OHIO LEGISLATIVE SERVICE COMMISSION

www.lsc.ohio.gov

Office of Research and Drafting

Legislative Budget Office

H.B. 558*
134th General Assembly

Bill Analysis

Click here for H.B. 558's Fiscal Note

Version: As Reported by Senate Health

Primary Sponsors: Reps. Roemer and Jordan

Audra Tidball, Attorney

SUMMARY

Drug repository program

- Revises the laws governing the State Board of Pharmacy's Drug Repository Program, including by exempting charitable pharmacies, hospitals, and nonprofit clinics from current law's general prohibition on accepting or distributing drugs 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 requires, as a risk evaluation and mitigation strategy, that the patient be registered with the drug's manufacturer.
- Exempts charitable pharmacies, hospitals, and nonprofit clinics from the existing law prohibition on reselling drugs donated to the program, by authorizing those entities to make occasional sales of donated drugs at wholesale.
- Exempts charitable pharmacies participating in the program 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.
- Makes other changes to the program's laws, including several conforming changes.

* This analysis was prepared before the report of the Senate Health Committee appeared in the Senate Journal. Note that the legislative history may be incomplete.

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 determines that the device is necessary for the drug's administration.
- Deems a prescription modified to include a drug delivery device a valid prescription for that device for purposes of reimbursement by any of the following: a health care insurer, government health care program, pharmacy benefit manager, or other entity offering health benefit plans.

Access to overdose reversal drugs

- Generally expands existing authority regarding 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 in current law, including those related to maintaining supplies, the authority of various health care providers, and immunities from liability.
- Authorizes 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 the month of March as "Bleeding Disorders Awareness Month."

TABLE OF CONTENTS

DETAILED ANALYSIS

Drug repository program

The bill 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]

Charitable pharmacies, hospitals, and nonprofit clinics

Two of the bill's substantive changes relate to charitable pharmacies, hospitals, and nonprofit clinics participating in the Drug Repository Program. Each is described briefly below.

Original sealed and tamper-evident unit dose packaging

In general under current law, only drugs in their original sealed and tamper-evident unit dose packaging may be accepted and distributed under the Drug Repository Program. The bill, however, authorizes drugs that are not in their original sealed and tamper-evident unit dose packaging 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 of Pharmacy. The existing law exclusion of controlled substances is retained.

The bill 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 bill retains a provision that permits drugs not in their original sealed and tamper-evident unit dose packaging 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 bill establishes an exemption to the current law prohibition on reselling drugs that are donated or given to the Drug Repository Program, by authorizing – in Board rules – charitable pharmacies, hospitals, and nonprofit clinics to make occasional sales of donated drugs at wholesale.[3]

Definitions

Under the bill, "**charitable pharmacy**" is defined as a pharmacy that meets all of the following requirements:

- Holds a terminal distributor license issued by the Board of Pharmacy;
- Is exempt from federal taxation;
- Is not a hospital.[4]

The bill expands the definition of "**nonprofit clinic**" to include those that provide health care services to underinsured persons, as defined in Board rules. At present, for purposes of the

[1] R.C. 3715.87 to 3715.873.

[2] R.C. 3715.871.

[3] R.C. 3715.871 and 3715.873.

[4] R.C. 3715.87 and 3719.811, not in the bill.

Drug Repository Program, a nonprofit clinic is one that provides health care services only to indigent and uninsured persons.[5]

Drugs under certain risk evaluation and mitigation strategies

The bill excludes from the Drug Repository Program a drug, as determined in accordance with Board of Pharmacy rules, for which the federal Food and Drug Administration (FDA) requires, as a risk evaluation and mitigation strategy, or REMS, that the patient be registered with the drug's manufacturer.[6] A 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

Under existing law, when an entity participating in the Drug Repository Program distributes a drug to an eligible individual, the distribution must be pursuant to a prescription. The bill clarifies this provision by referring to a pharmacist as the health professional who performs the action of dispensing a drug. In addition, the provision is broadened by authorizing a drug to be distributed by being personally furnished by a licensed health professional authorized to prescribe, often referred to as a prescriber.[8] The bill makes a conforming change to include prescribers in the immunity from civil liability provisions that currently apply under the program.[9]

Facilitating the donation or gift of drugs

At present, any pharmacy, drug manufacturer, health care facility, or other person or government entity may donate or give prescription drugs to the Drug Repository Program. The bill maintains this authority, but also permits any person or government entity to facilitate the donation or gift of drugs. The bill neither defines nor describes the act of facilitating a donation or gift.[10]

Rules on eligible drugs and forms for making donations

Existing law requires the Board of Pharmacy to adopt rules governing the program, including rules that establish lists of drugs that the program can and cannot accept. Separate lists must be established regarding drugs that may be donated by individuals and drugs that may be donated by health care facilities. Rather than requiring separate lists outlining the drugs

[5] R.C. 3715.87.

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

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

[8] R.C. 3715.871.

[9] R.C. 3715.872.

[10] R.C. 3715.871.

that can and cannot be accepted, with distinctions based on the type of donor, the bill instead requires just one: a list of the drugs or drug types ineligible for donation.

Current law also directs the Board to establish in rule a form that must be signed when a donation is made to the program directly by an individual. Under the bill, the Board also must establish a form to be signed by an individual who represents a person or government entity that is donating drugs to the program. The form must allow for the individual representative to state that the person or entity being represented is the drugs' owner and intends to voluntarily donate them to the program.[11]

Handling fees

Current law authorizes an entity participating in the Drug Repository Program to charge individuals receiving donated or given drugs a handling fee, with the fee to be set by the Board of Pharmacy according to a formula established in rules. Under existing Board rules, a participating entity may charge a handling fee up to $20.[12] The bill maintains a provision specifying that the handling fee is to cover restocking and distribution costs, but also specifies that the fee is to be nominal.[13]

Consultation with the Director of Health

The bill 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, the bill removes the Director from the current law provisions describing the persons and entities that receive immunity from civil liability under the program.[14]

Fee exemption for participating charitable pharmacies

Current law requires a pharmacy, including a charitable pharmacy, to hold a terminal distributor license issued by the Board of Pharmacy in order to operate in the state.[15] As part of the process of applying for an initial license and later renewing that license every two years, the pharmacy must submit to the Board a licensure or renewal fee, which may range from $320 to $440 depending on the type of terminal distributor license the pharmacy holds.[16] The bill

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

[12] O.A.C. 4729:5-10-07(G).

[13] R.C. 3715.871 and 3715.873.

[14] R.C. 3715.872 and 3715.873.

[15] R.C. 4729.54.

[16] At present, a pharmacy may hold a category II, limited category II, category III, or limited category III terminal distributor license. Under a category III license, a pharmacy may possess and distribute drugs, including schedule I, II, III, IV, and V controlled substances, while a category II license authorizes a pharmacy to possess and distribute drugs other than controlled substances. Under a limited category II or III license, a pharmacy may possess and dispense only the drugs listed in the application for licensure. *See* R.C. 4729.54(E).

exempts a charitable pharmacy participating in the Drug Repository Program from the requirement to pay such fees.[17]

Adding drug delivery devices to prescriptions

The bill 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.[18] The Pharmacy Board may adopt rules to implement this authorization. The rules must be adopted in accordance with the Administrative Procedure Act.[19]

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 bill states that a prescription modified as described in the bill is to be deemed a valid prescription for the drug delivery device.[20]

Access to overdose reversal drugs

Existing Ohio law contains numerous provisions related to accessing overdose reversal drugs, such as naloxone. Naloxone is a federally approved medication that can rapidly reverse opioid overdose. It is generally considered to be safe for laypersons to administer in emergency situations.[21] Existing laws addressing overdose reversal drugs are located throughout the Revised Code as they relate to law enforcement and criminal immunities (Chapter 2925), boards of health (Chapter 3707), and various licensed health care professionals (Chapters 4723 (advanced practice registered nurses), 4729 (pharmacists and pharmacy interns), 4730 (physician assistants), and 4731 (physicians)). As discussed below, the bill expands access to overdose reversal drugs, and also consolidates much of the existing law by moving it to Ohio's Pure Food and Drug Law (Chapter 3715).[22]

General access

While the bill largely maintains several of Ohio's more specific overdose reversal drug access laws (discussed in greater detail below), it expands access by establishing a more general, broadly applicable access. Specifically, the bill authorizes persons and government entities to purchase, possess, distribute, dispense, personally furnish, sell, or otherwise obtain

---

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

[18] R.C. 4729.391(A).

[19] R.C. 4729.391(B).

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

[21] Naloxone Drug Facts, available by searching "naloxone" on the National Institute of Drug Abuse's website: nida.nih.gov.

[22] R.C. 3715.50 through 3715.505; R.C. 2925.61, 3707.56 through 3707.562, 4723.484 through 4723.486, 4729.514, 4729.515, 4730.434 through 4730.436, and 4731.94 through 4731.943, all repealed; conforming changes in R.C. 149.43, 4729.01, 4729.16, 4729.28, 4729.29, 4729.51, 4729.541, and 4729.60; R.C. 4765.44 renumbered to R.C. 3715.505.

or provide an overdose reversal drug and any instrument or device to administer it, if the following conditions are met:[23]

1. The drug is in its original manufacturer's packaging;
2. Its packaging contains the manufacturer's instructions for use;
3. It is stored in accordance with the manufacturer's or distributor's instructions.

The bill's expanded access provisions do not affect other existing authority to issue a prescription for, or personally furnish a supply of, overdose reversal drugs.[24]

Emergency supplies and automated distribution

In addition to the general access provision, the bill authorizes persons and government entities to obtain and maintain a supply of overdose reversal drugs for use in emergency situations and for distribution through an automated mechanism.[25] This is similar to, although arguably more expansive than, current law, which authorizes (1) terminal distributors of dangerous drugs to acquire and maintain a supply of overdose reversal drugs for use in emergency situations and for distribution through an automated mechanism[26] and (2) service entities – 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, such as churches, schools, libraries, health departments, courts, prisons, and homeless shelters – to procure and maintain a supply of overdose reversal drugs to use in emergency situations and for personally furnishing under a protocol (discussed below).[27]

Similar to existing law for supplies maintained by terminal distributors, a person or government entity that maintains a supply of overdose reversal drugs for use in emergencies as authorized by the bill must:[28]

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

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

[24] R.C. 3715.50(D)(1).

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

[26] R.C. 4729.515, repealed.

[27] R.C. 4729.514, repealed.

[28] R.C. 3715.50(B)(1).

Similar to existing rules for automated distribution by terminal distributors,[29] a person or government entity that maintains a supply of overdose reversal drugs for automated distribution under the bill must:[30]

- 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 to individuals who access the overdose reversal drugs emergency administration instructions, including an instruction to summon emergency services as necessary;
- Develop a process for monitoring and replenishing the supply;
- Store the overdose reversal drugs in accordance with the manufacturer or distributor instructions.

Exemption from licensure as a terminal distributor

Related to the general access provision, the bill 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 bill also expressly exempts health care practitioners from the licensure requirement in order to maintain overdose reversal drugs for use in personally furnishing supplies of the drugs. Under current law, licensure exemptions apply only to law enforcement agencies and its officers and to service entities that maintain overdose reversal drugs.[31]

Immunity

The bill provides various immunities related to the general access and supply authorizations discussed above. The immunities are similar to those in existing law. Specifically, a person or government entity that exercises the authority granted by the bill is not subject to administrative action or criminal prosecution, and is not liable for civil damages arising from exercising that authority.[32] Additionally, after an overdose reversal drug has been dispensed or personally furnished, the person or government entity is not liable for damages in a civil action, criminal prosecution, or professional disciplinary action.[33]

The bill does not eliminate, limit, or reduce any other immunity or defense that a person or government entity may have under existing law governing the general immunity of public

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

[30] R.C. 3715.50(B)(2).

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

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

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

officers and employees,[34] political subdivision tort liability,[35] emergency medical personnel immunity,[36] or any other provision of Ohio law or common law of Ohio.[37]

Issuing prescriptions and personally furnishing supplies

The bill generally maintains current 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.[38] Similar to current law, the practitioner must provide to the individual receiving the prescription or supply instructions regarding the emergency administration, including a specific instruction to summon emergency services as necessary.

The bill 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.[39]

The bill 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.[40]

Protocols for pharmacist dispensing of overdose reversal drugs

The bill modifies existing law related to who may authorize a pharmacist or pharmacy intern to dispense overdose reversal drugs without a prescription pursuant to a protocol. Under current law, physicians and boards of health may authorize dispensing pursuant to a protocol. The bill eliminates the authority for boards of health to authorize dispensing pursuant to a protocol,[41] but expands the authority to physician assistants and advanced practice registered nurses (in addition to physicians, whose current authority is maintained).[42] The bill otherwise

---

[34] R.C. 9.86, not in the bill.

[35] R.C. Chapter 2744, not in the bill.

[36] R.C. 4765.49, not in the bill.

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

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

[39] R.C. 3715.501(B)(2). Current law instead specifies that a written, electronic, or oral order for an overdose reversal drug issued to and in the name of a family member, friend, or other individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose is a "prescription" under Ohio law (R.C. 4729.01(H)(2), eliminated by the bill).

[40] R.C. 3715.501(C).

[41] R.C. 3707.56, repealed; R.C. 3715.502 (renumbered from R.C. 4729.44). There is likely no practical effect to eliminating board of health authority given the broad authority in R.C. 3715.50, and because physicians, including presumably a physician serving as a board's health commissioner or medical director, will continue to be able to authorize dispensing without a prescription pursuant to a protocol.

[42] R.C. 3715.502(B); see R.C. 4731.942, repealed.

maintains current law regarding the details of a pharmacist and pharmacy intern dispensing pursuant to a protocol, such as who overdose reversal drugs may be dispensed to, emergency instructions, and immunity provisions.

Protocols for others to personally furnish overdose reversal drugs

In addition to the above protocol authority, the bill 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. The person furnishing the overdose reversal drugs need not examine the individual to whom the drugs may be administered.[43]

A protocol established must include all of the following:[44]

1. Any limitations concerning individuals to whom overdose reversal drugs may be personally furnished;
2. The dosage that may be furnished, and any variation in the dosage based on circumstances specified in the protocol;
3. Any labeling, storage, recordkeeping, and administrative requirements;
4. Training requirements for individuals to dispense or furnish overdose reversal drugs;
5. Any instructions or training that the authorized person must provide to the individual who is provided overdose reversal drugs.

The bill eliminates existing requirements that the protocol include a description of the clinical pharmacology of the overdose reversal drug and precautions and contraindications concerning furnishing it.[45]

The bill maintains the immunity in current law from civil damages, criminal prosecution, and professional disciplinary action for physicians, physician assistants, and advanced practice registered nurses who in good faith authorize personally furnishing overdose reversal drugs in accordance with a protocol, and for individuals who personally furnish in good faith.[46]

Administering overdose reversal drugs

The bill expressly authorizes an individual, when not otherwise authorized by the Revised Code 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.[47] While current law does not contain such a generally applicable express authorization, it does provide

[43] R.C. 3715.503(B).

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

[45] R.C. 4723.485(C)(1) and (2), 4730.435(C)(1) and (2), and 4731.941(C)(1) and (2), all repealed.

[46] R.C. 3715.305(D).

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

immunity to such individuals and others who administer an overdose reversal drug in good faith.[48] The bill generally maintains similar immunity, providing that 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 bill, (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.[49]

It appears the bill's express authorization to administer overdose reversal drugs encompasses a more specific authorization from current law that is eliminated by the bill, which permits certain prescribers to authorize, through a protocol, individuals associated with services entities (described above) to administer overdose reversal drugs to individuals who are apparently experiencing opioid-related overdoses.[50]

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 bill exempts state agencies and boards from review by the Common Sense Initiative Office when amending any rule solely to reflect the terminology change.[51]

Pediatric transition care programs

The bill carves out a type of program that is licensed as pediatric respite care program under current law, and instead requires registration for those programs, which are named "pediatric transition care programs" under the bill.[52] As defined by the bill,[53] a pediatric transition care program means 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 conditions. The services a pediatric transition care program may provide to patients are the following:

---

[48] R.C. 2925.61, repealed.

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

[50] R.C. 4723.486, 4730.436, and 4731.943, all repealed. The bill also eliminates board of health authority related to protocols to personally furnish supplies, and related to service entities. R.C. 3707.561 and 3707.562, repealed.

[51] Section 4.

[52] R.C. 3712.01, 3712.031, 3712.032, 3712.042, 3712.061, and 3712.063; conforming changes in other sections.

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

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 current law, pediatric respite care programs that provide the types of services described above are limited to providing services to not more than ten patients at any one time.[54] Under the bill, a pediatric transition care program may provide services to not more than 15 patients at any one time.[55] As under current law, the Director of Health may approve additional patients.

Registration required

Instead of licensing a program that provides pediatric transition care services as a pediatric respite care program, as is the case under current law, the bill 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.[56] The rules must establish fees for initial registration and renewal, which generally cannot exceed $600 for each three-year registration period, unless a higher fee is approved by the Controlling Board.[57]

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 bill and the rules adopted by the Director.

Department of Health duties

The bill requires the Department to do all of the following:[58]

1. Grant, suspend, and revoke registrations for pediatric transition care programs in accordance with the bill's provisions and rules the Director adopts;

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

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

[56] R.C. 3712.032(A)(1).

[57] R.C. 3712.032(A)(2) and (B).

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

2. Make any inspections necessary to determine whether pediatric transition care program homes and services meet the requirements of the bill and rules adopted under it;

3. Implement and enforce provisions of the bill and rules adopted under it.

Requirements applicable to pediatric transition care programs

All of the following apply to pediatric transition care programs that are registered under the bill:[59]

- The program must ensure that the medical care components of the program are under the direction of a physician;
- When a program arranges for a home health agency to furnish a component or components of the program to a pediatric transition care patient, the care must be provided by a home health agency pursuant to a written contract that requires all care, treatment, and services to be entered into the patient's medical record, and that it ensures conformance with the patient's established plan of care and physician orders;
- Care commensurate with a pediatric transition care patient's needs must be available 24 hours a day and seven days a week;
- The program must maintain in the home central clinical records on all pediatric transition care patients;
- The program must maintain in the home birth certificates, certified guardianship letters of authority, or other documentation related to health care decisionmaking, as applicable, for any pediatric transition care 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 bill also requires the Director to adopt rules to:[60]

- Establish an inspection fee, which cannot exceed $1,750, unless the Controlling Board approves a higher fee;
- Establish emergency and safety requirements;
- Provide a method of registration for pediatric transition care programs that are accredited or certified by an organization that the Director determines has standards for accreditation or certification that are equal to or exceed those set forth in the bill.

[59] R.C. 3712.063.

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

All of the rules discussed in this analysis must be adopted in accordance with the Administrative Procedure Act.[61] The rules are exempt from existing law that limits regulatory restrictions that are adopted by certain agencies.[62]

Awareness designations

The bill designates the following awareness days:

- The fourth Wednesday of February as "Hypertrophic Cardiomyopathy Awareness Day";[63]
- The month of March as "Bleeding Disorders Awareness Month."[64]

HISTORY

Action	Date
Introduced	02-01-22
Reported, H Health	03-30-22
Passed House (96-0)	04-06-22
Reported, S Health	---

ANHB0558RS-134/ts

[61] R.C. 3712.032(A).

[62] R.C. 3712.032(D); see also R.C. 121.95 to 121.953, not in the bill.

[63] R.C. 5.2532.

[64] R.C. 5.2533.