



**Sub. H.B. 331**

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(As Passed by the House)

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**BILL SUMMARY**

- Repeals current law governing maternity hospitals, lying-in hospitals, and places where women are received and cared for during partuition and replaces it with law providing for the licensure and regulation of "maternity homes" and "facilities in which obstetric or newborn care is offered."
- Prohibits a person from operating a maternity home or facility in which obstetric or newborn care is offered unless the person has a valid license issued by the Department of Health.
- Establishes licensure application and pre-licensure inspection processes for persons seeking to operate maternity homes or facilities in which obstetric or newborn care is offered.
- Permits the Director of Health to conduct scheduled or random inspections of licensed homes and facilities as the Director considers necessary as part of the Director's responsibility to monitor compliance with the bill.
- Permits the Director of Health to impose civil penalties, pursue disciplinary action, or seek an injunction against a person who does not comply with the bill.
- Permits a person operating a maternity home or facility in which obstetric or newborn care is offered pursuant to a license issued under current law to continuing operating under that license until it expires or is revoked.

- Creates the Maternity and Newborn Advisory Council in the Department of Health and specifies the Council's responsibilities.
- Requires the Public Health Council to adopt rules, as the Council considers necessary, to implement the bill.

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## CONTENT AND OPERATION

### Overview

#### Current law

(R.C. Chapter 3711.)

While hospitals are not licensed in Ohio, maternity units within hospitals are required to be licensed as "maternity hospitals, lying-in hospitals, or places where women are received and cared for during partuition." Current law also prohibits a person from maintaining a maternity boardinghouse or lying-in hospital unless licensed to do so by the Department of Health.

Although the terms, "maternity hospital," "lying-in hospital," and "place where women are received and cared for during partuition," are not defined, current law provides that "maternity hospital and lying-in hospital" includes a "limited maternity unit," which is a unit in a hospital that contains no other maternity unit, in which care is provided during all or part of the maternity cycle and newborns receive care in a private room serving all antepartum, labor, delivery, recovery, postpartum, and nursery needs. "Maternity boardinghouse," is not defined.<sup>1</sup>

### **The bill**

The bill repeals current law governing maternity hospitals, lying-in hospitals, and places where women are received and cared for during partuition and replaces it with law providing for the licensure and regulation of "maternity homes" and "facilities in which obstetric or newborn care is offered." The bill defines "maternity home" as a facility for pregnant girls and women where accommodations, medical care, and social services are provided during the prenatal and postpartal periods, except that it does not include a private residence where obstetric or newborn services are received by a resident of the home (R.C. 3711.01(B)). "Facility in which obstetric or newborn care is offered" means either a maternity unit,<sup>2</sup> or the portion of a hospital that provides inpatient care as a level III newborn care service intensive care nursery,<sup>3</sup> as reported by the hospital

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<sup>1</sup> Although the Revised Code does not define the terms discussed above, rules adopted by the Director of Health define "maternity hospital" as an institution registered under R.C. 3701.07 as a special hospital that provides inpatient care primarily to newborn infants and women during all or part of the maternity cycle (Ohio Administrative Code 3701-7-01) and "maternity home" as a maternity boardinghouse for pregnant women where accommodations, medical care, and social services are provided during prenatal and postpartal periods (O.A.C. 3701-7-07). Another rule defines a "maternity hospital" as a hospital providing inpatient care primarily to newborn infants and women during all or part of the maternity cycle (O.A.C. 3701-59-01).

<sup>2</sup> The bill defines a "maternity unit" as any unit or place in a hospital where women are regularly received and provided care during all or part of the maternity cycle, except an emergency department or similar place dedicated to providing emergency care (R.C. 3711.01(C)).

<sup>3</sup> The requirements for designation as a level III newborn care service are established by rule (Ohio Administrative Code 3701-84-59). A level III newborn care service relates to normal newborns, moderately ill newborns, and extremely ill newborns. A level III newborn care service must also have a neonatal intensive care unit staffed and equipped to provide care for critically ill newborns and an intermediate care unit for convalescing and moderately ill newborns.

pursuant to existing law (R.C. 3701.07) governing reports hospitals must make to the Department of Health (R.C. 3711.01(A)).

**Prohibition on operating without a license**

(R.C. 3711.02)

The bill prohibits a person from operating a maternity home or a facility in which obstetric or newborn care is offered unless that person has a valid license issued by the Department of Health (see "**Licensure process**," below). This prohibition does not extend to "health care facilities," which include, among other facilities, ambulatory surgical facilities and freestanding birth centers,<sup>4</sup> but health care facilities are subject to licensure and quality standards established by the Director of Health in rules required under current law (R.C. 3702.30).

A hospital that operates a maternity unit is not a "health care facility" and is required by the bill to obtain licensure to operate a facility in which obstetric or newborn care is offered.

**Licensure process**

**Application**

(R.C. 3711.04)

The bill requires each person seeking licensure to operate a maternity home or facility in which obstetric or newborn care is offered to apply to the Department of Health for a license. The application must be submitted in a form and manner

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<sup>4</sup> A "freestanding birth center" is any facility in which deliveries routinely occur, regardless of whether the facility is located on the campus of another health care facility, and which is not licensed under R.C. Chapter 3711. as a level I, II, or III maternity unit or a limited maternity unit (R.C. 3702.51). The Department of Health's web site explains that freestanding birth centers are limited to serving low-risk mothers during the antepartum and immediate postpartum periods. A freestanding birth center that is owned and operated by a religious entity and provide services exclusively to women who are members of that religious denomination, sect, or group is not required to obtain a license. These centers are, however, subject to minimum patient safety monitoring and evaluation requirements by the Department under R.C. 3702.301. Ohio Department of Health, Maternity (last visited Oct. 10, 2007), available at <<http://www.odh.ohio.gov/odhprograms/chcf/comhfs/munit/mu1.aspx>>.

prescribed by the Public Health Council in rules the Council must adopt under the bill.<sup>5</sup>

**Prior inspection**

(R.C. 3711.06)

The bill requires the Director of Health to inspect each maternity home or facility in which obstetric or newborn care is offered for which a person has applied for an initial license. Inspections must be conducted prior to issuing the license in accordance with inspection criteria, procedures, and guidelines the Public Health Council must establish in rules.

**License duration and renewal**

(R.C. 3711.08)

A license to operate a maternity home or facility in which obstetric or newborn care is offered is valid for three years, unless earlier revoked or suspended. A license may be renewed in the manner prescribed by the Public Health Council in rules. The license renewal fee is to be specified in the rules and must be paid not later than 60 days after the Department of Health mails an invoice to the license holder. A penalty equal to 10% of the fee must be assessed for each month it is overdue.

**Compliance monitoring and random inspections**

(R.C. 3711.10)

The bill requires the Director of Health to monitor compliance with the laws governing the licensure and regulation of maternity homes and facilities in which obstetric or newborn care is offered. The Director is permitted to conduct scheduled or random inspections of facilities as the Director considers necessary to adequately monitor compliance.

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<sup>5</sup> The Public Health Council is part of the Department of Health and is a rulemaking body. It consists of seven members appointed by the Governor: three physicians, a pharmacist, a registered nurse, a sanitarian, and a member of the public (R.C. 3701.33).

## *Penalties for noncompliance*

(R.C. 3711.14)

### *Civil penalties and disciplinary actions*

The bill permits the Director of Health, in accordance with the Ohio Administrative Procedure Act (R.C. Chapter 119.), to take the following actions for failure to comply with the law governing the licensure and regulation of maternity homes and facilities in which obstetric or newborn care is offered:

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

(2) Summarily suspend a license if the Director believes there is clear and convincing evidence that the continued operation of a maternity home or facility in which obstetric or newborn care is offered presents a danger of immediate and serious harm to the public;

(3) Revoke a license if the violation is done in such a manner as to pose an imminent threat of serious physical or life-threatening danger as determined by the Director.

To summarily suspend a license, the Director must issue a written order of suspension and cause it to be delivered by certified mail or in person in accordance with the Administrative Procedure Act. The bill prohibits the order from being subject to suspension by a court while an appeal is pending. If the individual subject to the suspension requests an adjudication, the date for the adjudication must be within 15 days but not earlier than seven days after the individual makes the request, unless another date is agreed to by the individual and the Director. The summary suspension remains in effect, unless reversed by the Director, until a final adjudication order issued by the Director becomes effective.

The bill requires the Director to issue a final adjudication order within 90 days after completion of the adjudication. If the Director does not issue a final order within the 90-day period, the summary suspension is void, but any final adjudication order issued after the 90-day period is not affected.

### *Injunctions*

The bill permits the Director, if the Director has issued an order revoking or suspending a license and the license holder continues to operate a maternity home or facility in which obstetric or newborn care is offered, to ask the Attorney General to apply to the court of common pleas of the county in which the person is located for an order enjoining the person from operating the home or facility. The

court must grant the order on a showing that the person is operating the home or facility.

**Transition--currently operating homes and facilities**

(Section 3)

The bill permits a person operating a maternity home or facility in which obstetric or newborn care is offered pursuant to a license issued under current law to continue operating under that license until it expires or is revoked.

Until the rules to be adopted under the bill are adopted, the bill permits the Department of Health to renew licenses and issue new licenses under the current rules governing maternity hospitals, lying-in hospitals, or places where women are received and cared for during partuition.

**Rulemaking authority**

(R.C. 3702.11 and 3711.12)

The bill eliminates the authority of the Director of Health to adopt rules establishing safety standards and quality-of-care standards for "obstetric or newborn care" and instead requires the Public Health Council to adopt rules in accordance with the Administrative Procedure Act as the Council considers necessary to implement the requirements for licensure and operation of maternity homes and facilities in which obstetric or newborn care is offered. The rules must include provisions for all of the following:

- (1) Licensure application forms and procedures;
- (2) Application renewal procedures, including rules that address the right of the Director, at the Director's sole discretion, to inspect a home or facility prior to renewal of a license;
- (3) Application and renewal fees, including rules on fees for inspections;
- (4) Safety standards, quality-of-care standards, and quality-of-care data reporting requirements;
- (5) Reporting and auditing requirements;
- (6) Inspection criteria, procedures, and guidelines;
- (7) Any other rules necessary to implement the bill.

When adopting rules, the Council must give consideration to recommendations regarding obstetric or newborn care issued by the American College of Obstetricians and Gynecologists; American Academy of Pediatrics; American Academy of Family Physicians; American Society of Anesthesiologists; American College of Nurse Midwives; U.S. Centers for Disease Control and Prevention; Association of Women's Health, Obstetrics, and Neonatal Nurses; and the Association of Operating Room Nurses; or their successor organizations. The Council must also consider the recommendations of the Maternity and Newborn Advisory Council created by the bill.

### **Use of fees**

(R.C. 3711.16)

The bill requires that all license application fees, renewal fees, late renewal penalties, and civil penalties collected by the Director of Health under the bill be deposited in the state treasury to the credit of the General Operations Fund created under current law. The moneys in the Fund must be used solely for administering and enforcing the law and rules governing the licensure and regulation of maternity homes and facilities in which obstetric or newborn care is offered.

### **Maternity and Newborn Advisory Council**

#### **Council membership; terms of office**

(R.C. 3711.20)

The bill creates the Maternity and Newborn Advisory Council in the Department of Health. The Governor, with the advice and consent of the Senate, must appoint the following members to the Council:

- (1) A board-certified obstetrician;
- (2) A board-certified pediatrician;
- (3) A nurse manager or administrator responsible for the organization and supervision of nursing services in a level I obstetric care service;<sup>6</sup>
- (4) A nurse manager or administrator responsible for the organization and supervision of nursing services in a level I newborn care service;<sup>7</sup>

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<sup>6</sup> The requirements for designation as a "level I obstetric care service" are in O.A.C. 3701-84-46. A level I obstetric care service relates to antepartum, intrapartum, and postpartum care for uncomplicated pregnancies and deliveries.



(5) A nurse manager or administrator responsible for the organization and supervision of nursing services in a level II obstetric care service;<sup>8</sup>

(6) A nurse manager or administrator responsible for the organization and supervision of nursing services in a level II newborn care service;<sup>9</sup>

(7) A nurse manager or administrator responsible for the organization and supervision of nursing services in a level III obstetric care service;<sup>10</sup>

(8) A nurse manager or administrator responsible for the organization and supervision of nursing services in a level III newborn care service;<sup>11</sup>

(9) A licensed dietitian with knowledge of newborn nutrition;

(10) A licensed social worker with knowledge of newborn psychosocial and family support services;

(11) A lactation consultant certified by the International Board of Lactation Consultant Examiners;

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<sup>7</sup> The requirements for designation as a "level I newborn care service" are in O.A.C. 3701-84-50. A level I newborn care service relates to newborns with uncomplicated conditions, newborns that require emergency resuscitation or stabilization for transport, and the management of newborns with selected complicated conditions.

<sup>8</sup> The requirements for designation as a level II obstetric care service are in O.A.C. 3701-84-51. A level II obstetric care service relates to antepartum, intrapartum, and postpartum care for uncomplicated pregnancies and deliveries, selected complicated maternity patients, selected high-risk maternity patients, and the management of emergencies.

<sup>9</sup> The requirements for designation as a level II newborn care service are in O.A.C. 3701-84-54. A level II newborn care service relates to normal newborns, moderately ill newborns, and selected extremely ill newborns.

<sup>10</sup> The requirements for designation as a level III obstetric care service are in O.A.C. 3701-84-55. A level III obstetric care service relates to antepartum, intrapartum, and postpartum care for uncomplicated pregnancies and deliveries, complicated and high-risk maternity patients, and the management of deliveries.

<sup>11</sup> The requirements for designation as a level III newborn care service are in O.A.C. 3701-84-59. A level III newborn care service relates to normal newborns, moderately ill newborns, and extremely ill newborns. A level III newborn care service must also have a neonatal intensive care unit staffed and equipped to provide care for critically ill newborns and an intermediate care unit for convalescing and moderately ill newborns.

- (12) An individual to represent the public;
- (13) A board-certified perinatologist;
- (14) A board-certified neonatologist;
- (15) A certified nurse-midwife, certified nurse practitioner, clinical nurse specialist, or certified registered nurse anesthetist;
- (16) A board-certified anesthesiologist;
- (17) A board-certified family practice physician who delivers children or provides newborn care.

The Governor is required to make the initial appointments to the Council not later than 60 days after the bill's effective date. Of the initial appointments, six must be for a term of three years, six for a term of four years, and five for a term of five years. Thereafter, the terms of office must be five years with each term ending on the same day of the same month as the term it succeeds. Each member holds office from the date of appointment until the end of the term for which the member was appointed, and members may be reappointed. Vacancies must be filled in the manner provided for original appointment. Any member appointed to fill a vacancy prior to the expiration of the term for which the member's predecessor was appointed holds office for the remainder of the term. If a replacement member is not appointed, a member continues in office subsequent to the expiration of the member's term or until a period of 60 days has elapsed, whichever occurs first.

The Council is required by the bill to hold four meetings in the first year after the initial appointments are made. Thereafter, the Council must hold two meetings each year. Additional meetings may be held at the call of the chairperson or the Director of Health.

The bill requires the Council chairperson to be selected annually by members of the Council. Following each meeting, the chairperson may submit a report to the Director of Health summarizing the activities, discussion, and recommendations of the Council. Seven voting members of the Council constitute a quorum.

Members of the Council must be reimbursed for actual and necessary expenses incurred in the performance of their official duties. The Department of Health must provide the Council the administrative support necessary to execute its duties.

### **Council responsibilities**

(R.C. 3711.21)

The bill requires the Maternity and Newborn Advisory Council to do all of the following:

(1) Advise and consult with the Director of Health in the development of rules to be presented to the Public Health Council for proposed adoption;

(2) Advise and consult with the Director concerning the implementation and enforcement of the bill;

(3) Advise and consult with the Director in the development of inspection criteria, procedures, and guidelines to be used in enforcement of the bill;

(4) Advise and consult with the Director regarding recommendations to be presented to the Public Health Council on improving maternity and obstetric or newborn care in Ohio;

(5) Prepare and submit to the Director an annual report evaluating the Department's enforcement of the bill.

### **Committees**

(R.C. 3711.22)

The bill permits the Maternity and Newborn Advisory Council to establish committees to focus on specific components of the enforcement of the bill. Chairpersons of the committees must be appointed by the Council's chairperson and be members of the Council. Other members of the committees must be appointed by the Council's chairperson and may include individuals who are not Council members.

The bill provides that the membership and responsibilities of each committee is subject to the approval of the Director of Health. Members of the committees must be reimbursed for actual and necessary expenses incurred in the performance of their official duties.

Committee reports must be presented to the Council at each regular Council meeting.

### **Conforming amendments and technical changes**

The bill includes non-substantive conforming or technical changes to the following sections of existing law:

- R.C. 3702.55: Eliminates a reference to "maternity boardinghouse or lying-in hospital."
- R.C. 3701.83 and 3709.09: Eliminates cross-references to R.C. 3711.05 and 3711.021, sections repealed by the bill.

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## HISTORY

ACTION	DATE
Introduced	10-02-07
Reported, H. Health	01-31-08
Passed House (93-0)	02-19-08

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