



# Ohio Legislative Service Commission

## Final Analysis

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### Sub. H.B. 314

130th General Assembly  
(As Passed by the General Assembly)

**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

**Sens.** Brown, Tavares, Beagle, Burke, Cafaro, Coley, Eklund, Faber, Gardner, Hite, Jones, Lehner, Manning, Oelslager, Patton, Peterson, Uecker, Widener

**Effective date:** September 17, 2014

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## ACT SUMMARY

### Opioid prescriptions issued to minors

- 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 containing 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 another authorized adult certain risks and dangers associated with taking controlled substances containing opioids, and obtaining the signature of the parent, guardian, or authorized adult on a consent form.
- Limits to not more than a 72-hour supply the quantity of a controlled substance containing an opioid that a prescriber may prescribe to a minor when another adult authorized by the minor's parent or guardian gives the required consent.
- Requires that the signed consent form, known as the "Start Talking!" consent form, be maintained in the minor's medical record.

- Authorizes regulatory boards to impose sanctions on prescribers who fail to comply with the act's informed consent requirement that are the same as those generally imposed for other disciplinary violations.
- Makes conforming changes to provisions specifying conditions that apply when an advanced practice registered nurse or physician assistant with prescriptive authority issues a prescription.

### **Child fatality review boards**

- Authorizes a county or regional child fatality review board to disclose confidential information to a fetal and infant mortality review team.
- Requires a health care entity that provided services to the mother of a child one year of age or younger whose death is being reviewed by a child fatality review board to submit to the review board, on the board's request, a summary of information from the mother's medical record.

### **Methadone treatment facilities**

- Authorizes the Ohio Department of Mental Health and Addiction Services (ODMHAS) to issue a declaration that a proposed methadone treatment facility location is not within 500 linear feet of a school, day-care center, or other child serving agency.
- Prohibits ODMHAS from considering the location of a school, day-care center, or other child serving agency when determining whether to issue, reissue, or relocate a methadone treatment facility's license if the facility obtains a declaration and applies for the license within two years of the declaration.
- Once a facility's license has been issued, prohibits ODMHAS from considering whether there is a school, day-care center, or other child serving agency within 500 linear feet of the location when determining whether to renew, withdraw, revoke, or reissue the license.

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## **CONTENT AND OPERATION**

### **Opioids prescriptions issued to minors**

#### **Overview**

The act 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 containing opioids to minors.<sup>1</sup> A prescriber who fails to comply with the requirement may be subject to sanctions that are imposed for other disciplinary violations under continuing law.<sup>2</sup> The prescribers subject to the act are dentists and physicians and certain optometrists, and advanced practice registered nurses and physician assistants who are authorized 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 containing an opioid (regardless of whether the prescriber modifies the dosage during the single course of treatment), the act requires a prescriber to meet three requirements:<sup>3</sup>

**(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 another adult authorized to consent to the minor's medical treatment all of the following:

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

--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.<sup>4</sup>)

--Any other information in the patient counseling information section of labeling for the controlled substance required by the federal regulation governing the content

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<sup>1</sup> R.C. 3719.061(B).

<sup>2</sup> R.C. 4715.30(A)(17), 4723.28(B)(34), 4725.19(B)(17), 4730.25(B)(25), and 4731.22(B)(48).

<sup>3</sup> R.C. 3719.061(B).

<sup>4</sup> U.S. Drug Enforcement Administration, *Get Smart About Drugs: A DEA Resource for Parents* (last visited June 20, 2014), available at <[www.getsmartaboutdrugs.com/drugs/benzodiazepines.html](http://www.getsmartaboutdrugs.com/drugs/benzodiazepines.html)>.



and format of labeling for human prescription drug and biological products.<sup>5</sup> (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.<sup>6</sup>

**(3) Signed consent form** – The prescriber must obtain written consent for the prescription from the minor's parent, guardian, or another adult authorized to consent to the minor's medical treatment. The consent must be recorded on a form known as the "Start Talking!" consent form. That form must be 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.

--A statement certifying that the prescriber discussed with the minor and the minor's parent, guardian, or another adult authorized to consent to the minor's medical treatment the matters the act 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 another adult authorized to consent to the minor's medical treatment and the date of signing.

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<sup>5</sup> 21 Code of Federal Regulations (C.F.R.) § 201.57(c)(18).

<sup>6</sup> 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>>.

## **Exemptions**

The act specifies that its informed consent requirement does not apply when any of the following is the case:<sup>7</sup>

- (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 act's informed consent requirement would be a detriment to the minor's health or safety;
- (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;<sup>8</sup> or
- (5) The prescription is for a compound that is a controlled substance containing an opioid that a prescriber issues to a minor at the time of discharge from a facility or other location described in (4), above.

## **Minor's medical record**

The act requires a signed "Start Talking!" consent form to be maintained in the medical record of the minor to which it pertains.<sup>9</sup>

## **Disciplinary action**

Continuing law authorizes regulatory boards to take disciplinary action against individuals for various reasons. Disciplinary actions range in severity and may include the issuance of reprimands, imposition of fines, and suspension or revocation of licenses or certificates. The act specifies that failure to comply with the act's informed consent requirement is another reason for which the boards may take disciplinary action.<sup>10</sup>

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<sup>7</sup> R.C. 3719.061(C).

<sup>8</sup> R.C. 3719.061(D).

<sup>9</sup> R.C. 3719.061(E).

<sup>10</sup> R.C. 4715.30(A)(17) (dentists), 4723.28(B)(34) (advanced practice registered nurses), 4725.19(B)(17) (optometrists), 4730.25(B)(25) (physician assistants), and 4731.22(B)(48).



## Background

Ohio common law presumes that minors are incompetent and, therefore, not permitted to initiate or consent to any form of medical treatment on their own.<sup>11</sup> This common law standard is incorporated in Revised Code § 2317.54(D) (not modified by the act), 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.<sup>12</sup> None expressly allow a minor to obtain a prescription drug without parental consent.

## Conforming changes

The act 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 act specifies that when a clinical nurse specialist, certified nurse-midwife, certified nurse practitioner, or physician assistant prescribes a controlled substance containing opioids, the nurse or physician assistant must comply with the act's informed consent requirement.<sup>13</sup>

## Terms

The act defines the following terms as follows:

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<sup>11</sup> 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).

<sup>12</sup> R.C. 2108.31, 2907.29, 3701.242, 3709.241, 3719.012, 5120.172, and 5122.04.

<sup>13</sup> R.C. 4723.481(G) (advanced practice registered nurses) and 4730.41(B)(5) (physician assistants).



--"Another adult authorized to consent to the minor's medical treatment" means an adult to whom a minor's parent or guardian has given written authorization to consent to the minor's medical treatment.

--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.<sup>14</sup>

--A "minor" is a person under 18 years of age who is not emancipated.<sup>15</sup> (For purposes of the act's informed consent requirement only, the act 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.<sup>16</sup>)

Current law unchanged by the act 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.<sup>17</sup>

--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 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.<sup>18</sup>

Preexisting law and the act do not define the term, "opioid." Federal regulations governing whether a practitioner is qualified under the federal Controlled Substances Act<sup>19</sup> to dispense certain drugs in the treatment of opioid addiction define an "opioid

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<sup>14</sup> R.C. 3719.061(A)(1)(a).

<sup>15</sup> R.C. 3719.061(A)(1)(b).

<sup>16</sup> R.C. 3719.061(A)(2).

<sup>17</sup> R.C. 3719.01(C).

<sup>18</sup> R.C. 4729.01(I). A veterinarian is authorized to prescribe only for animals (*see* R.C. 4741.01(B)(3)).

<sup>19</sup> 21 United States Code (U.S.C.) § 801 *et seq.*



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.<sup>20</sup>

## **Child fatality review boards**

### **Summary of information from mother's medical record**

Notwithstanding preexisting provisions that provide for HIV tests and AIDS or AIDS-related condition diagnoses to be confidential,<sup>21</sup> as well as other preexisting provisions, the act requires a health care entity that provided services to the mother of a child whose death (at age one or younger) is being reviewed by a child fatality review board to submit a summary sheet of information available and reasonably drawn from the mother's medical record created by the health care entity to the board on the board's request. Before submitting the summary sheet, the health care entity must attempt to obtain the mother's consent to do so. The act provides that the mother's lack of consent does not, however, preclude the health care entity from submitting the summary sheet.<sup>22</sup>

Under law not modified by the act, a health care entity must comply with a similar requirement concerning a summary sheet of information available and reasonably drawn from the medical record of a child whose death is being reviewed by a child fatality review board. Under that requirement, a health care entity must submit to a child fatality review board, on the board's request, a summary sheet of information containing only information available and reasonably drawn from the child's medical record created by the health care entity.<sup>23</sup>

### **Disclosure of confidential information to fetal and infant mortality review teams**

The act generally authorizes a child fatality review board to disclose all of the following items, classified as confidential under preexisting law, to a fetal and infant mortality review team: information, documents, and reports presented to a child fatality review board; all statements made by review board members during meetings; and a

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<sup>20</sup> 42 C.F.R. § 8.2.

<sup>21</sup> R.C. 3701.243, not in the act.

<sup>22</sup> R.C. 307.627(A)(2).

<sup>23</sup> R.C. 307.627(A).



review board's work products (other than annual reports to the Ohio Department of Health (ODH)).<sup>24</sup>

Neither the act, nor preexisting law, defines the term, "fetal and infant mortality review team." According to ODH, fetal and infant mortality review is an action-oriented community process that continually assesses, monitors, and works to improve service systems and community resources for women, infants, and families.<sup>25</sup>

### **Methadone treatment facility locations**

The act authorizes the Ohio Department of Mental Health and Addiction Services (ODMHAS) to issue a declaration that a proposed methadone treatment facility location is not within 500 linear feet of a school, day-care center, or other child serving agency. If a community addiction services provider obtains a declaration from ODMHAS and submits an application for a license to maintain a methadone treatment program within two years of the declaration, ODMHAS, in determining whether to issue, reissue, or relocate the license, may not consider whether there is a school, day-care center, or other child serving agency within 500 linear feet of the location that is subject to the declaration as would otherwise have been required under prior law.<sup>26</sup>

Once a license to maintain a methadone treatment program is issued, the act prohibits ODMHAS from considering whether there is a school, day-care center, or other child serving agency within 500 linear feet of the location in determining whether to renew, withdraw, or revoke the license or whether to reissue the license due to a change in ownership.<sup>27</sup>

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<sup>24</sup> R.C. 307.629(B).

<sup>25</sup> Ohio Department of Health, *Ohio's Commitment to Prevent Infant Mortality* (2013), available at <<http://www.odh.ohio.gov/~media/Images/Ohio%20Commitment%202013h%20%20FNL%2012172013.ashx>>.

<sup>26</sup> R.C. 5119.392.

<sup>27</sup> R.C. 5119.391(C) and (K).



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## HISTORY

ACTION	DATE
Introduced	10-24-13
Reported, H. Health & Aging	01-09-14
Passed House (86-7)	01-15-14
Reported, S. Medicaid, Health & Human Services	05-21-14
Passed Senate (32-0)	05-28-14
House concurred in Senate amendments (95-0)	06-03-14

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