



Ohio Legislative Service Commission

Bill Analysis

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Sub. H.B. 366

130th General Assembly

(As Reported by S. Medicaid, Health and Human Services)

Reps. Sprague, Buchy, Hood, Phillips, Ruhl, Smith, Antonio, Barnes, Bishoff, Brown, R. Hagan, Schuring, Sears, Johnson, R. Adams, Amstutz, Anielski, Ashford, Baker, Beck, Blair, Blessing, Boose, Boyce, Budish, Burkley, Butler, Conditt, Damschroder, Derickson, DeVitis, Dovilla, Duffey, Fedor, Gerberry, Green, Hackett, C. Hagan, Hall, Hayes, Heard, Henne, Huffman, Landis, Letson, Lundy, Mallory, McClain, Milkovich, O'Brien, Perales, Pillich, Rogers, Rosenberger, Stebelton, Stinziano, Strahorn, Wachtmann, Williams, Winburn, Young, Batchelder

Sens. Tavares, Brown

BILL SUMMARY

- 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 hospice patient or family member who receives a written request to relinquish controlled substances and fails to do so is guilty of a minor misdemeanor.
- Grants qualified immunity from civil liability to a hospice care program, program employee, officer, or director, or prescriber 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.

CONTENT AND OPERATION

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.¹

Existing law

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.² 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."³

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.⁴

¹ R.C. 3712.062(A).

² Ohio Administrative Code (O.A.C.) 3701-19-21.

³ O.A.C. 3701-19-21(C).

⁴ R.C. 3712.06(C), not in the bill.



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:

(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) 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;

(6) Investigate any sign of suspected diversion in accordance with ODH rules;

(7) Report the results of such an investigation in accordance with ODH rules.⁵

ODH rulemaking

Under the bill, the ODH Director must adopt rules regarding the suspected diversion of controlled substances containing opioids from homes where hospice care and services are provided. The bill requires that the rules establish the following:

(1) Procedures that a hospice care program must follow while investigating a sign of suspected diversion;

(2) Requirements for reporting to a local law enforcement agency the results of an investigation of suspected diversion.⁶

⁵ R.C. 3712.062(B)(1) to (7).

⁶ R.C. 3712.03(A)(5) and (6).

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.⁷

Disposal requirements

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

(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.⁸

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 the local law enforcement agency with jurisdiction over the territory in which the hospice patient's home is located the quantity and type of such drugs that were included in the patient's plan of care but not relinquished.⁹

Drug disposal by law enforcement

Following a report from a hospice program, the local law enforcement agency with jurisdiction over the territory in which the hospice patient's home is located must

⁷ R.C. 3712.062(B)(8).

⁸ R.C. 3712.062(A).

⁹ R.C. 3712.062(B)(9).



investigate and dispose of the remaining controlled substances containing opioids that were reported to the agency by the program.¹⁰

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.¹¹ Under existing law, a minor misdemeanor is punishable by a fine not to exceed \$150.¹²

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 in compliance with the bill's requirements.¹³ Such evidence must also be submitted as part of a program's application for license renewal.¹⁴

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 \$20,000.¹⁵

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.¹⁶

¹⁰ R.C. 3712.062(E).

¹¹ R.C. 3712.062(D) and 3712.99.

¹² R.C. 2929.28, not in the bill.

¹³ Section 3.

¹⁴ R.C. 3712.04(B).

¹⁵ R.C. 3712.062(F) and Section 3.

¹⁶ R.C. 3712.062(G).

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 following 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, unless the action or omission constitutes willful or wanton misconduct: (1) the program, (2) a program employee, officer, or director, or (3) a prescriber of controlled substances containing opioids that were included in the patient's interdisciplinary plan of care.¹⁷

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,¹⁸ 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.¹⁹ 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 appropriate safeguards to protect the privacy of personal health information²⁰ and sets limits and conditions on the uses and disclosures that may be made of such information

¹⁷ R.C. 3712.062(C).

¹⁸ R.C. 3712.062(B)(9).

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

²⁰ "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.

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.²¹

The Privacy Rule permits a covered entity to disclose protected health information to law enforcement, without patient authorization, under specified circumstances.²² 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.²³ 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.²⁴ 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.²⁵

HISTORY

ACTION	DATE
Introduced	12-02-13
Reported, H. Health & Aging	02-12-14
Passed House (97-0)	02-26-14
Reported, S. Medicaid, Health & Human Services	05-28-14

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²¹ U.S. Department of Health and Human Services, *Your Health Information Privacy Rights* (last visited May 29, 2014), available at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/consumer_rights.pdf>.

²² 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 May 29, 2014), available at <http://www.hhs.gov/ocr/privacy/hipaa/faq/disclosures_for_law_enforcement_purposes/505.html>.

²³ 45 C.F.R. 164.512(f).

²⁴ 45 C.F.R. 164.103.

²⁵ 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 May 29, 2014), available at <http://www.hhs.gov/ocr/privacy/hipaa/faq/disclosures_for_law_enforcement_purposes/349.html>.

