

# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

Agency Name: Department of Health

Regulation/Package Title: Maternity Unit, Newborn Care Nursery, and Maternity Home Licensure Rules

Rule Number(s): 3701-7-01 to 3701-7-17

Date: March 16, 2016 RESUBMITTED: September 12, 2016

**Rule Type:**

<input checked="" type="checkbox"/>	New	<input checked="" type="checkbox"/>	5-Year Review
<input checked="" type="checkbox"/>	Amended	<input checked="" type="checkbox"/>	Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

## **Regulatory Intent**

### **1. Please briefly describe the draft regulation in plain language.**

*Please include the key provisions of the regulation as well as any proposed amendments.*

As a part of Ohio's efforts to combat infant mortality and morbidity, the Ohio Department of Health is promulgating evidence-based rules that help ensure babies are delivered at a hospital that is properly equipped to care for their medical needs. Additionally, in accordance with recent national standards, Ohio's rules also require women to give birth in a place where their antepartum and postpartum medical needs can be met. While ODH understands this could mean some hospitals will not be able to care for a small number of patients they currently do, ultimately requiring delivery at a hospital that can meet the medical needs of both mother and baby will help ensure better health outcomes.

Generally, amendments to the rules have been made to change the levels of neonatal care from three levels, with five sublevels of care, to four levels of care to align with current professional standards in the seventh edition of the Guidelines for Perinatal Care. Also, the amended rules incorporate new four levels of obstetric care introduced by the American Congress of Obstetricians and Gynecologists in February, 2015. In response to stakeholder desires, requirements in current rules 3701-7-07 and 3701-7-08 have been placed in the rules for each level of care, which should allow for easier access to the information for regulated entities (e.g., all in one rule without having to cross-reference multiple rules).

#### 3701-7-01

The rule establishes the definitions for terms used in rules 3701-7-01 to 3701-7-17.

Amendments are made to correct terminology used; remove redundant language; remove references to sublevel of neonatal care; and to reflect the current edition of the Guidelines for Perinatal Care.

Amendments have been made to clarify "consultation" and define terms consistent with the ODH's Office of Vital Statistics.

#### 3701-07-02

The rule establishes that rules 3701-7-01 to 3701-7-17 apply to maternity unit, newborn care nurseries, and maternity homes.

No amendments have been made to this rule.

### 3701-07-03

The rule establishes the fees for license application and renewal, processes for issuing a license, and the requirements for renewal of a license, the requirements with regard to posting of the license, patient or resident occupancy, and license revocation, and the requirements for notification to the director when closing or selling a facility, and of certain construction projects.

The rule has been amended to add license fees for level IV hospitals; to add reporting requirements for types of beds to be licensed to reduce discrepancies between this rule and reports under the Hospital Reporting requirements in chapter 3701-14 of the Administrative Code with the understanding that this will meet the hospital's reporting requirements; moved the requirements for commensurate level of obstetric and newborn care from 3701-7-07 of the Administrative Code and allowed for the de-linking of the newborn care service at level IV obstetric services; clarifies the what must be put on the license; clarifies when the license expires; clarifies timeframes for notices of changes; notice for involuntary closure has been added; and notice requirements for major changes have been updated to reflect proposed new requirements.

### 3701-7-04

The rule prohibits the operation of an unlicensed maternity unit, newborn care nursery, or maternity home. The rule further prohibits interference with an inspection or investigation of a unit, nursery, or home conducted by the director of health. This rule also requires facilities to operate in accordance with Chapter 3701-7 of the Administrative Code.

The rule has been amended to remove an unnecessary date reference.

### 3701-7-05

The rule sets forth the fees ODH may charge for the inspection of maternity units, newborn care nurseries, and maternity homes, as well as timeframes for inspections. This rule also sets forth the penalties for violations of the licensure rules.

The rule has been amended to add inspection fees for level IV services; add new inspection fees ranging from \$300 to \$750 (currently, ODH charges the full inspection fee for any on-site inspection. The new fees will reduce costs to the regulated entities); and, clarify the factors the director may consider during enforcement actions.

### 3701-7-06

The rule sets forth the general facility and equipment requirements for maternity units, newborn care nurseries, and maternity homes. The requirements include disaster

preparedness drills, Code Adam drills, space and room requirements, equipment for transition periods, nursery requirements, and baby-holding nursery requirements.

The rule has been amended to increase the amount of capital expenditure required before a facility licensed under older versions of rules must come into compliance with current rules to \$500,000.00 from \$50,000.00. This was increased because it was clear the prior amount was too low and basic projects too often met this threshold. The new amount will only require those projects that significantly impact licensed space to come into compliance. Additionally, a “grandfather clause” for air changes was inadvertently left out of the rules effective in 2012. That oversight has been corrected and units built prior to January 1, 2012 require 15 air changes per hour instead of the current 20.

The rule has been further amended to continue to require providers who change their level designation to come into compliance with the current rules.

#### 3701-7-07 (rescind)

The rule sets forth the general service standards for maternity units, newborn care nurseries, and maternity homes. The standards require each provider to develop and follow policies and procedures in various areas, establish minimum competency for staff, ensure the provider is providing services appropriate for its classification, and to have infection control protocols in place.

ODH is proposing to rescind this rule and replace with new rule 3701-7-07. All requirements from this rule have been moved to the levels of care rules (new rules 3701-07 to 3701-7-10), the freestanding children’s hospitals rule (3701-7-11), and the maternity home rule (3701-7-12).

#### 3701-7-07 (replacement)

The rule sets forth the standards for Level I obstetric and newborn services. This rule requires Level I obstetric facilities to provide care to women with uncomplicated pregnancies, requires Level I newborn care units to provide care to newborns with uncomplicated conditions, and to provide for emergency resuscitation and stabilization for transport. The rule also requires Level I units to develop and follow policies and procedures for those services provided, and to have necessary equipment and personnel available to provide such services. The rule further requires minimum staffing standards to ensure quality of care.

The rule has been amended to include the ACOG Consensus Statement standards regarding appropriate types of obstetrical patients that can be cared for by a level I OB service. Other standards include transfers of obstetric patients to less than 35 weeks gestation to an appropriate hospital, transfer of a newborn under 35 weeks gestational age

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

[CSIOhio@governor.ohio.gov](mailto:CSIOhio@governor.ohio.gov)

to an appropriate hospital, unless there is concurrence the newborn can stay at the level I, and informed consent for all transfers. Various standards have been moved from rescinded rules 3701-7-07 and 3701-7-08 to this rule. Additionally, support service standards have been clarified as to who can be on call and who must be on site.

The rule has been further amended to reorganize parts of the written service plan requirements for consistency across the levels of care, reorganized the registered nurse staffing requirements, and to remove requirements that a physician with privileges to perform a caesarean section be on-site for all deliveries.

#### 3701-7-08 (rescind)

ODH is proposing to rescind this rule and replace with new rule 3701-7-08. All requirements from this rule have been moved to the levels of care rules (new rules 3701-07 to 3701-7-10), the freestanding children's hospitals rule (3701-7-11), and the maternity home rule (3701-7-12).

#### 3701-7-08 (replacement)

The rule sets forth the standards for Level II obstetric and newborn services. This rule requires Level II obstetric facilities to provide care to women with selected complicated pregnancies, requires Level II newborn care units to provide care to normal, moderately ill, and selected extremely ill newborns in addition to newborns with uncomplicated conditions. Additionally, the rule requires Level II units to develop and follow policies and procedures for those services provided, and to have necessary equipment and personnel available to provide such services. Further, the rule requires minimum staffing standards to ensure quality of care.

The rule has been amended to include the ACOG Consensus Statement standards regarding appropriate types of obstetrical patients that can be cared for by a level II OB service. Other standards include transfers of obstetric patients to less than 32 weeks gestation or with a newborn expected to weigh less than 1500 grams to an appropriate hospital, transfer of a newborn under less than 32 weeks gestational age or weighing less than 1500 grams to an appropriate hospital, unless there is concurrence the newborn can stay at the level II, and informed consent for all transfers. Various standards have been moved from rescinded rules 3701-7-07 and 3701-7-08 to this rule. Additionally, support service standards have been clarified as to who can be on call and who must be on-site.

The rule has been further amended to reorganize parts of the written service plan requirements for consistency across the levels of care, reorganized the registered nurse staffing requirements, and to remove requirements that a physician with privileges to perform a caesarean section be on-site for all deliveries. Additionally, the rule now

allows for an initial evaluation by a physician or CRNP of a newborn requiring mechanical ventilation or CPAP and for other qualified staff to be onsite when stable.

3701-7-09 (rescind)

ODH is proposing to rescind this rule and replace with new rule 3701-7-07. All requirements from this rule have been moved to that rule.

3701-7-09 (replacement)

The rule sets forth the standards for Level III obstetric and newborn services. This rule requires Level III obstetric facilities to provide care to women with uncomplicated, complicated, and high-risk pregnancies, requires Level III newborn care units to provide care to normal, moderately ill, and extremely ill newborns. Additionally, the rule requires Level III units to develop and follow policies and procedures for those services provided, and to have necessary equipment and personnel available to provide such services. Further, the rule requires minimum staffing standards to ensure quality of care.

The rule has been amended to include the ACOG Consensus Statement standards regarding appropriate types of obstetrical patients that can be cared for by a level III OB service. Other standards include transfers of obstetric patients requiring care beyond which that hospital can provide to an appropriate hospital, transfer of a newborn requiring care beyond which that hospital can provide to an appropriate hospital, unless there is concurrence the newborn can stay at the level III, and informed consent for all transfers. Various standards have been moved from rescinded rules 3701-7-07 and 3701-7-08 to this rule. Additionally, support service standards have been clarified as to who can be on call and who must be on-site.

The rule has been further amended to reorganize parts of the written service plan requirements for consistency across the levels of care, reorganized the registered nurse staffing requirements, and to remove requirements that a physician with privileges to perform a caesarean section be on-site for all deliveries. Additionally, the rule now allows for an initial evaluation by a physician or CRNP of a newborn requiring mechanical ventilation or CPAP and for other qualified staff to be onsite when stable.

3701-7-10 (rescind)

ODH is proposing to rescind this rule and replace with new rule 3701-7-08. All requirements from this rule have been moved to that rule.

3701-7-10 (new)

The rule sets forth the standards for Level IV obstetric and newborn services. This rule requires Level IV obstetric facilities to provide care to women with uncomplicated,

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

[CSIOhio@governor.ohio.gov](mailto:CSIOhio@governor.ohio.gov)

complicated, and high-risk pregnancies, requires Level IV newborn care units to provide care to normal, moderately ill, and extremely ill newborns. Additionally, the rule requires Level III units to develop and follow policies and procedures for those services provided, and to have necessary equipment and personnel available to provide such services. Further, the rule requires minimum staffing standards to ensure quality of care.

The rule has been amended to include the ACOG Consensus Statement standards regarding appropriate types of obstetrical patients that can be cared for by a level IV OB service. Various standards have been moved from rescinded rules 3701-7-07 and 3701-7-08 to this new rule. The rule sets forth which support service standards have been clarified as to who can be on call and who must be on-site.

The rule has been further amended to reorganize parts of the written service plan requirements for consistency across the levels of care, reorganized the registered nurse staffing requirements, and to remove requirements that a physician with privileges to perform a caesarean section be on-site for all deliveries. Additionally, the rule now allows for an initial evaluation by a physician or CRNP of a newborn requiring mechanical ventilation or CPAP and for other qualified staff to be onsite when stable.

#### 3701-7-11 (rescind)

ODH is proposing to rescind this rule and replace with new rule 3701-7-09 and 3701-7-10. All requirements from this rule have been moved to those rules.

#### 3701-7-11 (new)

The rule sets forth the standards for freestanding children's hospitals with Level III or Level IV neonatal intensive care units and those hospitals with special delivery services. The rule requires these facilities units to develop and follow policies and procedures for those services provided, and to have necessary equipment and personnel available to provide such services. The rule also requires minimum staffing standards to ensure quality of care.

The rule has been amended to include various standards have been moved from rescinded rules 3701-7-07 and 3701-7-08 to this new rule. The rule sets forth which support service standards have been clarified as to who can be on call and who must be on-site.

The rule has been further amended to reorganize for consistency across the levels of care rule when possible. The requirements for the written service plan have been reorganized for consistency and to include portions inadvertently left out of the previous draft. Pediatric surgical sub-specialists have been distinguished based on the level of care provided, special delivery services have been rework to better detail what is needed as part of the comprehensive plan of care, and that responsibility for provision of both

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

[CSIOhio@governor.ohio.gov](mailto:CSIOhio@governor.ohio.gov)

obstetric care and neonatal care is appropriately delineated. Further, staffing requirements for special delivery services have been changed to represent the unique nature of deliveries occurring in children's hospital.

3701-7-12 (rescind)

ODH is proposing to rescind this rule and replace with new rule 3701-7-11. All requirements from this rule have been moved to that rule.

3701-7-12

The rule sets forth the standards for maternity homes. This rule requires individuals working in the maternity home to have an evaluation by a licensed health professional, requires homes to develop and follow policies and procedures regarding infection control, require homes to document complications and adverse events affecting the health and safety of any resident, and to report reportable diseases to ODH.

The rule includes provisions that have been moved from 3701-7-07 and 3701-7-08. Additionally, the bathroom requirement has been reduced to allow for one bathroom for every three residents, rather than one bathroom for each resident.

Duplicative language for infant security drills has been removed.

3701-7-13 (rescind)

ODH is proposing to rescind this rule and replace with new rule 3701-7-12. All requirements from this rule have been moved to that rule.

3701-7-13 (replacement)

The rule sets forth the standards for maternal and newborn nutrition in maternity units, newborn care nurseries, and maternity homes. This rule requires each unit or nursery to develop and follow policies and procedures for administration of milk and milk products, the preparation and administration of parenteral nutrition, the provision of a feeding preparation area, or formula room if appropriate.

3701-7-14 (rescind)

ODH is proposing to rescind this rule and replace with new rule 3701-7-13. All requirements from this rule have been moved to that rule.

3701-7-14 (replacement)

The rule sets forth the standards for the investigation and reporting of complaints by maternity units, newborn care nurseries, and maternity homes. Additionally, the rule requires maternity units and newborn care nurseries to develop quality assurance and

improvement programs to evaluate the quality of care provided by the facility. The rule includes reporting requirements when there is a death in either a maternity unit or newborn care nursery by requiring the licensee to report:

- Fetal death, other than termination of the pregnancy, to include all fetuses of twenty weeks gestational age or greater that showed evidence of life at any point from the mother's admission through delivery;
- Neonatal death, to include all liveborn neonates before twenty eight days of age, from delivery or admission through transfer or discharge;
- Infant death, to include all liveborn infants twenty eight days of age through one year of age, from delivery or admission through transfer or discharge; and
- Maternal death, to include the death of a woman from any cause related to or aggravated by pregnancy or its management, from the woman's admission through transfer or discharge.

The rule also includes clarification as to the timeframe for quality assurance meetings, participation in the quality assurance committee, and investigations.

#### 3701-7-15 (rescind)

ODH is proposing to rescind this rule and replace with new rule 3701-7-14. All requirements from this rule have been moved to that rule.

#### 3701-7-15 (replacement)

The rule sets forth the recordkeeping requirements for maternity units, newborn care nurseries, and maternity homes. The rule requires facilities to maintain patient medical records to include specific notations of events. Additionally, the rule requires facilities to maintain records for a period of five years. The rule further requires maternity homes to maintain medical records of infant residents, if applicable. The rule requires each facility to keep a log of deliveries, which may be electronic.

#### 3701-7-16 (rescind)

ODH is proposing to rescind this rule and replace with new rule 3701-7-15. All requirements from this rule have been moved to that rule.

#### 3701-7-16 (replacement)

The rule sets forth the requirements for the director granting a maternity unit, newborn care nursery, or maternity home, a waiver or variance from OAC Chapter 3701-7. The rule does not allow for a waiver or variance from a statutory provision, nor does it allow a waiver or variance that could jeopardize the health or safety of patients or residents. The

**77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117**

**[CSIOhio@governor.ohio.gov](mailto:CSIOhio@governor.ohio.gov)**

rule includes statutory provisions allowing the local board of health to make a preliminary determination as to a waiver or variance request from a maternity home.

3701-7-17 (rescind)

ODH is proposing to rescind this rule and replace with new rule 3701-7-16. All requirements from this rule have been moved to that rule.

**Please list the Ohio statute authorizing the Agency to adopt this regulation.**

3711.12

- 2. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program? If yes, please briefly explain the source and substance of the federal requirement.**

No.

- 3. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

Not Applicable.

- 4. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

This rule implements the statutory requirement set forth in section 3711.12 of the Revised Code, which requires ODH to rules for the licensure and operation of maternity units, newborn care nurseries, and maternity homes.

Further, the rules are one part of the effort to reduce infant mortality and morbidity, as well as improve health outcomes for women.

- 5. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

Successful outcomes are measured through a standard survey (inspection) process. This process is generally conducted once every thirty-six months, though reports under this rule may necessitate an on-site inspection prior to the thirty-six month survey. Successful outcomes would be indicated by a finding of compliance the Chapter 3701-7 requirements. Further evidence of success would be represented by the number of complaints received and the number of validated complaint surveys.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

[CSIOhio@governor.ohio.gov](mailto:CSIOhio@governor.ohio.gov)

## **Development of the Regulation**

### **6. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

*If applicable, please include the date and medium by which the stakeholders were initially contacted.*

A series of three stakeholder meetings were held in 2015: April 14, June 10, and August 11. All licensees were notified and of the meeting and additional stakeholders were invited, including:

- The Ohio Hospital Association;
- The Ohio Children's Hospital Association
- The Ohio Perinatal Quality Collaborative
- The American Congress of Obstetricians and Gynecologists, Ohio Section
- The March of Dimes, Ohio Chapter
- American Academy of Pediatrics, Ohio Chapter

Ultimately, over 70 stakeholders participated in the stakeholder meetings.

Additionally, the comments received from stakeholders rules were considered by the Governor-appointed Maternity and Newborn Advisory Council (MNAC). The MNAC is required by section 3711.20 of the Revised Code and serves as an influential and active body in advising the Director of Health on issues relating to maternity units and newborn care nurseries in Ohio. The council provides significant technical input to the Office of Health Assurance and Licensing on all rulemaking activity.

The MNAC meetings are open to the public to encourage even more stakeholder participation. The MNAC reviewed stakeholder feedback and had active participation from stakeholders at the MNAC's October 27, 2015 meeting.

Further, ODH staff solicited informal comments twice before posting the rules for public comment - once in January and again in February, 2016. ODH staff met, either in person or via teleconference, with the hospital associations and a variety of hospital systems in February and March, 2016.

ODH received numerous responses to the first posting. The MNAC met on April 19, 2016 and again on July 12, 2016 in a special session. Both meetings were attended by a large number of stakeholders. At these meetings, the MNAC considered every comment

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

[CSIOhio@governor.ohio.gov](mailto:CSIOhio@governor.ohio.gov)

submitted and heard comments from stakeholders. The MNAC made numerous recommendations based on the body's medical expertise and judgement to ODH regarding the comments.

**7. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

Stakeholders provided significant input to nearly every rule and influenced much of the draft posted for public comment. Notably, the regulated community asked that the rules be collapsed as much as practicable so they can better reference them in the day-to-day operation of a unit. ODH eliminated two rules (3701-7-07 and 3701-7-08) and brought those requirements into the levels of care rules, eliminating the need for cross-referencing.

Additionally, licensees sought clarity as to what support services' staff must be in the hospital and when they can be on-call. This has been clarified throughout the levels of care. Additional clarification has been made to who must be in attendance at a delivery and hospital staffing requirements.

Another example is allowing a disconnect between the level of obstetric care and neonatal care at level IV obstetric services. While these are generally required to be commensurate with each other, stakeholders brought up the fact that often the level IV OB center is the general hospital in an area, while the level IV newborn care center is the children's hospital in the area. Allowing the level IV maternity unit to have a level III newborn care nursery (usually managed by the area children's hospital) will allow pregnant women to receive appropriate care and reflects the realities of health care delivery in Ohio.

As stated above, ODH received numerous comments to the first posting of these rules and the MNAC held two meetings to consider these comments. Based on the recommendations of the MNAC and ODH's own review and consideration of the comments, numerous changes have been made to the rules. Most significantly, ODH heard from many certified registered nurse midwives throughout Ohio that the initial posting for Level I services would effectively bar CRNMs and some family practice physicians from delivering babies in Ohio, especially in areas serving the Amish and Mennonite communities and other rural areas. The MNAC and ODH heard from these providers and ODH has changed the rule accordingly. Additionally, there was general concern that the "special delivery services" provided by children's hospitals did not have to meet the same standards as a similarly-situated obstetrical service. After hearing the concerns, the MNAC recommended changes to reflect the purpose of the service, the immediate surgical needs of the newborn, that also struck a balance for the obstetrical

needs of the woman without requiring an expensive hierarchical structure of obstetric staffing that would only be used several times per year (there are less than 20 deliveries at children's hospitals each year).

In sum, ODH considered each comment and concern from stakeholders and made numerous changes based on those comments and concerns received.

**8. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

- American Academy of Pediatrics and the American College of Obstetricians and Gynecologists, Guidelines for Perinatal Care, Seventh Edition, (2012).

Available at:

<https://evidencebasedpractice.osumc.edu/Documents/Guidelines/GuidelinesforPerinatalCare.pdf>.

The *Guidelines for Perinatal Care* support for the levels of neonatal care, services and staffing of a newborn care nursery, and physical plant requirements.

- American College of Obstetrician and Gynecologists, Levels of Maternal Care, (2014).

Available at: <https://www.acog.org/-/media/Obstetric-Care-Consensus-Series/oc002.pdf?dmc=1&ts=20160314T1002273396>.

This consensus statement sets forth level of obstetric care in significantly more detail than previous documents.

- American College of Obstetrician and Gynecologists, Levels of Maternal Care, (2014).

Available at:

<http://www.acog.org/~media/Districts/District%20VIII/HypertensionPregnancy.pdf?dmc=1&ts=20140527T0350044350>.

This document provides information regarding preeclampsia and discusses appropriate places for delivery of mothers and newborns.

- Association of Women's Health, Obstetric and Neonatal Nurses, Guidelines for Professional Registered Nurse Staffing for Perinatal Units, (2011).

Executive Summary available at: [http://www.jognn.org/article/S0884-2175\(15\)30522-0/pdf](http://www.jognn.org/article/S0884-2175(15)30522-0/pdf)

Provides support for nurse staffing considerations.

**9. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

ODH did not consider any alternatives to the proposed regulation. ODH is required to implement section 3711.12 of the Revised Code. The rule reflects the current statutory requirement and helps to ensure patient safety in licensed facilities.

**10. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

Rules 3701-7-01 to 3701-7-17 contain both structural (process) and performance (outcome) based requirements. When there is a poor outcome, ODH can then look to ensure that processes were implemented correctly and can identify break-downs in the processes that lead to those poor outcomes.

**11. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

The agency conducted a thorough review of the Ohio Revised Code and Ohio Administrative Code to ensure there are no other regulations in place pertaining to maternity units or newborn care nurseries.

**12. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

Providers will be surveyed at least once every 3 years to determine compliance with this regulation. The survey will be done by health care facility program staff using a standard survey tool. This staff will have been trained in the survey process, including understanding of the regulation(s).

**Adverse Impact to Business**

**13. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**

- a. Identify the scope of the impacted business community;**

The impacted business community consists of hospitals with maternity units and newborn care nurseries, children's hospitals with newborn care nurseries, and maternity homes. As of March 14, 2016, there are:

- 109 hospitals with licensed maternity units & newborn care nurseries;
- 6 children's hospital with licensed newborn care nurseries; and
- 2 licensed maternity homes.

As of September 1, 2016, there are:

- 107 hospitals with licensed maternity units & newborn care nurseries;
- 6 children's hospital with licensed newborn care nurseries; and
- 1 licensed maternity homes.

**b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**

In general, these rules do not represent costs that are independent of those already obligated to the licensee by the virtue of their participation in the industry, including Centers for Medicare and Medicaid Services and The Joint Commission requirements for hospitals. Those costs include, but are not limited to, the costs associated with the purchase or lease of real estate, equipment, and personnel. There are also time and manpower costs associated with administrative requirements, including, but not limited to, policy development/implementation and quality assurance and performance improvement. The similar requirements set forth in Ohio's rules are unlikely to require a significant amount of time or costs in addition to that which is already expended by the service and the services will, more likely than not, already meet or exceed the state requirements.

The adverse impact of these rules as a whole consist of financial penalties of up to \$250,000.00, license suspension, and license revocation. Individual rules have additional adverse impacts, including fees for licensing, fees for inspection, reporting, record review and transcription, as well as time completing and submitting required forms to ODH.

**c. Quantify the expected adverse impact from the regulation.**

*The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a*

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

[CSIOhio@governor.ohio.gov](mailto:CSIOhio@governor.ohio.gov)

***“representative business.” Please include the source for your information/estimated impact.***

Compliance with these rules may require:

(1) Licensing fees as follows:

- Level I - \$1,250.00
- Level II - \$1,750.00
- Level III - \$2,250.00
- Level IV - \$2,250.00

(2) Filing of initial/renewal license applications with ODH may require eight (8) to twelve (12) hours of work by administrative personnel.<sup>1</sup> While the rule requires additional reporting, there is actually a cost saving to a licensee as ODH will use this information for the hospital data reporting required by section 3701.07 of the Ohio Revised Code, alleviating duplicative reporting requirements.

(3) Notice requirements to ODH require less than one (1) hour of time by administrative personnel.<sup>1</sup>

(4) Inspections fees as follows:

- Level I - \$750.00
- Level II - \$2,750.00
- Level III - \$3,750.00
- Level IV - \$3,750.00
- Level II or IV freestanding children's hospital - \$3,750.00
- Maternity home - \$750.00
- On-site follow-up inspection fee - \$750.00
- Complaint inspection fee - \$750.00
- Environmental inspection fee - \$750.00
- Monitoring fee - \$750.00
- Desk review fee - \$325.00

While ODH added additional fee categories to this rule, those new, lesser fees will decrease costs to licensees as ODH currently can only charge the full inspection fee for these activities.

- (5) Civil monetary penalties may be charged in accordance with Chapter 119. of the Ohio Revised Code, to a maternity unit, newborn care nursery or maternity home for failure to meet licensing or safety requirements. These penalties are based upon the severity of the violation and range from one thousand to two hundred and fifty thousand dollars. A cease operation order may be obtained in the event of a second or subsequent violation or if the Director determines a first violation poses an imminent threat of serious physical or life-threatening danger.
- (6) General construction and physical plant requirements may require an expenditure of approximately \$300.00 per square foot for new buildings, and \$250.00 for remodel or renovation of existing buildings. (Construction cost estimates derived from RSMeans (<https://www.rsmeans.com/>), a provider of construction cost estimates to construction industry professionals.)
- (7) Time and manpower necessary to develop written service plans and associated policies and procedures.<sup>2,3</sup> All costs associated with policy and procedure development and training would be based upon the nature and complexity of the requirement and the staff chosen to perform the task. In most instances a physician or registered nurse would be responsible for this requirement.
- (8) Death reporting, estimated to be up to four (4) hours of time to gather and report information for each case.<sup>3</sup>
- (9) Time and manpower necessary to prepare a written request for a waiver or variance from the requirements of the Chapter; may include time to compile documentation and a cost analysis.<sup>1</sup>
- (10) Time to read the rules specific to the level of care provided; estimated to be 30 minutes for the entire Chapter.<sup>1, 2, 3</sup>

<sup>1</sup> Other Healthcare Practitioners: \$23.74 per hour\*

<sup>2</sup> Obstetrician and Gynecologists: An average of \$106.60 per hour\*.

<sup>3</sup> Registered Nurse: An average of \$30.04 per hour.\*

\*Figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May, 2014, using the codes for) Obstetrician and Gynecologists (29-1064), Registered Nurse (29-1111), All Health Care Practitioners and Technical Occupations (29-9099).

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

[CSIOhio@governor.ohio.gov](mailto:CSIOhio@governor.ohio.gov)

**14. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

Section 3711.12 requires ODH to establish rules for the licensure of maternity units, newborn care nurseries and maternity homes. These rules establish those licensing requirements to ensure quality of care and help ensure the health and safety of mothers and babies in Ohio.

**Regulatory Flexibility**

**15. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

Alternative means of compliance may be achieved through waiver or variance. Variances or waivers may be granted for any of the requirements of the Chapter if the Director determines: that the requirement has been met in an alternative manner, that the strict application of the requirement would result in undue hardship, and that the granting of the waiver or variance would not jeopardize the health or safety of any patient. The requirements for a waiver or variance are set forth in rule 3701-83-14 and are determined on a case-by-case basis.

**16. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

ODH's Regulatory Ombudsman has set forth a policy for ODH to follow regarding the waiver of fines and penalties for paperwork violations and first-time offenders. ODH implements this policy as part of its business process. Information regarding this policy can be found online at:

<http://www.odh.ohio.gov/rules/ombudsman/regulatoryombudsman.aspx>.

**17. What resources are available to assist small businesses with compliance of the regulation?**

The agency maintains program staff that can assist and provide guidance to licensee to improve their survey outcomes and maintain compliance through the Bureau of Community Health Care Facilities.

Maternity Units/Newborn Care Nurseries:

<http://www.odh.ohio.gov/odhprograms/chcf/comhfs/hagency/hha1.aspx>; and

Maternity Homes:

<http://www.odh.ohio.gov/odhprograms/chcf/comhfs/mhome/mh1.aspx>.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

[CSIOhio@governor.ohio.gov](mailto:CSIOhio@governor.ohio.gov)