



Alan Van Dyne

*Bill Analysis*  
*Legislative Service Commission*

## **Sub. H.B. 331**

127th General Assembly

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

**Reps. Wagoner, J. McGregor, Schindel, Fende, Goodwin, J. Stewart, Seitz, Brown, Sears, Bacon, Batchelder, Bolon, Chandler, Combs, Dyer, Evans, Flowers, Hughes, Patton, Schneider, Uecker, Ujvagi, Wachtmann, B. Williams**

**Sens. Schuring, Padgett**

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### **BILL SUMMARY**

- Repeals current law governing maternity hospitals, lying-in hospitals, maternity homes or boardinghouses and places where women are received and cared for during parturition and replaces it with law providing for the licensure and regulation of hospital "maternity units," hospital "newborn care nurseries," and "maternity homes."
- Prohibits a person from operating a maternity unit, newborn care nursery, or maternity home unless the person has a valid license issued by the Director of Health.
- Establishes license application and pre-licensure inspection processes.
- Permits the Director to conduct scheduled or random inspections as necessary to monitor compliance with the bill and permits boards of health to conduct scheduled or random inspections to monitor compliance with local health regulations.
- Permits the Director to impose civil penalties, pursue disciplinary action, or seek an injunction against a person who does not comply with the bill.
- 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.

- Permits a person operating a maternity unit, newborn care nursery, or maternity home pursuant to a license issued under current law to continue operating under that license until it expires or is revoked and authorizes license renewal and issuance of new licenses under existing administrative rules until new rules have been adopted under the bill.

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## CONTENT AND OPERATION

### Background

(R.C. 3702.11 and Chapter 3711.)

While hospitals in general are not licensed in Ohio, current law provides for the licensure of certain hospital maternity services. Specifically, the Director of Health is authorized to grant licenses to maintain "maternity hospitals, lying-in hospitals, or places where women are received and cared for during parturition." Although these terms are not defined, current law provides that "maternity hospital or 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.<sup>1</sup>

Separate from the maternity licensing statutes, current law also requires the Director to adopt rules establishing safety standards and quality-of-care standards for obstetric and newborn care services. Failure to comply with the rules may result in the imposition of a civil penalty of \$1,000 to \$250,000, or an injunction to cease operation of the services.

The existing maternity licensure statutes include provisions for the licensure of maternity homes, which are also referred to as maternity boardinghouses. Neither term is defined in statute, but under administrative rules, "maternity home" is defined as a maternity boardinghouse for pregnant women where accommodations, medical care, and social services are provided during prenatal and postpartal periods.<sup>2</sup>

Licenses issued under existing law to provide maternity and newborn care services and to operate maternity homes must be renewed annually. A person who operates without the required license or otherwise violates the existing licensing statutes is subject to a fine of not more than \$300.

**Licensure of maternity units, newborn care nurseries, and maternity homes**

(R.C. 3711.01)

The bill repeals current law governing maternity hospitals, lying-in hospitals, maternity homes or boardinghouses, and places where women are received and cared for during parturition, including the separate existing law under which the Director of Health must adopt rules establishing safety standards and quality-of-care standards for obstetric and newborn care services. In place of existing law, the bill provides for the licensure and regulation of "maternity units" in hospitals, "newborn care nurseries" in hospitals, and "maternity homes." The bill defines these terms as follows:

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<sup>1</sup> In current rules adopted by the Director of Health, "maternity hospital" is defined 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). 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> O.A.C. 3701-7-07.

--**Maternity unit:** a distinct portion of hospital in which inpatient care is provided to women during all or part of the maternity cycle.

--**Newborn care nursery:** a distinct portion of a hospital in which inpatient care is provided to infants. The bill specifies that the term includes a distinct portion of a hospital in which intensive care is provided to infants.

--**Maternity home:** a facility for pregnant girls and women where accommodations, medical care, and social services are provided during the prenatal and postpartal periods. The bill specifies that the term does not include a private residence where obstetric or newborn services are received by a resident of the home.

**Prohibition on operating without a license**

(R.C. 3711.02)

The bill prohibits a person from operating a maternity unit, newborn care nursery, or maternity home unless the person holds the appropriate license issued under the bill and the license is valid. This prohibition does not extend to certain types of "health care facilities," which include, among other facilities, ambulatory surgical facilities and freestanding birth centers,<sup>3</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).<sup>4</sup>

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<sup>3</sup> 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 provides 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 May 12, 2008), available at <<http://www.odh.ohio.gov/odhprograms/chcf/comhfs/munit/mu1.aspx>>.

<sup>4</sup> A hospital is not included as one of the types of "health care facilities" subject to these licensure requirements and quality standards; thus, the bill's exemption for health care facilities does not extend to a hospital.

## Licensure process

### Application submission

(R.C. 3711.04)

The bill requires each person seeking to operate maternity unit, newborn care nursery, or a maternity home to apply to the Director of Health for a license. The application must be submitted in the form and manner prescribed by the Public Health Council in rules the Council must adopt under the bill.<sup>5</sup>

The bill provides that a single application and license is required if an applicant will operate both a maternity unit and a newborn care nursery.

### Application review by the Director and board of health

(R.C. 3711.05(A))

The bill requires the Director to review all applications received. On receipt of a complete application, the Director must send a copy of the application to the board of health<sup>6</sup> of the city or general health district in which the maternity unit, newborn care nursery, or maternity home is to be operated.

Unless the board of health finds that an applicant is not in compliance with an applicable health regulation adopted by the board, the board is required by the bill to approve the application. The board must notify the Director of its determination to approve or disapprove the application. If the board does not notify the director of its determination by the end of the 30th day after it receives the copy of the application, the bill provides that the application is deemed to have been approved by the board.

### Prior inspection

(R.C. 3711.06)

The bill requires the Director to inspect each maternity unit, newborn care nursery, or maternity home for which a person has applied for an initial license.

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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).

<sup>6</sup> The bill defines "board of health" as the board of health of a city or general health district, or the authority having the duties of a board of health in a city that has exercised its authority to establish an alternative to a board of health (R.C. 3711.01).

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 issuance; notice to board of health**

(R.C. 3711.05(B))

The bill requires the Director to issue a license to an applicant if (1) the board of health approves the application or the application is deemed to have been approved, (2) the applicant meets the standards specified in rules the Public Health Council is to adopt under the bill, and (3) the applicant passes the inspection conducted by the Director. On issuance of the license, the Director must notify the appropriate board of health. In the notice, the Director must specify the terms that apply to the license.

**License duration and renewal**

(R.C. 3711.08)

A license to operate a maternity unit, newborn care nursery, or maternity home 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 Director mails an invoice to the license holder. A penalty equal to 10% of the fee must be assessed for each month the fee is overdue.

**Compliance monitoring and inspections**

(R.C. 3709.09 and 3711.10)

The bill requires the Director to monitor compliance with the laws and rules governing the licensure and regulation of maternity units, newborn care nurseries, and maternity homes. The Director is permitted to conduct inspections as necessary to adequately monitor compliance. The bill specifies that the inspections may be scheduled or random.

The bill permits the appropriate board of health to conduct inspections of a maternity unit, newborn care nursery, or maternity home as necessary to adequately monitor compliance with any applicable health regulation adopted by the board. The bill specifies that the inspections may be scheduled or random. Any fees charged by a board for conducting the inspections must be established in accordance with the process the board must use under existing law to establish a uniform system of fees for the services it provides.

## *Penalties for noncompliance*

(R.C. 3711.14)

### *Civil penalties and disciplinary actions*

The bill permits the Director of Health, in accordance with the Administrative Procedure Act (R.C. Chapter 119.), to take the following actions:

(1) Impose a civil penalty of not less than \$1,000 and not more than \$250,000 on a person who violates a provision of the bill or the rules adopted under it;

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

(3) Revoke a license if the Director determines that a violation of the bill or the rules adopted under it has occurred in such a manner as to pose an imminent threat of serious physical or life-threatening danger.

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 not later than 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 unit, newborn care nursery, or maternity home, 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 unit, nursery, or home. The court

must grant the order on a showing that the person is operating the unit, nursery, or home.

**Transition period**

(Section 3)

The bill permits a person operating a maternity unit, newborn care nursery, or maternity home pursuant to a license issued under current law to continue operating under that license until it expires or is revoked.

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

**Rulemaking authority**

(R.C. 3702.11 and 3711.12)

The bill eliminates the duty 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 units, newborn care nurseries, and maternity homes. The rules must include provisions for the following:

- (1) Licensure application forms and procedures;
- (2) Renewal procedures, including procedures that address the right of the Director, at the Director's sole discretion, to conduct an inspection prior to renewal of a license;
- (3) Initial license fees and license renewal fees;
- (4) Fees for inspections conducted by the Director to monitor for compliance with the requirements of the bill and the rules adopted under it;
- (5) Safety standards, quality-of-care standards, and quality-of-care data reporting requirements;
- (6) Reporting and auditing requirements;
- (7) Inspection criteria, procedures, and guidelines;

(8) 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, Obstetric, and Neonatal Nurses; and Association of Perioperative Registered 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 initial license fees, renewal fees, late renewal penalties, fees for inspections conducted by the Director, and civil penalties collected under the bill be deposited in the state treasury to the credit of the existing General Operations Fund. The moneys in the Fund must be used solely for administering and enforcing the law and rules governing the licensure and regulation of maternity units, newborn care nurseries, and maternity homes.

### **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:<sup>7</sup>

(1) Two board-certified obstetricians;

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<sup>7</sup> For purposes of the bill's provisions specifying the qualifications of the Council members who are physicians, "board-certified" means that a physician has been certified in an area of practice by a medical specialty board of the American Medical Association or the American Osteopathic Association. For purposes of the bill provisions specifying the qualifications of the Council members who are nurse managers or administrators from a hospital's obstetric or newborn care service, "level I," "level II," and "level III" means the service-level designation applicable to the portion of a hospital in which obstetric or newborn care is provided, as those levels are reported by the hospital to the Department of Health under existing law. (R.C. 3711.20(A).)

- (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>8</sup>
- (4) A nurse manager or administrator responsible for the organization and supervision of nursing services in a level I newborn care service;<sup>9</sup>
- (5) A nurse manager or administrator responsible for the organization and supervision of nursing services in a level II obstetric care service;<sup>10</sup>
- (6) A nurse manager or administrator responsible for the organization and supervision of nursing services in a level II newborn care service;<sup>11</sup>
- (7) A nurse manager or administrator responsible for the organization and supervision of nursing services in a level III obstetric care service;<sup>12</sup>
- (8) A nurse manager or administrator responsible for the organization and supervision of nursing services in a level III newborn care service;<sup>13</sup>

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<sup>8</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.

<sup>9</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>10</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>11</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>12</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>13</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

- (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;
- (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 six 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.

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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.

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 summarizing the activities, discussion, and recommendations of the Council. Eight 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 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 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 are 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: Eliminates a cross-reference to R.C. 3711.05, which is 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
Reported, S. Health, Human Services & Aging	05-08-08

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