

## MEMORANDUM

To: Interested Parties

From: Jayson Rogers, Office of Health Assurance and Licensing  
Ohio Department of Health

Subject: Five Year Rule Review of Ohio Administrative Code Rules 3701-7-01 to 3701-7-17  
("Licensing of Maternity Units, Newborn Care Nurseries and Maternity Homes")

Date: September 12, 2016

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Based on recent changes to professional standards and in accordance with Ohio Revised Code Section 119.04, the Ohio Department of Health ("ODH") is conducting an early five year rule review of Ohio Administrative Code rules 3701-7-01 to 3701-7-17 ("Licensing of Maternity Units, Newborn Care Nurseries and Maternity Homes"). This is the second posting of these rules for public comment.

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). The rules have been amended or proposed as new in accordance with Legislative Services Commission rule-drafting requirements, with one rule being filed as "no change" as follows (new information **highlighted in yellow**):

### 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 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, 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 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 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 review the draft amended rules and provide any comments you may have by **October 12, 2016** to the address below. Please include the words “Maternity/Newborn Licensure” in the subject line of all comments sent via regular mail or e-mail. ODH will review and consider the comments received before the rule is submitted for formal rule proposal and adoption proceedings. Thank you.

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