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H.B. 193*
134th General Assembly

Bill Analysis

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Version: As Reported by Senate Health

Primary Sponsors: Reps. Cutrona and Pavliga

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SUMMARY

Pharmacist dispensing of schedule II controlled substances

- Generally limits pharmacist dispensing of schedule II controlled substances to those prescribed electronically, rather than in writing or electronically as under current law.
- Establishes the requirement that a prescriber issue an electronic prescription when prescribing a schedule II controlled substance, but also allows for the issuance of a written prescription in specified circumstances.

Pilot to dispense controlled substances in lockable containers

- Modifies an existing pilot program for dispensing schedule II controlled substances in lockable or tamper-evident containers by clarifying that pharmacy participation in the pilot program is voluntary.

Overdose reversal drugs

- Defines “overdose reversal drug” as naloxone and any other drug that the Pharmacy Board designates through rules as a drug that is approved by the federal Food and Drug Administration for the reversal of a known or suspected opioid-related overdose.
- Replaces existing references to “naloxone” in the Revised Code with “overdose reversal drug.”

* 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.

Out-of-state physician consultation with Ohio-licensed physician

- Requires an Ohio-licensed physician who receives a consultation from an out-of-state physician to have an established physician-patient relationship with the patient who is the subject of the consultation, in place of current law that requires the Ohio-licensed physician to be responsible for the examination, diagnosis, and treatment of that patient.

Home-like pediatric respite care programs

- Provides for licensure of an additional type of pediatric respite care program that provides inpatient respite care and related services, including skilled nursing care, in a home-like setting for up to ten children who have been diagnosed with life-threatening diseases and conditions, but who may not be leading up to the final stages of illness and death.
- Generally applies the same licensure requirements as existing pediatric respite care providers under current law, but also requires the home-like programs to maintain birth certificates and certified guardianship letters of authority for any patient who receives care for longer than 30 days, unless waived by the Director of Health.

DETAILED ANALYSIS

Pharmacist dispensing of schedule II controlled substances

The bill limits pharmacist dispensing of schedule II controlled substances to those prescribed electronically, with specified exceptions.¹ At present, a pharmacist may dispense controlled substances to any person upon a prescription for that person issued by a prescriber while acting in the course of his or her professional practice.² In the case of a schedule II controlled substance, current law authorizes a pharmacist to dispense the drug only upon a written or electronic prescription, except in emergency situations.³

Exceptions to dispensing only upon electronic prescriptions

The bill maintains a current law provision allowing – in emergency situations – for schedule II controlled substances to be dispensed upon oral prescriptions when the conditions established in federal law are satisfied.⁴ These include limiting the pharmacist to dispensing an amount adequate to treat the patient for the duration of the emergency period only and

¹ R.C. 3719.05.

² R.C. 3719.05(A) and 3719.06.

³ R.C. 3719.05(A)(3).

⁴ R.C. 3719.05(A)(3)(b).

requiring the prescriber to deliver a prescription to the pharmacist within seven days after authorizing the emergency prescription.⁵

The bill also authorizes a pharmacist to dispense a schedule II controlled substance upon a written prescription rather than an electronic one if either of the following is the case:

- A temporary technical, electrical, or broadband failure prevents dispensing upon an electronic prescription;
- The prescriber issued the written prescription under specified circumstances (see **“Prescriber issuance of schedule II controlled substance prescriptions,”** below).⁶

Safe harbor provisions

Under the bill, a pharmacist who receives a faxed, oral, or written prescription for a schedule II controlled substance is not required to verify that the prescription was issued under an exception to the bill’s requirement that a prescriber issue the prescription electronically.⁷

Pharmacist dispensing of other drugs

The bill specifies that a pharmacist may continue to dispense any other drug upon an otherwise valid faxed, oral, or written prescription that is consistent with state and federal statutes, rules, and regulations.⁸

Prescriber issuance of schedule II controlled substance prescriptions

In the case of a prescriber who is authorized to prescribe schedule II controlled substances, the bill requires the prescriber to issue an electronic prescription when prescribing a schedule II controlled substance, with specified exceptions.⁹

Exceptions to issuing only electronic prescriptions

Under the bill, a prescriber may issue a written rather than an electronic prescription for a schedule II controlled substance only in the following circumstances:

- In the event of a temporary technical, electrical, or broadband failure;
- When the prescription is issued for a nursing home resident or hospice care patient;
- When the prescriber is employed by or under contract with the same entity that operates the pharmacy;

⁵ See 21 Code of Federal Regulations 1306.11.

⁶ R.C. 3719.05(A)(3)(c).

⁷ R.C. 3719.05(A)(3)(d).

⁸ R.C. 3719.05(A)(3)(d).

⁹ R.C. 3719.06(C).

- When the prescriber determines that an electronic prescription cannot be issued in a timely manner and the patient’s medical condition is at risk;
- When the prescription is issued from a health care facility, which may include an emergency department, and the prescriber reasonably determines that an electronic prescription would be impractical for the patient or would cause delay that may adversely impact the patient’s medical condition;
- When the prescriber issues per year not more than 50 prescriptions for schedule II controlled substances;
- When the prescriber is a licensed veterinarian.¹⁰

Additionally, the bill has one temporary exception. For 12 months after the bill’s effective date, a prescriber may issue a written prescription for a schedule II controlled substance if the drug is to be dispensed by a pharmacist employed by or under contract with any state agency.¹¹

Pilot to dispense controlled substances in lockable containers

The bill modifies a pilot program created in the Main Operating Budget under which all schedule II controlled substances in solid oral dosage formulations are dispensed by participating pharmacies in lockable containers or tamper-evident containers. The bill makes two clarifications regarding pharmacy participation:¹²

- It expressly states that pharmacy participation in the pilot program is voluntary; and
- It requires the Department of Mental Health and Addiction Services to select participating pharmacies from among those pharmacies that volunteer.

Overdose reversal drugs

The bill replaces existing references to “naloxone” in the Revised Code with “overdose reversal drug.” An overdose reversal drug, as defined by the bill, is naloxone and any other drug that the Pharmacy Board designates as a drug that is approved by the federal Food and Drug Administration for the reversal of a known or suspected opioid-related overdose. The Pharmacy Board may designate a drug as an overdose reversal drug through rules adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119).¹³

Out-of-state physician consultation with Ohio licensed physician

The bill modifies an existing provision in Ohio law that permits out-of-state physicians who are not licensed in Ohio to consult with Ohio-licensed physicians, without the out-of-state

¹⁰ R. C. 3719.06(C).

¹¹ Section 3.

¹² Section 4, amending Section 337.205 of H.B. 110 of the 134th General Assembly.

¹³ R.C. 4729.01(CC); conforming changes in other Revised Code sections.

physician being subject to regulation by the State Medical Board. Under current law, the Ohio-licensed physician must be responsible for the examination, diagnosis, and treatment of the patient who is the subject of the consultation. Instead, the bill requires the Ohio-licensed physician to have an established physician-patient relationship with the patient who is the subject of the consultation.¹⁴

Home-like pediatric respite care programs

License required

The bill requires licensure for an additional type of pediatric respite care program that provides inpatient respite care and related services in a home-like setting for children who have been diagnosed with life-threatening diseases and conditions.¹⁵ The license generally has the same requirements as existing pediatric respite care providers under current law, with many details to be specified in rules, as is the case under current law. In addition to being a home-like setting, the new programs are different from existing pediatric respite care programs in the following ways:

--The children being served may not necessarily be leading up to the final stages of illness, dying, and bereavement;

--The program is limited to serving not more than ten patients at any time, unless additional patients are authorized by the Director of Health;¹⁶

--The inpatient care provided need not be short-term;

--Skilled nursing care may be provided;¹⁷

--Counseling and other services may be provided to parents and siblings of the patient, but not to other designated relatives or individuals with significant personal ties to the patient;

--The program must maintain birth certificates and certified guardianship letters of authority for any patient who receives care for longer than thirty days, unless this requirement is waived by the Director of Health.¹⁸

Adoption of rules

Under the bill, the Director of Health has the same authority to adopt rules as the Director has for existing pediatric respite care programs, including establishing license, renewal, and inspection fees.¹⁹ The bill specifies, however, that the rules adopted for the home-like

¹⁴ R.C. 4731.36(A)(3).

¹⁵ R.C. 3712.01(J)(2).

¹⁶ R.C. 3712.061(A)(7).

¹⁷ R.C. 3712.01(J)(2)(b) and (M).

¹⁸ R.C. 3712.061(A)(6).

¹⁹ R.C. 3712.031(A).

programs are not subject to existing law that limits the adoption of new rules by state agencies, including prohibiting a state agency from adopting a new regulatory restriction unless it simultaneously removes two or more other existing regulatory restrictions.²⁰

Other changes

For all pediatric respite care programs, the bill requires that the care that must be provided 24/7 under existing law must be commensurate with a pediatric respite care patient's needs. Regarding each patient's interdisciplinary care plan, it specifies that patient-family participation in decision making is to be related to the patient's health care and well-being.²¹ Regarding the definition of a pediatric respite care patient, it specifies that a parent or guardian of the patient, if the patient is under eighteen years of age or under guardianship, may voluntarily request care from the program.²²

HISTORY

Action	Date
Introduced	03-09-21
Reported, H. Health	06-15-21
Passed House (95-0)	06-23-21
Reported, S. Health	---

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²⁰ R.C. 3712.031(D); R.C. 121.95 to 121.953, not in the bill.

²¹ R.C. 3712.061(A).

²² R.C. 3712.01(K)(3).