



Sub. S.B. 124

124th General Assembly
(As Passed by the General Assembly)

Sens. Jordan, Amstutz, Austria, DiDonato, Randy Gardner, Harris, Hottinger, Jacobson, Spada, Wachtmann, Ryan

Reps. Jolivette, Gilb, Schuring, Kearns, Roman, McGregor, Raga, Patton, Seitz, Kilbane, Beatty, Hartnett, Schmidt, Faber, Brinkman, Trakas, Setzer, D. Miller, Seaver, Coates, Schneider, Niehaus, Flowers, Distel, Carano, Allen, Sferra, Clancy, Young, Buehrer, Reidelbach, Schaffer, Hughes, Hoops, Rhine, G. Smith

Effective date: *

ACT SUMMARY

- Requires the imposition of one or more sanctions, including civil penalties, for operating one of the following health care facilities without a license: ambulatory surgical facility, freestanding dialysis center, freestanding inpatient rehabilitation facility, freestanding birthing center, freestanding radiation therapy center, or freestanding or mobile diagnostic imaging center.
- Authorizes the Director to impose one or more sanctions against a licensed health care facility for failure to comply with statutory requirements or administrative rules establishing quality standards.
- Requires an ambulatory surgical facility to require each physician who practices at the facility to comply with all statutes related to obtaining informed consent from a patient.

* *The Legislative Service Commission had not received formal notification of the effective date at the time this analysis was prepared. Additionally, the analysis may not reflect action taken by the Governor.*

- Creates an immunity for ambulatory surgical facilities from liability for a physician's failure to obtain informed consent from a patient unless the physician is an employee of the ambulatory surgical facility.
- Specifies procedures that a hospital must follow in applying to the American College of Surgeons for verification or reverification as a trauma center.
- Provides that a hospital may operate as a trauma center under provisional status in the following circumstances: (1) after it properly applies for verification or reverification, (2) until the final results of its reverification are received, if its application was submitted within one year before the verification ceased, and (3) if the process of applying for verification or reverification was initiated on or before May 20, 2002.
- Specifies the period of time during which a trauma center may operate under provisional status.
- Requires a hospital to provide prompt written notice of its status as a trauma center or provisional trauma center to the Director of Health, Emergency Medical Services Division of the Department of Public Safety, and the physicians and physician advisory boards serving the emergency medical services region.

CONTENT AND OPERATION

HEALTH CARE FACILITIES

Sanctions for operating a health care facility without a license

(secs. 3702.30 and 3702.32)

Ohio law prohibits the following health care facilities from operating without a license issued by the Director of Health: ambulatory surgical facilities, freestanding dialysis centers, freestanding inpatient rehabilitation facilities, freestanding birthing centers, freestanding radiation therapy centers, and freestanding or mobile diagnostic imaging centers. Prior law, however, did not specify penalties for violating the prohibition.

Under the act, if the Director determines that one of these health care facilities is operating without a license, the Director is required to do one or more of the following:

(1) Provide an opportunity for the health care facility to apply for a license within a specified time, not exceeding 30 days after the health care facility receives the order;

(2) Issue an order requiring that the facility cease its operations;

(3) Issue an order prohibiting the facility from performing certain types of services;

(4) Impose a civil penalty of not less than \$1,000 and not more than \$250,000;

(5) Impose an additional civil penalty of not less than \$1,000 and not more than \$10,000 for each day the facility operates without a license.

The act requires the Director to adopt rules governing the issuance of orders and the imposition of civil penalties, including a scale for determining the amount of the penalties.

Sanctions for violations by a licensed health care facility

(sec. 3702.32)

The act authorizes the Director to impose sanctions against a health care facility for violations other than operating without a license. The sanctions may be imposed for violating any provision of the quality standards established in rules adopted by the Director and for violating any of the statutes under which the facility is licensed. If the Director determines that a violation has occurred, the Director may do any or all of the following:

(1) Provide an opportunity for the health care facility to correct the violation within a specified period of time;

(2) Revoke, suspend, or refuse to renew the facility's license;

(3) Prior to or during the pendency of an administrative hearing, issue an order that prohibits the facility from performing certain types of services;

(4) Provide an opportunity for the facility to correct the violation;

(5) Impose a civil penalty of not less than \$1,000 and not more than \$250,000;

(6) Impose an additional civil penalty of not less than \$500 and not more than \$10,000 for each day the facility fails to correct the violation.

Informed consent requirements

(secs. 2317.54, 3702.30(C) and (D), and 3702.32(C))

Ambulatory surgical facilities

Under the act, every ambulatory surgical facility must require each physician who practices at the facility to comply with all relevant provisions in the Revised Code that relate to the obtaining of informed consent from a patient. While the Revised Code does not contain a general provision requiring informed consent for all types of medical procedures, there are provisions that apply to specific procedures. For example, criminal penalties can be imposed against a person who performs or induces an abortion without the patient's informed consent.

As a condition of receiving a license to operate an ambulatory surgical facility, the act requires the facility to demonstrate to the Director that it satisfies the act's informed consent compliance requirements.

All health care facilities

If the Department of Health finds that a physician employed in an health care facility is not complying with any informed consent compliance requirement, the act requires the Department to report its findings to the State Medical Board, the physician, and the facility.¹ The act specifies that this requirement does not create a new cause of action or substantive legal right against a health care facility and in favor of a patient who allegedly sustains harm as a result of the failure of the patient's physician to obtain the patient's informed consent before performing a procedure on or otherwise caring for the patient in the facility.

Under the act, if, after making its report, the Department finds that the physician has persisted in the reported violation at the same health care facility and the facility has not taken reasonable steps to correct the physician's violation, the Department may, after providing the facility an opportunity for a hearing pursuant to the Administrative Procedure Act (R.C. Chapter 119.), impose a civil penalty of not less than \$1,000 and not more than \$50,000 on the facility.

¹ *Even though it requires only ambulatory surgical facilities to require physicians to comply with informed consent requirements in the Revised Code, the act requires the Department of Health to report violations of such requirements that occur in any of the health care facilities subject to the act.*

Use of funds from civil penalties

(sec. 3702.31)

Moneys collected from imposition of civil penalties under the act are to be deposited into the Quality Monitoring and Inspection Fund and used to administer and enforce the Department of Health's health care facility licensing program. The money may also be used in administering and enforcing provisions of continuing law that require health care providers of certain specialized services to meet safety and quality-of-care standards established in rules adopted by the Director.²

Injunctions

(sec. 3702.32(B) and (D))

If a health care facility does not comply with an order issued by the Director requiring the facility to cease its operations or prohibiting the facility from performing certain types of services, the Director is authorized by the act to seek an injunction enjoining the facility from not complying with the order.³ The petition for the injunction must be filed in the court of common pleas of the county in which the health care facility is located. The act requires the court to grant an injunction on a showing that the facility is operating without a license or is providing the types of services prohibited by the Director's order.

Immunity

(sec. 2317.54)

Under continuing law, a hospital, home health agency, or provider of a hospice care program is immune from liability for a physician's failure to obtain informed consent from a patient before performing a procedure on or otherwise caring for the patient, unless the physician is an employee of the hospital, home health agency, or provider. The act extends this immunity to ambulatory surgical facilities.

² *The health care services that must meet safety and quality-of-care standards are solid organ and bone marrow transplantation, stem cell harvesting and reinfusion, cardiac catheterization, open-heart surgery, obstetric and newborn care, pediatric intensive care, operation of linear accelerators, operation of cobalt radiation therapy units, and operation of gamma knives.*

³ *This provision of the act has incorrect division cross references.*

References to original rules

(sec. 3702.30)

The act eliminates provisions that referred to the deadlines that applied to the original adoption of rules establishing quality standards for health care facilities.

HOSPITAL TRAUMA CENTERS

Trauma centers

(secs. 3727.09, 3727.10, and 4765.50)

Beginning November 3, 2002, continuing law prohibits a hospital from knowingly representing that it is able to provide adult or pediatric trauma care that is inconsistent with its level of categorization as a trauma center or making an inappropriate transfer of a trauma patient. At the same time, continuing law prohibits a physician from purposefully admitting a trauma patient to a hospital that is not a trauma center or failing to transfer trauma patients to a trauma center in accordance with the law or protocol and transfer agreements.

The act clarifies the effective date of these provisions by specifying that the provisions apply on and after November 3, 2002.

Verification of trauma centers

(secs. 3727.101 and 4765.01)

To be a trauma center, an Ohio hospital must be verified as an adult or pediatric trauma center by the American College of Surgeons.⁴ The act establishes the following requirements pertaining to a hospital's application for verification or reverification:

(1) If a hospital is seeking initial verification as an adult or pediatric trauma center, verification at a different level, or reverification after having ceased to be verified for one year or longer, the hospital must submit an application to the American College of Surgeons for a consultation visit.

(2) If a hospital is seeking reverification after having ceased to be verified for less than one year, the hospital must submit an application for either a consultation visit or a reverification visit.

⁴ *Until December 31, 2004, certain pediatric trauma centers may operate under a designation issued by the Director of Health (sec. 3727.081, not in the act).*

(3) The hospital must undergo the visit and obtain a written report of the results of the visit. If the report is not obtained on or before one year after the application for the visit is submitted, the hospital must submit a new application.

(4) Not later than one year after obtaining a report of the results of the visit, a hospital is permitted to apply to the American College of Surgeons for verification or reverification as an adult or pediatric trauma center if certain conditions are met. First, the hospital's chief medical officer and chief executive officer must certify in writing to the hospital's governing board that the hospital is committed and able to provide adult or pediatric trauma care consistent with the level of verification or reverification being sought. Second, the hospital's governing board must adopt a resolution stating that the hospital is committed and able to provide adult or pediatric trauma care consistent with the level of verification or reverification being sought. Third, the hospital's governing board must approve a written plan and timetable for obtaining the level of verification or reverification being sought, including provisions for correcting at the earliest practicable date any deficiencies identified in the report obtained from the visit.

Provisional status trauma centers

(secs. 3727.101 and 4765.01)

The act recognizes as trauma centers certain hospitals that are not verified by the American College of Surgeons. Under the act, a hospital is permitted to operate as a trauma center "under provisional status," as follows:

(1) On submission of an application for verification or reverification from the American College of Surgeons, in accordance with the act's provisions regarding applications.

(2) Until it receives the final results of its reverification, if the application was submitted within one year before it ceased to be verified.

Under the act, a trauma center operating under provisional status must limit its provisional status activities to those activities authorized by the level of verification or reverification being sought. The trauma center must also make a reasonable, good faith effort to comply with all requirements established by the American College of Surgeons that must be met for the level of verification or reverification being sought.

Ceasing operation under provisional status

The act requires a hospital to cease operating as a trauma center under provisional status if any of the following applies:



(1) The application for verification or reverification is denied, suspended, terminated, or withdrawn.

(2) In the case of a hospital seeking initial verification, verification at a different level, or reverification after having ceased to be verified for one year or longer, the hospital has not obtained verification or reverification by the date that occurs 18 months after commencing to operate under provisional status.

(3) In the case of a hospital seeking reverification after having ceased to be verified for less than one year, the hospital has not obtained reverification by the date that occurs one year after commencing to operate under provisional status.

Under the act, a hospital that is required to cease to operate as an adult or pediatric trauma center under provisional status must do all of the following:

(1) Except as otherwise provided by federal law, at the earliest practicable date transfer to one or more appropriate trauma centers all trauma patients in the hospital to whom the hospital is not permitted to provide trauma care.

(2) Promptly comply with the laws that prohibit a hospital from misrepresenting its trauma center status and from improperly admitting trauma patients.

(3) Not later than 180 days after ceasing to operate under provisional status, comply with the trauma care laws according to its current status by adopting appropriate trauma care protocols and entering into appropriate patient transfer agreements. The act specifies that a hospital is not in violation of the trauma care laws during the time it develops different trauma care protocols and enters into different patient transfer agreements.

A hospital that ceases to operate as an adult or pediatric trauma center under provisional status may not operate as an adult or pediatric trauma center under provisional status until two years have elapsed since it ceased to operate under that status.

Availability of records

The act provides that a trauma center operating under provisional status must make available for public inspection during normal working hours a copy of its declarations to being committed and able to provide trauma care and a copy of its application for verification or reverification. On request, the trauma center must provide a copy of the documents. The trauma center is permitted to charge a reasonable fee to cover the necessary expenses incurred in furnishing the copies, except that no fee can be charged if the copies are being furnished to the Director of Health.

On request, the trauma center must furnish to the Director a copy of the report of the consultative or reverification visit obtained from the American College of Surgeons and a copy of the plan and timetable for obtaining verification. The act specifies the following:

(1) Patient-identifying information can be omitted.

(2) Submission of the documents does not waive any privilege or right of confidentiality that otherwise applies to the documents and the information in them.

(3) The documents and the information in them are not public records and cannot be disclosed to any person except employees of the Department of Health who are expressly authorized by the Director to examine the copies and information in them.

(4) The documents and information in them are not subject to discovery or introduction into evidence in a civil action, except an action brought by the Director against the trauma center or a person that authorized, approved, or created the original documents and the information in them.

Pending applications for verification

Irrespective of its provisions regarding the receipt of a report of the results of a consultation visit or reverification visit from the American College of Surgeons, the act provides that a hospital may operate under provisional status if it submitted an application for a consultation visit or reverification visit on or before May 20, 2002. The act requires the hospital to do all of the following:

(1) Comply substantively with the act's requirements to attest to the hospital's commitment and ability to provide trauma care;

(2) Approve through its governing board a written plan and timetable for obtaining the level of verification or reverification being sought, including provisions for correcting at the earliest practicable date any deficiencies identified in the exit interview and any subsequent report received;

(3) Comply with all other provisions of the act applicable to the operation of trauma centers under provisional status, including the act's provisions expressing when a hospital must cease operating under provisional status.

Trauma center notices to state and local entities

(sec. 3727.102)

The act requires a hospital to provide prompt written notice of its trauma center status to the Director of Health, the Emergency Medical Services Division of the Department of Public Safety, and the physicians and physician advisory boards serving as regional directors and regional advisory boards for the applicable emergency medical service region. Specifically, a notice must be provided when any of the following occurs:

(1) The hospital ceases to be an adult or pediatric trauma center verified by the American College of Surgeons.

(2) The hospital changes its level of verification as an adult or pediatric trauma center verified by the American College of Surgeons.

(3) The hospital commences to operate as an adult or pediatric trauma center under provisional status.

(4) The hospital changes the level of verification or reverification it is seeking under its provisional status.

(5) The hospital ceases to operate under its provisional status.

(6) The hospital receives verification or reverification in place of its provisional status.

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	06-06-01	p. 626
Reported, S. Health, Human Services & Aging	06-28-01	pp. 778-779
Passed Senate (32-0)	06-28-01	p. 782
Reported, H. Health & Family Services	05-21-02	p. 1787
Passed House (95-0)	05-22-02	pp. 1794-1795
Senate concurred in House amendments (28-0)	05-23-02	pp. 1814-1815

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