Ohio Legislative Service Commission

Bill Analysis

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Sub. H.B. 314

130th General Assembly
(As Passed by the House)

Reps. Baker and Kunze, C. Hagan, Landis, Antonio, Sprague, Boose, Smith, Stebelton, Hood, Green, Sears, Driehaus, Patterson, O'Brien, Becker, Wachtmann, Hill, Schuring, Amstutz, Beck, Blair, Brown, Buchy, Burkley, Derickson, Dovilla, Hayes, Henne, Lynch, McClain, Pelanda, Perales, Pillich, Rosenberger, Ruhl, Sheehy, Slaby, Strahorn, Terhar, Thompson, Young, Batchelder

BILL SUMMARY

- Establishes in the Revised Code an explicit informed consent requirement for prescribers who, in the absence of a medical emergency or other specified circumstances, intend to prescribe to minors controlled substances that contain opioids.
- Specifies that the informed consent requirement has three components: assessing the minor's mental health and substance abuse history, discussing with the minor and the minor's parent, guardian, or other responsible person certain risks and dangers associated with taking controlled substances containing opioids, and obtaining the signature of the minor's parent, guardian, or other responsible person on a consent form.
- Requires the signed consent form to be maintained in the minor's medical record.
- Requires a prescriber to notify the appropriate public children services agency if the informed consent required by the bill is not obtained because the prescriber believes that doing so would be a detriment to the minor's health or safety.
- Permits a regulatory board to impose a maximum $20,000 fine for an initial violation of the bill's informed consent requirement, and, for each subsequent violation, an additional fine of up to $20,000, a minimum six-month suspension of the prescriber's license or certificate to practice, or both.

- Makes conforming changes to provisions specifying conditions that apply when an advanced practice registered nurse or physician assistant with prescriptive authority issues a prescription.

CONTENT AND OPERATION

Opioids prescriptions issued to minors

Overview

The bill establishes in the Revised Code an explicit informed consent requirement for prescribers who, in the absence of a medical emergency or other specified circumstances, intend to prescribe controlled substances that contain opioids to minors.[1] The bill specifies sanctions for a prescriber's failure to comply with the informed consent requirement.[2] The prescribers subject to the bill are dentists and physicians and certain optometrists, and advanced practice registered nurses and physician assistants who have the authority to prescribe.

Components of the informed consent requirement

In the absence of a medical emergency or other specified circumstances (see "**Exemptions,**" below), and before issuing the first prescription in a single course of treatment for a particular compound that is a controlled substance that contains an opioid (regardless of whether the prescriber modifies the dosage during the single course of treatment), the bill requires a prescriber to meet three requirements:[3]

(1) Assessment – As part of the prescriber's examination of the minor, the prescriber must assess whether the minor has ever suffered, or is currently suffering, from mental health or substance abuse disorders and whether the minor has taken or is currently taking prescription drugs for treatment of those disorders.

(2) Discussion – The prescriber must discuss with the minor and the minor's parent, guardian, or other person responsible for the minor all of the following:

--The risks of addiction and overdose associated with the controlled substance being prescribed.

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[1] R.C. 3719.061(B).

[2] R.C. 3719.061(B), 4715.30(C)(2), 4723.283, 4725.191, 4730.252, and 4731.229.

[3] R.C. 3719.061(B).

--The increased risk of addiction to controlled substances of individuals suffering from both mental and substance abuse disorders.

--The dangers of taking controlled substances containing opioids with benzodiazepines, alcohol, or other central nervous system depressants. (Benzodiazepines are depressants that produce sedation, induce sleep, relieve anxiety and muscle spasms, and prevent seizures.[4])

--Any other information in the patient counseling information section of labeling for the controlled substance required by the federal regulation governing the content and format of labeling for human prescription drug and biological products.[5] (The information in this section should, according to the U.S. Food and Drug Administration (FDA), "summarize the information that a health care provider should convey to a patient (or caregiver when applicable) when a counseling discussion is taking place (e.g., a physician prescribing a drug during an office visit, a nurse providing discharge instructions at a hospital, or a pharmacist conveying information at a pharmacy)." It includes (1) information necessary for patients to use the drug safely and effectively, and (2) if applicable, reference to FDA-approved patient labeling.[6]

(3) Signed consent form – The prescriber must obtain written consent for the prescription from the minor's parent, guardian, or other person responsible for the minor. The consent must be recorded on a form separate from any other document the prescriber uses to obtain informed consent for other treatment provided to the minor and contain all of the following information:

--The name and quantity of the controlled substance being prescribed and the amount of the initial dose.

--A statement indicating that a controlled substance is a drug or other substance that the U.S. Drug Enforcement Agency has identified as having a potential for abuse.

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[4] U.S. Drug Enforcement Administration, *Get Smart About Drugs: A DEA Resource for Parents (*last visited January 27, 2014*)*, available at <www.getsmartaboutdrugs.com/drugs/benzodiazepines.html>.

[5] 21 Code of Federal Regulations (C.F.R.) § 201.57(c)(18).

[6] U.S. Department of Health and Human Services, Food and Drug Administration, *Draft: Guidance for Industry Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products – Content and Format* (September 2013), at p. 2, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM368602.pdf>.

--A statement certifying that the prescriber discussed with the minor and the minor's parent, guardian, or other person responsible for the minor the matters the bill requires the prescriber to discuss (see "**(2) Discussion**," above).

--The number of refills authorized by the prescription.

--The signature of the minor's parent, guardian, or other person responsible for the minor and the date of signing.

Exemptions

The bill specifies that its informed consent requirement does not apply when any of the following is the case:[7]

(1) The minor's treatment is associated with or incident to a medical emergency;

(2) The minor's treatment is associated with or incident to surgery, regardless of whether the surgery is performed on an inpatient or outpatient basis;

(3) In the prescriber's professional judgment, fulfilling the bill's informed consent requirement would be a detriment to the minor's health or safety; or

(4) The minor's treatment is rendered in a hospital, ambulatory surgical facility, nursing home, pediatric respite care program, residential care facility, freestanding rehabilitation facility, or similar institutional facility. This exemption does not apply, however, when the treatment is rendered in a prescriber's office that is located on the premises of or adjacent to any of the foregoing facilities or locations.

Notification to a public children services agency

If a prescriber chooses to invoke the third exemption described above, the prescriber must notify the appropriate public children services agency of the circumstances precipitating the prescriber's professional judgment to invoke the exemption.[8]

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[7] R.C. 3719.061(C).

[8] R.C. 3719.061(D).

Minor's medical record

The bill requires the consent form that the minor's parent, guardian, or other person responsible for the minor has signed to be maintained in the minor's medical record.[9]

Sanctions

The bill permits the boards that regulate prescribers to impose the following sanctions for violation of the bill's informed consent requirement:

--For the initial violation, a fine not to exceed $20,000.

--For each subsequent violation, an additional fine not to exceed $20,000, a minimum six-month suspension, or both.

Under current law, the boards generally cannot take disciplinary action without giving the prescriber notice and an opportunity for a hearing as required by the Administrative Procedure Act (R.C. Chapter 119.).[10] The bill generally extends the notice and hearing requirement to disciplinary actions taken for violation of the bill's informed consent requirement.[11]

Regarding disciplinary actions taken by the State Medical Board and Board of Nursing under the bill, the bill specifies that those boards are not required to hold a hearing if the individual subject to notice does not timely request a hearing in accordance with the Administrative Procedure Act.[12] Instead, each board may adopt a final order that contains the board's findings.[13] (The boards already have this authority

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[9] R.C. 3719.061(E).

[10] R.C. 4715.30(C) (dentists), 4723.28(C) (advanced practice registered nurses), 4725.19(A) (optometrists), 4730.25(C) (physician assistants), and 4731.22(C) (physicians).

[11] R.C. 4715.30(C)(2) (dentists), 4723.283 (advanced practice registered nurses holding certificates to prescribe who are clinical nurse specialists, certified nurse-midwives, or certified nurse practitioners, 4725.191 (optometrists holding therapeutic pharmaceutical agents certificates), 4730.252 (physician assistants holding certificates to prescribe), and 4731.229 (physicians).

[12] An Ohio appeals court found that this procedure meets due process requirements in appropriate cases. *Davidson v. State Med. Bd.*, 10th Dist. Franklin No. 97APE08-1038, 1998 Ohio App. LEXIS 2104 (May 7, 1998), discussing the requirements set forth in *Goldman v. State Med. Bd. of Ohio*, 110 Ohio App. 3d 124, 128-129 (10th Dist. 1996).

[13] Physician assistants (R.C. 4730.252), physicians (R.C. 4731.229), and advanced practice registered nurses (R.C. 4723.283).

when conducting disciplinary actions under current law.[14]) The bill also extends to disciplinary actions the Nursing Board may take under the bill authority the Board currently has when conducting other disciplinary investigations to investigate an individual's criminal background, require the individual to submit to a criminal records check, and require the individual to submit to a mental or physical examination, or both.[15]

Background

Ohio common law[16] presumes that minors are incompetent and, therefore, not permitted to initiate or consent to any form of medical treatment on their own.[17] This common law standard is incorporated in Revised Code § 2317.54(D), which specifies, for purposes of determining when consent to a surgical or medical procedure or course of procedures will be presumed to be valid, who may authorize written consent for medical treatment. The provision lists minors among those who lack the legal capacity to sign a written consent for medical treatment. Regarding minors, the statute specifies that only the parent of the minor (whether the parent is an adult or a minor) or an adult for whom the parent of the minor has given written authorization to consent to treatment may sign the written consent.

Over time, the General Assembly has carved out exceptions to the common law rule–specific circumstances in which a minor may receive medical services without parental consent. These include (1) blood donation, (2) emergency medical care for sexual abuse victims, (3) human immunodeficiency virus (HIV) testing, (4) venereal disease diagnosis and treatment, (5) drug and alcohol abuse diagnosis and treatment, (6) medical care for minors prosecuted as adults and confined in state correctional institutions, and (7) outpatient mental health services.[18] None expressly allow a minor to obtain a prescription drug without parental consent.

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[14] Physician assistants (R.C. 4730.25(J)), physicians (R.C. 4731.22(J)), and advanced practice registered nurses (R.C. 4723.28(D)).

[15] R.C. 4723.28(F) and (G) (current law) and 4723.283 (the bill).

[16] Common law is the body of law derived from judicial decisions, rather than from statutes or constitutions. *Black's Law Dictionary* 313 (9th ed. 2009).

[17] Note, *Do Not Resuscitate Decision-Making*: *Ohio's Do Not Resuscitate Law Should be Amended to Include a Mature Minor's Right to Initiate a DNR Order*, 17 J.L. & HEALTH 359 (2002-2003), citing Melinda T. Derish & Kathleen Vanden Heuvel, *Mature Minors Should have the Right to Refuse Life-Sustaining Medical Treatment*, 28 J.L. MED. & ETHICS 109, 112 (2000).

[18] R.C. 2108.31, 2907.29, 3701.242, 3709.241, 3719.012, 5120.172, and 5122.04.

Conforming changes

The bill makes conforming changes to provisions specifying conditions that apply when an advanced practice registered nurse or physician assistant with prescriptive authority issues a prescription. In particular, the bill specifies that when a clinical nurse specialist, certified nurse-midwife, certified nurse practitioner, or physician assistant prescribes a controlled substance that contains opioids, the nurse or physician assistant must comply with the bill's informed consent requirement.[19]

Terms

The bill defines the following terms as follows:

--A "medical emergency" is a situation that in the prescriber's good faith medical judgment creates an immediate threat of serious risk to the life or physical health of a minor.[20]

--A "minor" is a person under 18 years of age who is not emancipated.[21] (For purposes of the bill's informed consent requirement only, the bill specifies that a person under 18 years of age is to be considered emancipated only if the person has married, entered the armed services of the United States, became employed and self-sustaining, or has otherwise become independent from the care and control of the person's parent, guardian, or custodian.[22])

Current law unchanged by the bill defines the following terms as follows:

--A "controlled substance" is a drug, compound, mixture, preparation, or substance included in schedule I, II, III, IV, or V of the state's controlled substance list, codified in R.C. 3719.41.[23]

--A "prescriber" is an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice, including only the following: a licensed dentist; a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a certificate to prescribe; a licensed optometrist who holds a therapeutic pharmaceutical agents

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[19] R.C. 4723.481(G) (advanced practice registered nurses) and 4730.41(B)(5) (physician assistants).

[20] R.C. 3719.061(A)(1)(a).

[21] R.C. 3719.061(A)(1)(b).

[22] R.C. 3719.061(A)(2).

[23] R.C. 3719.01(C).

certificate; a physician authorized to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery; a physician assistant who holds a certificate to prescribe; and a licensed veterinarian.[24]

Current law and the bill do not define the term, "opioid." Federal regulations governing whether a practitioner is qualified under the federal Controlled Substances Act[25] to dispense certain drugs in the treatment of opioid addiction define an "opioid drug" as any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.[26]

HISTORY

ACTION	DATE
Introduced	10-24-13
Reported, H. Health & Aging	01-09-14
Passed House (86-7)	01-15-14

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[24] R.C. 4729.01(I). A veterinarian is authorized to prescribe only for animals (*see* R.C. 4741.01(B)(3)).

[25] 21 United States Code (U.S.C.) § 801 *et seq.*

[26] 42 C.F.R. § 8.2.