CHAPTER 150
IOWA REGIONALIZED SYSTEM OF PERINATAL HEALTH CARE

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/1/30

641—150.1(135) Participation and designation. Hospitals within the state must determine whether to participate in Iowa's regionalized system of perinatal health care and will select the hospital's level of participation in the regionalized system. A hospital having determined to participate in the regionalized system must comply with the rules appropriate to the levels of participation for maternal care and neonatal care selected by the hospital. Maternal levels of designation and neonatal levels of designation are evaluated separately, and a hospital may have a level of designation for maternal care that is different from the level of designation for neonatal care; however, a pregnant woman should be cared for at the hospital that best meets both her and her newborn infant's needs.
[**ARC 9178C**, IAB 4/30/25, effective 7/1/25]

641—150.2(135) Definitions.

"Categorization" means a preliminary determination by the department that a hospital is capable of providing maternal care and neonatal care at Level I, Level II, Level III, or Level IV.

"Certificate of verification" means a document awarded by the department that identifies a hospital's level of maternal care and neonatal care at Level I, Level II, Level III, or Level IV and the term of verification at that level.

"Hospital" means a facility licensed under Iowa Code chapter 135B.

"Late preterm" means that a newborn infant is born between 34 0/7 and 36 6/7 weeks' gestation.

"Levels-of-care assessment tool" or *"tool"* means a tool to assess the maternal and neonatal risk-appropriate care, using the minimum information necessary to identify a hospital's maternal level of care based on criteria by the American Congress of Obstetricians and Gynecologists/Society for Maternal-Fetal Medicine and a hospital's neonatal level of care based on criteria by the American Academy of Pediatrics. The tool will be chosen by the department in consultation with the perinatal guidelines advisory committee.

"Neonate" means a newborn infant, up to 28 days of life.

"On-site verification survey" means an on-site survey conducted by the department's statewide perinatal care team based at the University of Iowa health care medical center or by a survey team of members (medical experts) contracted to assess a hospital's ability to meet the level of designation selected by the hospital.

"Perinatal" means the five months before and one month after birth.

"Perinatal center" means a medical facility capable of providing complex obstetric, fetal and neonatal care.

"Prenatal" means during pregnancy.

"Readily available" means on site or at a closely related institution by prearranged consultative agreement.

"Regionalized system of perinatal health care" means the department's program for designating regional perinatal health care services at a verified level of care, based on a hospital's functional capabilities. Levels of care designations are stratified in an increasing order of intensity and complexity for both maternal health care and neonatal health care.

"Regionalized system of perinatal health care coordinator" means the department's program manager for the regionalized system of perinatal health care.

"Respiratory distress" means tachypnea (respiratory rate of 60 or more per minute), grunting, tugging, retracting, nasal flaring, or cyanosis. Any or all of these may constitute respiratory distress in a neonate.

"Reverification" means the process of periodic review, conducted at least every six years, to certify that a hospital has maintained its designated level of care in accordance with criteria established under these rules for hospitals that are participating in the regionalized system of perinatal health care.

"Statewide perinatal care program" means a program consisting of the regionalized system of perinatal health care coordinator, the statewide perinatal care team contracted by the department, and the regionalized system of perinatal health care as defined in these rules.

"Statewide perinatal care team" means the educational team based at the University of Iowa health care medical center and contracted by the department to support the regionalized system of perinatal health care and to provide services to decrease perinatal morbidity and mortality.

"Verification" means a process by which the department certifies a hospital's capacity to provide perinatal care in accordance with criteria established under these rules for hospitals that are participating in the regionalized system of perinatal health care.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25; **ARC 0785D**, IAB 11/25/26, effective 1/1/27]

641—150.3(135) Duties of statewide perinatal care team. The team will:

1. Promote evidence-based and evidence-informed care of pregnant women and newborns.
2. Provide education and consultation to regional and primary providers of perinatal care.
3. Provide chart review to assess quality of care provided and additional education required.
4. Promote change in practice when needed through sharing best practice ideas, policies and procedures.
5. Promote maternal-fetal transfer if delivery of an at-risk infant or mother is anticipated and a higher level of care is anticipated.
6. Provide on-site verification to determine a hospital's ability to meet its level-of-care designation.

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641—150.4(135) Duties of the department. The department will:

1. Certify a hospital's capacity to provide perinatal health care in accordance with criteria established under these rules.
2. Provide technical assistance to the hospitals that choose to participate.
3. Review the submitted levels-of-care assessment tool from all participating hospitals.
4. Conduct or coordinate the on-site verification of determined levels of care for maternal and neonatal care hospitals designated as Level I, Level II, Level III and Level IV.

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641—150.5(135) Maternal and neonatal levels of care—categorization and verification. Categorization and verification of hospitals participating in Iowa's regionalized system of perinatal health care will be made by the department based on national recommendations from the American Academy of Pediatrics and the American Congress of Obstetricians and Gynecologists.

150.5(1) *Application for initial verification.*

a. An application for initial verification may be submitted when:

(1) A new hospital with a perinatal service is opened;

(2) A hospital is reopening after a previously inactive obstetrical unit; or

(3) A hospital requests a change to a higher-level designation in maternal care or neonatal care.

b. A hospital requesting an initial verification may obtain application materials from the department.

c. Upon receipt of an application from a hospital that is requesting to change to a higher level of maternal or neonatal care, the department will request and review copies of the results of the last site visit to the hospital by the statewide perinatal team or request a site visit. The results of the site visit along with the application will be shared with the statewide perinatal team and any clinical experts appointed by the department to determine if all requirements are met. The recommendations will be sent to the department, which will notify the hospital if its application is approved or denied. If the application is denied, the applicant will be informed of the applicant's right to appeal the department's decision.

150.5(2) *Application for a hospital that has previously participated in the regionalized system of perinatal health care.*

a. If a hospital chooses to continue its participation, the hospital must select the levels for maternal care and neonatal care appropriate for the hospital's capacity to provide perinatal health care in accordance with the criteria outlined in these rules.

b. To maintain continuous participation in the regionalized system of perinatal health care, a hospital must complete the levels-of-care assessment tool and an attestation statement. These can be obtained from the department.

c. The department will set dates when each hospital's certification of verification will expire based on the statewide perinatal health care team's site visit schedule and the level of care selected.

150.5(3) *Reverification of level designation.* The levels-of-care assessment tool will be used for all reverifications. The process of reverification of a hospital participating in the regionalized system of perinatal health care will take place once every six years as follows:

a. Reverification of a Level I, Level II or Level III maternal care or neonatal care hospital will be completed through use of the levels-of-care assessment tool and an on-site reverification visit. A hospital must complete and return the levels-of-care assessment tool to the department at least 120 days before the hospital's certification is due to expire. The department will ensure that arrangements are made for the on-site reverification visit. Level II and Level III hospitals may utilize one of two on-site reverification visit options:

(1) A review conducted by the statewide perinatal care team, or

(2) A review by an independent out-of-state team identified by the hospital, approved by the department and paid for by the hospital.

b. Reverification of a Level IV maternal care and neonatal care hospital will be completed through the same process as that for a Level I, Level II or Level III maternal care or neonatal care hospital except that the on-site reverification team will consist of an out-of-state team identified by the hospital and approved by the department. The team will include, at a minimum, a maternal-fetal specialist, a neonatologist, an obstetrical nurse and a neonatal nurse. The Level IV hospital will pay the expense of the review team. All department staff and staff contracted by the department involved in the on-site reverification process will sign a confidentiality statement that will be kept on file at the department.

c. Reverification shall not be construed to imply any guarantee on the part of the department as to the level of perinatal health care services available at a hospital.

d. Hospital reverification of the level of care is valid for a period of six years from the effective date unless otherwise specified on the certificate of verification or unless sooner suspended or revoked.

e. As part of the reverification and renewal process, the department or a designated survey team may conduct periodic on-site reviews of the services of the maternal care and neonatal care hospitals, including chart reviews.

150.5(4) *Level designation maintenance, waiver and confidential records.*

a. A hospital that is unable to maintain its designated level of care will notify the department, in writing, within 60 days of the change in capacity to meet the designated level of care.

b. The director may grant a waiver from the requirements of rules adopted under this chapter for any hospital participating in the regionalized system of perinatal health care.

c. Proceedings, records, and reports developed pursuant to this chapter are confidential pursuant to Iowa Code section 135.11(22) and constitute peer review records under Iowa Code section 147.135, and are not subject to discovery, subpoena, or other means of legal compulsion for their release to a person other than the affected hospital, and are not admissible in evidence in a judicial or administrative proceeding other than a proceeding involving verification of the participating hospital.

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641—150.6(135) Levels of maternal care. The levels of maternal care include basic obstetrical care Level I, specialty care Level II, subspecialty care Level III and regional perinatal health care Level IV. The levels reflect the overall evidence for risk-appropriate care in a hospital through the availability of appropriate personnel, physical space, equipment, technology, and organization. Each level reflects the minimal capabilities, provider type and functional criteria required.

150.6(1) *Level I maternal care hospital.*

a. Provider of basic obstetrical care. A Level I maternal care hospital provides care to women who are low risk and are expected to have an uncomplicated birth.

b. Capabilities. A Level I maternal care hospital has the following capabilities:

(1) To perform routine intrapartum and postpartum care that is anticipated to be uncomplicated. Care of uncomplicated pregnancies includes the ability to detect, stabilize and initiate management of unanticipated maternal, fetal or neonatal problems that occur during the antepartum, intrapartum, or postpartum period until the patient can be transferred to a facility that provides specialty maternal care.

(2) To begin an emergency cesarean delivery within a time interval that best incorporates maternal and fetal risks and benefits with the provision of emergency care.

c. Types of health care providers. A Level I maternal care hospital will have:

(1) Maternity care providers, including certified nurse-midwives, family practice physicians, or obstetrician-gynecologists, available to attend all births.

(2) Every birth attended by at least two professionals, including the primary maternal care provider and a person competent to provide neonatal resuscitation and postnatal care to stabilize the infant.

(3) Adequate numbers of registered nurses available who have completed orientation and demonstrated competence in the care of obstetric patients, including women and fetuses, consistent with Level I care criteria and who are able to stabilize and transfer high-risk women and newborns.

(4) Nursing leadership with expertise in perinatal nursing care.

(5) A provider with privileges to perform an emergency cesarean delivery, available to attend all deliveries. The provider may be a general surgeon, an obstetrician-gynecologist, or a family practice physician with certification.

(6) A provider of anesthesia services available to provide labor analgesia and surgical anesthesia.

d. Functional criteria of support services. Support services include but are not limited to access to obstetric ultrasonography, laboratory testing, and blood bank supplies at all times. A Level I maternal care hospital will:

(1) Have protocols and capabilities in place for:

1. Massive transfusion,
2. Emergency release of blood products (before full compatibility testing is complete),
3. Management of multiple component therapy.

(2) Ensure optimal care of all pregnant women by having formal transfer plans established in partnership with a higher-level receiving hospital. These plans will include:

1. Risk identification,
2. Determination of conditions necessitating consultation,
3. Referral and transfer, and
4. A reliable, accurate, and comprehensive communication system between the participating hospital and the transport team.

(3) Have education and quality improvement programs to maximize patient safety, provide such programs through collaboration with facilities with higher levels of care that receive transfers, or both.

(4) Have data collection, storage and retrieval to support quality improvement.

150.6(2) *Level II maternal care hospital.*

a. Provider of specialty care. In addition to meeting the criteria of a Level I maternal care hospital, a Level II maternal care hospital provides care of appropriate high-risk pregnant women, both those directly admitted to the hospital and those transferred from another hospital.

b. Capabilities. In addition to having the capabilities of a Level I maternal care hospital, a Level II maternal care hospital has the following capabilities:

(1) The infrastructure for continuous availability of adequate numbers of registered nurses who have demonstrated competence in the care of obstetric patients (women and fetuses).

(2) Orientation and demonstrated competence consistent with Level II care criteria and the capability to stabilize and transfer high-risk women and newborns who exceed Level II care criteria.

c. Types of health care providers. In addition to meeting the health care provider requirements of a Level I maternal care hospital, a Level II maternal care hospital will have:

(1) Health care providers, including certified nurse-midwives or family physicians.

(2) Nursing leaders and staff with formal training and experience in the provision of perinatal nursing care who can coordinate with respective neonatal care services.

(3) An attending obstetrician-gynecologist available at all times.

(4) A board-certified or board-eligible obstetrician-gynecologist with special interest and experience in obstetric care as the director of obstetric services.

(5) Access to a maternal-fetal medicine subspecialist for consultation, available on site, by telephone, or by telemedicine as needed.

(6) A provider of anesthesia services available at all times to provide labor analgesia and surgical anesthesia.

(7) A board-certified or board-eligible anesthesiologist with special training or experience in obstetric anesthesia, available for consultation.

(8) Medical and surgical consultants available to stabilize obstetric patients who have been directly admitted to the facility or transferred from other hospitals.

d. Functional criteria of support services. In addition to meeting the support services requirements of a Level I maternal care hospital, a Level II maternal care hospital will have:

(1) Computed tomography scan and, ideally, magnetic resonance imaging with interpretation available.

(2) Basic ultrasonographic imaging services for maternal and fetal assessment at all times, either in house or on call.

(3) Special equipment needed to accommodate the care and services needed for obese women. In addition, based on the patient's BMI and other risk factors, a consultation with an obstetrician-gynecologist or a maternal fetal medicine specialist should be considered.

(4) The ability to provide high-risk obstetrical care, but efforts should be made to transfer women whose newborns are likely to need a higher level of care than a Level II maternal care hospital can provide, or when the pregnancy has risk factors that require the consultation or care of a maternal-fetal medicine specialist.

150.6(3) *Level III maternal care hospital.*

a. Provider of subspecialty care. A Level III maternal care hospital provides care to women that includes all Level I and Level II services and has subspecialists available on site, by telephone, or by telemedicine to assist in providing care for more complex maternal and fetal conditions.

b. Capabilities. A Level III maternal care hospital functions as the regional perinatal health care center for some areas of Iowa if there are no Level IV maternal care hospitals available. In these areas, a Level III maternal care hospital will be responsible for the leadership; facilitation of transport and referral; educational outreach; and data collection, storage and retrieval to support quality improvement. Designation of Level III maternal care hospital should be based on the demonstrated experience and capability of the facility to provide comprehensive management of severe maternal and fetal complications.

c. Types of health care providers. In addition to meeting the health care provider requirements of a Level II maternal care hospital, a Level III maternal care hospital will have:

(1) An obstetrician-gynecologist with inpatient privileges, available on site at all times.

(2) A maternal-fetal medicine subspecialist with inpatient privileges, available at all times, either on site, by telephone, or by telemedicine.

(3) A director of the maternal-fetal medicine service who is a board-certified or board-eligible maternal-fetal medicine subspecialist.

(4) A board-certified or board-eligible obstetrician-gynecologist with special interest and experience in obstetric care directing obstetric services.

(5) A provider of anesthesia services available at all times on site.

(6) A board-certified or board-eligible anesthesiologist with special training or experience in obstetric anesthesia who is in charge of obstetric anesthesia services.

(7) A full complement of subspecialists, available for inpatient consultations, including subspecialists in:

1. Critical care,
2. General surgery,
3. Infectious disease,
4. Hematology,
5. Cardiology,

6. Nephrology,
7. Neurology, and
8. Neonatology.

(8) Nursing leaders and adequate numbers of registered nurses who have completed orientation and demonstrated competence in the care of obstetric patients (women and fetuses) consistent with Level III care criteria, including the transfer of high-risk women who exceed Level III care criteria, and who have special training and experience in the management of women with complex maternal illnesses and obstetric complications. Nursing personnel will be continuously available.

d. Functional criteria of support services. In addition to meeting the support services requirements of a Level II maternal care hospital, a Level III maternal care hospital will have:

(1) An on-site intensive care unit to accept pregnant women.

(2) Critical care providers on site to actively collaborate with maternal-fetal specialists at all times.

(3) Equipment and personnel with expertise available on site to ventilate and monitor women in the labor and delivery unit until they can be safely transferred to the intensive care unit.

(4) The ability to provide the following imaging services, with interpretation available at all times:

1. Basic interventional radiology,
2. Maternal echocardiography,
3. Computed tomography,
4. Magnetic resonance imaging, and
5. Nuclear medicine imaging.

(5) The ability to perform detailed obstetric ultrasonography and fetal assessment, including Doppler studies.

150.6(4) *Level IV maternal care hospital.*

a. Provider of services as a regional perinatal health care center. In addition to meeting the requirements for a Level III maternal care hospital, a Level IV maternal care hospital provides care to women with additional requirements and has considerable experience in the care of the most complex and critically ill pregnant women throughout antepartum, intrapartum, and postpartum care. The particular specialty of fetal surgery, advanced neurosurgery, transplant, and advanced cardiovascular capabilities may not all be available at an individual Level IV maternal care hospital. In some cases, specific advanced care will require care coordination to the Level IV maternal care hospital by availability of specific expertise, including but not limited to fetal surgery, advanced neurosurgery, transplant, and advanced cardiovascular capabilities. Each hospital will have a clear understanding of the categories of perinatal patients who can be managed appropriately in the local hospital and those who must be transferred.

b. Capabilities. Although Level III and Level IV maternal care hospitals may seem to overlap, a Level IV maternal care hospital is distinct from a Level III maternal care hospital in the approach to the care of pregnant women and women in the postpartum period with complex and critical illnesses. In addition to having an intensive care unit on site for obstetric patients, a Level IV maternal care hospital must have evidence of a maternal-fetal medicine care team that has the expertise to assume responsibility for pregnant women and women in the postpartum period who are in critical condition or have complex medical conditions. The maternal-fetal medicine team collaborates actively in the co-management of all obstetric patients who require critical care and intensive care unit services, including co-management of intensive care unit-admitted obstetric patients.

c. Types of health care providers. In addition to meeting the health care provider requirements of a Level III maternal care hospital, a Level IV maternal care hospital will have:

(1) A maternal-fetal medicine team member with full privileges, available at all times for on-site consultation and management.

(2) A board-certified maternal-fetal medicine subspecialist with expertise in critical care obstetrics to lead the team.

(3) A maternal-fetal medicine team with expertise in critical care at the physician level, nursing level, and ancillary services level.

(4) Institutional support for the routine involvement of a maternal-fetal medicine care team with the critical care units and specialists. A key principle of caring for critically ill pregnant and peripartum women

is the hospital's recognition of the need for seamless communication between maternal-fetal medicine subspecialists and other subspecialists in the planning and facilitation of care for women with the most high-risk complications of pregnancy.

(5) A commitment to having physician and nursing leaders with expertise in maternal intensive and critical care, as well as adequate numbers of available registered nurses in a Level IV maternal care hospital who have experience in the care of women with complex medical illnesses and obstetric complications; this experience includes completed orientation and demonstrated competence in the care of obstetric patients (women and fetuses) consistent with Level IV maternal care criteria.

(6) A director of obstetric services who is a board-certified maternal-fetal medicine subspecialist or a board-certified obstetrician-gynecologist with expertise in critical care obstetrics.

(7) A provider of anesthesia services available on site at all times.

(8) A board-certified anesthesiologist with special training or experience in obstetric anesthesia who is in charge of obstetric anesthesia services.

(9) Adult medical and surgical specialty and subspecialty consultants, a minimum of those listed for a Level III maternal care hospital, available on site at all times to collaborate with the maternal-fetal medicine care team.

d. Functional criteria of support services. In addition to meeting the support services requirements of a Level III maternal care hospital, a Level IV maternal care hospital will have:

(1) The capability for on-site medical and surgical care of complex maternal conditions (e.g., congenital maternal cardiac lesions, vascular injuries, neurosurgical emergencies, and transplants) with the availability of critical (or intensive) care unit beds.

(2) Perinatal system leadership, including facilitation of maternal referral and transport, outreach education for facilities and health care providers in the region and analysis and evaluation of regional data, including perinatal complications, outcomes and quality improvement.

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641—150.7(135) Maternal-fetal transport—all levels. Maternal-fetal transport is an essential component of perinatal care. A hospital participating in the regionalized system of perinatal health care must be familiar with its own resources and capabilities in dealing with obstetrical and neonatal complications. In most instances, maternal-fetal transport is preferable to neonatal transport. Each hospital, when transporting or accepting a transport, needs a system in place to facilitate a smooth transition of care in the most expeditious manner possible. The majority of maternal-fetal transports can be carried out by ground transportation. It is important for ambulance services to be equipped for maternal-fetal transport and have appropriately trained staff.

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641—150.8(135) Levels of neonatal care. The levels of neonatal care include basic neonatal care Level I, specialty care Level II, and subspecialty intensive care Level III and Level IV. The levels reflect the overall evidence for risk-appropriate care through the availability of appropriate functional criteria, physical facilities, medical and nursing personnel, outreach education, allied health personnel and services, infection control, newborn or neonatal safety, neonatal transport and quality improvement.

150.8(1) *Level I neonatal care hospital.*

a. Provider of basic neonatal care. A Level I neonatal care hospital provides a basic level of care to neonates without complications. A Level I neonatal care hospital has the following capabilities:

(1) To provide neonatal resuscitation at every delivery.

(2) To evaluate and provide postnatal care to stable term newborn infants.

(3) To stabilize and provide care for infants born at 35 to 37 weeks' gestation who remain physiologically stable.

(4) To stabilize newborn infants who are ill and those born at less than 35 weeks' gestation until transfer to a higher level of care.

(5) To provide leadership in early risk identification before and after birth.

(6) To seek consultation or referral for high-risk neonates.

(7) To provide public and professional education.

b. Functions. A Level I neonatal care hospital has a family-centered philosophy. Parents have reasonable access to their newborns 24 hours a day within all functional units and are encouraged to participate in the care of their newborns. Generally, a newborn can be with its parents in the mother's room.

c. Physical facilities. A Level I neonatal care hospital will maintain a nursery for normal-term or late preterm neonates.

d. Medical personnel. At a Level I neonatal care hospital, neonatal care is under the supervision of one of the following:

(1) A board-eligible or board-certified neonatologist,
(2) A pediatrician,
(3) A family medicine physician,
(4) A board-eligible or board-certified advanced registered nurse practitioner, or
(5) A physician associate.

e. Nursing personnel. At a Level I neonatal care hospital, a registered nurse assigned to the neonatal service has nursing orientation to and demonstrates competency in the care of a neonate.

f. Outreach education. A Level I neonatal care hospital will assume an active role in the development and coordination of wellness and preventive programs concerning neonatal and child health at the community level, including parenting, breastfeeding, and cessation of smoking.

g. Allied health personnel and services. A Level I neonatal care hospital will have available, at a minimum, the following allied health personnel and services:

(1) Dietitian with knowledge of maternal and neonatal nutrition management,
(2) Social worker,
(3) Bioengineer-safety and environmental control,
(4) Pharmacy,
(5) Radiology,
(6) Laboratory,
(7) Pathology, and
(8) Chaplain, spiritual support.

h. Infection control.

(1) Each Level I neonatal care hospital will establish written policies and procedures for assessing the health of personnel assigned to the perinatal care services and of those who have significant contact with the newborn. The policies and procedures will include restricting contact with patients when necessary and screening per department recommendations for health care providers. Routine culturing of specimens obtained from personnel is not useful, although selective culturing may be of value when a pattern of infection is suspected.

(2) No special or separate isolation facility is required for neonates born at home or in transit to the hospital. Detailed descriptions of the isolation categories and requirements will be available in each hospital's infection control manual.

i. Newborn safety. At a Level I neonatal care hospital, the protection of newborns is the responsibility of all personnel in the neonatal care hospital. Newborns will always be within the sight and supervision of hospital staff, the mother, or other family members or friends designated by the mother. Each neonatal care hospital has a policy established that addresses strategies to promote newborn safety.

150.8(2) *Level II neonatal care hospital.*

a. Provider of specialty care. In addition to meeting the requirements for care and services as a Level I neonatal care hospital, a Level II neonatal care hospital will:

(1) Provide management of certain high-risk neonates with selected complications.

(2) Have a board-certified or board-eligible neonatologist(s) or a board-certified or board-eligible pediatrician(s) on staff, one of whom directs the special care nursery.

b. Functions. In addition to performing the functions of a Level I neonatal care hospital, a Level II neonatal care hospital will have the capability to:

(1) At a minimum, manage neonates of greater than or equal to 32 weeks' gestation and weighing greater than or equal to 1,500 grams who have physiological immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an

urgent basis and, for neonates of 32 weeks' gestation and weighing less than 1,500 grams, recommend consultation with a higher-level facility by prearranged consultative agreement.

(2) Provide mechanical ventilation for a brief duration (less than 24 hours).

(3) Provide continuous positive airway pressure as needed (less than 24 hours).

(4) Stabilize infants born before 32 weeks and weighing less than 1,500 grams until transfer to a Level III or Level IV neonatal care hospital.

(5) Provide care for infants convalescing after intensive care.

c. Physical facilities. In addition to having the physical facilities of a Level I neonatal care hospital, a Level II neonatal care hospital will have:

(1) A special care nursery (a special area designated for the care of sick neonates),

(2) A mechanical ventilator,

(3) A portable X-ray machine,

(4) A laboratory with a blood gas analyzer,

(5) Physiologic monitoring equipment, and

(6) A pharmacy.

d. Medical personnel. In addition to having the medical personnel of a Level I neonatal care hospital, a Level II neonatal care hospital will:

(1) Be under the co-direction/supervision of a board-eligible or board-certified neonatologist or pediatrician.

(2) Have a neonatologist or pediatrician on staff. Other provider types that may be utilized include a pediatric hospitalist, a neonatal nurse practitioner or pediatric nurse practitioner or a physician associate with appropriate training.

(3) Have allied medical specialists in various disciplines on staff, including specialists in internal medicine, radiology, and pathology.

e. Nursing personnel. In addition to having the nursing personnel of a Level I neonatal care hospital, a Level II neonatal care hospital has nursing orientation to and demonstrates competency in the care of sick neonates.

f. Outreach education. A Level II neonatal care hospital has the same responsibility for outreach education as that of a Level I neonatal care hospital.

g. Allied health personnel and services. In addition to having the allied health personnel and services of a Level I neonatal care hospital, a Level II neonatal care hospital has:

(1) Respiratory therapists,

(2) Certified laboratory technicians/blood gas technicians, and

(3) X-ray technologists and ultrasound technicians with neonatal/perinatal experience.

h. Infection control. A Level II neonatal care hospital has the same infection control guidelines as those for a Level I neonatal care hospital.

i. Neonatal safety. A Level II neonatal care hospital has the same requirements for newborn safety as those for a Level I neonatal care hospital.

j. Neonatal transport. In addition to having the Level I neonatal care hospital capabilities for neonatal transport, a Level II neonatal care hospital is expected to accept patient referrals when appropriate. A critical function of providers at a Level II neonatal care hospital is to communicate with the providers at a Level I neonatal care hospital in deciding whether a particular patient should be transported to the Level II neonatal care hospital. Careful assessment of the hospital's capabilities for perinatal management will be critical in these decisions. This information will need to be disseminated among the hospital staff. Providers of obstetric care need to know the critical gestational age limitations for their particular nursery. Below this gestational age, maternal-fetal transport should be utilized if delivery is anticipated and the circumstances permit.

k. Perinatal care committee.

(1) A Level II neonatal care hospital must maintain a perinatal care committee. Members of this committee will represent, at a minimum, the fields of:

1. Obstetrics,
2. Pediatrics,

3. Family practice,
4. Nursing,
5. Administration,
6. Laboratory,
7. Respiratory therapy,
8. Anesthesia, and
9. Social services.

(2) Responsibilities of the perinatal care committee include the following:

1. To develop policies for the unit, including provisions to ensure adequate patient care by qualified providers.
2. To conduct a meeting, at least semiannually, to resolve problems related to the unit.
3. To review educational activities conducted by the unit.
4. To serve as a general liaison between the various groups represented on the committee.

150.8(3) *Level III neonatal care hospital.*

a. Provider of subspecialty intensive care. In addition to providing the care and services of a Level II neonatal care hospital, a Level III neonatal care hospital will manage high-risk neonates, including infants born at less than 32 weeks or weighing less than 1,500 grams. High-risk neonates requiring surgical intervention or pediatric subspecialty should go to a Level IV neonatal care hospital.

b. Functions. In addition to performing the functions of a Level II neonatal care hospital, a Level III neonatal care hospital will have the capability to:

(1) Provide sustained life support.

(2) Provide comprehensive care for infants born at less than 32 weeks and weighing less than 1,500 grams and infants born at all gestations and birth weights who have critical illness.

(3) Provide an organized program for monitoring treatment and follow-up of retinopathy of prematurity.

(4) Maintain a prearranged consultative agreement with a higher-level hospital within the Level III neonatal care hospital's referral area.

(5) Transfer a surgical patient within approximately two hours from the time the referral call is made until arrival at the referral hospital.

(6) Provide follow-up care for high-risk newborns.

c. Physical facilities. In addition to having the physical facilities of a Level II neonatal care hospital, a Level III neonatal care hospital:

(1) Has a neonatal intensive care unit with continuously available personnel, including a neonatologist, neonatal nurses and respiratory therapists to provide life support for as long as necessary.

(2) Provides a full range of respiratory support that includes invasive mechanical ventilation and may include high-frequency ventilation or inhaled nitric oxide or both.

(3) Performs advanced imaging, with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging, and echocardiography.

(4) Maintains a neonatal transport team for the regional area served.

d. Medical personnel. In addition to having the medical personnel of a Level II neonatal care hospital, a Level III neonatal care hospital will:

(1) Have a medical director of the neonatal intensive care unit who is a full-time, board-eligible or board-certified neonatologist.

(2) Provide prompt and readily available access to the following, either on site or by prearranged consultative agreement. Using telemedicine technology or telephone consultation, a prearranged consultation can be performed from a distant location by:

1. Pediatric medical subspecialists,
2. A pediatric surgical specialist,
3. A pediatric anesthesiologist, and
4. A pediatric ophthalmologist.

(3) Have a neonatologist on the premises when an unstable critically ill infant is in the Level III neonatal care hospital.

e. Nursing personnel. A Level III neonatal care hospital has the same requirements for nursing personnel as those of a Level II neonatal care hospital.

f. Outreach education. Outreach education is provided to each hospital in the referral area at least once per year. This outreach education can be achieved by one or more of the following:

(1) Sponsoring an annual conference.

(2) Visiting a Level I neonatal care hospital and a Level II neonatal care hospital.

(3) Providing educational programs and materials for the staff members of the Level I and Level II neonatal care hospitals.

g. Allied health personnel and services. In addition to having the allied health personnel and services of a Level II neonatal care hospital, a Level III neonatal care hospital has:

(1) X-ray technologists and ultrasound technicians with neonatal/perinatal experience, available on a 24-hour basis.

(2) Social work services with social workers assigned specifically to the neonatal units.

h. Infection control. A Level III neonatal care hospital has the same infection control guidelines as those of a Level I neonatal care hospital.

i. Neonatal safety. A Level III neonatal care hospital has the same requirements for newborn safety as those for a Level I neonatal care hospital.

j. Neonatal transport. In addition to having the Level II neonatal care hospital transport capabilities, a Level III neonatal care hospital is capable of providing neonatal transport with crews who have demonstrated competence in neonatal resuscitation and stabilization. Important decisions to be made jointly will include:

(1) The appropriateness of transport.

(2) The best mode of transportation.

(3) The need for additional personnel accompanying the transport.

(4) The appropriate medical management to initiate prior to transport.

k. Perinatal care committee. A Level III neonatal care hospital shall maintain a perinatal care committee that meets the same criteria as those for a Level II neonatal care hospital.

150.8(4) *Level IV neonatal care hospital.*

a. Provider of subspecialty intensive care. In addition to providing the level-of-care services of a Level III neonatal care hospital, a Level IV neonatal care hospital manages higher-risk neonates. The differentiating factor between a Level III neonatal care hospital and a Level IV neonatal care hospital is primarily one of having additional professional staff with considerable experience in the care of the most complex and critically ill infants and having the ability to provide surgical repair of complex congenital or acquired conditions.

b. Physical facilities. In addition to having the physical facilities of a Level III neonatal care hospital, a Level IV neonatal care hospital has more equipment, more extensive physical facilities and will serve a more complicated patient population.

c. Medical personnel. In addition to having the medical personnel of a Level III neonatal care hospital, a Level IV neonatal care hospital will:

(1) Have a medical director of the neonatal intensive care unit who is a full-time, board-certified neonatologist.

(2) Have anesthesia providers on staff with special training or experience in pediatric anesthesia.

(3) Maintain a full range of pediatric medical subspecialists and pediatric surgical subspecialists at the site.

(4) Have the subspecialist physicians immediately available to the Level IV neonatal care hospital.

(5) Have a neonatologist on the premises when an unstable critically ill infant is in the Level IV neonatal care hospital.

d. Nursing personnel. A Level IV neonatal care hospital has the same requirements for nursing personnel as those for a Level II neonatal care hospital.

e. Outreach education. A Level IV neonatal care hospital has the same responsibilities for outreach education as those for a Level III neonatal care hospital.

f. Allied health personnel and services. A Level IV neonatal care hospital has the same level of allied health personnel and services as that of a Level III neonatal care hospital.

g. Infection control. A Level IV neonatal care hospital has the same infection control guidelines as those for a Level I neonatal care hospital.

h. Neonatal safety. A Level IV neonatal care hospital has the same requirements for neonatal safety as those for a Level I neonatal care hospital.

i. Neonatal transport. In addition to meeting the neonatal transport requirements of a Level III neonatal care hospital, a Level IV neonatal care hospital is capable of providing ground and air transportation with crews who have demonstrated competencies in neonatal resuscitation and stabilization.

j. Perinatal care committee. In addition to maintaining a perinatal care committee that meets the same criteria as those for a Level II neonatal care hospital, a Level IV neonatal care hospital maintains a perinatal care committee that has additional representation by surgical specialties. The Level IV neonatal care hospital's perinatal care committee will maintain and analyze data on long-term outcomes to evaluate the effectiveness of the delivery of perinatal health care services.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25; Editorial change: IAC Supplement 6/10/26]

641—150.9(135) Grant or denial of certificate of verification; and offenses and penalties.

150.9(1) Upon receipt of the levels-of-care assessment tool and the on-site survey results, if required, the department will within 90 days issue its decision to grant or deny the hospital a certificate of verification. The department may deny verification or may give a citation and warning, place on probation, suspend, or revoke existing verification if the department finds reason to believe the hospital's perinatal care program has not been or will not be operated in compliance with these rules. The denial, citation and warning, period of probation, suspension or revocation will be effected and may be appealed in accordance with the requirements of Iowa Code section 17A.12.

150.9(2) All complaints regarding the operation of a participating hospital's perinatal care program shall be reported to the department and to the department of inspections, appeals, and licensing.

150.9(3) Complaints and the investigative process will be treated as confidential to the extent they are protected by Iowa Code sections 22.7 and 135.11(27).

150.9(4) Complaint investigations may result in the department's issuance of a notice of denial, citation and warning, probation, suspension or revocation.

150.9(5) Notice of denial, citation and warning, probation, suspension or revocation will be effected in accordance with the requirements of Iowa Code section 17A.12. Notice to the hospital of denial, citation and warning, probation, suspension or revocation will be served by certified mail, return receipt requested, or by personal service.

150.9(6) Any request for a hearing concerning the denial, citation and warning, probation, suspension or revocation must be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice to take action. If the request is made within the 20-day time period, the notice to take action will be deemed to be suspended pending the hearing. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the denial, citation and warning, probation, suspension or revocation has been or will be removed. If no request for a hearing is received within the 20-day time period, the department's notice of denial, citation and warning, probation, suspension or revocation will become the department's final agency action.

150.9(7) Upon receipt of a request for hearing, the request will be forwarded within five working days to the department of inspections, appeals, and licensing pursuant to the rules adopted by that agency regarding the transmission of contested cases. The information upon which the adverse action is based and any additional information, which may be provided by the aggrieved party, shall also be provided to the department of inspections, appeals, and licensing.

150.9(8) The hearing shall be conducted according to the procedural rules of the department of inspections, appeals, and licensing found in 481—Chapter 10.

150.9(9) When the administrative law judge makes a proposed decision and order, it will be served by certified mail, return receipt requested, or delivered by personal service. That proposed decision and order

then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken.

150.9(10) Any appeal to the director for review of the proposed decision and order of the administrative law judge must be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal will also be mailed to the administrative law judge. Any request for an appeal must state the reason for appeal.

150.9(11) Upon receipt of an appeal request, the administrative law judge will prepare the record of the hearing for submission to the director. The record shall include the following:

a. All pleadings, motions, and rules.

b. All evidence received or considered and all other submissions by recording or transcript.

c. A statement of all matters officially noticed.

d. All questions and offers of proof, objections and rulings on them.

e. All proposed findings and exceptions.

f. The proposed decision and order of the administrative law judge.

150.9(12) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and will be delivered by certified mail, return receipt requested, or by personal service.

150.9(13) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

150.9(14) Any petition for judicial review of a decision and order must be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal will be sent to the department by certified mail, return receipt requested, or by personal service.

150.9(15) The party that appeals a final agency action to the district court must pay the cost of the preparation of a transcript of the contested case hearing for the district court.

150.9(16) Final decisions of the department relating to disciplinary proceedings may be transmitted to the department of inspections, appeals, and licensing and to the appropriate professional associations or news media.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25]

641—150.10(135) Prohibited acts. A hospital that imparts or conveys, or causes to be imparted or conveyed, that it is a participating hospital in Iowa's regionalized system of perinatal health care, or that uses any other term, such as a designated level of care, to indicate or imply that the hospital is a participating hospital in the regionalized system of perinatal health care without having obtained a certificate of verification from the department is subject to licensure disciplinary action by the department of inspections, appeals, and licensing, as well as to the application by the director to the district court for a writ of injunction to restrain the use of the term or terms "Level I maternal care or neonatal care hospital," "Level II maternal care or neonatal care hospital," "Level III maternal care or neonatal care hospital" and "Level IV maternal care or neonatal care hospital" in relation to the provision of perinatal health care services.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25]

641—150.11(135) Construction of rules. Nothing in these administrative rules shall be construed to restrict a hospital from providing any services for which it is duly authorized.

[**ARC 9178C**, IAB 4/30/25, effective 7/1/25]

These rules are intended to implement Iowa Code section 135.11.

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