

CHAPTER 150
IOWA REGIONALIZED SYSTEM OF PERINATAL HEALTH CARE

641—150.1(135,77GA,ch1221) Purpose and scope. Hospitals within the state shall determine whether to participate in Iowa's regionalized system of perinatal health care and shall select the hospital's level of participation in the regionalized system. A hospital having determined to participate in the regionalized system shall comply with the rules appropriate to the level of participation selected by the hospital.

Iowa's regionalized system of perinatal health care helps practitioners in rural Iowa to rapidly access specialty services for their patients even though such services may not exist in the local community. This is predicated on several factors, including the willingness of certain hospitals in moderate-to-large Iowa cities to provide specialty services and the presence of a functional system of patient transportation. These rules address how participating Iowa hospitals relate to the regionalized system and suggest a level of functioning which should identify the role each participating hospital plays in the system.

The following rules present a description of the levels of care among Iowa perinatal hospitals. The levels are as follows: Level I hospital, Level II hospital, Level II regional center, Level II regional neonatology center, and Level III center. The department is very much aware of the need for organization of limited resources in a rural state. Accordingly, the rules are designed to encourage and support the presence of a Level II regional center in areas not populous enough to support a Level III center.

These rules are not meant to hold Iowa hospitals and Iowa perinatal professionals to an impractical ideal. Although the rules are clearly not intended to serve as standards, they do specify particulars when feasible. For example, specification of a designated level of care for a hospital should be clearly evident from the descriptions. Levels of care are designated by the functional capacity of the hospital. Thus, it may be possible to have a number of Level II hospitals or Level III centers in one city.

The primary purpose of designation is to ensure Iowa perinatal patients appropriate care as close to their homes as possible. In an ideal situation, no community hospital would be more than 50 miles from a perinatal center. Unfortunately, Iowa's low population density precludes this. Accordingly, Iowa developed a network of regional centers.

The further intent of these rules is to ensure that when a hospital markets itself at a particular level of perinatal care, it is capable of providing that care. The public is entitled to know the level of functioning. The rules provide the framework to be used in defining and evaluating the level of perinatal services being offered.

641—150.2(135,77GA,ch1221) Definitions. For the purpose of these rules, the following definitions shall apply:

"Categorization" means a preliminary determination by the department that a hospital is capable of providing perinatal care at Level I, Level II, Level II regional, Level II regional neonatology center, or Level III care capabilities.

"Certificate of verification" means a document awarded by the department that identifies a hospital's level of perinatal care and term of verification at that level.

"Department" means the Iowa department of public health.

"Director" means the director of the Iowa department of public health.

"Hospital" means a facility licensed under Iowa Code chapter 135B or a comparable facility located and licensed in another state.

"On-site verification survey" means an on-site survey conducted by the department's statewide perinatal care program based at the University of Iowa hospitals and clinics to assess a hospital's ability to meet the level of designation selected by the hospital.

"Perinatal advisory committee" means the committee that provides review and counsel to the statewide perinatal care program based at the University of Iowa hospitals and clinics.

"Perinatal guidelines advisory committee" means the committee that provides consultation to the department regarding these rules for the regionalized system of perinatal health care.

"Regionalized system of perinatal health care" means the department's program for the provision of appropriate perinatal care as close to patients' homes as possible.

“*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.

“*Statewide perinatal health care program*” means the educational team based at the University of Iowa hospitals and clinics and retained by the department of public health.

“*Verification*” means a process by which the department certifies a hospital’s capacity to provide perinatal care in accordance with criteria established for Level I hospitals, Level II hospitals, Level II regional centers, Level II regional neonatology centers, and Level III centers under these rules.

641—150.3(135,77GA,ch1221) Perinatal guidelines advisory committee.

150.3(1) Purpose. The director shall appoint an advisory committee to consult with the department in its development and maintenance of the regionalized system of perinatal health care. This advisory committee should not be confused with the perinatal advisory committee that provides review and counsel to the statewide perinatal care program.

150.3(2) Appointment.

a. Members of the advisory committee shall include a representative from each of the following organizations that chooses to designate a nominee to the director: Iowa Hospitals and Health Systems; Iowa Medical Society; Iowa Osteopathic Medical Association; Iowa Chapter, American Academy of Pediatrics; Iowa Section, American College of Obstetricians and Gynecologists; Iowa Academy of Family Physicians; Iowa Nurses Association; Iowa Association of Neonatal Nurses; Iowa Association of Women’s Health, Obstetrical and Neonatal Nurses; and Iowa Chapter, Great Plains Organization for Perinatal Health Care.

b. Nonvoting ex officio members of the committee shall include representatives from the department of inspections and appeals, the statewide perinatal health care program at the University of Iowa hospitals and clinics and the division of family and community health medical director at the department.

c. Vacancies shall be filled in the same manner in which the original appointments were made.

d. Three consecutive unexcused absences shall be grounds for the director to consider dismissal of the committee member and appointment of another. The chairperson of the committee shall notify the director of the department.

150.3(3) Officers. Officers of the committee shall be a chairperson and a vice-chairperson and shall be elected at the first meeting of each fiscal year unless designated at the time of appointment. Vacancies in the office of chairperson shall be filled by elevation of the vice-chairperson. Vacancies in the office of vice-chairperson shall be filled by election at the next meeting after the vacancy occurs. The chairperson shall preside at all meetings of the committee, appoint such subcommittees as deemed necessary, and designate the chairperson of each subcommittee. If the chairperson is absent or unable to act, the vice-chairperson shall perform the duties of the chairperson. When so acting, the vice-chairperson shall have all the powers of and be subject to all restrictions upon the chairperson. The vice-chairperson shall also perform such other duties as may be assigned by the chairperson.

150.3(4) Meetings.

a. The committee shall establish a meeting schedule on an annual basis to conduct its business. Meetings may be scheduled as business requires, but notice to members must be at least five working days prior to the meeting date. A four-week notice is encouraged to accommodate the schedules of members.

b. Robert’s Rules of Order shall govern all meetings.

c. Action on any issue before the committee can be taken only by a majority vote of the entire membership. The committee shall maintain information sufficient to indicate the vote of each member present.

150.3(5) Subcommittees. The committee may designate one or more subcommittees to perform such duties as may be deemed necessary.

150.3(6) Expenses of committee members. The following may be considered necessary expenses for reimbursement of committee members when incurred on behalf of committee business and are subject to established state reimbursement rates:

- a. Reimbursement for travel in a private car.
- b. Actual lodging and meal expenses including sales tax on lodging and meals.
- c. Actual expense of public transportation.

641—150.4(135,77GA,ch1221) Categorization and selection of level of care designation. Hospitals that have previously participated in the regionalized system of perinatal health care shall be categorized by the department at the level of care designation last verified by the department. A hospital that has chosen to participate in the regionalized system for the first time or that has chosen to select a new level of care designation shall:

1. Submit the following information to the department:
 - Description of the geographic area to be served.
 - Identification of the target population to be served.
 - Identification of Level I hospitals to be served.
 - Identification of unmet needs of the area to be served.
 - Demonstration of the ability to meet these rules.
2. Mail the information to:

Iowa Regionalized System of Perinatal Health Care
Iowa Department of Public Health
Division of Health Promotion and Chronic Disease Prevention
321 East 12th Street, Lucas State Office Building
Des Moines, Iowa 50319-0075

641—150.5(135,77GA,ch1221) Recommendation by the statewide perinatal care program.

150.5(1) Upon receipt of the hospital's application information from the department, the statewide perinatal care program will provide verification of the hospital's ability to meet the criteria for the level of designation selected by the hospital. The results of the verification shall be submitted to the department, along with a recommendation to grant or deny the hospital a certificate of verification.

150.5(2) The statewide perinatal health care program shall also perform periodic on-site verification surveys of established perinatal service programs to verify the continued ability of each hospital visited to meet the criteria for the level of designation selected by the hospital. The results of each survey shall also be submitted to the department, along with a recommendation to continue, suspend, or revoke the hospital's certificate of verification.

150.5(3) Any review and evaluation of the University of Iowa hospitals and clinics' established perinatal service program shall be performed by the department, or for the department, by a person or entity unaffiliated with the University of Iowa hospitals and clinics.

641—150.6(135,77GA,ch1221) Level I hospitals.

150.6(1) Definition. Level I hospitals provide basic inpatient care for pregnant women and newborns without complications; manage perinatal emergencies, including neonatal resuscitation; provide leadership in early risk identification before and after birth; seek consultation or referral for high-risk patients; and provide public and professional education.

150.6(2) Functions. Level I hospitals have 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, parents can be with their newborns in the mother's room. Noninfectious siblings may visit in the mother's room or in a designated space.

Level I hospitals have the capability to:

- a. Provide surveillance and care of all patients admitted to the obstetric service with an established triage system for identifying high-risk patients who should be transferred to a facility that provides Level II or higher care, prior to delivery;
- b. Provide proper detection and supportive care of unanticipated maternal-fetal problems that occur during labor and delivery;

- c. Perform emergency Cesarean sections as soon as possible after the decision to do the operation has been made;
- d. Provide transfusions of blood and fresh frozen plasma on a 24-hour basis;
- e. Provide anesthesia, pharmacy, radiology, respiratory support, electronic fetal heart-rate monitoring, and laboratory services on a 24-hour basis;
- f. Provide care of postpartum conditions;
- g. Evaluate the condition of healthy neonates and their continuing care until discharge;
- h. Resuscitate all neonates using the neonatal resuscitation program guidelines as published by the American Heart Association/American Academy of Pediatrics;
- i. Stabilize all neonates including unexpectedly small or sick neonates before transfer;
- j. Consult and arrange transfers in conjunction with the obstetrician, pediatrician or neonatologist at the referral center;
- k. Maintain a nursery for normal-term or near-term newborns.

150.6(3) Physical facilities. Physical facilities for perinatal care in hospitals should be conducive to care that meets the normal physiologic and psychosocial needs of mothers, neonates, fathers, and families. Special facilities should be available when deviations from the norm require uninterrupted physiologic, biochemical, and clinical observations of patients throughout the perinatal period. Labor, delivery, and newborn care facilities should be located contiguously.

The following recommendations are intended as general guidelines and are meant to be flexible enough to meet local needs. It is recognized that individual limitations of physical facilities for perinatal care may impede strict adherence to the recommendations. Furthermore, not all hospitals will have all the functional units described. Provisions for individual units should be consistent within the framework of a regionalized perinatal care system and the state and local public health regulations.

a. *Obstetric functional units.*

(1) Labor. Areas used for women in labor are equipped with the following components:

1. Adequate space for support persons, personnel, and equipment;
2. Adequate ventilation and temperature control;
3. A labor or birthing bed;
4. A storage area for the patient's clothing and personal belongings;
5. Adjustable lighting that is pleasant for the patient and adequate for examinations;
6. An emergency signal and an intercommunication system;
7. A sphygmomanometer and stethoscope;
8. Mechanical infusion equipment;
9. Fetal monitoring equipment;
10. Oxygen and suction outlets;
11. Access to at least one shower for use by labor patients; and
12. Storage facilities for supplies and equipment.

(2) Delivery.

1. Delivery rooms should be close to the labor rooms in order to afford easy access and to provide privacy to women in labor. A waiting area for families should be adjacent to the delivery suite, and restrooms should be located nearby.

2. Traditional delivery rooms and Cesarean birth rooms are similar in design to operating rooms. Vaginal deliveries can be performed in either room, whereas Cesarean birth rooms are designed especially for that purpose and are thus larger. Each type of birthing room is well lighted and environmentally controlled to prevent chilling of the mother and neonate.

3. It is desirable that Cesarean deliveries be performed in the obstetric unit; however, if this is not possible due to cost and space, equipment for neonatal stabilization and resuscitation, as described herein under 150.6(3) "b"(1), is available during delivery.

4. Each delivery room is maintained as a separate unit with the following equipment and supplies necessary for normal delivery and for the management of complications:

- Delivery/operating table that allows variation in position for delivery;
- Instrument table and solution basin stand;

- Instruments and equipment for vaginal delivery, repair of laceration, Cesarean delivery, and the management of obstetric emergencies;
- Solutions and equipment for the intravenous administration of fluids;
- Equipment for administration of all types of anesthesia, including equipment for emergency resuscitation of the mother;
- Individual oxygen, air, and suction outlets for mother and neonate;
- An emergency call system;
- Mirrors for patients to observe the birth;
- Wall clock with a second hand;
- Equipment for fetal heart rate monitoring; and
- Scrub sinks with controls strategically placed to allow observation of the patient.

5. 5. Trays containing drugs and equipment necessary for emergency treatment of both mother and neonate are kept in the delivery room area. Equipment necessary for the treatment of cardiac arrest is easily accessible.

(3) Postpartum care. The postpartum unit is flexible enough to permit comfortable accommodation of patients when the patient census is at its peak and use of beds for alternate functions when the patient census is low. Ideally, single-occupancy rooms should be provided; however, not more than two patients should share one room. If possible, each room in the postpartum unit should have its own toilet and hand-washing facilities. When this is not possible and it is necessary for patients to use common facilities, patients should be able to reach them without entering a general corridor. When the newborn rooms-in with the mother, the room should have hand-washing facilities, a mobile bassinet unit, and supplies necessary for the care of the newborn.

(4) Combined units (labor/delivery/recovery or labor/delivery/recovery/postpartum room).

1. Comprehensive obstetric and neonatal care can be provided to the low-risk and the high-risk parturient and infant and the family in a single room. A homelike, family-centered environment with the capability for providing high-risk care is a key design criterion for both the labor/delivery/recovery (LDR) and labor/delivery/recovery/postpartum (LDRP) rooms. Each room is equipped for all types of delivery except Cesarean deliveries or those that may require general anesthesia.

2. During the labor, delivery, and recovery phases, care can be provided in an LDR room or can be extended to include the postpartum period in an LDRP room.

3. Nurses providing care in combined units are knowledgeable in antepartum care, labor and delivery, postpartum care, and neonatal care, making the use of staff cost-effective and increasing the continuity and quality of care.

b. Neonatal functional units.

(1) Resuscitation/stabilization.

1. A resuscitation and stabilization bed should be available in the immediate area of delivery for those neonates who require it. Contingent upon their condition, neonates are moved from this area to the nursery for admission and stabilization and possible transfer to a Level II regional center or Level III center.

2. The resuscitation area contains the following items:

- Overhead source of radiant heat that can be regulated based on the infant's temperature; radiant warmers with accommodations for X-ray capabilities are recommended;
- Thin resuscitation/examination mattress that allows access on three sides;
- Wall clock;
- Equipment and medications as recommended by the neonatal resuscitation program. This includes a laryngoscope with infant-sized blades, endotracheal tubes, and resuscitation (breathing) bags with masks for full-term and preterm neonates;
- Oxygen, compressed air and suction sources that are separate from those for the mother;
- Equipment for examination, immediate care, and identification of the neonate.

3. The resuscitation area is usually within the delivery room, although it may be in a designated, contiguous, separate room. If resuscitation takes place in the delivery room, the area is large enough to ensure that the resuscitation of the neonate can be achieved without interference with or from the ongoing

care of the mother. Following stabilization of the neonate, the newborn's vital signs must be maintained (e.g., by using prewarmed blankets). The room temperature is kept at a level higher than that customary for patient rooms or operating suites. Qualified nursing staff is available to assess the newborn during this period.

(2) Admission/observation (transitional care stabilization).

1. The admission/observation area is for careful assessment of the neonate's condition during the first 24 hours after birth (i.e., during the period of physiologic adjustment to extrauterine life). This assessment may take place within one or more functional areas (e.g., the room in which the mother is recovering, the LDRP room, the newborn nursery, or a separate admission/observation area). In some hospitals, the newborn nursery is the primary area for transitional care, both for neonates born within the hospital and for those born outside the hospital.

2. The admission/observation area should be near the delivery/Cesarean birth room. If it is part of the maternal recovery area, which is preferable, physical separation of the mother and newborn during this period can be avoided.

3. The capacity of the admission/observation area depends on the size of the delivery service and the duration of close observation. The admission/observation area is well lighted, has a wall clock, and contains emergency resuscitation equipment similar to that in the designated resuscitation area.

4. The physicians' and registered nurses' assessments of the neonate's condition determine the subsequent level of care. Most neonates are transferred from the admission/observation area to the newborn nursery or to the postpartum area for rooming-in. Some neonates may require transfer to another facility. Consultation with a pediatrician or neonatologist and possible referral to a hospital offering a higher level of care should be initiated for infants with respiratory distress or those infants requiring oxygen therapy for more than two hours.

(3) Newborn nursery. Routine care of apparently normal full-term neonates who have demonstrated successful adaptation to extrauterine life may be provided either in the newborn nursery or in the area where the mother is receiving postpartum care. The nursery should be relatively close to the postpartum area. The newborn nursery is well lighted, has a large wall clock, and is equipped for emergency resuscitation.

150.6(4) Medical personnel.

a. The obstetric/newborn care area is under the supervision of a board-eligible or board-certified obstetrician-gynecologist, pediatrician or a physician with special interest and experience in obstetrics or pediatrics.

b. Adequate anesthesia coverage by a qualified anesthesia provider is available in a timely fashion for emergency situations on a 24-hour-a-day, 7-day-a-week basis.

c. For Cesarean sections or if neonatal problems are anticipated during vaginal delivery, a second physician or attendant who is skilled in resuscitation and care of the neonate should be in attendance.

150.6(5) Nursing personnel. Nurses assigned to the obstetrical/neonatal service demonstrate competency in the care of the mother and infant.

a. *Staffing.* Registered nurses assigned to the obstetrical/neonatal service must be licensed to practice in Iowa, complete an obstetrical or neonatal orientation and demonstrate obstetrical or neonatal competencies as defined by each hospital. At least one of these registered nurses must be available at all times. The primary responsibility of the registered nurse is the delivery of nursing care and departmental organization.

b. *Labor/delivery/immediate postpartum/newborn.*

(1) A registered nurse is responsible for the admission assessment of the gravida in labor, as well as continuing assessment and support of the mother and fetus during labor, delivery and the early postpartum period.

(2) A registered nurse is responsible for the admission assessment of the newborn, as well as continuing assessment during the stabilization period.

(3) Licensed practical nurses, nursing assistants and other appropriate technical personnel may assist in the care of the gravida in labor, but should be under the direct supervision of the registered nurse.

c. Later postpartum period/newborn care.

(1) Nursing care of the mother and newborn is directed and supervised by a registered nurse. A licensed practical nurse may provide care for patients without complications.

(2) Nurses have a supporting and teaching role in assisting mothers to care for their infants. This should be recognized and fostered.

150.6(6) *Outreach education.* Level I hospitals should assume an active role in the development and coordination of wellness and preventive programs concerning maternal/child health at the community level (e.g., programs on family planning, family-life education, parenting, breast feeding, cessation of smoking).

150.6(7) *Allied health personnel and services.* Level I hospitals have available, but are not limited to, the following allied health personnel and services:

- a.* Registered dietitian with knowledge of maternal and neonatal nutrition management;
- b.* Social worker;
- c.* Bioengineer-safety and environmental control;
- d.* Pharmacy;
- e.* Radiology;
- f.* Laboratory;
- g.* Pathology.

150.6(8) *Infection control.*

a. Each hospital establishes written policies and procedures for assessing the health of personnel assigned to the perinatal care services and those who have significant contact with the newborn. This includes restricting their contact with patients when necessary. These policies and procedures include screening for tuberculosis and rubella. Routine culturing of specimens obtained from personnel is not useful, although selective culturing may be of value when a pattern of infection is suspected.

b. No special or separate isolation facilities are required for neonates born at home or in transit to the hospital. Detailed descriptions of the isolation categories and requirements should be available in each hospital's infection control manual.

150.6(9) *Newborn safety.* The protection of infants is the responsibility of all personnel in a facility. Infants are to be transported in a bassinet or stroller and should never be carried. Infants are transported one at a time and are never grouped in a hallway without direct supervision. Infants should always be within the sight and supervision of staff, the mother, or other family members or friends designated by the mother. Each hospital has a policy established that addresses strategies to promote infant safety.

150.6(10) *Maternal-fetal transport.* Maternal-fetal transport is an essential component of modern perinatal care. All facilities in the state providing obstetrics need to be familiar with their 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.

641—150.7(135,77GA,ch1221) Level II hospitals.

150.7(1) *Definition.* Level II hospitals provide the same care and services as Level I hospitals plus they provide management of certain high-risk pregnancies and services for newborns with selected complications. These hospitals deliver approximately 500 or more babies annually and have an obstetrician and pediatrician on staff. The perinatal unit is under the co-direction of a pediatrician and an obstetrician.

150.7(2) *Functions.* In addition to the functions of Level I hospitals, Level II hospitals have the capability to:

- a.* Manage selected high-risk pregnancies.
- b.* At a minimum, manage neonates of 34 weeks and greater gestation.
- c.* Manage recovering neonates who can be appropriately transferred from the referral center.
- d.* Maintain a special area designated for the care of sick neonates.

- e. Maintain nursing personnel with demonstrated competency in the care of sick neonates.
- f. Maintain nursing personnel with demonstrated competency in the care of high-risk mothers.

Consultation with a pediatrician or neonatologist and possible referral to a higher-level perinatal center should be initiated for infants requiring oxygen therapy for more than six hours or ventilatory care for more than two hours.

150.7(3) *Physical facilities.* Level II hospitals have the same physical facilities as Level I hospitals.

150.7(4) *Medical personnel.* Level II hospitals have the same medical personnel as Level I hospitals. In addition, the perinatal units in Level II hospitals are under the co-direction/supervision of either a board-eligible or board-certified obstetrician/gynecologist or a board-eligible or board-certified pediatrician for their respective areas. Allied medical specialists in various disciplines are on staff, including specialists in internal medicine, radiology, and pathology. Psychiatric services are available.

150.7(5) *Nursing personnel.* Level II hospitals have the same minimal requirements for nursing personnel as Level I hospitals. Nursing orientation and competencies in a Level II hospital are specific to the patient population they serve.

150.7(6) *Outreach education.* Level II hospitals have the same responsibility for outreach education as Level I hospitals.

150.7(7) *Allied health personnel and services.* Level II hospitals have the same allied health personnel and services available as Level I hospitals, with the addition of the following:

- a. Respiratory therapy.
- b. Ultrasound.

150.7(8) *Infection control.* Infection control guidelines are the same as for Level I hospitals.

150.7(9) *Newborn safety.* Level II hospitals have at least the same requirements for newborn safety as Level I hospitals.

150.7(10) *Maternal-fetal transport.* Level II hospitals have the same requirements for maternal-fetal transport as Level I hospitals. In addition, Level II hospitals are expected to accept patient referrals when appropriate. A critical function of providers at Level II hospitals is to communicate with the providers at Level I hospitals in deciding whether a particular patient should be transported to the Level II 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.

150.7(11) *Perinatal care committee.*

a. All Level II hospitals maintain a perinatal care committee. Members of this committee should represent, but not be limited to, the fields of obstetrics, pediatrics, family practice, nursing, administration, laboratory, respiratory therapy, anesthesia and social services.

b. Responsibilities of the perinatal care committee include the following:

(1) Develop policies for the unit including provisions to ensure adequate patient care by qualified providers.

(2) Conduct a meeting at least semiannually to resolve problems related to the unit.

(3) Review educational activities conducted by the unit.

(4) Serve as a general liaison between the various groups represented on the committee.

641—150.8(135,77GA,ch1221) Level II regional centers.

150.8(1) *Definition.*

a. Level II regional centers have a developed neonatal intensive care unit (NICU). The sizes of the units vary because of the differing demands in the various regions in Iowa. Accordingly, a Level II regional center may have as few as four neonatal intensive care beds.

b. The obstetric service in a Level II regional center provides services for maternity patients at higher risk than those in Level II hospitals because of the presence of an NICU. However, reasonable efforts should be expended to transfer those patients whose newborns are likely to require a higher intensity of care not available in the Level II regional center but offered in a Level III center.

c. Level II regional centers provide the same care and services as Level II hospitals. In addition, Level II regional centers have the following differentiating characteristics:

- (1) A defined referral area;
- (2) A defined relationship with a Level III center either in Iowa or a contiguous state;
- (3) A minimum of three pediatricians and three obstetricians on staff; and
- (4) The ability to manage patients at higher risk than Level I or Level II hospitals. Complexity of care is determined by the training and experience of physicians and nursing staff and extent of support services available.

150.8(2) Functions. Level II regional centers have the same functions as Level II hospitals. In addition, Level II regional centers have the capability to:

- a. Accept selected maternal transports based on criteria developed in conjunction with the Level III center;
- b. Maintain nursing personnel demonstrating competency in the care of high-risk mothers;
- c. Maintain a defined neonatal intensive care unit;
- d. Maintain nursing personnel that demonstrate competency in the care of infants in neonatal intensive care;
- e. Provide care for infants requiring ventilatory support;
- f. Maintain a functioning neonatal transport team for the regional area served; and
- g. Provide for follow-up care of high-risk newborns in accordance with the Iowa high-risk infant follow-up program.

150.8(3) Physical facilities. Level II regional centers have the same physical facilities as Level II hospitals with the addition of the following.

a. *Obstetric functional units.*

(1) Labor/delivery. Patients who have significant medical or obstetric complications are cared for in a room especially equipped with cardiopulmonary resuscitation equipment and other monitoring equipment necessary for observation and special care. It is preferable that this room be located in the labor and delivery area and meet the physical requirements of any other intensive care room in the hospital. When patients with significant medical or obstetric complications are cared for in the labor and delivery area, the unit has the same capabilities as an intensive care unit.

(2) Postpartum. Larger services may have a specific recovery room for postpartum patients with a separate area for high-risk patients. Required equipment is similar to that needed in any surgical recovery room and includes equipment for monitoring vital signs, suctioning, administering oxygen, and infusing fluids intravenously. Cardiopulmonary resuscitation equipment must be immediately available.

b. *Neonatal functional units.*

(1) Continuous cardiopulmonary monitoring and constant nursing care and other support for severely ill infants are provided in the intensive care area. Because emergency care is provided in this area, laboratory and radiological services are readily available 24 hours a day. The results of blood gas analysis are available soon after blood sample collection.

(2) The neonatal intensive care area should be near the delivery/Cesarean birth room and should be easily accessible from the hospital's ambulance entrance. It should be away from routine hospital traffic.

(3) The amount and complexity of equipment are considerably greater than required in Level I and Level II nurseries. Equipment and supplies in the intensive care area include the same items as needed in the resuscitation and intermediate care areas. Immediate availability of emergency oxygen is essential. Continuous monitoring of delivered oxygen concentrations, patient oxygenation, body temperature, ECG, respirations and blood pressure should be available. Supplies should be kept close to the patient station so that nurses are not away from the neonate unnecessarily and may use their time and skills efficiently.

150.8(4) Medical personnel.

a. Level II regional centers have the same medical personnel as Level II hospitals with the addition of a board-eligible or board-certified pediatrician serving as director of the NICU. This physician maintains a consultative relationship with Level III physicians. Additionally, Level II regional centers have a minimum of three pediatricians and three obstetricians on staff.

b. If an infant is placed on mechanical ventilation, a physician, nurse practitioner, physician assistant, or appropriate person capable of airway management and experienced in diagnosis is available in-house on a 24-hour basis.

150.8(5) *Nursing personnel.* Level II regional centers have the same minimal requirements for nursing personnel as Level II hospitals. Additionally, Level II regional center registered nurses have demonstrated competency in high-risk obstetrics or neonatal care.

150.8(6) *Outreach education.* Outreach education is provided to each hospital in the referral area at least once per year. This can be achieved by one or more of the following:

- a.* Sponsoring an annual conference;
- b.* Visiting Level I and Level II hospitals;
- c.* Providing educational programs at the regional center for the staff members of the Level I and Level II hospitals;
- d.* Sending written educational materials to the Level I and II hospitals.

150.8(7) *Allied health personnel and services.* Level II regional centers have the same allied health personnel and services available as Level II hospitals, with the addition of the following:

a. A respiratory therapist, certified lab technician/blood gas technician and an X-ray technologist should be in-house on a 24-hour basis when a neonate is being managed on mechanical ventilation.

b. Allied personnel should have special training and an interest in high-risk mothers and infants.

150.8(8) *Infection control.* Infection control guidelines are the same as for Level II hospitals.

150.8(9) *Newborn safety.* Level II regional centers have at least the same requirements for newborn safety as Level II hospitals.

150.8(10) *Maternal-fetal transport.* Level II regional centers have the same requirements for maternal-fetal transport as Level II hospitals. In addition, Level II regional centers are expected to provide transportation services.

150.8(11) *Perinatal care committee.* Level II regional centers have at least the same requirements for a perinatal care committee as Level II hospitals.

641—150.9(135,77GA,ch1221) Level II regional neonatology centers.

150.9(1) *Definition.*

a. Level II regional neonatology centers provide the same care and services as Level II regional centers with the addition of a demonstrated commitment to providing a higher level of neonatology care. The Level II regional neonatology center will manage high-risk pregnancies and infants born at less than 34 weeks' gestation or weighing less than 1500 grams. Exceptions will be cases for which surgical intervention or pediatric subspecialty care is anticipated or needed.

b. The obstetric service in a Level II regional neonatology center provides services for maternity patients at higher risk than those in Level II hospitals because of the presence of a NICU. However, reasonable efforts should be expended to transfer those patients whose newborns are likely to require a higher intensity of care not available in the Level II regional neonatology center but offered in a Level III center. Efforts should also be made to transfer those patients to a Level III center when the pregnancy has risk factors that require the care of a maternal-fetal medicine specialist.

c. Level II regional neonatology centers provide the same care and services as Level II regional centers. In addition, Level II regional neonatology centers have the following differentiating characteristics:

- (1) A defined referral area;
- (2) A defined relationship with a Level III center either in Iowa or a contiguous state;
- (3) A minimum of two board-eligible or board-certified neonatal/perinatal medicine subspecialists on staff;
- (4) Neonatology care available on a continuous 24-hour basis, with at least three obstetricians on staff; and
- (5) A medical director in the neonatal intensive care unit who is a full-time, board-eligible or board-certified pediatrician with board eligibility or certification in neonatal/perinatal medicine.

150.9(2) Functions. Level II regional neonatology centers have the same functions as Level II regional centers.

- a. Accept selected maternal transports based on criteria developed in conjunction with the Level III center;
- b. Maintain nursing personnel demonstrating competency in the care of high-risk mothers;
- c. Maintain a defined neonatal intensive care unit;
- d. Maintain nursing personnel that demonstrate competency in the care of infants in neonatal intensive care;
- e. Provide care for infants requiring ventilatory support;
- f. Maintain a functioning neonatal transport team for the regional area served; and
- g. Provide for follow-up care of high-risk newborns in accordance with the Iowa high-risk infant follow-up program.

150.9(3) Physical facilities. Level II regional neonatology centers have the same physical facilities as Level II regional centers; however, they have special equipment for infants born at less than 34 weeks' gestation or weighing less than 1500 grams, and they serve a more complicated patient population.

150.9(4) Medical personnel.

- a. Level II regional neonatology centers have the same medical personnel as Level II regional centers.
- b. The medical director of the neonatal intensive care unit is a full-time, board-eligible or board-certified pediatrician with certification in neonatal/perinatal medicine. This physician maintains a consultative relationship with Level III physicians.
- c. Anesthesia providers on staff have special training or experience in obstetric and pediatric anesthesia.
- d. A pediatric cardiologist is active on staff.
- e. A neonatologist shall be on the premises when unstable critically ill infants are in the Level II regional neonatology center.

150.9(5) Nursing personnel. Level II regional neonatology centers have the same minimal requirements for nursing personnel as Level II regional centers. Additionally, registered nurses in the NICU of Level II regional neonatology centers must have specialty certification or advanced training and experience in the nursing management of high-risk neonates and their families.

150.9(6) Outreach education. Outreach education is provided to each hospital in the referral area at least once per year. This can be achieved by one or more of the following:

- a. Sponsoring an annual conference;
- b. Visiting Level I and Level II hospitals;
- c. Providing educational programs at the regional center for the staff members of the Level I and Level II hospitals;
- d. Sending written educational materials to the Level I and II hospitals.

150.9(7) Allied health personnel and services. Level II regional neonatology centers have the same allied health personnel and services available as Level II regional centers, with the addition of the following:

- a. Respiratory therapists, certified lab technicians/blood gas technicians, X-ray technologists, and ultrasound technicians with neonatal/perinatal experience available on a 24-hour basis.
- b. Social services, with social workers assigned specifically to the maternal and neonatal units.

150.9(8) Infection control. Infection control guidelines are the same as for Level II hospitals and Level II regional centers.

150.9(9) Newborn safety. Level II regional neonatology centers have at least the same requirements for newborn safety as Level II regional centers.

150.9(10) Maternal-fetal transport. Level II regional neonatology centers have the same requirements for maternal-fetal transport as Level II hospitals and Level II regional centers. In addition, Level II regional neonatology centers are expected to provide neonatal transportation services.

150.9(11) *Perinatal care committee.* Level II regional neonatology centers maintain a perinatal care committee with the same required meetings and membership as the Level II hospitals and Level II regional centers.

150.9(12) *Quality improvement.* Centers that routinely provide care to infants born at less than 34 weeks' gestation or weighing less than 1500 grams shall maintain a patient database of all NICU admissions that includes an accounting of patient mortality and morbidity for the benchmarking of results against other centers (national or statewide) and for the purpose of continuous review and quality improvement.

641—150.10(135,77GA,ch1221) Level III centers.

150.10(1) *Definition and function.* Level III centers provide the same care and services as Level II regional centers, plus they manage high-risk pregnancies and neonates, with the possible exception of a few very specialized complications. The Level III center is an extension of the Level II regional center and serves the same regional functions. The differentiating factor between them is primarily one of additional professional staff and more extensive physical facilities. There may be multiple Level III centers in the same city.

150.10(2) *Physical facilities.* Level III centers have the same physical facilities as Level II regional centers; however, they have more equipment and serve a more complicated patient population.

150.10(3) *Medical personnel.*

a. The medical director of the maternal-fetal intensive care unit is a full-time, board-eligible or board-certified obstetrician with certification in maternal-fetal medicine.

b. The medical director of the neonatal intensive care unit is a full-time, board-eligible or board-certified pediatrician with certification in neonatal/perinatal medicine.

c. Anesthesia providers on staff have special training or experience in obstetric and pediatric anesthesia.

d. A pediatric surgeon is on staff.

e. A pediatric cardiologist is on staff.

f. These physicians must be immediately available to the Level III center and reside in the same metropolitan area as the hospital.

g. A neonatologist should be on the premises when unstable critically ill infants are in the Level III center. An obstetrician should be on the premises when unstable critically ill mothers are in the Level III center.

150.10(4) *Nursing personnel.* Level III centers have the same minimal requirements for nursing personnel as Level II regional centers. The nurse managers of the perinatal units in Level III centers have prior experience in maternal or pediatric nursing and have a minimum of a bachelor of science in nursing degree, or a bachelor's degree in a related field.

150.10(5) *Outreach education.* Level III centers have the same responsibilities for outreach education as Level II regional centers.

150.10(6) *Allied health personnel and services.* Level III centers have the same allied health personnel and services as Level II regional centers. Additionally, Level III centers have respiratory therapists, certified lab technicians/blood gas technicians, X-ray technologists and ultrasound technicians with neonatal/perinatal experience available on a 24-hour basis. Level III centers also have social work services with social workers assigned specifically to the maternal and neonatal units.

150.10(7) *Infection control.* Infection control guidelines are the same as for Level II regional centers.

150.10(8) *Newborn safety.* Level III centers have at least the same requirements for newborn safety as Level II regional centers.

150.10(9) *Maternal-fetal transport.* Level III centers have the same requirements for maternal-fetal transport as Level II regional centers. In addition, Level III centers are capable of providing ground and air transportation whose crews have demonstrated competencies in maternal/neonatal resuscitation. Important decisions to be made jointly will include the appropriateness of transport, the best mode of transportation, the need for additional personnel accompanying the transport, and the appropriate medical management to initiate prior to transport.

150.10(10) *Perinatal care committee.* Level III centers maintain a perinatal care committee with additional representation by surgical specialties.

641—150.11(135,77GA,ch1221) Grant or denial of certificate of verification; and offenses and penalties.

150.11(1) Upon receipt of the on-site survey results, the department shall within 30 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 shall be effected and may be appealed in accordance with the requirements of Iowa Code section 17A.12.

150.11(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 and appeals.

150.11(3) Complaints and the investigative process shall be treated as confidential to the extent they are protected by Iowa Code section 22.7.

150.11(4) Complaint investigations may result in the department's issuance of a notice of denial, citation and warning, probation, suspension or revocation.

150.11(5) Notice of denial, citation and warning, probation, suspension or revocation shall 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 shall be served by certified mail, return receipt requested, or by personal service.

150.11(6) Any request for a hearing concerning the denial, citation and warning, probation, suspension or revocation shall 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. The address is: Iowa Regionalized System of Perinatal Health Care, Iowa Department of Public Health, Division of Health Promotion and Chronic Disease Prevention, 321 East 12th Street, Lucas State Office Building, Des Moines, Iowa 50319-0075. If the request is made within the 20-day time period, the notice to take action shall 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 shall become the department's final agency action.

150.11(7) Upon receipt of a request for hearing, the request shall be forwarded within five working days to the department of inspections and appeals 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 and appeals.

150.11(8) The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10, Iowa Administrative Code.

150.11(9) When the administrative law judge makes a proposed decision and order, it shall 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.

150.11(10) Any appeal to the director for review of the proposed decision and order of the administrative law judge shall 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 shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

150.11(11) Upon receipt of an appeal request, the administrative law judge shall 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.

150.11(12) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by certified mail, return receipt requested, or by personal service.

150.11(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.

150.11(14) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Iowa Regionalized System of Perinatal Health Care, Iowa Department of Public Health, Division of Health Promotion and Chronic Disease Prevention, 321 East 12th Street, Lucas State Office Building, Des Moines, Iowa 50319-0075.

150.11(15) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

150.11(16) Final decisions of the department relating to disciplinary proceedings may be transmitted to the department of inspections and appeals and to the appropriate professional associations or news media.

641—150.12(135,77GA,ch1221) 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 and appeals, 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 hospital," "Level II hospital," "Level II regional center," "Level II regional neonatology center," and "Level III center" in relation to the provision of perinatal health care services.

641—150.13(135,77GA,ch1221) 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.

These rules are intended to implement 1998 Iowa Acts, chapter 1221, section 5, subsection 4 "a" (2)(c).

[Filed 1/21/99, Notice 11/18/98—published 2/10/99, effective 3/17/99]

[Filed 1/10/07, Notice 11/22/06—published 1/31/07, effective 3/7/07]