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Final Analysis

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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 only those prescribed electronically.
- Establishes the requirement that a prescriber issue an electronic prescription when prescribing a schedule II controlled substance, but also allows for issuance of a written prescription in specified circumstances.

Pharmacy participation in pilot program

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

Overdose reversal drugs

- Defines the term "overdose reversal drug" as naloxone and any other drug approved for the reversal of an opioid-related overdose and replaces references to "naloxone" in the Revised Code with that term.

Out-of-state physician consultation with Ohio 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 prior law that required the Ohio-licensed physician to be responsible for examining, diagnosing, and treating that patient.

Home-like pediatric respite care programs

- Recognizes an additional type of pediatric respite care program, one that provides services in a home-like setting for ten or fewer children who have been diagnosed with life-threatening diseases and conditions, and extends the pediatric respite care licensing requirements to them.

- Establishes other requirements on home-like programs, including requiring them 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 act limits pharmacist dispensing of schedule II controlled substances to only those prescribed electronically, with specified exceptions. 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. In the case of a schedule II controlled substance, prior law authorized a pharmacist to dispense the drug upon either a written or electronic prescription, except in emergency situations.[1]

Exceptions to dispensing only upon electronic prescriptions

The act maintains a statutory law allowing – in emergency situations – for schedule II controlled substances to be dispensed upon oral prescriptions when the conditions established in federal law are satisfied.[2] These include limiting the pharmacist to dispensing an amount adequate to treat the patient for the duration of the emergency period only and requiring the prescriber to deliver a prescription to the pharmacist within seven days after authorizing the emergency prescription.[3]

The act also allows 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 prescriptions**," below).[4]

Safe harbor provision

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 act's requirement that a prescriber issue the prescription electronically.[5]

[1] R.C. 3719.05 and 3719.06.

[2] R.C. 3719.05(A)(3)(b).

[3] See 21 Code of Federal Regulations 1306.11.

[4] R.C. 3719.05(A)(3)(c).

[5] R.C. 3719.05(A)(3)(d).

Pharmacist dispensing of other drugs

The act 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.[6]

Prescriber issuance of prescriptions

In the case of a prescriber who is authorized to prescribe schedule II controlled substances, the act requires the prescriber to issue an electronic prescription when prescribing a schedule II controlled substance, with specified exceptions.[7]

Exceptions

A prescriber may issue a written – rather than 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;
- 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.[8]

Additionally, the act includes the following temporary exception – for 12 months after the act'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.[9]

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[6] R.C. 3719.05(A)(3)(d).

[7] R.C. 3719.06(C).

[8] R. C. 3719.06(C).

[9] Section 3.

Pharmacy participation in pilot program

The act modifies a pilot program created in the FY 2022-FY 2023 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 act makes two clarifications regarding pharmacy participation:[10]

- 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 act replaces existing references to "naloxone" throughout the Revised Code with "overdose reversal drug." An overdose reversal drug, as defined by the act, is naloxone and any other drug that the Pharmacy Board designates as one approved by the federal Food and Drug Administration for the reversal of a known or suspected opioid-related overdose. The Pharmacy Board may designate an overdose reversal drug through rules adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119).[11]

Out-of-state physician consultation with Ohio physician

The act modifies law that permits a physician authorized to practice in another state to consult with an Ohio-licensed physician in certain circumstances, without the out-of-state physician being subject to regulation by the State Medical Board. Under former law, the Ohio-licensed physician must have been responsible for the examination, diagnosis, and treatment of the patient who is the subject of the consultation. The act instead requires the Ohio-licensed physician to have an established physician-patient relationship with the patient who is the subject of the consultation.[12]

Under continuing law, the foregoing exception from Medical Board regulation applies only when one of the following is the case:

- The out-of-state physician does not provide consultation in Ohio on a regular or frequent basis;
- The out-of-state physician provides consultation without compensation of any kind; or
- The consultation is part of the curriculum of an Ohio medical school or an internship, residency, clinical fellowship program, or elective clinical rotation.

[10] Section 4, amending Section 337.205 of H.B. 110 of the 134th General Assembly.

[11] R.C. 4729.01(CC); conforming changes in other Revised Code sections.

[12] R.C. 4731.36(A)(3).

Home-like pediatric respite care programs

License required

The act recognizes an additional type of pediatric respite care program, one that provides inpatient pediatric respite care and related services in a home-like setting, and requires these program types to be licensed by the Department of Health, just as continuing law requires licensure for other pediatric respite care programs.[13] The act extends the law governing the licensure of other pediatric respite care providers to these additional programs, with many details to be specified in rules, just as is the case for the currently licensed programs. In addition to being a home-like setting, the new programs are different from previously licensed pediatric respite care programs in the following ways:

- The children being served have been diagnosed with life-threatening diseases and conditions (rather than fatal conditions in their final stages);
- The program is limited to serving not more than ten patients at any time, unless additional patients are authorized by the Director of Health;[14]
- The inpatient care provided need not be short-term;
- Skilled nursing care may be provided;[15]
- 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.[16]

Adoption of rules

The Director of Health is required to adopt rules for home-like pediatric respite care programs just as continuing law requires the Director to do for other pediatric respite care programs, including rules establishing license, renewal, and inspection fees.[17] The act specifies, however, that rules adopted for home-like programs are not subject to continuing law limits on the adoption of new rules by state agencies, including the limit prohibiting a state agency from

[13] R.C. 3712.01(J)(2).

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

[15] R.C. 3712.01(J)(2)(b) and (M).

[16] R.C. 3712.061(A)(6).

[17] R.C. 3712.031(A).

adopting a new regulatory restriction unless it simultaneously removes two or more other restrictions.[18]

Other changes

For all pediatric respite care programs, the act directs that care, which is to be available 24 hours a day and seven days a week under continuing 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.[19] And with respect to the definition of a pediatric respite care patient, the act specifies that a parent or guardian of the patient, if the patient is younger than 18 or under a guardianship, may voluntarily request care from the program.[20]

HISTORY

Action	Date
Introduced	03-09-21
Reported, H. Health	06-15-21
Passed House (95-0)	06-23-21
Reported, S. Health	06-01-22
Passed Senate (31-1)	06-01-22
House concurred in Senate amendments (92-0)	06-01-22

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[18] R.C. 3712.031(D); R.C. 121.95 to 121.953, not in the act.

[19] R.C. 3712.061(A).

[20] R.C. 3712.01(K)(3).