug types ineligible for donation, with no distinctions based on the type of donor.

The act retains the Board's duty to adopt rules establishing a form that must be signed when a donation is made to the program, but it requires recognition of others who may sign the form. This is accomplished by referring not only to an individual who is donating, but also an individual who represents the person or government entity that is donating. As before, the form is used to acknowledge ownership of the drugs being donated and the intention to voluntarily donate them.[10]

Handling fees

A pharmacy or other distributor participating in the Drug Repository Program is permitted to charge individuals receiving donated drugs a handling fee to cover restocking and

[7] Risk Evaluation and Mitigation Strategies, available through the FDA's website: fda.gov.

[8] R.C. 3705.871 and 3715.872.

[9] R.C. 3715.871 and 3715.873.

[10] R.C. 3715.873. See also Ohio Administrative Code (O.A.C.) 4729:5-10-06(A)(2).

distribution costs, with the fee to be set by the Board according to a formula established in rules. The act specifies that the fee is to be nominal.[11]

Consultation with the Director of Health

The act eliminates the requirement that the Board of Pharmacy consult with the Director of Health when adopting rules governing the Drug Repository Program. In a corresponding change, it removes the Director from the program's immunity from civil liability provisions.[12]

Fee exemption for charitable pharmacies

The act exempts a charitable pharmacy participating in the Drug Repository Program from paying fees for its license from the Board to operate as a terminal distributor of dangerous drugs. The exemption applies to both the initial license fee and the biennial renewal fee.[13]

DRUG DELIVERY DEVICES ON PRESCRIPTIONS

Pharmacist authority to add

The act authorizes a pharmacist to modify a drug's prescription to also include a drug delivery device, if the pharmacist determines that the device is necessary for the drug's administration. The Pharmacy Board may adopt rules to implement this authorization. The rules must be adopted in accordance with the Administrative Procedure Act.[14]

For purposes of reimbursement under the terms of a health benefit plan by a health care insurer, government health care program, pharmacy benefit manager, or other entity that offers health benefit plans, the act states that a prescription modified to include a drug delivery device is to be deemed a valid prescription for the device.[15]

ACCESS TO OPIOID OVERDOSE REVERSAL DRUGS

The act consolidates and revises the laws governing access to overdose reversal drugs, which include naloxone.[16] Naloxone is a federally approved medication that can rapidly reverse

[11] R.C. 3715.871 and 3715.873.

[12] R.C. 3715.872 and 3715.873.

[13] R.C. 4729.54(G) and (I). See also O.A.C. 4729:5-2-02(B).

[14] R.C. 4729.391(A) and (B).

[15] R.C. 4729.391(C).

[16] R.C. 3715.50, 3715.501, 3715.502, 3715.503, and 3715.504; conforming changes in R.C. 149.43, 4729.01, 4729.16, 4729.28, 4729.29, 4729.51, 4729.541, 4729.60, and 4765.44 (renumbered as 3715.505).

opioid overdose and is generally considered to be safe for laypersons to administer in emergency situations.[17]

General access

While the act largely maintains a number of Ohio's more specific laws on access to overdose reversal drugs, it expands access by establishing a more generalized authority for any person or government to engage in a series of activities related to the drugs. The act describes these activities as the authority to purchase, possess, distribute, dispense, personally furnish, sell, or otherwise obtain or provide an overdose reversal drug and any instrument or device to administer it. For a person or government entity to exercise this authority, the drug must:[18]

1. Be in its original manufacturer's packaging;
2. Have packaging that contains the manufacturer's instructions for use;
3. Be stored in accordance with the manufacturer's or distributor's instructions.

The act specifies that its general access provisions do not affect any other authority to issue a prescription for, or personally furnish a supply of, overdose reversal drugs.[19]

Emergency supplies and automated distribution

In addition to its general access provisions, the act authorizes any person or government entity to obtain and maintain a supply of overdose reversal drugs for use in emergency situations and for distribution through an automated mechanism.[20] Prior law had similar provisions, but they applied to only two groups: (1) terminal distributors of dangerous drugs, for both emergency use and automated distribution,[21] and (2) service entities, for emergency use and personally furnishing supplies under prescriber-based protocol (discussed below). Service entities were described as public and private entities that provide services to or interact with individuals who there is reason to believe may be at risk of overdosing on opioids. Examples included churches, schools, libraries, health departments, courts, prisons, and homeless shelters.[22]

Similar to prior law that applied to terminal distributors (but did not apply to service entities), a person or government entity that maintains a supply of overdose reversal drugs for use in emergencies as authorized by the act must:[23]

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[17] See R.C. 4729.01(CC) and Naloxone Drug Facts, available by searching "naloxone" on the National Institute on Drug Abuse's website: nida.nih.gov.

[18] R.C. 3715.50(B).

[19] R.C. 3715.50(E)(1).

[20] R.C. 3715.50(C).

[21] R.C. 4729.515, repealed.

[22] R.C. 4729.514, repealed.

[23] R.C. 3715.50(C)(1).

- Provide to individuals who access the drugs instructions on emergency administration, including an instruction to summon emergency services as necessary;
- Establish a process to replace accessed drugs within a reasonable time period;
- Store the drugs in accordance with manufacturer or distributor instructions.

Similar to rules adopted prior to the act for terminal distributors using automated mechanisms for distribution,[24] a person or government entity that maintains a supply of overdose reversal drugs for automated distribution under the act must:[25]

- Ensure that the mechanism is securely fastened to a permanent structure or is of a size and weight to reasonably prevent it from being removed from its intended location;
- Provide emergency administration instructions, including an instruction to summon emergency services as necessary;
- Develop a process for monitoring and replenishing the supply;
- Store the drugs in accordance with the manufacturer or distributor instructions.

Exemption from licensure as a terminal distributor

Related to its general access provisions, the act exempts all persons and government entities that possess overdose reversal drugs, including those that use automated mechanisms, from the requirement to be licensed as a terminal distributor of dangerous drugs. The act also expressly exempts an individual from the licensure requirement in order to possess overdose reversal drugs for use in personally furnishing supplies under a prescriber-based protocol. Prior to the act, licensure exemptions for possessing the drugs applied only to: (1) law enforcement agencies and its officers and (2) service entities.[26]

Immunity

The act provides various immunities related to the general access and supply authorizations discussed above. The immunities are similar to those that existed prior to the act. Specifically, a person or government entity that exercises the authority granted by the act is not subject to administrative action or criminal prosecution, and is not liable for civil damages arising from exercising that authority.[27] Additionally, after an overdose reversal drug has been dispensed or personally furnished, the person or government entity is not liable for or subject to civil damages, criminal prosecution, or professional disciplinary action.[28]

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[24] O.A.C. 4729:5-3-19.

[25] R.C. 3715.50(C)(2).

[26] R.C. 4729.541(A)(11) and (12).

[27] R.C. 3715.50(D)(1); see also R.C. 2925.61, repealed.

[28] R.C. 3715.50(D)(2).

The act specifies that it does not eliminate, limit, or reduce any other immunity or defense that a person or government entity may have under the laws governing the general immunity of public officers and employees,[29] political subdivision tort liability,[30] and emergency medical personnel immunity[31] or under any other Ohio statute or common law.[32]

Issuing prescriptions and personally furnishing supplies

The act generally maintains the preexisting law that authorizes physicians, physician assistants, and advanced practice registered nurses to issue prescriptions for overdose reversal drugs and personally furnish supplies of those drugs without having examined the individual to whom it may be administered.[33] The practitioner must provide instructions regarding the emergency administration, including a specific instruction to summon emergency services as necessary.

The act specifies that if a prescription for an overdose reversal drug does not include the name of the individual to whom the drug may be administered, a pharmacist or pharmacy intern may dispense the drug to the individual who received the prescription. Prior law similarly authorized such prescriptions to be filled, but did so by including them within the definition of "prescription" under the laws governing the practice pharmacy.[34]

The act provides immunity from civil damages, criminal prosecution, and professional disciplinary action for practitioners who prescribe, personally furnish, or dispense in accordance with the authority described above. For prescribers, these immunities are generally unchanged from prior law. For pharmacists and pharmacy interns, the immunities are new.[35]

Protocols for pharmacist dispensing

The act modifies the prescribers who may authorize a pharmacist or pharmacy intern to dispense overdose reversal drugs without a prescription pursuant to a protocol. In addition to continuing the authority of physicians to establish these protocols, the act permits physician assistants and advanced practice registered nurses to do so.[36] The act otherwise maintains preexisting law regarding the details of dispensing pursuant to a protocol, such as who may receive the drugs, emergency instructions, and immunity provisions.[37]

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[29] R.C. 9.86, not in the act.

[30] R.C. Chapter 2744, not in the act.

[31] R.C. 4765.49, not in the act.

[32] R.C. 3715.50(E)(2).

[33] R.C. 3715.501(A)(1); see also R.C. 4723.484, 4730.434, and 4731.94, all repealed.

[34] R.C. 3715.501(A)(2) and 4729.01(H)(2).

[35] R.C. 3715.501(B).

[36] R.C. 3715.502(A); see R.C. 4731.942, repealed.

[37] R.C. 3715.502 (renumbered from R.C. 4729.44).

Protocols for others to personally furnish supplies

In addition to the protocol authority for pharmacist dispensing, the act continues to authorize physicians, physician assistants, and advanced practice registered nurses to establish protocols authorizing any individual to personally furnish a supply of overdose reversal drugs to another individual pursuant to a protocol. As before, the person furnishing the supply of drugs need not examine the individual to whom the drugs may be administered.[38]

The act eliminates requirements for the protocol to include a description of the clinical pharmacology of the overdose reversal drug and precautions and contraindications concerning furnishing it. Otherwise, it retains requirements for the protocol to address any limitations concerning who may receive the supplies; the dosage that may be furnished and any variation based on circumstances; labeling, storage, recordkeeping, and administrative requirements; training requirements; and instructions to be given to those receiving the drug supplies.[39]

The act maintains provisions granting immunity from civil damages, criminal prosecution, and professional disciplinary action to physicians, physician assistants, and advanced practice registered nurses who in good faith authorize the drugs to be personally furnished under the protocols. The immunities also continue to apply to individuals who in good faith furnish the drugs under the protocols.[40]

Administering overdose reversal drugs

The act expressly authorizes an individual, when not otherwise authorized by statute to administer drugs, to administer an overdose reversal drug if the individual is in a position to assist another who is apparently experiencing an opioid-related overdose.[41] While prior law did not directly establish this general authority, it did grant individuals immunity from civil and criminal liability when the drugs were obtained and administered in good faith.[42] The act maintains similar immunity, with the addition of immunity from administrative action. Specifically, under the act, an individual who administers an overdose reversal drug is not liable for damages in a civil action, or subject to administrative action or criminal prosecution, so long as the individual, acting in good faith, (1) obtains the drug in a manner authorized by the act, (2) administers it to an individual who is apparently experiencing an opioid-related overdose, and (3) attempts to summon emergency services as soon as practicable, unless emergency services have already been summoned or are present.[43]

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[38] R.C. 3715.503(A).

[39] R.C. 3715.503(B); see also R.C. 4723.485 and 4731.941, all repealed.

[40] R.C. 3715.503(C).

[41] R.C. 3715.504(A).

[42] R.C. 2925.61, repealed.

[43] R.C. 3715.504(B).

As part of establishing the general authority of individuals to administer overdose reversal drugs, the act eliminates laws that were more limited in nature. Under those laws, certain prescribers could authorize individuals to administer the drugs, through a protocol, if the individuals were associated with services entities (described above).[44]

Boards of health

The act eliminates provisions expressly authorizing boards of health to be involved in providing access to overdose reversal drugs, but in the context of the act's other changes, the elimination may have no practical effect. Under prior law, a board of health could (1) authorize pharmacists and pharmacy interns to dispense the drugs without a prescription, (2) authorize individuals to personally furnish supplies of the drugs, and (3) authorize individuals associated with service entities to administer the drugs. However, for a board of health to authorize any of these activities, a protocol had to be established through a physician serving as the board's health commissioner or medical director.[45] Since the act continues to permit protocols to be established by physicians as well as other prescribers, and the act also establishes a more generalized access to overdose reversal drugs, access to the drugs through a board of health may continue to be available.

Rules reflecting terminology change

H.B. 193 of the 134th General Assembly replaced Revised Code references to "naloxone" with "overdose reversal drug." Related to that change, the act exempts state agencies and boards from review by the Common Sense Initiative Office when amending any rule solely to reflect the alternate terminology and the drugs in addition to naloxone that it involves.[46]

PEDIATRIC TRANSITION CARE PROGRAMS

Separation from pediatric respite care programs

The act carves out a type of program that, prior to the act, was licensed as a pediatric respite care program, and instead requires registration for those programs, which are named "pediatric transition care programs" under the act.[47] As defined by the act,[48] a pediatric transition care program is a program operated by a person or public agency that arranges for the provision of health care and related services in a private home setting only to pediatric transition care patients, who are not related by birth or adoption to the person that arranges for the care and services, in order to meet the physical, psychological, social, spiritual, and other special needs of children who have been diagnosed with life-threatening diseases and

[44] R.C. 4723.486, 4730.436, and 4731.943, all repealed.

[45] R.C. 3707.56, 3707.561, and 3707.562, all repealed.

[46] Section 4. In this section, the act mistakenly refers to the 132nd General Assembly.

[47] R.C. 3712.01, 3712.031, 3712.032, 3712.042, 3712.061, and 3712.063; conforming changes in R.C. 2317.54, 3721.01, 3722.02, 4752.02, and 5123.19.

[48] R.C. 3712.01(K).

conditions. The act continues provisions specifying that a patient must have received the qualifying diagnosis before age 18, but may be served until age 27.[49]

Services and number of patients

The services a pediatric transition care program may provide to patients include:

1. Inpatient care and procedures;
2. Skilled nursing care;
3. Nursing care by or under the supervision of a registered nurse;
4. Physician's services;
5. Medical supplies, including drugs and biologicals, and the use of medical appliances.

Additionally, a pediatric transition care program may provide counseling, education, and visitation to patients' parents to promote reunification.

Under the act, a pediatric transition care program may provide services to not more than 15 patients at any one time.[50] This 15-patient limit is an increase over the previous 10-patient limit that applied when the services were regulated through licensure of pediatric respite care programs.[51] Similar to the previous licensure system, the act permits the Director of Health to approve additional patients for a registered pediatric transition care program.

Registration procedures

The act requires the Director to adopt rules providing for the registration of pediatric transition care programs, as well as rules related to suspending and revoking registrations. The rules must establish fees for initial registration and renewal, which generally cannot exceed $600 for each three-year registration period, unless the Controlling Board approves a higher fee.[52]

A person or public agency that wishes to provide a pediatric transition care program must register with the Department of Health, using forms prescribed by the Department. A registration is valid for three years and may be renewed. In accordance with the Administrative Procedure Act, the Department may suspend or revoke a registration if the registration holder made any material misrepresentation related to the registration or no longer meets the requirements specified by the act and the rules adopted by the Director.[53]

[49] R.C. 3712.01(M).

[50] R.C. 3712.063(F).

[51] R.C. 3712.061(A)(7).

[52] R.C. 3712.032(A) and (B).

[53] R.C. 3712.042.

Department of Health duties

The act requires the Department to do all of the following:[54]

1. Grant, suspend, and revoke registrations for pediatric transition care programs in accordance with the act's provisions and rules the Director adopts;
2. Make any inspections necessary to determine whether pediatric transition care program homes and services meet the requirements of the act and rules adopted under it;
3. Implement and enforce the pediatric transition care program provisions of the act and rules adopted under it.

Operating requirements

The following apply with respect to how a registered pediatric transition care program is to be operated:[55]

- The program must ensure that its medical care components are under the direction of a physician;
- When a program arranges for a home health agency to furnish one or more program components to a patient, the care must be provided by the agency pursuant to a written contract that includes conditions involving maintenance of the patient's medical record and conformance with the patient's established plan of care and physician orders;
- Care commensurate with a patient's needs must be available 24 hours a day, seven days a week;
- In the home, the program must maintain central clinical records on all patients;
- Also in the home, the program must maintain birth certificates, certified guardianship letters of authority, or other documentation related to health care decision-making, as applicable, for any patient who receives care for longer than 30 days, unless, on written request by the program, this requirement is waived by the Director.

Other rules

The act also requires the Director to adopt rules to:[56]

- Establish an inspection fee, which cannot exceed $1,750, unless the Controlling Board approves a higher fee;
- Establish emergency and safety requirements;

[54] R.C. 3712.032(C).

[55] R.C. 3712.063.

[56] R.C. 3712.032(A) and (B).

- Provide a method of registration for pediatric transition care programs that are accredited or certified by an organization that the Director determines has standards that are equal to or exceed those set forth in the act.

All of the rules governing pediatric transition care programs must be adopted in accordance with the Administrative Procedure Act. The rules are exempt from the law that limits regulatory restrictions adopted by certain agencies.[57]

AWARENESS DESIGNATIONS

Hypertrophic cardiomyopathy

The act designates the fourth Wednesday of February as "Hypertrophic Cardiomyopathy Awareness Day."[58]

Bleeding disorders

The act designates the month of March as "Bleeding Disorders Awareness Month."[59]

HISTORY

Action	Date
Introduced	02-01-22
Reported, H. Health	03-30-22
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[57] R.C. 3712.032(A) and (D); see also R.C. 121.95 to 121.953, not in the act.

[58] R.C. 5.2532.

[59] R.C. 5.2533.