



Ohio Legislative Service Commission

Bill Analysis

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Sub. H.B. 485* 130th General Assembly (As Reported by H. Health and Aging)

Reps. Smith and Johnson

BILL SUMMARY

Office of Human Services Innovation

- Creates the Office of Human Services Innovation in the Ohio Department of Job and Family Services.
- Requires the Office, not later than January 1, 2015, to submit to the Governor recommendations regarding public assistance programs.

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 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.

* This analysis was prepared before the report of the House Health and Aging Committee appeared in the House Journal. Note that the list of co-sponsors and the legislative history may be incomplete.

- 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.

Review of patient information in OARRS

- Beginning April 1, 2015, establishes several conditions related to the State Board of Pharmacy's Ohio Automated Rx Reporting System (OARRS) that apply to a prescriber when prescribing or personally furnishing certain drugs, including the following:
 - That the prescriber, before initially prescribing or personally furnishing an opioid analgesic or a benzodiazepine, request patient information from OARRS that covers at least the previous 12 months;
 - That the prescriber make periodic requests for patient information from OARRS if the course of treatment continues for more than 90 days.
- Establishes several exceptions from the required review of an OARRS report, including drugs prescribed to hospice or cancer patients, drugs to be administered in hospitals or long-term facilities, drugs to treat acute pain from surgery or a delivery, and drug amounts for use in seven days or less.
- Beginning January 1, 2015, requires that certain prescribers, as well as pharmacists, when renewing their professional licenses, provide evidence to their licensing boards that they have access to OARRS.

Licensed hospice care programs and opioid diversion policies

- Requires a licensed hospice care program that provides hospice care and services in a patient's home to establish a written policy and adopt certain practices for preventing the diversion of controlled substances containing opioids.

- Requires a program to request, in writing, that the hospice patient or family relinquish any controlled substances containing opioids included in the patient's plan of care that are no longer needed by the patient.
- Requires the program to report to local law enforcement the quantity and type of controlled substances not relinquished to the program following the written request.
- Requires the local law enforcement agency to investigate and dispose of those controlled substances.
- Provides that a person who receives a written request to relinquish controlled substances and fails to do so is guilty of a minor misdemeanor.
- Grants a qualified immunity from civil liability to a hospice care program and its employees, officers, or directors for certain actions required by the bill.
- Requires a hospice care program that provides care and services in a patient's home to include in its license renewal application written evidence of compliance with the bill.
- Permits the Ohio Department of Health to suspend a program's license for not more than six months and impose a fine not to exceed \$20,000 if it determines that the program is not in compliance with the bill.

Private, nonprofit therapeutic wilderness camps

- Exempts private, nonprofit therapeutic wilderness camps from certification by the Department of Job and Family Services required for child caring institutions and associations.
- Requires the Director of Job and Family Services to license a private, nonprofit therapeutic wilderness camp that meets specified minimum standards.
- Prohibits the operation of a private, nonprofit therapeutic wilderness camp without a license.
- Permits the Director to inspect private, nonprofit therapeutic wilderness camps and to access their records or written policies.
- Specifies that persons responsible for a child's care in a private, nonprofit therapeutic wilderness camp are subject to existing criminal records check requirements.

- Requires that administrators and employees of private, nonprofit therapeutic wilderness camps report suspected child abuse or neglect.

State Medical Board teleconferencing pilot program

- Permits the State Medical Board to conduct a teleconferencing pilot program.

Collection of health information through OARRS

- Authorizes the State Board of Pharmacy to collect any health information submitted by prescribers, pharmacies, or wholesale distributors of dangerous drugs through OARRS and to transmit the information to the Ohio Department of Health.

Ohio Healthier Buckeye Council and grant program

- Establishes the Ohio Healthier Buckeye Council and the Ohio Healthier Buckeye Council Grant Program.

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CONTENT AND OPERATION

Office of Human Services Innovation

The bill establishes the Office of Human Services Innovation in the Ohio Department of Job and Family Services (ODJFS).¹ The ODJFS Director is required to establish the Office's organizational structure, is permitted to reassign ODJFS's staff and resources as necessary to support the Office's activities, and is responsible for the Office's operations. The Superintendent of Public Instruction, Chancellor of the Ohio Board of Regents, Director of the Governor's Office of Workforce Transformation, and Director of the Governor's Office of Health Transformation are required by the bill to assist the ODJFS Director with leadership and organizational support for the Office.

¹ R.C. 5101.061.



The bill requires the Office to submit recommendations to the Governor not later than January 1, 2015, for all of the following:

- (1) Coordinating services across all public assistance programs to help individuals find employment, succeed at work, and stay out of poverty;
- (2) Revising incentives for public assistance programs to foster person-centered case management;
- (3) Standardizing and automating eligibility determination policies and processes for public assistance programs;
- (4) Other matters the Office considers appropriate.

The Office is required, in its development of the recommendations, to do both of the following:

- (1) Have as its goal the coordination and reform of state programs to assist Ohioans in preparing for life and the dignity of work, to promote individual responsibility and work opportunity, and to improve self-sufficiency to increase income levels;
- (2) Not later than three months after the bill's effective date, in consultation with the Ohio Healthier Buckeye Council, establish clear principles to guide the development of the recommendations, clearly identify problems to be addressed in the recommendations, and make an inventory of all existing state and other resources that the Office considers relevant to the development of the recommendations.

The bill requires the Office to convene the Ohio Healthier Buckeye Council, the directors and staff of the departments, agencies, boards, commissions, and institutions of the executive branch of the state as necessary to develop the recommendations. The Council, departments, agencies, boards, commissions, and institutions must comply with all requests and directives that the Office makes, subject to the supervision of the Council's chairperson and the directors of the departments, agencies, offices, boards, and commissions. The Office also must convene other individuals interested in the issues that the Office addresses in the development of the recommendations to obtain their input on, and support for, the recommendations.

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.² The bill specifies sanctions for a prescriber's failure to comply with the informed consent requirement.³ 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:⁴

(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.

--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.⁵)

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

² R.C. 3719.061(B).

³ R.C. 3719.061(B), 4715.30(C)(2), 4723.283, 4725.191, 4730.252, and 4731.229.

⁴ R.C. 3719.061(B).

⁵ 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>.

and format of labeling for human prescription drug and biological products.⁶ (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.⁷

(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.

--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:⁸

⁶ 21 Code of Federal Regulations (C.F.R.) § 201.57(c)(18).

⁷ 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>>.

⁸ R.C. 3719.061(C).

- (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.⁹

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.¹⁰

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

⁹ R.C. 3719.061(D).

¹⁰ R.C. 3719.061(E).

Administrative Procedure Act (R.C. Chapter 119.).¹¹ The bill generally extends the notice and hearing requirement to disciplinary actions taken for violation of the bill's informed consent requirement.¹²

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.¹³ Instead, each board may adopt a final order that contains the board's findings.¹⁴ (The boards already have this authority when conducting disciplinary actions under current law.¹⁵) 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.¹⁶

Background

Ohio common law¹⁷ presumes that minors are incompetent and, therefore, not permitted to initiate or consent to any form of medical treatment on their own.¹⁸ This

¹¹ 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).

¹² 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).

¹³ 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).

¹⁴ Physician assistants (R.C. 4730.252), physicians (R.C. 4731.229), and advanced practice registered nurses (R.C. 4723.283).

¹⁵ Physician assistants (R.C. 4730.25(J)), physicians (R.C. 4731.22(J)), and advanced practice registered nurses (R.C. 4723.28(D)).

¹⁶ R.C. 4723.28(F) and (G) (current law) and 4723.283 (the bill).

¹⁷ 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).

¹⁸ 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 &



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.¹⁹ None expressly allow a minor to obtain a prescription drug without parental consent.

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.²⁰

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.²¹

Kathleen Vanden Heuvel, *Mature Minors Should have the Right to Refuse Life-Sustaining Medical Treatment*, 28 J.L. MED. & ETHICS 109, 112 (2000).

¹⁹ R.C. 2108.31, 2907.29, 3701.242, 3709.241, 3719.012, 5120.172, and 5122.04.

²⁰ R.C. 4723.481(G) (advanced practice registered nurses) and 4730.41(B)(5) (physician assistants).

²¹ R.C. 3719.061(A)(1)(a).



--A "minor" is a person under 18 years of age who is not emancipated.²² (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.²³)

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. 3719.41.²⁴

--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.²⁵

Current law and the bill do not define the term, "opioid." Federal regulations governing whether a practitioner is qualified under the federal Controlled Substances Act²⁶ 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.²⁷

Review of patient information in OARRS

Beginning April 1, 2015, the bill establishes several conditions related to a prescriber's use of information available from the Ohio Automated Rx Reporting

²² R.C. 3719.061(A)(1)(b).

²³ R.C. 3719.061(A)(2).

²⁴ R.C. 3719.01(C).

²⁵ R.C. 4729.01(I). A veterinarian is authorized to prescribe only for animals (*see* R.C. 4741.01(B)(3)).

²⁶ 21 United States Code (U.S.C.) § 801 *et seq.*

²⁷ 42 C.F.R. § 8.2.



System (OARRS) (see "**OARRS and current law**," below). The conditions apply to a prescriber when prescribing or personally furnishing a drug that is either an opioid analgesic or a benzodiazepine as part of a patient's course of treatment for a particular condition.²⁸ The bill does not define opioid analgesic or benzodiazepine.²⁹

The bill requires a prescriber, before initially prescribing or personally furnishing the opioid analgesic or benzodiazepine, to request, or have a delegate request, patient information from OARRS that covers at least the previous 12 months.³⁰ If the patient's course of treatment for the condition continues for more than 90 days, the bill requires the prescriber to make periodic requests for patient information from OARRS until the course of treatment ends. Such requests must be made at intervals not exceeding 90 days.³¹

The bill also requires the prescriber to assess the information in the OARRS report on receipt of the report and to document in the patient's record that the report was received and assessed.³²

Prescribers subject to the bill

The bill applies to the following prescribers: dentists, advanced practice registered nurses holding certificates to prescribe, optometrists holding therapeutic pharmaceutical agents certificates, physician assistants holding certificates to prescribe, and physicians authorized to practice medicine, osteopathic medicine, or podiatry.³³

²⁸ R.C. 4715.302(B), 4723.487(B), 4725.092(B), 4730.53(B), and 4731.055(B) and Section 4.

²⁹ An opioid is a medication that relieves pain. It reduces the intensity of pain signals reaching the brain and affects those brain areas controlling emotion. See National Institute of Drug Abuse, *Prescription Drugs: Abuse and Addiction, What are opioids?* (last visited February 21, 2014), available at <<http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/what-are-opioids>>. A benzodiazepine is a depressant prescribed to relieve anxiety and sleep problems. Valium and Xanax are among the most widely prescribed benzodiazepines. See National Institute of Drug Abuse, *Prescription Drugs: Abuse and Addiction, Glossary* (last visited February 20, 2014), available at <<http://www.drugabuse.gov/publications/research-reports/prescription-drugs/glossary>>.

³⁰ R.C. 4715.302(B)(1), 4723.487(B)(1), 4725.092(B)(1), 4730.53(B)(1), and 4731.055(B)(1).

³¹ R.C. 4715.302(B)(2), 4723.487(B)(2), 4725.092(B)(2), 4730.53(B)(2), and 4731.055(B)(2).

³² R.C. 4715.302(B)(3), 4723.487(B)(3), 4725.092(B)(3), 4730.53(B)(3), and 4731.055(B)(3).

³³ R.C. 4715.302, 4723.487, 4725.092, 4730.53, and 4731.055.

Prescriptions issued in other states

The bill requires a prescriber who practices primarily in an Ohio county that adjoins another state to request information available in OARRS pertaining to prescriptions issued or drugs furnished to the patient in the state adjoining that county.³⁴ The bill does not define the phrase "practices primarily."

Exceptions to OARRS review

The bill provides for several exceptions from the required review of an OARRS report. These include all of the following:

- (1) The OARRS report is not available;
- (2) The drug is prescribed or personally furnished to a hospice patient or to any other patient who has been diagnosed as terminally ill;
- (3) The drug is prescribed or personally furnished in an amount indicated for a period not to exceed seven days;
- (4) The drug is prescribed or personally furnished for the treatment of cancer or another condition associated with cancer;
- (5) The drug is prescribed or personally furnished for administration in a hospital, nursing home, or residential care facility;
- (6) The drug is prescribed or personally furnished by a physician to treat acute pain resulting from a surgical or other invasive procedure or a delivery.

Disciplinary action

The bill authorizes the following boards to discipline prescribers for failure to request patient information in OARRS as required by the bill: the State Dental Board, the Board of Nursing, the State Board of Optometry, and the State Medical Board.³⁵

Required access to OARRS

The bill requires that each prescriber who prescribes or personally furnishes opioid analgesics or benzodiazepines as part of the prescriber's regular practice, as well

³⁴ R.C. 4715.302(B), 4723.487(B), 4725.092(B), 4730.53(B), and 4731.055(B).

³⁵ R.C. 4715.30, 4723.28, 4725.19, 4730.25, and 4731.22. The State Medical Board is responsible for the licensure of both physician assistants and physicians.



as pharmacists, obtain access to OARRS not later than January 1, 2015. The bill does not define the phrase "regular practice."

The bill's requirement does not apply if the State Board of Pharmacy has restricted the professional from obtaining information from OARRS. Failure to obtain access to OARRS by January 1, 2015, constitutes grounds for license or certificate suspension.³⁶

License renewals

Beginning January 1, 2015, the bill requires that each prescriber who prescribes or personally furnishes opioid analgesics or benzodiazepines as part of the prescriber's regular practice, as well as pharmacists, when renewing a license or certificate, provide evidence to the board responsible for licensure or certification that demonstrates the professional has been granted access to OARRS. As noted above, the bill does not define the phrase "regular practice."

The bill's requirement regarding license renewals does not apply if the State Board of Pharmacy has notified the relevant board that the professional has been restricted from obtaining further information from OARRS (see "**State Board of Pharmacy notification**," below).³⁷

Restricting access to OARRS

The bill specifies that the State Board of Pharmacy may restrict a person from obtaining further information from OARRS if the person creates, by clear and convincing evidence, a threat to the security of information contained in OARRS.³⁸ Current law permits the Board to restrict a person from obtaining further information under certain circumstances, including the following: (1) when providing false information to OARRS with the intent to obtain or alter information and (2) when using information obtained from OARRS as evidence in any civil or administrative proceeding.³⁹

³⁶ Section 5.

³⁷ R.C. 4715.14(A), 4723.486(B), 4725.16(A), 4729.12, 4730.48(A), and 4731.281(B) and Sections 3 and 5.

³⁸ R.C. 4729.86(C)(1)(d).

³⁹ R.C. 4729.86(C).



Notice and hearing

The bill also specifies that the Board may restrict a person from obtaining information from OARRS after providing notice and affording an opportunity for hearing in accordance with the Administrative Procedure Act (R.C. Chapter 119.).⁴⁰

Summary restriction

The bill does permit the Board, if it determines that the allegations regarding a person's actions warrant restricting the person from obtaining further information from OARRS without a prior hearing, to summarily impose the restriction. The bill specifies that a telephone conference call may be used by the Board for reviewing the allegations and taking a vote on the summary restriction. The bill also provides that a summary restriction remains in effect, unless removed by the Board, until the Board's final adjudication order becomes effective.⁴¹

State Board of Pharmacy notification

The bill requires the State Board of Pharmacy to notify the government entity responsible for licensing a prescriber if the Board restricts the prescriber from obtaining further information from OARRS.⁴²

OARRS and certain workers' compensation claimants

The bill requires that the State Board of Pharmacy provide to the medical director of a managed care organization (MCO) an OARRS report relating to a workers' compensation or other claimant assigned to the MCO.⁴³ Under current law, the Board is authorized or required to provide information from OARRS to various individuals, including prescribers, pharmacists, law enforcement officials, and medical directors of Medicaid MCOs.⁴⁴

The bill directs that a contract between the Workers' Compensation Administrator and an MCO include a requirement that the MCO enter into a data

⁴⁰ R.C. 4729.86(C)(1).

⁴¹ R.C. 4729.86(C)(2).

⁴² R.C. 4729.861.

⁴³ R.C. 4729.80(A)(10).

⁴⁴ R.C. 4729.80(A).



security agreement with the State Board of Pharmacy.⁴⁵ A similar requirement applies under current law to Medicaid MCOs.⁴⁶

OARRS and opioid dependent infants

The bill requires that the State Board of Pharmacy provide to a prescriber treating a newborn or infant patient diagnosed as opioid dependent an OARRS report relating to the patient's mother.⁴⁷

OARRS and current law

OARRS is the drug database established and maintained under current law by the State Board of Pharmacy.⁴⁸ Rules adopted by the Board require that when a reported drug (controlled substance, carisoprodol, or tramadol)⁴⁹ is dispensed by a pharmacy or personally furnished by a dentist, optometrist, or physician⁵⁰ to an outpatient, this information must be reported to OARRS on a weekly basis.⁵¹ Prescribers and pharmacists may request patient information from the database, including information from ten other states: Arizona, Connecticut, Indiana, Kansas, Kentucky, Michigan, Minnesota, South Carolina, South Dakota, and Virginia.⁵²

Under existing law, the State Dental Board, Board of Nursing, State Board of Optometry, and State Medical Board must adopt rules that establish standards and procedures to be followed by the prescribers whom the board regulates regarding the

⁴⁵ R.C. 4121.443.

⁴⁶ R.C. 5167.14, not in the bill.

⁴⁷ R.C. 4729.80(A)(12).

⁴⁸ R.C. 4729.75, not in the bill.

⁴⁹ Carisoprodol is a muscle relaxant used to relieve pain and discomfort caused by strains, sprains, and other muscle injuries. See <<http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682578.html>>. Tramadol is an opiate analgesic used to relieve moderate to moderately severe pain. See <<http://www.nlm.nih.gov/medlineplus/druginfo/meds/a695011.html>>.

⁵⁰ Current law does not permit advanced practice registered nurses or physician assistants holding certificates to prescribe to personally furnish controlled substances. See R.C. 4723.481(E)(3) and 4730.43(A)(3).

⁵¹ O.A.C. 4729-37-03 and 4729-37-07.

⁵² R.C. 4729.80. See also written testimony provided by the State Board of Pharmacy to the House Health and Aging Opiate Addiction Treatment and Reform Subcommittee, January 21, 2014.



review of patient information available through OARRS.⁵³ These rules vary by profession.

Dentists, nurses, and physicians

Under rules adopted by their respective boards, if a dentist, advanced practice registered nurse, or physician believes or has reason to believe that a patient may be abusing or diverting drugs, he or she must use sound clinical judgment in determining whether or not the reported drug should be prescribed or furnished under the circumstances.⁵⁴ The rules specify the extent to which patient information available from OARRS is to be accessed for assistance in making this determination if certain signs of drug abuse or diversion are exhibited.⁵⁵ A dentist is required to consider whether to access OARRS.⁵⁶ An advanced practice registered nurse cannot prescribe a reported drug without first reviewing a patient's OARRS report.⁵⁷ A physician is required to access OARRS.⁵⁸ When a dentist, advanced practice registered nurse, or physician accesses OARRS, the receipt and assessment of patient information must be documented.⁵⁹

Regarding advanced practice nurses and physicians, current rules also provide that other signs of possible abuse or diversion may necessitate review of the patient's OARRS report.⁶⁰

⁵³ R.C. 4715.302, 4723.487, 4725.092, 4730.53, and 4731.055.

⁵⁴ O.A.C. 4715-6-01(B), 4723-9-12(B), and 4731-11-11(B).

⁵⁵ Some of the signs of drug abuse or diversion specified in the rules are having a history of drug-related criminal activity, refusing to participate in a drug screen, and having a family member express concern related to the patient's drug use. O.A.C. 4715-6-01(B), 4723-9-12(B), and 4731-11-11(B).

⁵⁶ O.A.C. 4715-6-01(B).

⁵⁷ O.A.C. 4723-9-12(B)(1).

⁵⁸ O.A.C. 4731-11-11(B)(1).

⁵⁹ O.A.C. 4715-6-01(B), 4723-9-12(B), and 4731-11-11(B).

⁶⁰ O.A.C. 4723-9-12(B)(2) and 4731-11-11(B)(2). Other signs of abuse or diversion may include frequently requesting early refills of reported drugs, recurring emergency department visits to obtain reported drugs, and appearing impaired or sedated during an office visit or examination.

Optometrists and physician assistants

Although the State Board of Optometry and the State Medical Board have yet to adopt rules regarding the review of patient information available through OARRS, such rules have been proposed and are currently under consideration.⁶¹

Written policy to prevent opioid diversion

The bill requires a licensed hospice care program that provides hospice care and services in a patient's home to establish a written policy for preventing the diversion of controlled substances containing opioids that are prescribed for a patient. The policy must include procedures for the disposal of any such drugs prescribed to a patient as part of the patient's interdisciplinary plan of care and relinquished to the program after the patient's death or when no longer needed by the patient.⁶²

Current Ohio Department of Health (ODH) rules require each hospice care program to have a policy for disposing of controlled drugs maintained in the patient's home when those drugs are no longer needed by the patient.⁶³ Such rules include an interpretative guideline that notes that "the policy . . . shall account for the fact that the drugs legally have been dispensed to the patient and remain under his or her legal control."⁶⁴

Hospice patient interdisciplinary plan of care

Existing law requires that a licensed hospice care program establish an interdisciplinary plan of care for each hospice patient and the patient's family that: (1) is coordinated by one designated individual who must ensure that all components of the plan of care are addressed and implemented, (2) addresses maintenance of patient-family participation in decision making, and (3) is periodically reviewed by the patient's attending physician and by the patient's interdisciplinary team.⁶⁵

As part of this plan of care, the bill requires each hospice care program providing hospice care and services in the patient's home to do all of the following:

⁶¹ Telephone conversation with representatives of the Ohio State Board of Optometry, December 10, 2013. E-mail correspondence with representatives of the State Medical Board of Ohio, December 11, 2013.

⁶² R.C. 3712.062(A).

⁶³ Ohio Administrative Code (O.A.C.) 3701-19-21.

⁶⁴ O.A.C. 3701-19-21(C).

⁶⁵ R.C. 3712.06(C), not in the bill.



(1) Before providing hospice care and services, distribute to the patient and patient's family a copy of the written policy required by the bill for preventing drug diversion and discuss the procedures included in the policy with the patient and patient's family;

(2) Assess the patient, the patient's family, and the care environment for any risk factors associated with diversion;

(3) Maintain records of controlled substances containing opioids prescribed to the patient and included in the patient's plan of care, including accurate counts of the numbers dispensed and used;

(4) Monitor the use and consumption of controlled substances containing opioids prescribed to the patient and included in the plan of care, including prescription refills, for signs of diversion;

(5) Report any sign of suspected diversion to a local law enforcement agency;

(6) Before providing hospice care and services, inform the patient and the patient's family that the hospice care program will dispose of any controlled substances containing opioids that are no longer needed by the patient and were included in the plan of care.⁶⁶

Drug disposal by hospice programs

The bill contains several provisions relating to the disposal by a hospice program of controlled substances containing opioids no longer needed by a patient.

Written request

After a patient's death or when certain drugs are no longer needed by the patient, the bill requires a hospice program to request, in writing, that the patient or patient's family relinquish to the program for disposal any remaining controlled substances containing opioids that were included in the patient's plan of care.⁶⁷

Disposal requirements

The disposal must be documented by a program employee and conducted in any of the following ways:

⁶⁶ R.C. 3712.062(B)(1) to (6).

⁶⁷ R.C. 3712.062(B)(7).



(1) Performed by a program employee and witnessed by the patient or patient's family member;

(2) Performed by the patient or patient's family member and witnessed by a program employee;

(3) Performed by a program employee and witnessed by another program employee.⁶⁸

Report to law enforcement

Following a program's written request, if the patient or patient's family fails to relinquish any remaining controlled substances containing opioids to the program, the bill requires that the program report to a local law enforcement agency the quantity and type of such drugs that were included in the patient's plan of care but not relinquished.⁶⁹

Drug disposal by law enforcement

Immediately following a report from a hospice program, the local law enforcement agency must investigate and dispose of the remaining controlled substances containing opioids that were reported to the agency by the program.⁷⁰

Criminal penalty for failure to relinquish drugs

The bill provides that a patient or family member who receives a written request to relinquish controlled substances containing opioids that were included in the plan of care and fails to relinquish the drugs to the hospice program is guilty of a minor misdemeanor.⁷¹ Under existing law, a minor misdemeanor is punishable by a fine not to exceed \$150.⁷²

Evidence of compliance

Not later than one year after the bill's effective date, each hospice care program that provides care and services in a patient's home and holds a license on the bill's effective date must submit to ODH written evidence demonstrating that the program is

⁶⁸ R.C. 3712.062(A).

⁶⁹ R.C. 3712.062(B)(8).

⁷⁰ R.C. 3712.062(E).

⁷¹ R.C. 3712.062(D) and 3712.99.

⁷² R.C. 2929.28, not in the bill.

in compliance with the bill's requirements.⁷³ Such evidence must also be submitted as part of a program's application for license renewal.⁷⁴

Penalties

After a review of the written evidence submitted, if ODH determines that a program is not in compliance with the bill's requirements, ODH may suspend the program's license for not more than six months and impose a fine not to exceed \$20,000.⁷⁵

ODH rulemaking

Not later than one year after the bill's effective date, the ODH Director must adopt rules establishing standards and procedures for the submission and review of written evidence demonstrating compliance with the bill's requirements.⁷⁶

Qualified immunity from civil liability

The bill provides that, if a hospice care program (1) requests, in writing, that a patient or patient's family relinquish to the program any remaining drugs included in the patient's plan of care and (2) reports to a local law enforcement agency the quantity and type of drugs that are not relinquished, the program and its employees, officers, or directors are not liable in damages to any person or government entity in a civil action for injury, death, or loss to person or property that allegedly arises from an action or omission of the program or an employee, unless the action or omission constitutes willful or wanton misconduct.⁷⁷

Exemption from certification

The bill exempts private, nonprofit therapeutic wilderness camps from a requirement that they be certified by the Ohio Department of Job and Family Services (ODJFS).⁷⁸ It defines "private, nonprofit therapeutic wilderness camp" as a structured, alternative residential setting for children who are experiencing emotional, behavioral, moral, social, or learning difficulties at home or school in which (1) the children are

⁷³ Section 3.

⁷⁴ R.C. 3712.04(B).

⁷⁵ R.C. 3712.062(F) and Section 3.

⁷⁶ R.C. 3712.062(G).

⁷⁷ R.C. 3712.062(C).

⁷⁸ R.C. 5103.02.

placed by their parents or another relative with custody, (2) the children spend the majority of their time either outdoors or in a primitive structure, and (3) the camp accepts no public funds for use in its operations.

Under current law, with limited exceptions, any institution or association that receives or desires to receive and care for children for two or more consecutive weeks must be certified by ODJFS. It is likely that a private, nonprofit therapeutic wilderness camp is considered an institution or association and classified as a children's residential center under rules adopted by ODJFS.⁷⁹ Extensive ODJFS regulations establish the certification process for children's residential centers and the specific criteria that those centers must meet.⁸⁰ The bill exempts private, nonprofit therapeutic wilderness camps from ODJFS certification by excluding them from the definitions of "association" and "institution" in the certification law.⁸¹

Regulation of private, nonprofit therapeutic wilderness camps

License requirement

The bill requires the ODJFS Director to issue a license to a private, nonprofit therapeutic wilderness camp that applies for such a license on a form prescribed by the Director and meets certain minimum standards.⁸² Those minimum standards are as follows:

- The camp must develop and implement a written policy that establishes (1) standards for hiring, training, and supervising staff, (2) standards for behavioral intervention, including standards prohibiting the use of prone restraint and governing the use of other restraints or isolation, (3) standards for recordkeeping, including specifying information that must be included in each child's record, who may access records, confidentiality, maintenance, security, and disposal of records, (4) a procedure for handling complaints about the camp from the children attending the camp, their families, staff, and the public, (5) standards for emergency and disaster preparedness, including procedures for emergency evacuation and standards requiring that a method of emergency communication be accessible at all times, (6) standards that ensure the protection of children's civil rights, and (7) standards for the

⁷⁹ Ohio Administrative Code (O.A.C.) 5101:2-1-01(B)(47).

⁸⁰ O.A.C. 5101:2-9-02 through 5101:2-9-36.

⁸¹ R.C. 5103.02.

⁸² R.C. 5103.50.



admission and discharge of children attending the camp, including standards for emergency discharge.

- The camp must cooperate with any request from the Director for an inspection or access to the camp's records or written policies.

A license issued pursuant to the bill is valid for five years (unless earlier revoked). A private, nonprofit therapeutic wilderness camp seeking license renewal must apply to the Director. If the camp meets the minimum standards described above, the Director must renew the license.⁸³

It appears that therapeutic wilderness camps will also have to comply with current rules for "resident camps." Under existing law, resident camps must meet requirements that the Ohio Department of Health (ODH) adopts under its general authority to regulate the public health.⁸⁴ Under ODH rules, "resident camp" is a facility primarily utilized for the purpose of camping that requires overnight residence.⁸⁵ The rules require that a resident camp receive an annual permit from the local board of health, that the camp be inspected by the local health commissioner before the permit is issued and annually thereafter, and that the camp meet various other health and safety requirements.⁸⁶

Prohibition against operating without a license

The bill prohibits a private, nonprofit therapeutic wilderness camp from operating without a license.⁸⁷ If the ODJFS Director determines that a camp is operating without a license, the Director may petition the court of common pleas of the county in which the camp is located for an order enjoining its operation. The bill requires the court to grant the injunction upon a showing that the camp is operating without a license.

Failure to meet minimum standards

If a licensed private, nonprofit therapeutic wilderness camp fails to meet the minimum standards for such a camp (see "**License requirement**," above), the ODJFS

⁸³ R.C. 5103.51.

⁸⁴ R.C. 3701.13 and 3701.34, not in the bill.

⁸⁵ O.A.C. 3701-25-01.

⁸⁶ O.A.C. 3701-25-01 through 3701-25-22.

⁸⁷ R.C. 5103.53.

Director must notify the camp that the Director intends to revoke the license.⁸⁸ Unless the violation poses an imminent risk to the life, health, or safety of one or more children attending the camp, the Director must give the camp 90 days to come into compliance. If the violation does pose such an imminent risk or the camp fails to meet the minimum standards within 90 days after notice, the bill requires the Director to revoke the license. An order of revocation may be appealed pursuant to the Administrative Procedure Act (R.C. Chapter 119.).

Inspections

The bill authorizes the ODJFS Director to inspect a private, nonprofit therapeutic wilderness camp at any time and to delegate this authority to a county department of job and family services. The Director may request access to the camp's records or its policies adopted under the bill. This authority also may be delegated to a county department.⁸⁹

Criminal records check requirements

Existing law requires a person responsible for a child's care in out-of-home care to undergo a criminal records check.⁹⁰ Out-of-home care includes residential camps. The law regarding out-of-home care defines "residential camp" as a program that accepts children overnight for recreational purposes or for both recreational and educational purposes, but it is not entirely clear whether a private, nonprofit therapeutic wilderness camp is a residential camp under the definition.⁹¹ The bill adds private, nonprofit therapeutic wilderness camps to the settings that are considered to be out-of-home care, thereby expressly subjecting their employees and others who care for children there to criminal records check requirements.⁹²

Mandatory child abuse reporting

The bill adds administrators and employees of private, nonprofit therapeutic wilderness camps to the list of persons who are required to report suspected child

⁸⁸ R.C. 5103.54.

⁸⁹ R.C. 5103.52.

⁹⁰ R.C. 2151.86, not in the bill.

⁹¹ R.C. 2151.011(B)(45).

⁹² R.C. 2151.011(B)(29).

abuse to a public children services agency or law enforcement official.⁹³ Existing law includes this requirement for residential camps.

Compulsory school attendance

The bill specifies that a parent of a child attending a private, nonprofit therapeutic wilderness camp is not relieved of the parent's legal obligations regarding compulsory school attendance.⁹⁴

State medical board teleconferencing pilot program

The bill permits the State Medical Board to conduct a two-year pilot program under which any method of teleconferencing, including interactive video teleconferencing, may be used for the purposes of Board committee meetings, including committee meetings at which licenses or certificates are issued.

If a pilot program is conducted, the Board may permit any of its members to attend a committee meeting by teleconference in lieu of being physically present at the meeting. A member who attends by teleconference must be counted in determining whether a quorum is present at the meeting and must be permitted to participate in any vote taken at the meeting.

A pilot program may be commenced at any time on or after the bill's effective date, but must conclude two years after the date it is commenced. After the pilot program concludes, the bill requires the Board to prepare and submit to the General Assembly a report of its findings and recommendations. The report must include a description of the effects that the use of teleconferencing had on the Board's committee and licensing operations, Board member participation in meetings, and public attendance at committee meetings. The Board must submit the report to the Governor and General Assembly.⁹⁵

Collection of health information through OARRS

The bill permits the State Board of Pharmacy to use the Board's drug database, also known as OARRS, to collect any health information submitted by any prescriber, pharmacy, or wholesale distributor of dangerous drugs required by current law to

⁹³ R.C. 2151.421.

⁹⁴ R.C. 5103.55 and 3321.04, not in the bill.

⁹⁵ Section 10.



submit drug-related information to OARRS. The bill also permits the Board to transmit such information to the Ohio Department of Health (ODH).⁹⁶

Under the bill, the Board must collaborate with ODH in determining the health information that may be collected and transmitted. The bill specifies that health information may include records of immunizations administered by pharmacists and pharmacy interns. The bill also provides that any health information received is not a public record and cannot be released by the Board other than for the purposes of transmitting the information to ODH as provided in the bill and in rules adopted pursuant to the bill.

The bill requires that the Board, in consultation with ODH, adopt rules, in accordance with the Administrative Procedure Act (R.C. Chapter 119.), as necessary to implement the bill's provisions.

Ohio Healthier Buckeye Council and grant program

The bill establishes the Ohio Healthier Buckeye Council and Ohio Healthier Buckeye Council grant program.⁹⁷

Council membership

Under the bill, the Council consists of the following members:

- (1) The state Auditor, or the Auditor's designee;
- (2) Three members representing administrative departments, appointed by the Governor;
- (3) Five members representing affected local private and public entities or individuals, appointed by the Governor;
- (4) Two members of the Ohio Senate, one appointed by the Senate President, one appointed by the Senate Minority Leader;
- (5) Two members of the Ohio House of Representatives, one appointed by the Speaker of the House, one appointed by the House Minority Leader;
- (6) One member representing the judicial branch of government, appointed by the Chief Justice of the Supreme Court.

⁹⁶ R.C. 4729.75 and 4729.80.

⁹⁷ R.C. 121.25, 121.26, 121.27, 121.28, 355.01, 355.03, and 355.04.



Appointments to the Council must be made not later than September 30, 2014, and members may be reappointed. Initial terms vary in length, depending on the type of member, but do not exceed four years. Vacancies are to be filled in the same manner as original appointments. The Council must select a chairperson from among its members. Under the bill, the Council must meet at the call of the chairperson or on the request of a majority of its members.

Council duties

The bill requires that the Council do all of the following:

(1) Promote the establishment of county healthier buckeye councils throughout the state through whatever means the Council determines to be the most efficient;

(2) Develop and promote means by which county councils may reduce the reliance of individuals on publicly funded assistance programs with an emphasis on the following:

(a) Programs that have been demonstrated to be effective;

(b) Identification and elimination of eligibility requirements for publicly funded assistance programs;

(3) Establish eligibility criteria, application processes, and maximum grant amounts for the Ohio Healthier Buckeye grant program;

(4) Collect and analyze data submitted to the Council;

(5) Develop the best practices for the administration of publicly funded assistance programs in Ohio, taking into consideration any recommendations received from county councils;

(6) Issue annual reports required by the bill.

Not later than December 31, 2014, the Council must establish all of the following:

(1) The application processes, eligibility criteria, and grant amounts to be awarded under the Ohio Healthier Buckeye grant program (see "**Grant Program**," below);

(2) The form and manner to be used by county councils when submitting enrollment and outcome data to the Council;



(3) The certification programs that the Council consider acceptable for independent life plan coordinators.

Ohio Healthier Buckeye grant program

The bill establishes the Ohio Healthier Buckeye grant program to be administered by the Ohio Healthier Buckeye Council. Under the bill, the program provides grants to county healthier buckeye councils for the following:

(1) To assist county councils with costs associated with gathering data regarding enrollment and outcome information related to publicly funded assistance programs;

(2) To provide funding to county councils to enable independent life plan coordinators to seek certification;

(3) To award grants to county councils for projects that focus on the following:

(a) Developing, maintaining, and strengthening families;

(b) Improving self-sufficiency to increase income levels;

(c) Using volunteer workers;

(d) Using incentives to encourage designated behaviors;

(e) Using peer leaders and mentors.

Grant eligibility

To be eligible for a grant, the bill requires that a county council demonstrate an active partnership with most, if not all, of the following public and private sector entities:

(1) Local health departments;

(2) County departments of job and family services;

(3) Medicaid managed care organizations;

(4) Primary and secondary schools;

(5) Vocational education programs;

(6) Chambers of commerce and other economic development organizations;

(7) Employers;



- (8) Nonprofit organizations serving low-income individuals;
- (9) Hospitals and health systems;
- (10) Community health centers;
- (11) Free clinics;
- (12) Community behavioral health boards and providers;
- (13) Regional planning commissions;
- (14) Local elected officials.

Grant awards

The bill provides that grants may be awarded on an individual county council basis, multi-county basis, or both. In awarding grants, the Ohio Healthier Buckeye Council must give priority to county councils with existing projects or initiatives that do the following:

- (1) Improve the health and well-being of low-income individuals;
- (2) Align and coordinate public and private resources to assist low-income individuals in achieving self-sufficiency;
- (3) Use local matching funds from private sector sources;
- (4) Implement or adapt evidence-based practices;
- (5) Use volunteers and peer supports;
- (6) Were created as a result of local assessment and planning processes;
- (7) Demonstrate collaboration between entities that participate in assessment and planning processes.

Rulemaking

With respect to grants awarded by the Council, the bill requires that the Council, in consultation with county councils, adopt rules in accordance with the Administrative Procedure Act that do all of the following:

- (1) Establish standards and procedures for reporting program descriptions, costs, and participant numbers, including numbers of participants who have successfully completed programs;



(2) Establish program process and outcome metrics;

(3) Establish standards and procedures for submitting annual reports as required by the bill.

County council reports

The bill requires that county councils use the metrics established by the Council in rule to track outcomes and to prepare and submit an annual report to the Council, Governor, and General Assembly.

Council reports and collaboration

The bill further requires that, not later than April 1, 2016, and every year thereafter, the Council submit an annual report to the Joint Medicaid Oversight Committee, as well as each county council. The report must include the following:

(1) Enrollment and outcome information submitted by county councils, including comparisons with past information, if available;

(2) Recommendations developed by the Council regarding the best practices for the administration of publicly funded assistance programs.

The bill requires the Council to collaborate with the Committee on policy issues that pertain to physical and behavioral health.

COMMENT

Disclosure to law enforcement and HIPAA Privacy Rule

Because the bill requires a hospice care program to report certain health information to law enforcement,⁹⁸ a question may be raised as to whether there is a conflict with the federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. Given that the Privacy Rule permits disclosure to law enforcement when "required by law," it appears that the Rule would not interfere with the bill's operation.

The HIPAA Privacy Rule establishes national standards to protect individuals' medical records or other personal health information.⁹⁹ It applies to covered entities, defined as health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Privacy Rule requires

⁹⁸ R.C. 3712.062(B)(8).

⁹⁹ 45 Code of Federal Regulations (C.F.R.) Part 160 and Subparts A and E of Part 164.

appropriate safeguards to protect the privacy of personal health information¹⁰⁰ and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Privacy Rule also gives patients rights regarding their health information, including rights to examine and obtain copies of their health records and to request corrections.¹⁰¹

The Privacy Rule permits a covered entity to disclose protected health information to law enforcement, without patient authorization, under specified circumstances.¹⁰² The circumstances include reporting protected health information when required by law to do so, including state laws that require the reporting of certain types of wounds or other physical injuries.¹⁰³ The Privacy Rule defines "required by law" as a mandate contained in law that compels an entity to make a disclosure of protected health information and is enforceable in court. The Rule further states that "required by law" includes statutes or regulations that require the production of information.¹⁰⁴ According to the U.S. Department of Health and Human Services, the agency charged with issuing the Privacy Rule, the Rule does not interfere with the operation of state laws that require disclosure to law enforcement.¹⁰⁵

¹⁰⁰ "Protected health information," in general, is individually identifiable health information that is transmitted or maintained in electronic media or any other form or medium. "Individually identifiable health information" is health information, including demographic information collected from an individual that meets all of the following criteria: (1) is created or received by a health care provider, a health plan, an employer, or a health care clearinghouse, (2) relates to (a) the past, present, or future physical or mental health or condition of an individual, (b) the provision of health care to an individual, or (c) the past, present, or future payment for the provision of health care to an individual, and (3) identifies the individual, or there is a reasonable basis to believe it could be used to identify the individual. 45 C.F.R. 160.103.

¹⁰¹ U.S. Department of Health and Human Services, *Your Health Information Privacy Rights* (last visited March 31, 2014), available at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/consumer_rights.pdf>.

¹⁰² 45 C.F.R. 164.512(f). See also U.S. Department of Health and Human Services, *When does the Privacy Rule allow covered entities to disclose protected health information to law enforcement officials?* (last visited March 31, 2014), available at <http://www.hhs.gov/ocr/privacy/hipaa/faq/disclosures_for_law_enforcement_purposes/505.html>.

¹⁰³ 45 C.F.R. 164.512(f).

¹⁰⁴ 45 C.F.R. 164.103.

¹⁰⁵ U.S. Department of Health and Human Services, *Health Information Privacy, Will this HIPAA Privacy Rule make it easier for police and law enforcement agencies to get my medical information?* (last visited March 31, 2014), available at <http://www.hhs.gov/ocr/privacy/hipaa/faq/disclosures_for_law_enforcement_purposes/349.html>.

HISTORY

ACTION

DATE

Introduced
Reported, H. Health & Aging

03-18-14

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