

NOTICE OF PUBLIC RULES HEARING

DATE: Thursday, April 11, 2019
TIME: 11:00 a.m.
LOCATION: Ohio Department of Health
35 E. Chestnut Street
Columbus, Ohio 43215
ROOM: ODH Basement Training Room A

In accordance with *Chapter 119* of the Revised Code (R.C.), the Director of the Ohio Department of Health announces a Public Hearing at the date and time listed above to hear comments regarding the following action:

Ohio Revised Code (O.A.C.) Chapter 3701-12 – Certificate of Need.

The rules set forth in Chapter 3701-12 of the Ohio Administrative Code (“OAC”) establish the reviewability, application, approval and monitoring requirements for the Certificate of Need (“CON”) program. The CON program ensures the public access to quality long-term care services by requiring review and approval of activities involving the location and utilization of long-term care beds and services. Revisions have been made to the rules to incorporate recent changes to Section 3702.52 of the Ohio Revised Code that were included in House Bill 49 as well as a change to Section 3702.511 from House Bill 470 in March of this year. The new statutory language requires the implementation of an expedited process for reviewability determinations and certificate of need applications. The revisions set forth the requirements for both applicants and the Ohio Department of Health.

The following amendments are being proposed:

3701-12-05 The rule establishes the scope of review for certificate of need projects by detailing what is and what is not a reviewable activity. The rule has been revised to include revisions to section 3702.511 that were included in HB 470 of the 131st General Assembly in March 2017. This revision adds to the list of reviewable activities the failure to conduct a reviewable activity in substantial accordance with the approved application for which a certificate of need was granted, including a change in the site, if the failure occurs from the time the application is approved until five years after implementation of the reviewable activity for which the certificate was granted.

3701-12-08 The rule establishes the CON application and completeness process, public notice, review, decision process, and appeal requirements for all CON applications, except those CON applications filed under ORC section 3702.593. The rule has been revised to incorporate the statutory changes to section 3702.52 of the Revised Code that were included in HB 49. These revisions include requiring an applicant to submit a letter expressly requesting an expedited review in addition to the information already required of paragraph (D). Paragraph (H) has been revised to require applicants who have requested an expedited review to provide a response to a director’s request for additional information within fourteen days from the date of the letter. Revisions also include the incorporation of a fourteen-day timeframe for the director’s determination of completeness for expedited reviews and that the notice of completeness for an expedited review must be granted or denied by the director within thirty days. Finally, paragraph (E) has been revised to include an additional fee of \$1000 for each request for an expedited review.

3701-12-09 The rule establishes the CON application and completeness process, public notice, review, decision process, and appeal requirements for CON applications, filed under ORC section 3702.593. The rule has been revised to include required dates for citations to federal code.

3701-12-18 This rule establishes the validity, follow-up, and withdrawal requirements for CONs. The rule is being revised to incorporate the statutory changes to section 3702.52 of the Revised Code that were included in HB 49 that a reviewable activity shall not be determined to not be in substantial accordance with a certificate of need solely because of a decrease in bed capacity or a change in the owner or operator of the facility unless any of the circumstances specified in (B) of section 3702.59 of the Revised Code apply to the new owner or operator.

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New Rule(s)

3701-12-04 This new rule replaces the existing rule in accordance with Legislative Service Commission rule drafting requirements due to changes to greater than fifty percent of the existing rule. The rule sets forth the requirements pertaining to reviewability determinations. These requirements include, but are not limited to, the director issuing a reviewability determination within specified timeframes and any affected person may appeal a reviewability determination. The rule has been revised to incorporate the statutory changes to section 3702.52 of the Revised Code that were included in HB 49. These revisions include the allowance for an expedited reviewability determination to be issued within thirty days of receipt by the director and that the date the director signs the reviewability ruling shall be the date of issuance.

3701-12-11 This new rule replaces the existing rule in accordance with Legislative Service Commission rule drafting requirements due to changes to greater than fifty percent of the existing rule. The rule establishes the timeframes in which affected persons can file written comments during the course of a CON review. The rule has been revised to require written comments on an application that is under an expedited review, to be submitted within 21 days after the application has been accepted for processing by the director. This revision will allow for the consideration of comments and meet the expedited review timelines set in statute.

Rescinded Rule(s)

3701-12-04 This rule is being rescinded in accordance with Legislative Service Commission rule drafting requirements due to changes to greater than fifty percent of the existing rule.

3701-12-11 This rule is being rescinded in accordance with Legislative Service Commission rule drafting requirements due to changes to greater than fifty percent of the existing rule.

Ohio Revised Code (O.A.C.) Chapter 3701-7 – Maternity Units and Homes.

The rules set forth in Chapter 3701-7 of the Ohio Administrative Code (“OAC”) are 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.

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). Based on comments received from previous postings of these rules, recommendations from the statutorily-created Maternity and Newborn Advisory Council, and comments received from an informal draft shared with stakeholders, ODH is proposing substantive changes to four rules and two new supplemental rules that are the subject of this fourth posting.

3701-7-01

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

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.

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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.

3701-7-04

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.

3701-7-06

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

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. 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. The rule has also been amended to clarify when an anesthesiologist or certified registered nurse anesthetist ("CRNA") is to remain in attendance with a patient and their availability to return. Finally, the rule has been re-organized to clarify who is required to attend anticipated uncomplicated, complicated, and high risk deliveries, and the expectation for a second physician or certified registered nurse practitioner at unanticipated complicated or high risk deliveries, with the recognition that this may not always be feasible based on the specifics of the situation and to more closely track the language used by ACOG about types of deliveries that can be provided by a level I obstetrical service. The language now reads "low-risk" and "uncomplicated" deliveries. This language is used throughout this rule for consistency. Similarly, the requirements for attendance have been expanded to include these ACOG definitions.

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. 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. The rule has been further amended to reorganize parts of the written service plan requirements for consistency across the levels of care. 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.

3701-7-09 (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.

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3701-7-09 (replacement)

The rule sets forth the standards for Level III obstetric and newborn services. 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. 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.

The rule has also been amended to clarify that the individual or individuals required to have neonatal resuscitation program training and be capable of “complete resuscitation” must be able to intubate a patient.

Finally, the rule has been re-organized to clarify who is required anticipated uncomplicated, complicated and high-risk deliveries, and the expectation for a second physician or certified registered nurse practitioner for unanticipated complicated or high-risk deliveries, with the recognition that this may not always be feasible based on the specifics of the situation. The rule has been amended to more closely track the language used by ACOG about types of deliveries that can be provided by a level III obstetrical service. The language now reads “low-risk,” “uncomplicated,” “higher-risk,” and “more complex” deliveries. This language is used throughout this rule for consistency. Similarly, the requirements for attendance have been expanded to include these ACOG definitions and attendance requirements for more complex deliveries have been added. Under this revision, neonatal resuscitation program training is now only required of those likely to attend to newborns at a high-risk delivery. Additionally, the rule now recognizes the “team” or “Code Pink” concept of resuscitation, with the first person starting resuscitation and the second person arriving to provide full ventilation.

Finally, after further review by ODH, the requirement to provide pregnant women with education regarding LARC, and if requested, LARC, has been removed from the licensure rules.

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. 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 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. The rule has also been amended to clarify that the individual or individuals required to have neonatal resuscitation program training and be capable of “complete resuscitation” must be able to intubate a patient.

Finally, the rule has been re-organized to clarify who is required anticipated uncomplicated, complicated and high-risk deliveries, and the expectation for a second physician or certified registered nurse practitioner for unanticipated complicated or high risk deliveries, with the recognition that this may not always be feasible based on the specifics of the situation.

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 has been 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

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distinguished based on the level of care provided, special delivery services have been reworked 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. This rule has become very complicated and confusing. To help clarify, we have broken special delivery services into rule 11.1, and level IV FCH with Level III OB into rule 11.2.

3701-7-11.1 (new)

This new supplemental rule sets forth the components required for a special care service, including the delineation of responsibilities between providers, antepartum and postpartum obstetrical staffing requirements, and staffing requirements for intrapartum care and delivery.

3701-7-11.2 (new)

This new supplemental rule sets forth the requirements for a freestanding children's hospital with a level IV neonatal care service to provide a level III obstetrical service. The rule incorporates the Level III OB requirements, discussed above, including who is required anticipated more complex deliveries and most complex deliveries.

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. 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. 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

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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.

Hearing and Contact Information:

At the hearing, people affected by the proposed action may appear and be heard in person or accompanied by an attorney. They may present their positions, arguments, or contentions orally or in writing; may offer witnesses; and may present evidence showing that the proposed rule, if adopted or effectuated, will be unreasonable or unlawful.

To aid in getting visitors through building security, any persons intending to testify at the hearing or planning to observe are encouraged to pre-register by writing to the Office of the General Counsel, Ohio Department of Health, 246 North High Street, 7th Floor, Columbus, Ohio 43215, or by phone to (614) 466-4882, or send an e-mail to odhrules@odh.ohio.gov.

Copies of the proposed rule will be available on the Register of Ohio website:

<http://www.registerofohio.state.oh.us/jsps/publicdisplayrules/searchRuleNumber.jsp> approximately a half day after the rule is filed, or from the Office of the General Counsel, Ohio Department of Health (<https://www.odh.ohio.gov/rules/drafts/drafts.aspx>).

Please e-mail any written comments to ODHrules@odh.ohio.gov by 5:00 p.m. on April 10, 2019.