



Ohio Legislative Service Commission

Final Analysis

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Sub. H.B. 366

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

- 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, Balderson, Beagle, Burke, Eklund, Gardner, Jones, Lehner, Manning, Oelslager, Peterson, Uecker, Widener

Effective date: September 17, 2014

ACT 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, and requires the agency to investigate and dispose of those controlled substances.
- Grants qualified immunity from civil liability to a hospice care program, employee, officer, or director, or prescriber for certain actions required by the act.

CONTENT AND OPERATION

Written policy to prevent opioid diversion

The act 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

Hospice licensing rules adopted by the Ohio Department of Health (ODH) prior to the act 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. The rules include an interpretative guideline noting 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."²

Hospice patient interdisciplinary plan of care

Continuing law requires a licensed hospice care program to establish an interdisciplinary plan 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 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.³

As part of this plan of care, the act 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 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;

¹ R.C. 3712.062(A).

² Ohio Administrative Code 3701-19-21.

³ R.C. 3712.06(C), not in the act.



(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 the investigation in accordance with ODH rules.⁴

ODH rulemaking

Under the act, the ODH Director must adopt rules regarding the suspected diversion of controlled substances containing opioids from homes where hospice care and services are provided. Specifically, the rules must 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.⁵

Drug disposal by hospice programs

The act requires a hospice program to request, in writing, that a patient or the 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. The request is to be made after the patient's death or when the drugs are no longer needed by the patient.⁶

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

⁴ R.C. 3712.062(B)(1) to (7).

⁵ R.C. 3712.03(A)(5) and (6).

⁶ R.C. 3712.062(B)(8).



- (1) By a program employee, witnessed by the patient or patient's family member;
- (2) By the patient or patient's family member, witnessed by a program employee;
- (3) By a program employee, witnessed by another program employee.⁷

Drug disposal by law enforcement

If a hospice patient or patient's family fails to relinquish any remaining controlled substances containing opioids to the program, the program must report to the local law enforcement agency with jurisdiction over the territory in which the patient's home is located the quantity and type of drugs that were not relinquished.⁸ Following the report, the local law enforcement agency must investigate and dispose of the remaining controlled substances containing opioids that were reported by the program.⁹

Penalty for failure to relinquish drugs

The act 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.¹⁰ Under continuing law, a minor misdemeanor is punishable by a fine not to exceed \$150.¹¹

Compliance by hospices

The act requires each hospice care program that provides care and services in a patient's home to submit to ODH written evidence demonstrating that the program is in compliance with the act's requirements. In general, the evidence must be submitted as part of a program's application for license renewal. In the case of a program that holds a license on the act's effective date, the program must submit the evidence not later than September 17, 2015.¹²

⁷ R.C. 3712.062(A).

⁸ R.C. 3712.062(B)(9).

⁹ R.C. 3712.062(E).

¹⁰ R.C. 3712.062(D) and 3712.99.

¹¹ R.C. 2929.28, not in the act.

¹² R.C. 3712.04(B) and Section 3.



The act requires the ODH Director to adopt rules establishing standards and procedures for the submission and review of the evidence demonstrating compliance. The rules must be adopted not later than September 17, 2015.¹³

After reviewing the evidence submitted, if ODH determines that a program is not in compliance, ODH may suspend its license for not more than six months and impose a fine not to exceed \$20,000.¹⁴

Qualified immunity from civil liability

The act 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 the applicable local law enforcement agency the quantity and type of drugs 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.¹⁵

COMMENT

Disclosure to law enforcement and HIPAA regulations

Because the act requires a hospice care program to report certain health information to law enforcement,¹⁶ a question may be raised as to whether there is a conflict with regulations implementing portions of the federal Health Insurance Portability and Accountability Act (HIPAA). Given that the HIPAA regulations permit disclosure to law enforcement when "required by law," it appears that they would not interfere with this act's operation.

HIPAA regulations establishing national standards to protect individuals' medical records or other personal health information permit disclosure to law enforcement, without patient authorization, under specified circumstances.¹⁷ The circumstances include reporting otherwise protected health information when required

¹³ R.C. 3712.062(G).

¹⁴ R.C. 3712.062(F) and Section 3.

¹⁵ R.C. 3712.062(C).

¹⁶ R.C. 3712.062(B)(9).

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



by law to do so, including state laws that require the reporting of certain types of wounds or other physical injuries.¹⁸ The HIPAA regulations define "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 regulations further state that "required by law" includes statutes or regulations that require the production of information.¹⁹ According to the U.S. Department of Health and Human Services, the agency charged with adopting the regulations, HIPAA does not interfere with the operation of state laws that require disclosure to law enforcement.²⁰

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
Passed Senate (33-0)	06-03-14
House concurred in Senate amendments (96-0)	06-04-14

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¹⁸ 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?* available at www.hhs.gov/ocr/privacy/hipaa/faq/disclosures_for_law_enforcement_purposes/505.html.

¹⁹ 45 C.F.R. 164.103.

²⁰ 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?* available at www.hhs.gov/ocr/privacy/hipaa/faq/disclosures_for_law_enforcement_purposes/349.html.

