

**OHIO DEPARTMENT OF HEALTH**  
**MATERNITY LICENSURE**  
**Questions and Answers**

**3701-7-03 and 3701-7-05**

**03 (A) (1) and 05 (C)**

Is the application fee a one-time fee or will we pay it annually?

**The application fee is paid at the time of application for an initial license and the renewal fee is paid every three years. The required inspection fee and complaint inspection fee will be invoiced at the time of an inspection or a complaint inspection, respectively.**

**3701-7-06**

**(C)**

Would you please clarify Rule 3701-7-06 (C) which states the maternity unit, newborn care nursery, or maternity home shall develop and follow a disaster preparedness plan including evacuation in the event of a fire. Evacuation procedures shall be reviewed at least annually, and practice drills shall be conducted quarterly on each shift. Will house wide drills count toward meeting this requirement?

**The rule requires practice drills to be conducted quarterly on each shift, to include participation of staff on the maternity unit. Participation by staff on the maternity unit in each of the house wide drills would count towards meeting this requirement.**

Can infant abduction drills and fire drills be conducted at the change of shifts to cover the staff on both shifts?

**Yes.**

In 2012 we will be required to increase our documented infant abduction drills from one per year to one every six months. What does ODH consider an infant abduction drill? Is going through and checking the mechanical/electrical functions of our infant alarm system while reviewing the overall function with the staff sufficient? Is a drill considered trying to remove a doll off the maternity unit or is it an ODH requirement to try to remove the doll off the campus?

**An infant abduction drill must check for functioning systems and staff awareness of their individual and aggregate responsibilities during execution. While ODH does not require the practice of removing a doll, this practice could confirm that both mechanical and staff safeguards are effective.**

**3701-7-07**

**(D)**

How many beds does a holding nursery need to have?

**While the rules do not specify the number of beds a holding nursery needs to have, this rule requires sufficient beds to accommodate those rooming-in babies whose mothers choose to temporarily place their babies in the holding nursery. Additionally, the nursery must meet the space and utility requirements of paragraphs (P) and (Q) of rule 3701-7-06.**

**(G) (2)**

Is an employee health assessment still required under the new rules?

**No. However, the hospital is required to develop and implement policies and procedures related to infection control consistent with current infection control guidelines issued by the CDC. This would include the CDC's Guidelines for Infection Control in Health Care Personnel.**

**OHIO DEPARTMENT OF HEALTH  
MATERNITY LICENSURE  
Questions and Answers**

**3701-7-08**

**(A)**

How does the state define "protocols?"

**"Protocols" include those plans, procedures, tasks, guidelines, and other items that allow a hospital or unit to conduct its business and meet its responsibilities.**

**3701-7-09**

**(B)**

Are Level I facilities required to transport all women who are being treated with Magnesium Sulfate or Terbutaline for Preterm Labor < 35 weeks if we have them stabilized and not contracting? Or should transfer occur only if we cannot stop the contractions?

**Under rule 3701-7-09, women in pre-term labor less than 35 weeks, if stabilized and are safe to transfer, whether having contractions or not, must be transferred to a facility with a level of care designation suitable to provide necessary services. See, Guidelines for Perinatal Care, Sixth Edition, Chapter 3.**

It is my understanding that a Level I facility cannot admit any pregnant woman at less than 35 weeks that is having contractions, no matter what the reason for the contractions (UTI, dehydration, etc.). The rule states "A level I obstetric service shall not admit as an obstetric patient any pregnant woman less than 35 weeks for intrapartum care except where an emergency condition exists as evidenced by: (1) The mother is having contractions. This is very confusing. Could you please clarify, so that we can be in compliance with the rules?"

**Paragraph (B) of this rule recognizes a hospital's responsibility under EMTALA when an emergency condition exists. When determining whether an emergency condition exists under this rule, the obstetric service must consider paragraphs (B) (1) (2) and (3). If, in the judgment of the OB service, paragraphs, (B) (1) (2) and (3) are not met, the individual must be transferred to a hospital with a level of care designation suitable to provide the necessary services.**

**(E)**

The rule for a Level I does not specify a weight limit for an infant as it does in a Level II. Is this an oversight?

**The rules do not specify a weight limit for Level I neonatal care services. See, Guidelines for Perinatal Care, Sixth Edition, page 10.**

**(J) and (K) (5)**

In a Level I facility, does the anesthesiologist have to be in-house or can he/she be on-call?

**A Level I obstetrical and neonatal service is not required to have an anesthesiologist to be in-house on a 24-hour basis. The anesthesiologist may be on-call, but must be able to meet the 30-minute response time for an emergency cesarean section.**

**(L) (3)**

A physician or certified nurse midwife in attendance at all deliveries and responsible for ascertaining that the newborn adaptations to extra uterine life are proceeding normally and for ensuring immediate post-delivery care of the newborn. Does this rule mean that there needs to be another physician at every delivery other than the OB/GYN or midwife, specifically for the newborn? Can this physician be the OB physician? And the pediatrician is available for consultation if needed?

**OHIO DEPARTMENT OF HEALTH  
MATERNITY LICENSURE  
Questions and Answers**

**This rule requires that every delivery is attended by either a physician or Certified Nurse Midwife. It does not require a second physician at each delivery, unless medically indicated.**

**(L) (4)**

This rule requires a single, designated registered nurse responsible for leading the organization and supervision of nursing services in the obstetric and newborn care services. I currently am over obstetrics and the newborn nursery. Am I permitted to have responsibilities over other units as well (in addition to OB and nursery)?

**The rule requires that there be a single, designated RN responsible for leading the organization and supervision of nursing services in the obstetric and newborn care services areas and does not allow for that nurse to be responsible for other units. However, a facility may request a variance to the specifics of this rule if the hospital believes it meets the variance criteria in rule 3701-7-17.**

**(L) (5)**

If a level I does not have an IBCLC on staff – do we need an actual written agreement or contract with an IBCLC?

**Each provider shall have on-staff or available for consultation, qualified staff appropriate for the services provided including a certified lactation consultant. If the hospital does not have an IBCLC on-staff they must have a written agreement with an IBCLC to provide consulting services as needed.**

**(M) (1-4)**

What is the minimum number of nurses needed for a Level I if they have only one patient in labor?

**If there is one patient in labor, there must be a minimum of one registered nurse. If that patient is in the second stage of labor, a second registered nurse is required to be available to provide care to any other patient that may present.**

If a Level I has no patients, how many staff must be on-site?

**The rule requires each provider to have qualified staff on-duty appropriate for the services provided including a registered nurse competent in obstetric and neonatal care. There must be at least one registered nurse on duty competent in obstetric and neonatal care to provide care for any patient that may present even if there are no patients on the unit.**

**(P)**

Each provider shall maintain the ability to obtain the services of a physician to assist the primary physician or CNM in the case of unavoidable delivery of a high risk patient, emergency cesarean delivery, or unexpected fetal or neonatal stress. Would this be our physician on call for the newborn emergencies or does this mean we need backup two deep for OB/GYN coverage. Our FP's (Pediatricians) can be 30 minutes away per policy. Would this be covered by our anesthesia providers, who are on campus, of which one is an MD and the others are CRNA's?

**This requirement can be met by an in-house physician capable of assisting the primary physician in the case of an emergency. The qualifications of the physician to perform that function must be decided per hospital policy.**

**3701-7-10**

**(D) (4)**

Would you expand on the phrase under 3701-7-10 (D) (4) which states: A Level IIA neonatal care service or a Level IIB neonatal care service may provide for the management of newborns with selected complicated conditions including newborns who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need

**OHIO DEPARTMENT OF HEALTH  
MATERNITY LICENSURE  
Questions and Answers**

subspecialty services on an urgent basis. Clarification of “resolve rapidly” is needed.

**The rule does not allow for a Level IIA to keep a newborn that requires or may require sustained mechanical ventilation or might require subspecialty services that are not readily available. “Resolves rapidly” means that the problem or problems present, such as uncomplicated preterm labor, are not anticipated to require urgent sub-specialty care and/or do not require more advanced levels of care that can’t be provided based on the level of care. See, Guidelines for Perinatal Care, Sixth Edition, page 10.**

**(F) (15)**

Could you please describe this rule in greater detail? Each provider shall provide developmental follow-up of at-risk newborns in the service or refer such newborns at-risk to appropriate programs. Is referring the newborn to the physician acceptable or is the facility responsible for setting up program follow up?

**The rule requires either developmental follow-up of at-risk newborns by the hospital or referral to an appropriate program. Generally, referring an at-risk newborn to a physician would not meet the requirements of this rule. The facility/social service department is responsible for referring the newborns to appropriate community programs based on the newborn’s needs.**

**(H) (3)**

Would you describe what is needed for the written referral policy for obtaining public health, dietetic, genetic, and toxicology services not available in-house? Is this asking about follow up care with community agencies?

**This rule requires a written referral policy for obtaining public health, dietetic, genetic and toxicology services not available in-house. Therefore, if these services are not offered in-house, there must be a written referral policy with an appropriate community agency to obtain these services.**

**(J) (2)**

What is the intent for the 24 hour MRI coverage for Level IIA? I can’t foresee using the MRI for the level of care intended for a Level IIA nursery.

**The rule requires that a Level IIA facility be able to perform an MRI if needed, to include both obstetric and newborn patients. See, the Guidelines for Perinatal Care, Sixth Edition, page 33.**

**(K) (3)**

Does a Level IIA require a Neonatologist to be “on-staff”?

**The neonatologist required by this rule may be either on-staff or a consultant.**

**(K) (5) and (6)**

I am from a Level I unit and considering declaring a Level II. I am the manager of the entire unit and have my MSN. The unit also has an assistant manager. The current person in charge of the nursery is retiring and I am in the midst of the hiring process. The applicant I am currently considering has her BS and MS and has post-graduate courses towards her PhD. However she does not have a BSN. She is attaining her certification. She has many years of nursery experience. Would she qualify under the new Level II rule? Is there a preference in the position title (nursery charge, assistant nurse manager) from the licensure perspective?

**This rule requires a registered nurse with a bachelor’s degree in nursing. ODH has no preference as to the position title.**

**3701-7-11**

**OHIO DEPARTMENT OF HEALTH  
MATERNITY LICENSURE  
Questions and Answers**

**(D) (2) (c) and (L)**

Since Level III NICUs require the support of pediatric subspecialists (surgeons, cardiologists, etc.), sometimes these people are needed on an urgent basis. Do the regulations include any language on timeliness or proximity of coverage?

**Rule 3701-7-11 (L) requires that each provider have qualified staff available for consultation appropriate for the services provided, including medical-surgical subspecialists based upon the medical needs of the patients. The rule further allows for these specialists to be on-call, but must be available for patient care if necessary. Rule 3701-7-11 (D)(2)(c) requires a Level IIIB neonatal care service have all the capabilities of a Level IIIA neonatal care service and can provide: prompt access to a full range of pediatric medical subspecialists. While the rule does not prescribe a specific timeframe in which these subspecialists need to arrive or proximity of coverage, the subspecialists must be available in a timeframe and in close enough proximity to cover the medical needs of patients provided by the Level III.**

**3701-7-09, 3701-7-10, 3701-7-11**

**(E) (1)**

What is a memorandum of agreement and do you have a sample or template of a Memorandum of Agreement?

**A "memorandum of agreement" is a signed, written record of an agreement between two or more. Each hospital should consult with their legal counsel to develop a Memorandum of Agreement specific to their circumstance.**

**(H) (5)**

What is meant by a formal post-resuscitation care program?

**ODH recognizes that there are a variety of formal post-resuscitation programs, including those post-resuscitation programs developed by individual hospitals. A formal program includes learning objectives with competency evaluated post-training. See, the Guidelines for Perinatal Care, Sixth Edition, pages 205-206**

**3701-7-14**

Does human milk prep need to be in a separate or designated room?

**No.**

**3701-7-15**

**(E)**

Do infant and maternal deaths have to be reported within 24 hours? What if it occurs over the weekend? I do not see the 24 hour reporting requirement in rule.

**Infant and maternal deaths are to be reported within 24 hours. The 24 hour requirement is in the instructions on the form that has been prescribed by the Director and may be downloaded from the ODH website. If a death occurs over a weekend, the death must be reported as soon as possible, but no later than Monday morning.**

**(E) (1)**

The rule requires reporting of an infant death. Do you mean all deaths or just unanticipated deaths?

**For the purpose of this rule, this includes reporting the death of a fetus that showed evidence of life upon admission and then died during labor or delivery; the death of a fetus that exhibited life on delivery other**

**OHIO DEPARTMENT OF HEALTH  
MATERNITY LICENSURE  
Questions and Answers**

than transient cardiac contractions and/or fleeting respiratory efforts or gasps; and the death of any newborn following delivery through discharge from the delivering hospital. The maternity rules do not include reporting of induced termination of the pregnancy. However, other abortion reporting laws may apply.

**(E) (2)**

How is maternal death defined?

**For the purposes of this rule, any maternal death that occurs from admission to discharge in the facility to which the patient has been admitted for antepartum and intrapartum care.**

Will the infant and maternal death reporting forms become public record?

**Yes, with redactions as required by applicable law.**

**3701-7-17**

If a hospital maternity unit or newborn care nursery currently has a waiver or variance under the old rules, do they need to reapply for the waiver/variance under the new rules?

**No**

How does a hospital maternity unit or newborn care nursery apply for a waiver or a variance?

**The hospital should submit a written request on letterhead to the Director Health requesting the waiver or variance and should include:**

- 1. In the case of a variance request, the alternative means by which the maternity unit or newborn care nursery is meeting the intent of the requirement; and**
- 2. In the case of a waiver request, the undue hardship caused by the requirement will not jeopardize the health and safety of any patient.**

**GENERAL**

I am looking for clarification on the transfer rule. If we need to transfer a mother or a baby, are we required to send them to a facility in Ohio?

**No, a hospital may have a transfer agreement with an out-of-state hospital if necessitated by the transferring hospital's location.**

If a complaint investigation is conducted prior to a triennial inspection, will ODH go ahead and do a full inspection at that time?

**ODH would consider several factors to determine if this would be warranted, including when the complaint inspection was conducted, the scope of the inspection, and the time until the triennial inspection. In most cases, because the scope of a complaint inspection is limited by the allegations, it will have no impact on the regularly scheduled triennial inspection.**

Can a hospital keep a patient under the gestational age restriction while ruling out dehydration, UTI, etc.?

**This rule does not allow a hospital's maternity unit to admit patients if they are under the gestational age restriction for that level of service. Each patient must be assessed by a physician to determine if the patient is in labor; if there is a need to transfer the patient to a higher level of care; and if it is safe to transfer the patient. When a patient is contracting and the physician is making a determination as to whether or not this patient is in labor, they may choose to hydrate with IV fluids, administer antibiotics, and/or give**

**OHIO DEPARTMENT OF HEALTH  
MATERNITY LICENSURE  
Questions and Answers**

**Terbutaline . If this occurs while the physician is still assessing the patient and the treatment stops the contractions, the rule does not require the transfer of the patient.**

Does ODH specify how gestational age should be determined?

**No. Gestational age may be based on a variety of prenatal and postnatal indicators and is determined by each facility's protocol.**

Does ODH have definitions for high risk, at risk, or complicated?

**ODH does not define "complicated pregnancy," "high risk pregnancy" or "complicated labor and delivery patients." A maternity unit's scope of service should define these cases based on accepted standards of practice. Complicated pregnancies and complicated labor and delivery patients may be based on genetics, medical history, vaginal birth after cesarean section, or a condition or conditions caused by the pregnancy. See, the Guidelines for Perinatal Care, Sixth Edition, Chapters 6 and 8.**

Will surveyors continue to ask to see delivery logs?

**Yes.**

Does a Level IIIA require an on-staff Neonatologist or can they have one as a consultant. If the NICU is operated by a Children's Hospital and they have a Neonatologist consulting from the Children's Hospital, is this acceptable?

**The rule states that each provider shall have either on-staff or available for consultation, qualified staff appropriate for the services provided including a board certified maternal-fetal medicine subspecialist and a board-certified neonatologist as co-directors for the obstetric and newborn care service. The neonatologist can be consulting. ODH would look at the availability and capability of the neonatologist to provide timely on-site consultation when needed.**

If a patient comes in under the allowable gestational age with ruptured membranes but is not contracting and delivery is not imminent, can they keep that mom until she is either over the gestational age restriction or until she goes into labor?

**The rules for Levels I, IIA, IIB, and IIIA require transfer if it is determined by competent authority that there is no imminent danger to the mother or fetus.**

What is ODH's position on adherence to AWHONN staffing guidelines?

**ODH takes no position on the AWHONN staffing guidelines. Each facility must meet the applicable minimum staffing guidelines required by the rule for the facility's level of care. In addition, each hospital must have a staffing policy in place. Surveyors will review that policy to ensure that the hospital is following that policy.**