

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 1) Heading of the Part: Hospital Licensing Requirements
- 2) Code Citation: 77 Ill. Adm. Code 250
- 3)

<u>Section Numbers:</u>	<u>Proposed Action:</u>
250.285	New
250.290	New
250.1090	Amend
250.1300	Amend
250.1305	Amend
250.1830	Amend
- 4) Statutory Authority: Hospital Licensing Act [210 ILCS 85]
- 5) A Complete Description of the Subjects and Issues Involved: The Hospital Licensing Requirements regulate hospitals, including the control of infectious disease and operating room procedures.

Section 250.285 (Smoking Restrictions) is being added to require hospitals to comply with the Smoke Free Illinois Act. This Section replaces non-smoking language in Section 250.1830.

Section 250.290 (Safety Alert Notifications) is being added to ensure that hospitals receive notification directly from the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) on issues such as recalled medical devices, contaminated products and medications, disease outbreaks, and other important public health issues. Section 250.1090 (Sterilization and Processing of Supplies) is being amended to update the current standards for sterilization processes and to add a new requirement for maintaining records with regard to transmissible spongiform encephalopathies. Section 250.1830 (General Requirements for all Maternity Departments) is being amended to change outdated language about diarrhea and Staphylococcus infections in the nursery. This change will bring the hospital rules into compliance with the Department's Control of Communicable Diseases Code (77 Ill. Adm. Code 690).

Section 250.1300 (Operating Room) is being amended to update the hospital surgical requirements to current standards. Section 250.1305 (Visitors in Operating Room) is being amended to update the requirements for hospital visitors to better protect the patients and the visitors from infections.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

The economic effect of this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect.

The Department anticipates adoption of this rulemaking approximately six to nine months after publication of the Notice in the *Illinois Register*.

- 6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: None
- 7) Will this rulemaking replace any emergency rulemaking currently in effect? No
- 8) Does this rulemaking contain an automatic repeal date? No
- 9) Does this rulemaking contain incorporations by reference? Yes
- 10) Are there any other proposed rulemakings pending on this Part? No
- 11) Statement of Statewide Policy Objectives: This rulemaking does not create a State Mandate.
- 12) Time, Place, and Manner in which interested persons may comment on this proposed rulemaking: Interested persons may present their comments concerning this rulemaking within 45 days after this issue of the *Illinois Register* to:

Susan Meister
Division of Legal Services
Illinois Department of Public Health
535 West Jefferson St., 5th Floor
Springfield, Illinois 62761

217/782-2043
e-mail: dph.rules@illinois.gov
- 13) Initial Regulatory Flexibility Analysis:
 - A) Type of small businesses, small municipalities and not-for-profit corporations affected: hospitals

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- B) Reporting, bookkeeping or other procedures required for compliance: This rulemaking will require more recordkeeping.
- C) Types of professional skills necessary for compliance: None
- 14) Regulatory Agenda on which this rulemaking was summarized: This rulemaking was not included on either of the two most recent Regulatory Agendas because: the need for the rulemaking was not known when the regulatory agenda was drafted.

The full text of the Proposed Amendments begins on the next page:

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

TITLE 77: PUBLIC HEALTH

CHAPTER I: DEPARTMENT OF PUBLIC HEALTH

SUBCHAPTER b: HOSPITALS AND AMBULATORY CARE FACILITIES

PART 250

HOSPITAL LICENSING REQUIREMENTS

SUBPART A: GENERAL

Section

- 250.110 Application for and Issuance of Permit to Establish a Hospital
- 250.120 Application for and Issuance of a License to Operate a Hospital
- 250.130 Administration by the Department
- 250.140 Hearings
- 250.150 Definitions
- 250.160 Incorporated and Referenced Materials

SUBPART B: ADMINISTRATION AND PLANNING

Section

- 250.210 The Governing Board
- 250.220 Accounting
- 250.230 Planning
- 250.240 Admission and Discharge
- 250.250 Visiting Rules
- 250.260 Patients' Rights
- 250.265 Language Assistance Services
- 250.270 Manuals of Procedure
- 250.280 Agreement with Designated Organ Procurement Agencies
- [250.285 Smoking Restrictions](#)
- [250.290 Safety Alert Notifications](#)

SUBPART C: THE MEDICAL STAFF

Section

- 250.310 Organization
- 250.315 House Staff Members
- 250.320 Admission and Supervision of Patients
- 250.330 Orders for Medications and Treatments

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

250.340 Availability for Emergencies

SUBPART D: PERSONNEL SERVICE

Section

- 250.410 Organization
- 250.420 Personnel Records
- 250.430 Duty Assignments
- 250.435 Health Care Worker Background Check
- 250.440 Education Programs
- 250.450 Personnel Health Requirements
- 250.460 Benefits

SUBPART E: LABORATORY

Section

- 250.510 Laboratory Services
- 250.520 Blood and Blood Components
- 250.525 Designated Blood Donor Program
- 250.530 Proficiency Survey Program (Repealed)
- 250.540 Laboratory Personnel (Repealed)
- 250.550 Western Blot Assay Testing Procedures (Repealed)

SUBPART F: RADIOLOGICAL SERVICES

Section

- 250.610 General Diagnostic Procedures and Treatments
- 250.620 Radioactive Isotopes
- 250.630 General Policies and Procedures Manual

SUBPART G: GENERAL HOSPITAL EMERGENCY SERVICE

Section

- 250.710 Classification of Emergency Services
- 250.720 General Requirements
- 250.725 Notification of Emergency Personnel
- 250.730 Community or Areawide Planning
- 250.740 Disaster and Mass Casualty Program
- 250.750 Emergency Services for Sexual Assault Victims

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

SUBPART H: RESTORATIVE AND REHABILITATION SERVICES

Section	
250.810	Applicability of Other Parts of These Requirements
250.820	General
250.830	Classifications of Restorative and Rehabilitation Services
250.840	General Requirements for all Classifications
250.850	Specific Requirements for Comprehensive Physical Rehabilitation Services
250.860	Medical Direction
250.870	Nursing Care
250.880	Additional Allied Health Services
250.890	Animal-Assisted Therapy

SUBPART I: NURSING SERVICE AND ADMINISTRATION

Section	
250.910	Nursing Services
250.920	Organizational Plan
250.930	Role in hospital planning
250.940	Job descriptions
250.950	Nursing committees
250.960	Specialized nursing services
250.970	Nursing Care Plans
250.980	Nursing Records and Reports
250.990	Unusual Incidents
250.1000	Meetings
250.1010	Education Programs
250.1020	Licensure
250.1030	Policies and Procedures
250.1035	Domestic Violence Standards
250.1040	Patient Care Units
250.1050	Equipment for Bedside Care
250.1060	Drug Services on Patient Unit
250.1070	Care of Patients
250.1075	Use of Restraints
250.1080	Admission Procedures Affecting Care
250.1090	Sterilization and Processing of Supplies
250.1100	Infection Control

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 250.1110 Mandatory Overtime Prohibition
- 250.1120 Staffing Levels
- 250.1130 Nurse Staffing by Patient Acuity

SUBPART J: SURGICAL AND RECOVERY ROOM SERVICES

- Section
- 250.1210 Surgery
- 250.1220 Surgery Staff
- 250.1230 Policies & Procedures
- 250.1240 Surgical Privileges
- 250.1250 Surgical Emergency Care
- 250.1260 Operating Room Register and Records
- 250.1270 Surgical Patients
- 250.1280 Equipment
- 250.1290 Safety
- 250.1300 Operating Room
- 250.1305 Visitors in Operating Room
- 250.1310 Cleaning of Operating Room
- 250.1320 Postoperative Recovery Facilities

SUBPART K: ANESTHESIA SERVICES

- Section
- 250.1410 Anesthesia Service

SUBPART L: RECORDS AND REPORTS

- Section
- 250.1510 Medical Records
- 250.1520 Reports

SUBPART M: FOOD SERVICE

- Section
- 250.1610 Dietary Department Administration
- 250.1620 Facilities
- 250.1630 Menus and Nutritional Adequacy
- 250.1640 Diet Orders

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

250.1650	Frequency of Meals
250.1660	Therapeutic (Modified) Diets
250.1670	Food Preparation and Service
250.1680	Sanitation

SUBPART N: HOUSEKEEPING AND LAUNDRY SERVICES

Section

250.1710	Housekeeping
250.1720	Garbage, Refuse and Solid Waste Handling and Disposal
250.1730	Insect and Rodent Control
250.1740	Laundry Service
250.1750	Soiled Linen
250.1760	Clean Linen

SUBPART O: MATERNITY AND NEONATAL SERVICE

Section

250.1810	Applicability of other Parts of these regulations
250.1820	Maternity and Neonatal Service (Perinatal Service)
250.1830	General Requirements for All Maternity Departments
250.1840	Discharge of Newborn Infants from Hospital
250.1850	Rooming-In Care of Mother and Infant
250.1860	Special Programs
250.1870	Single Room Maternity Care

SUBPART P: ENGINEERING AND MAINTENANCE OF THE PHYSICAL PLANT, SITE,
EQUIPMENT, AND SYSTEMS – HEATING, COOLING, ELECTRICAL, VENTILATION,
PLUMBING, WATER, SEWER, AND SOLID WASTE DISPOSAL

Section

250.1910	Maintenance
250.1920	Emergency electric service
250.1930	Water Supply
250.1940	Ventilation, Heating, Air Conditioning, and Air Changing Systems
250.1950	Grounds and Buildings Shall be Maintained
250.1960	Sewage, Garbage, Solid Waste Handling and Disposal
250.1970	Plumbing
250.1980	Fire and Safety

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

SUBPART Q: CHRONIC DISEASE HOSPITALS

Section	
250.2010	Definition
250.2020	Requirements

SUBPART R: PHARMACY OR DRUG AND MEDICINE SERVICE

Section	
250.2110	Service Requirements
250.2120	Personnel Required
250.2130	Facilities for Services
250.2140	Pharmacy and Therapeutics Committee

SUBPART S: PSYCHIATRIC SERVICES

Section	
250.2210	Applicability of other Parts of these Regulations
250.2220	Establishment of a Psychiatric Service
250.2230	The Medical Staff
250.2240	Nursing Service
250.2250	Allied Health Personnel
250.2260	Staff and Personnel Development and Training
250.2270	Admission, Transfer and Discharge Procedures
250.2280	Care of Patients
250.2290	Special Medical Record Requirements for Psychiatric Hospitals and Psychiatric Units of General Hospitals or General Hospitals Providing Psychiatric Care
250.2300	Diagnostic, Treatment and Physical Facilities and Services

SUBPART T: DESIGN AND CONSTRUCTION STANDARDS

Section	
250.2410	Applicability of these Standards
250.2420	Submission of Plans for New Construction, Alterations or Additions to Existing Facility
250.2430	Preparation of Drawings and Specifications – Submission Requirements
250.2440	General Hospital Standards
250.2442	Fees

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

250.2443	Advisory Committee
250.2450	Details
250.2460	Finishes
250.2470	Structural
250.2480	Mechanical
250.2490	Plumbing and Other Piping Systems
250.2500	Electrical Requirements

SUBPART U: CONSTRUCTION STANDARDS FOR EXISTING HOSPITALS

Section	
250.2610	Applicability of these Standards
250.2620	Codes and Standards
250.2630	Existing General Hospital Standards
250.2640	Details
250.2650	Finishes
250.2660	Mechanical
250.2670	Plumbing and Other Piping Systems
250.2680	Electrical Requirements

SUBPART V: SPECIAL CARE AND/OR SPECIAL SERVICE UNITS

Section	
250.2710	Special Care and/or Special Service Units
250.2720	Day Care for Mildly Ill Children

SUBPART W: ALCOHOLISM AND INTOXICATION TREATMENT SERVICES

Section	
250.2810	Applicability of Other Parts of These Requirements
250.2820	Establishment of an Alcoholism and Intoxication Treatment Service
250.2830	Classification and Definitions of Service and Programs
250.2840	General Requirements for all Hospital Alcoholism Program Classifications
250.2850	The Medical and Professional Staff
250.2860	Medical Records
250.2870	Referral
250.2880	Client Legal and Human Rights

250.APPENDIX A	Codes and Standards (Repealed)
----------------	--------------------------------

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

250.EXHIBIT A	Codes (Repealed)
250.EXHIBIT B	Standards (Repealed)
250.EXHIBIT C	Addresses of Sources (Repealed)
250.ILLUSTRATION A	Seismic Zone Map
250.TABLE A	Measurements Essential for Level I, II, III Hospitals
250.TABLE B	Sound Transmission Limitations in General Hospitals
250.TABLE C	Filter Efficiencies for Central Ventilation and Air Conditioning Systems in General Hospitals (Repealed)
250.TABLE D	General Pressure Relationships and Ventilation of Certain Hospital Areas (Repealed)
250.TABLE E	Piping Locations for Oxygen, Vacuum and Medical Compressed Air
250.TABLE F	General Pressure Relationships and Ventilation of Certain Hospital Areas
250.TABLE G	Insulation/Building Perimeter

AUTHORITY: Implementing and authorized by the Hospital Licensing Act [210 ILCS 85].

SOURCE: Rules repealed and new rules adopted August 27, 1978; emergency amendment at 2 Ill. Reg. 31, p. 73, effective July 24, 1978, for a maximum of 150 days; amended at 2 Ill. Reg. 21, p. 49, effective May 16, 1978; emergency amendment at 2 Ill. Reg. 31, p. 73, effective July 24, 1978, for a maximum of 150 days; amended at 2 Ill. Reg. 45, p. 85, effective November 6, 1978; amended at 3 Ill. Reg. 17, p. 88, effective April 22, 1979; amended at 4 Ill. Reg. 22, p. 233, effective May 20, 1980; amended at 4 Ill. Reg. 25, p. 138, effective June 6, 1980; amended at 5 Ill. Reg. 507, effective December 29, 1980; amended at 6 Ill. Reg. 575, effective December 30, 1981; amended at 6 Ill. Reg. 1655, effective January 27, 1982; amended at 6 Ill. Reg. 3296, effective March 15, 1982; amended at 6 Ill. Reg. 7835 and 7838, effective June 17, 1982; amended at 7 Ill. Reg. 962, effective January 6, 1983; amended at 7 Ill. Reg. 5218 and 5221, effective April 4, 1983 and April 5, 1983; amended at 7 Ill. Reg. 6964, effective May 17, 1983; amended at 7 Ill. Reg. 8546, effective July 12, 1983; amended at 7 Ill. Reg. 9610, effective August 2, 1983; codified at 8 Ill. Reg. 19752; amended at 8 Ill. Reg. 24148, effective November 29, 1984; amended at 9 Ill. Reg. 4802, effective April 1, 1985; amended at 10 Ill. Reg. 11931, effective September 1, 1986; amended at 11 Ill. Reg. 10283, effective July 1, 1987; amended at 11 Ill. Reg. 10642, effective July 1, 1987; amended at 12 Ill. Reg. 15080, effective October 1, 1988; amended at 12 Ill. Reg. 16760, effective October 1, 1988; amended at 13 Ill. Reg. 13232, effective September 1, 1989; amended at 14 Ill. Reg. 2342, effective February 15, 1990; amended at 14 Ill. Reg. 13824, effective September 1, 1990; amended at 15 Ill. Reg. 5328, effective May 1, 1991; amended at 15 Ill. Reg. 13811, effective October 1, 1991; amended at 17 Ill. Reg. 1614, effective January 25, 1993; amended at 17 Ill. Reg. 17225, effective October 1, 1993; amended at 18 Ill. Reg. 11945, effective July 22, 1994; amended at 18 Ill. Reg. 15390, effective October 10, 1994; amended at 19 Ill. Reg. 13355, effective September 15, 1995;

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

emergency amendment at 20 Ill. Reg. 474, effective January 1, 1996, for a maximum of 150 days; emergency expired May 29, 1996; amended at 20 Ill. Reg. 3234, effective February 15, 1996; amended at 20 Ill. Reg. 10009, effective July 15, 1996; amended at 22 Ill. Reg. 3932, effective February 13, 1998; amended at 22 Ill. Reg. 9342, effective May 20, 1998; amended at 23 Ill. Reg. 1007, effective January 15, 1999; emergency amendment at 23 Ill. Reg. 3508, effective March 4, 1999, for a maximum of 150 days; amended at 23 Ill. Reg. 9513, effective August 1, 1999; amended at 23 Ill. Reg. 13913, effective November 15, 1999; amended at 24 Ill. Reg. 6572, effective April 11, 2000; amended at 24 Ill. Reg. 17196, effective November 1, 2000; amended at 25 Ill. Reg. 3241, effective February 15, 2001; amended at 27 Ill. Reg. 1547, effective January 15, 2003; amended at 27 Ill. Reg. 13467, effective July 25, 2003; amended at 28 Ill. Reg. 5880, effective March 29, 2004; amended at 28 Ill. Reg. 6579, effective April 15, 2004; amended at 29 Ill. Reg. 12489, effective July 27, 2005; amended at 31 Ill. Reg. 4245, effective February 20, 2007; amended at 31 Ill. Reg. 14530, effective October 3, 2007; amended at 32 Ill. Reg. 3756, effective February 27, 2008; amended at 32 Ill. Reg. 4213, effective March 10, 2008; amended at 32 Ill. Reg. 7932, effective May 12, 2008; amended at 32 Ill. Reg. 14336, effective August 12, 2008; amended at 33 Ill. Reg. 8306, effective June 2, 2009; amended at 34 Ill. Reg. 2528, effective January 27, 2010; amended at 34 Ill. Reg. 3331, effective February 24, 2010; amended at 34 Ill. Reg. _____, effective _____.

SUBPART B: ADMINISTRATION AND PLANNING

Section 250.285 Smoking Restrictions

The hospital shall comply with the Smoke Free Illinois Act [410 ILCS 82].

(Source: Added at 34 Ill. Reg. _____, effective _____)

Section 250.290 Safety Alert Notifications

- a) Each hospital shall subscribe to the free e-mail notification services of the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention.
- 1) FDA: MedWatch E-List, which can be accessed at www.fda.gov/medwatch/elist.htm; and
 - 2) CDC: Rapid Notification System for Healthcare Professionals, which can be accessed at www2a.cdc.gov/ncidod/hip/rns/hip_rns_subscribe.html.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

b) [Actions in response to these notifications shall be taken promptly.](#)

(Source: Added at 34 Ill. Reg. _____, effective _____)

SUBPART I: NURSING SERVICE AND ADMINISTRATION

Section 250.1090 Sterilization and Processing of Supplies

- a) All sterilization and processing of all sterile supplies and equipment shall be under competent, qualified supervision.
- 1) The director or person responsible for central services shall be responsible to the chief executive officer either directly or through a designated department head. [The director of the central sterile supply](#)~~This person~~ shall be qualified for the position by education, training, and experience and ~~shall~~[should](#) be a member of the Infection Control Committee. [\(See Section 250.1100\(a\).\)](#)
 - 2) The number of supervisory and support personnel shall be related to the scope of the services provided. New employees shall receive initial orientation and on-the-job training, and all employees shall participate in a continuing in-service education program, which shall be documented.
 - 3) Educational efforts, though directed primarily at sterile-supply processing and handling techniques, shall also include management concepts, safety, personal hygiene, health requirements, and work attire.
- b) There shall be written policies and procedures for the decontamination and sterilization activities performed in central services and elsewhere in the hospital. [The hospital shall comply with the Centers for Disease Control and Prevention Guidelines for Disinfection and Sterilization in Healthcare Facilities.](#) These policies and procedures shall ~~include~~[relate](#), but are not limited, to, the following:
- 1) The receiving, decontaminating, cleaning, preparing, disinfecting and sterilizing of reusable items.
 - 2) The assembly, wrapping, storage, distribution, and quality control of sterile equipment and medical supplies. Load control numbers shall be used to designate the hospital sterilization equipment used for each item,

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

including the sterilization date and cycle.

- 3) The use of sterilization process monitors, including temperature and pressure recordings, and the use and frequency of appropriate chemical indicator and bacteriological spore tests for all sterilizers.
- 4) Designation of the shelf life for each hospital-wrapped and -sterilized medical item and, to the maximum degree possible, for each commercially prepared item.
 - A) Designation of a shelf life may be a specific expiration date, i.e., 30 days, six months, etc., based on manufacturer's recommendation, a nationally recognized authority, or other standard approved by the facility's Infection Control Committee.
 - B) Designation of shelf life may be event related if policies and procedures, approved by the Infection Control Committee, address at least the following:
 - i) requirements for wrapping, storage and rotation of sterile supplies;
 - ii) definition of an event that may cause a sterile item to be or be suspected of being compromised, such as the package being wet or torn, or the seal being broken or tampered with;
 - iii) clear direction that the final inspection of the package and the ultimate decision to use the contents of the package rest with the clinician; and
 - iv) orientation, in-service and other follow-up training to assure that all necessary staff understand and implement the policies and procedures.
 - C) A facility may choose to use both a specific expiration date and event-related shelf life designation specific for certain wrappings, areas of the hospital, etc., as long as the policies and procedures, as approved by the Infection Control Committee, and the training of

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

staff define this practice.

- 5) Acquisition of supplies after normal working hours or any time the central service or sterile supply unit is considered "closed" or unstaffed.
 - 6) Preventive maintenance of all central supply service equipment, including performance verification records and reports.
 - 7) The recall and disposal or reprocessing of expired or inadequately sterilized~~outdated sterile~~ supplies.
 - 8) The emergency collection and disposition of supplies when special warnings have been issued by the manufacturer. The~~There shall be appropriate notification of the~~ attending physician shall be notified~~when~~where patient exposure is known.
 - 9) Specific aeration requirements for each category of gas-sterilized items to eliminate the hazard of toxic residues.
 - 10) The cleaning and sanitizing of work surfaces, floors, utensils, and equipment used in central service functions.
- c) Space shall be provided for the efficient operation of all central service functions. Functional design and work flow patterns shall~~should~~ provide for the separation of soiled and contaminated supplies from those that are clean and sterile. Equipment of adequate design, size, and type shall~~should~~ be provided for the effective decontaminating, disinfecting, cleaning, packaging, sterilizing, storing, and distributing of medical instruments, supplies, and equipment used in patient care.
- d) Equipment and procedures
- 1) The facilities, equipment, and procedures for clean-up, preparation, and sterilization shall be adequate to allow proper cleaning, processing, and sterilizing of patient care supplies and equipment.
 - 2) When clean-up, preparation, and sterilization functions are carried out in the same room or unit (as in a central sterilizing department) the physical facilities and equipment and the policies and procedures for their use shall

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

be such as to effectively separate soiled or contaminated supplies and equipment from the clean or sterilized supplies and equipment.

- 3) Sterilization equipment shall be maintained in good repair and under the provisions of a preventive maintenance program of the Engineering and Maintenance Services. (Refer to Subpart P.)
 - 4) All pressure steam autoclaves shall have recording thermometers, and the sterilization performance shall be otherwise checked.
- e) Sterilization of instruments and utensils
- 1) All surgical instruments not adversely affected by high temperature shall be sterilized by pressure steam sterilization.
 - 2) The steam method of sterilization is the preferred method for sterilizing medical and surgical instruments that are not damaged by heat, steam, pressure, or moisture. Low-temperature sterilization technologies (e.g., EtO, hydrogen peroxide gas plasma) may be used for reprocessing patient care equipment that is heat or moisture sensitive. In addition, a peracetic acid immersion system of sterilization may be used to sterilize heat-sensitive immersible medical and surgical items, and dry-heat sterilization may be used to sterilize items (e.g., powders, oils) that can sustain high temperatures. Operating parameters and guidelines for each method or system of sterilization shall be followed for whichever method is used. Whenever possible, throughout the hospital, sterilization shall be accomplished by pressure steam sterilization. Hot air sterilization or gas sterilization may be used. When gas sterilization is used, there shall be policies and tested procedures for proper aeration to permit safe utilization. Pressure steam sterilization of reusable syringes and needles is required.
 - 3) All instruments, whether used on infected cases or clean cases, shall be thoroughly cleaned before sterilization. Instruments used on infected cases shall be disinfected before transport to Central Supply.
 - 4) Boiling is not an approved method of sterilization.
- f) Water sterilization

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 1) When non-commercial sterile water is utilized, water sterilization equipment shall be maintained and operated in a manner ~~that~~^{which} will protect the sterilized water from contamination.
 - 2) An acceptable method for checking the sterility of the water shall be utilized. Water may be sterilized either in approved water sterilizers or autoclaved in approved flasks.
- g) Sterilization and storage of supplies and equipment
- 1) Supplies and equipment shall be properly wrapped and labeled before sterilization.
 - 2) The effectiveness of hospital sterilization shall be checked. Mechanical, chemical, and biologic monitors shall be used to ensure the effectiveness of the sterilization process. ~~This should include bacteriological testing of all sterilization units throughout the hospital in accordance with Infection Control Committee procedures.~~ Indicators shall be used to show that the items have a wrapped package has been sterilized. A procedure shall be established for the recall of expired or inadequately sterilized goods for both in-house and commercially sterilized supplies and equipment. Refer to Section 250.1100(a)~~(5)~~.
 - 3) Supplies and equipment commercially prepared so as to retain sterility indefinitely are acceptable. The hospital ~~shall~~^{should} satisfy itself of the sterility of such materials.
 - 4) Sterile equipment and supplies shall be stored properly in clean cabinets, cupboards or other suitable enclosed spaces. An orderly system of rotation of supplies is recommended so that supplies stored first will be used first.
- h) Transmissible spongiform encephalopathies (TSEs)
- 1) Records shall be maintained for at least 20 years regarding quarantine, disposal, decontamination, and sterilization of surgical instruments used for patients with a confirmed or suspected TSE.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 2) For the purposes of this Section, TSEs are a group of rapidly progressive, invariably fatal neurodegenerative diseases that affect both humans and animals. TSEs in humans include Creutzfeldt-Jakob disease (CJD), kuru, Gerstmann-Straussler-Scheinker syndrome (GSS), fatal familial insomnia (FFI), and variant CJD (vCJD).

(Source: Amended at 34 Ill. Reg. _____, effective _____)

SUBPART J: SURGICAL AND RECOVERY ROOM SERVICES

Section 250.1300 Operating Room

- a) The surgical area shall be a controlled traffic area. A control point shall be established to monitor the flow of patients, personnel, and materials.
- b) The surgical area is composed of restricted, semi-restricted, monitored unrestricted, and transition areas.
 - 1) Restricted area: Traffic shall be restricted to authorized personnel and patients. No street clothing shall be worn in the restricted area. Health care workers shall wear hospital laundered scrub attire. Head and facial hair shall be contained within protective covering. Cloth head coverings shall be laundered by the hospital. Additional garments shall be completely contained or covered within the scrub attire. Masks shall be worn in restricted areas where open sterile supplies and equipment are present or scrubbed persons are located. Patients shall wear attire appropriate for their surgical procedure and shall wear hair covering.
 - 2) Semi-restricted area: Traffic shall be restricted to authorized personnel and patients. No street clothing shall be worn in the semi-restricted area. Health care workers shall wear hospital laundered scrub attire. Head and facial hair shall be contained within protective covering. Cloth head coverings shall be laundered by the hospital. Additional garments shall be completely contained or covered within the scrub attire. Masks are not required in this area. Patients shall wear attire appropriate for their surgical procedure and shall wear hair covering.
 - 3) Transition area: Traffic shall be permitted to allow movement of personnel from unrestricted to semi-restricted areas or restricted areas.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

Personnel may enter in street clothing and shall exit into the semi-restricted or restricted area in surgical attire.

- 4) Monitored unrestricted area: Permitted traffic includes authorized personnel, patients, and their families. Health care workers in scrub attire may use this area as a transition area for the purpose of patient management and hospital business.
- c) Signage shall clearly define the traffic flow and surgical attire requirements.
- d) Movement of clean and sterile items shall be separated from contaminated or dirty items by space, time, or traffic patterns. The handling of clean and soiled linen shall meet the requirements set forth in Sections 250.1750 and 250.1760.
- e) All jewelry shall be removed prior to the surgical scrub. Jewelry shall not be worn in the operating room.
- f) Additional personal protective equipment shall be worn when exposure to blood or other potentially infectious material is anticipated.
- g) Whenever scrub attire or personal protective equipment is soiled, it shall be removed promptly and placed in an appropriately designated container.
- h) The sterile gown and gloves used when participating in surgical procedures shall be removed and discarded prior to leaving the operating room.
- i) The gloves used when participating in surgical procedures shall be removed and discarded prior to leaving the operating room.
- j) The use of single-use coverall suits shall be determined by hospital policy.
- k) Shoe covers shall be worn when it can reasonably be anticipated that splashes or spills may occur. If shoe covers are worn, they shall be changed whenever they become torn, wet, or soiled. They shall be removed and discarded before leaving the surgical area.
- l) The use of cover gowns for covering the scrub attire when outside of the surgical area shall be determined by hospital policy. Scrub attire worn into the institution from outside shall be changed before entering the semi-restricted or restricted

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

areas. Persons exiting the hospital shall don hospital laundered scrub attire on return to the surgical area.

- a) ~~No street clothing shall be worn in a restricted surgical area.~~
- b) ~~All persons in the operating room during surgery shall:~~
 - 1) ~~Wear clean outer apparel (scrub dress or suit) which shall be limited to use in the surgery suite.~~
 - 2) ~~Wear protective cover so as to cover all possible head and facial hair.~~
 - 3) ~~Wear masks covering the mouth and nose when entering a sterile operating room.~~
 - 4) ~~Wear sterile or disposable garment over scrub dress for each surgical case.~~
 - 5) ~~The sterile or disposable gown worn over the scrub dress or suit shall be removed before leaving the operating room and shall not be reused.~~
 - 6) ~~A clean cover gown shall be worn over the scrub dress or scrub suite when leaving the surgical area.~~
 - 7) ~~Wear conductive shoes and/or conductive shoe covers which have been tested, as satisfactorily conductive immediately prior to the operation, in hospitals where flammable anesthetics are permitted.~~
 - 8) ~~Wear no jewelry.~~
- me) Communicable Disease or Infections
Personnel suffering from communicable diseases ~~infection~~ shall be excluded from the surgical area~~operating rooms~~.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

Section 250.1305 Visitors in Operating Room

- a) No lay visitor shall be given access to the operating rooms during surgery.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- b) Only individuals in the categories authorized herein and individuals authorized in accordance with hospital policy shall be allowed access to the operating rooms during surgery. Individuals authorized herein shall be members of the medical staff, persons covered by Section 250.310(a)(14), persons employed by the hospital and assigned to the operating room, and persons participating in residency or clinical training programs approved by the Department of [Financial and Professional Regulation](#) under the Medical Practice Act of 1987.
- c) Where hospital policy approved by the ~~Governing~~[governing](#) Board permits other persons to be in attendance in the operating room during surgery, the policy shall provide for the screening of such persons to ensure the necessity of their presence, such as documentation that they have appropriate licensure, qualifications or competence and that the person performing the procedure, the patient's attending physician and the chairman of the department of surgery in departmentalized hospitals have agreed to allow such access. [These individuals shall follow the requirements set forth in Section 250.1300.](#)
- d) The presence of a parent or guardian, or other [designated](#) individual selected by a child's parent or guardian, may be allowed in the operating room during the induction of anesthesia on an individual who is 12 years of age or younger [and for a mentally disabled adult](#), at the discretion of the hospital if the hospital has first adopted a policy on the matter, approved by the Governing Board.; [The policy which](#) shall include, but not be limited to, the following conditions:
- 1) Written consent of the parent, guardian or other [designated](#) individual, the anesthesia provider, and the physician performing the surgery;
 - 2) Notation in the patient's medical record of the presence of [the additional personpersons](#) in the operating room during the induction of anesthesia;
 - 3) Application of safeguards against the introduction of infection or other hazards by the parent, guardian or other [designated](#) individual, including orientation, education and training of the person prior to performance of the procedure; this shall include, at a minimum, specifics regarding the procedure and what can be expected, basic infection control practices expected of the person, and instruction that the person must leave the operating room after the induction of anesthesia is completed;
 - 4) [Requirements that the parent, guardian, or other designated individual](#)

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

wear a mask, cover all head and facial hair and don hospital laundered scrub attire or a single-use coverall suit designed to totally cover outside apparel;

- 54) Provision of at least one additional staff person in the operating room assigned to oversee, supervise and assist the parent, guardian or other designated individual for the period of time the parent, guardian or other designated individual is present; and
- 65) If, at any point during the induction of the anesthesia, ~~it is determined by~~ the physician performing the surgery or the attending anesthesia provider determines that the parent, guardian or other designated individual poses a threat to the safe completion of the induction of the anesthesia, he or she may require the parent, guardian or other designated individual to leave the operating room.

(Source: Amended at 34 Ill. Reg. _____, effective _____)

SUBPART O: MATERNITY AND NEONATAL SERVICE

Section 250.1830 General Requirements for All Maternity Departments

- a) The temperature and humidity in the nurseries and in the delivery suite shall be maintained at a level best suited for the protection of mother and baby as determined by the responsible people in the maternity department and as recommended by the American Academy of Pediatrics and ACOG. Chilling of the neonate shall be avoided; the neonate shall be immediately placed in an approved radiant heat source ready to receive the infant and that allows access for resuscitation efforts. Personnel trained to use the equipment to maintain a neutral thermal environment for the neonate shall be available. For general temperature and humidity requirements, see Section 250.2480(d)(1). In general, a temperature between 72 degrees and 76 degrees and relative humidity between 35% and 60% are acceptable.
- b) Linens and Laundry:
- 1) Nursery linens shall be washed separately from other hospital linens.
 - 2) Soiled linens shall be discarded into impervious plastic bags placed in

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

hampers that are easy to clean and disinfect. Chutes from nursery to laundry shall be used only if a system of negative air pressure exists.

- 3) Plastic bags of soiled diapers (reusable or disposable) and other linens shall be sealed and removed from the nursery at least every eight hours.
 - 4) Linens shall be transported to the nursery in an enclosed unit or otherwise protected from contamination.
 - 5) No new unlaundered garments shall be used in the nursery. Linen used in observation and special care nurseries shall be autoclaved.
- c) Sterilizing equipment, as required in Section 250.1090, shall be available. This may be provided in the maternity department or in a central sterilizing unit, provided that flash sterilizing equipment or adequate sterile supplies and instruments are provided in the maternity department.
- d) Accommodations and facilities for mothers
- 1) The hospital shall identify specific rooms and beds, adjacent when possible to other maternity facilities, as maternity rooms and beds. These rooms and beds shall be used exclusively for maternity patients or for combined maternity and gynecological service beds in accordance with Section 250.1820(h).
 - 2) Whenever feasible, adjacent patient rooms and beds may be used as "swing beds" to be made a part of another nursing unit. Adjacent rooms and beds may be used for clean cases. A corridor partition with doors is recommended to provide a separation between the maternity beds and maternity facilities and the nonmaternity rooms. The doors shall be kept closed except when in active use as a passageway.
 - 3) Facilities shall be available for the immediate isolation of all patients in whom an infectious condition or other conditions inimical to the safety of other maternity and neonatal patients are thought to exist.
 - 4) It is preferred that labor rooms be private or two-bed rooms. Labor rooms shall be conveniently located with reference to the delivery rooms and shall have facilities for examination and preparation of patients.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 5) Delivery rooms shall be equipped and staffed to provide emergency resuscitation for infants. Equipment shall include an infant size positive pressure bag with capability of 100% O₂ delivery; bag and mask with attachment for oxygen; laryngoscope with 0- and 1-size blades; endotracheal tubes sizes 10, 12, 14 French or equivalent; oral airways; and an appropriate device to provide a source of continuous suction for aspiration of the pharynx and stomach. An umbilical vessel catheterization tray ~~shall~~ be available. Only personnel qualified and trained to do so ~~shall~~ use this equipment.
 - 6) If only one delivery room is required, one labor room shall be arranged as an emergency delivery room and shall have a minimum clear floor area of 180 square feet.
 - 7) A recovery room is recommended. The patient shall be kept under close observation until her condition is stabilized following delivery. Observations at established time intervals shall be recorded as a part of the patient's chart. A recovery area shall be provided. Emergency equipment and supplies shall be available for use in the recovery area. Continuing education for personnel providing recovery room care shall be provided. Refer to Section 250.1410(g).
- e) Accommodations and facilities for infants
- 1) Primary Care Nurseries:
 - A) A clean nursery or nurseries shall be provided, near the mothers' rooms with adequate lighting and ventilation. There shall be a minimum of 30 square feet of floor area for each bassinet and ~~3~~ feet between bassinets. Equipment shall be provided to prevent direct draft on the infants. Because one nursing staff person is required for every six to eight normal infants, individual nursery rooms ~~shall~~ have a capacity of six to eight or 12 to 16. The normal newborn infant care area in a smaller hospital ~~shall~~ limit room size to eight, so that two or more rooms are available to permit cohorting in the presence of infection.
 - B) Bassinets equipped to provide for the medical examination of the

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

newborn infant and for the storage of necessary supplies and equipment shall be provided in a number to exceed obstetric beds by at least 20% to accommodate multiple births, extended stay, and fluctuating patient loads. Bassinets shall be separated by a minimum of ~~3~~three feet measuring from the edge of one bassinet to the edge of the adjacent one.

- C) A glass observation window shall be provided through which babies may be viewed.
- D) Resuscitation equipment as described for the delivery suite and below, and personnel trained to use it, shall be available in the nursery at all times.
- E) Each primary care nursery shall have immediately on hand equipment necessary to stabilize the sick infant prior to transfer. Such equipment shall consist of:
 - i) A heat source capable of maintaining the core temperature of even the smallest infant at 98 degrees (an incubator, or preferably a radiant heat source);
 - ii) Equipment with the ability to monitor blood sugar frequently (Dextrostix);
 - iii) A resuscitation tray containing at least a laryngoscope, 0- and 1-size blades, endotracheal tubes of various neonatal sizes, infant size positive pressure bag and appropriate sized masks, gavage tubes, and an umbilical vessel catheterization tray; and
 - iv) Equipment for delivery of 100% oxygen concentration, and the ability to measure delivered oxygen in fractional inspired concentrations (FI O₂). The oxygen analyzer shall be calibrated and serviced at least monthly by the hospital's respiratory therapy department or other responsible personnel trained to perform the task.
- F) Consultation and Referral Protocols:

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- i) Each primary care nursery shall have a clearly designated Level II or Level III nursery to which it refers patients and from which it seeks consultation and advice. The telephone number of the Level II or Level III nursery and the name of the nursery director shall be posted in the nursery. A log of communication between the general nursery and the referral nursery shall be maintained by the head nurse of the general nursery.
 - ii) Protocols for management of certain disease states, and for consultation and referral shall be developed by the nursery director in conjunction with the director of the Level II or Level III unit to which referrals are sent.
 - iii) These protocols shall spell out details for local management of disease states and specific transfer criteria. These protocols shall be maintained in the nursery.
- 2) Intermediate and Intensive Care Nurseries shall meet all of the conditions described above except that infant cribs shall be separated by ~~4~~four to ~~6~~six feet of space to allow for ease of movement of additional personnel, and to allow space for additional equipment used in care of infants in these areas. There ~~shall~~should be 80 to 100 square feet of space for each infant cared for in the Level III or Intensive Care area.
 - 3) Facilities shall be available for the immediate isolation of all newborn infants who have or are suspected of having an infectious disease.
 - 4) When an infectious condition is thought to exist, the infant shall be isolated in accordance with policies and procedures established and approved by the hospital and consistent with recommended procedures of ACOG, AAP, and the Control of Communicable Diseases Code.
- f) The personnel requirements and recommendations set forth in Subpart D apply to the operation of the maternity department in addition to the following:
 - 1) Nursing Staff – General Requirements:

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- A) Nursing supervision by a registered professional nurse shall be provided for the entire 24-hour period for each occupied unit of the maternity and neonatal services. This nurse shall have education and experience in maternity and/or neonatal nursing.
 - B) At least one maternity or neonatal nurse trained in maternity and nursery care shall be assigned to the care of mothers and infants at all times. When infants are present in the nursery, at least one person trained to give care to the newborn infants shall be assigned at all times to the nursery with duties restricted to the care of the infants. Infants shall never be left unattended.
 - C) A registered professional nurse shall be in attendance at all deliveries, and must be available to monitor the mother's general condition and that of the fetus during labor and for at least two hours after delivery and longer if complications occur.
 - D) Nursing personnel providing care for obstetric and other patients shall be instructed on a continuing basis in the proper technique to prevent cross-infection. When necessary for the same nurse to care for both maternity and nonmaternity patients in the gynecologic unit, proper technique shall be followed.
 - E) Nursing personnel are permitted to be assigned to the maternity neonatal division only for an entire shift.
 - F) Temporary relief from outside the maternity neonatal division by qualified personnel shall be permitted as necessary according to appropriate infection control policy.
- 2) Nursing Staff – Level I or Primary Care for occupied units. These units shall meet the following requirements in addition to General Care Requirements in Section 250.1830(f)(1).
- A) Labor and Delivery Unit Staffing shall be planned to ensure that the total nursing personnel on each shift is equal to one-half the average number of deliveries per 24 hours. At least half of the personnel on each shift shall be R.N.s, and at no time shall the nursing staff on any shift be fewer than two. The nursing staff of

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

the labor and post delivery recovery area shall not have other responsibilities in the labor/delivery suite except for emergencies.

- B) Postpartum and General Care Newborn Unit:
- i) If these units are organized as separate nursing units, staffing ~~shall~~should be based on a formula of one nursing personnel per six to eight patients and shall ensure one R.N. per unit per shift.
 - ii) If the units are combined as a rooming-in or modified rooming-in unit, the nursing staff shall be planned to provide one nursing personnel per four mother baby units and shall never be staffed at fewer than two nursing personnel per shift. One shall be an R.N.
- C) At least one member of the nursing staff on each shift, who is skilled in cardiopulmonary resuscitation of the newborn, shall be immediately available to the delivery suite and newborn nursery area.
- D) Changes in medical staff regulations, where applicable, shall be provided to permit the perinatal medicine service to fully utilize the services of specially trained paramedical and nursing personnel where these personnel are needed and/or desired.
- 3) Nursing Staff – Level II Intermediate Perinatal Care Requirements. These units shall meet the following requirements in addition to General Care Requirements in Section 250.1830(f)(1).
- A) Labor and delivery shall include at least one registered professional nurse on each shift who must be competent in the use of continuous electronic fetal monitoring techniques.
 - B) Intermediate Care Nursery:
 - i) A staffing ratio of one licensed nursing personnel per three or four infants shall be available.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- ii) Nursing personnel may be shared with the general care nursery as needed.
 - iii) There shall never be fewer than two licensed nursing personnel available in the general and intermediate care nurseries, at least one of whom is an R.N.
- 4) Nursing Staff – Level III Tertiary Perinatal Care. These units shall meet the following requirements in addition to Intermediate Care Requirements in subsection (f)(3).
- A) Staffing patterns on each shift shall be such that a 1:1 ratio between patients who require intensive care during labor and delivery and a registered professional nurse who is competent, by virtue of training and/or experience, in the care of high risk obstetric patients can be maintained as necessary. A ratio of at least one registered professional nurse to 1½ patients shall be maintained at all times.
 - B) Neonatal intensive care nursing on a 1:1 basis shall be available as indicated. A ratio of at least one registered professional nurse to 1½ patients shall be maintained at all times.
- 5) Medical Personnel
- A) Level I or Primary Care:
 - i) One physician ~~shall~~ be Chief of Neonatal Care. He or she ~~shall~~ be a board certified pediatrician. Where this is not possible, a physician with experience and regular practice may be the Chief and responsible for neonatal care, and a source of pediatric and/or neonatology consultation shall be documented.
 - ii) The director of obstetrical service ~~shall~~ be a board certified obstetrician. Where this is not possible, a physician with experience and regular practice may be Chief and responsible for obstetric care, and a source of obstetric consultation shall be documented.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- B) Level II or Intermediate Care:
- i) A board certified pediatrician with special interest and training in neonatal/perinatal medicine or a certified neonatologist ~~shall~~ be Chief of Neonatal Care. A board certified obstetrician ~~shall~~ be Chief of Obstetrical Care. Obstetrical anesthesia ~~shall~~ be directed by a board certified anesthesiologist with experience and competence in obstetrical anesthesia. Hospital staff ~~shall~~ also include a pathologist and an "on call" radiologist 24 hours a day. Specialized medical and surgical consultation shall be readily available.
 - ii) Other staff: Laboratory and X-ray technicians in the hospital shall be readily available at all times. In addition, a respiratory therapist may be part of the staff.
- C) Level III or Intensive Care:
- i) The Chief of Neonatal Pediatrics shall be eligible for certification by the American Board of Pediatrics' subspecialty board of neonatal/perinatal medicine, and is responsible for care in intensive care areas. Only physicians eligible for certification in neonatal/perinatal medicine shall be responsible for care of infants in the Intensive Care area, but other physicians ~~shall~~ be encouraged to participate. The Chief shall be full-time with the hospital service. There shall be sufficient number of qualified or certified neonatologists to assure availability of such care at all times. The chief of obstetric/perinatal service at the Level III facility shall be a board certified obstetrician and preferably certified in fetal/maternal medicine.
 - ii) Pediatric medical and surgical subspecialists shall be available for consultation. An anesthesiologist with special training in maternal fetal and neonatal anesthesia shall be in charge of anesthesia services. A pathologist and radiologist

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

with experience in interpretation of radiographs of neonatal patients shall be members of the hospital staff.

6) Nutritionist Staff:

A) For Level II units, a registered dietitian with professional experience and/or course work that relates to perinatal maternal and newborn dietary management ~~shall~~^{should} be available.

B) For Level III units, a registered dietitian with professional experience and/or course work that relates to perinatal maternal and newborn dietary management shall be available.

g) Practices and procedures for care of mothers and infants:

1) The hospital shall effect all necessary precautionary measures against the admission to the maternity department of actual or suspected infectious patients.

2) Patients with clean obstetric complications (regardless of month of gestation), such as toxemia of pregnancy for observation and treatment, placenta praevia for observation or delivery, ectopic pregnancy, and hypertensive heart disease in a pregnant patient, may be admitted to the maternity department and be under the same rules as any other maternity case. (See Section 250.1820(h)(6)(B).)

3) The physician shall determine whether a prenatal serological test for syphilis has been done on each mother and the results recorded. If no such test has been done before the admission of the patients, the test shall be performed as soon as possible. Specimens may be submitted in appropriate containers to an Illinois Department of Public Health laboratory for testing without charge.

4) No maternity patient under the effect of an analgesic or an anesthetic, in active labor or delivery, shall be left unattended at any time.

5) Fetal maturity shall be established and documented prior to elective inductions and Cesarean sections. The hospital shall establish a written policy and procedure concerning the administration of oxytocic drugs.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- A) Oxytocin ~~shall~~should be used for the contraction stress test only when qualified personnel, determined by the hospital staff and administration, can attend the patient closely. Written policies and procedures shall be available to the team members assuming this responsibility. It is recommended that Oxytocin be administered by controlled infusion.
- B) Oxytocin shall be used for medical induction or stimulation of labor only when qualified personnel, determined by the hospital staff and administration, can attend the patient closely. Written policies and procedures shall be available to the team members assuming this responsibility. It is recommended that the following be included in these policies:
- i) The attending physician ~~shall~~should evaluate the patient for induction or stimulation, especially with regard to indications.
 - ii) The physician or other individuals starting the Oxytocin shall be familiar with its effect and complications and be qualified to identify both maternal and fetal complications.
 - iii) A qualified physician shall be immediately available as is necessary to manage any complication effectively.
 - iv) The intravenous route is the only acceptable mode of administration. It is recommended that an infusion pump, or other device for accurate control of the rate of flow, and a two-bottle system, one of which contains no Oxytocin substance, be used.
 - v) During Oxytocin administration, the fetal heart rate; the resting uterine tone; and the frequency, duration and intensity of contractions shall be monitored electronically and recorded. Maternal blood pressure and pulse shall be monitored and recorded at intervals comparable to the dosage regimen; that is, at 30 to 60 minute intervals, when the dosage is evaluated for maintenance, increase or

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

decrease. Evidence of maternal and fetal surveillance shall be documented.

- 6) Identification of infants:
 - A) While the neonate is still in the delivery room, the nurse in the delivery room shall prepare identical identification bands for both the mother and the neonate. Wrist bands alone may be used; however, it is recommended that both wrist and ankle bands be used on the neonate. The hospital shall not use footprinting and fingerprinting alone as methods of patient identification. The bands shall indicate the mother's admission number, the neonate's gender, the date and time of birth, and any other information required by hospital policy. Delivery room personnel shall review the bands prior to securing them on the mother and the neonate to ensure that the information on the bands is identical. The nurse in the delivery room shall securely fasten the bands on the neonate and the mother without delay as soon as he/she has verified the information on the identification bands. The birth records and identification bands shall be checked again before the neonate leaves the delivery room.
 - B) If the condition of the neonate does not allow the placement of identification bands, the identification bands shall accompany the neonate and shall be attached as soon as possible. Identification bands shall be affixed to the bassinet or incubator until they are placed on the infant and shall not be left unattached and unattended in the nursery.
 - C) When the neonate is taken to the nursery, both the delivery room nurse and the admitting nurse shall check the neonate's identification bands and birth records, verify the gender of the neonate, and sign the neonate's medical record. The admitting nurse shall complete the bassinet card and attach it to the bassinet.
 - D) When the neonate is taken to the mother, the nurse shall examine the mother's and the neonate's identification bands, verify the gender of the neonate and verify that the information on the bands is identical.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- E) The umbilical cord (cords, with multiple births) shall be identified according to hospital policy (e.g., by the use of a different number of clamps) so that umbilical cord blood specimens are correctly labeled. All umbilical cord blood samples shall be labeled correctly with an indication that these are a sample of the neonate's umbilical cord blood and not the blood of the mother.
- F) The hospital shall develop a newborn infant security system. This system shall include instructions to the mother regarding safety precautions designed to avoid abduction when her newborn infant is rooming in. Electronic sensor devices may be included as well.
- 7) Within one hour after delivery, a one-percent silver nitrate solution or ophthalmic ointment or drops containing tetracycline or erythromycin shall be instilled into the eyes of the newborn infant as a preventive against ophthalmia neonatorum. Do not irrigate immediately. This solution may be obtained free of charge from the Department.
- 8) Each infant shall be given complete individual cribside care. The use of a common bath table is prohibited. Scales shall be adequately protected to prevent cross-infection.
- 9) Artificial feedings and formula changes shall not be instituted except by written order of the attending physician.
- 10) Facilities for drug services. See Section 250.2130(a).
- 11) Transport of newborn infants from the delivery room to the nursery shall be done in a safe manner. Adequate support systems (heating, oxygen, suction) ~~shall~~should be incorporated into the transport units for these infants (e.g., to x-ray). Chilling of the newborn and cross-infection shall be avoided. Where travel is excessive and through other areas, special transport incubators may be required. The method of transporting infants from the nursery to the mothers shall be individual, safe and free from cross-infection hazards.
- 12) The stay of the mother and the baby in the hospital after delivery ~~shall~~should be planned to allow the identification of problems and to

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

reinforce instructions in preparation for the infant's care at home. The mother and infant shall be carefully observed for a sufficient period of time and assessed prior to discharge to ensure that their conditions are stable. Healthy infants ~~shall~~should be discharged from the hospital simultaneously with the mother or to other authorized (by the mother) personnel ~~if~~should the mother ~~remains~~remain in the hospital for an extended stay. It is recommended that there be a provision for follow-up for the mothers and babies discharged within 24 hours. This follow-up ~~shall~~should include a face-to-face encounter with a health care provider who will assess the condition of mother and baby and arrange for intervention if problems are identified.

- 13) When a patient's condition permits, an infant may be transferred from an intensive care nursery to the referring nursery or to another nursery that is nearest the home and at which an appropriate level of care may be provided.
 - 14) Circumcisions by a Mohel shall be performed under aseptic conditions. Such circumcisions shall not be performed in the delivery room. A registered nurse or physician shall be in attendance, and attendance by visitors shall be limited.
 - 15) Circumcisions shall not be performed in the delivery room or within the first six hours after birth. A physician may order and perform a circumcision when the infant is over the age of six hours and, in the physician's professional judgment, is healthy and stable.
 - 16) A single parenteral dose of vitamin K-1, water soluble 0.5 mgm, shall be given to the infant soon after birth as a prophylaxis against hemorrhagic disorder in the first days of life.
 - 17) The hospital shall adhere to the practices prescribed in Guidelines for Perinatal Care and Guidelines for Women's Health Care (American College of Obstetricians and Gynecologists) (see Section 250.160).
- h) Medical Records
- 1) Obstetric records:

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- A) Adequate, accurate, and complete medical records shall be maintained for each patient. The medical records shall include findings during the prenatal period, which ~~shall~~^{should} be available in the maternity department prior to the patient's admission and shall include medical and obstetric history, observations and proceedings during labor, delivery and the postpartum period, and laboratory and x-ray findings.
- B) Records shall be maintained in accordance with the minimum observations and laboratory tests outlined in Guidelines for Perinatal Care and Guidelines for Women's Health Care. The physician director of the maternity department shall require all physicians delivering obstetrics care to send copies of the prenatal records to the obstetrical unit at or before 37 weeks of gestation.
- 2) Infant records. Accurate and complete medical records shall be maintained for each infant. The medical records shall include:
- A) History of maternal health and prenatal course.
- B) Description of labor, including drugs administered, method of delivery, complications of labor and delivery, and description of placenta and amniotic fluid.
- C) Time of birth and condition of infant at birth, including the Apgar score at one and five minutes, the age at which respiration became spontaneous and sustained, a description of resuscitation if required, and a description of abnormalities and problems occurring from birth until transfer from the delivery room.
- D) Report of a complete and detailed physical examination within 24 hours following birth; report of a medical examination within 24 hours of discharge and one at least every three days during the hospital stay.
- E) Physical measurements, including length, weight and head circumference at birth, and weight every day; temperature twice daily.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- F) Documentation of infant feeding: intake, content, and amount if by formula.
 - G) Clinical course during hospital stay, including treatment rendered and patient response; clinical note of status at discharge.
- 3) The hospital shall keep a record of births that contains data sufficient to duplicate the birth certificate. The requirement may be met:
- A) by retaining the yellow "hospital copy" of the birth certificate properly bound in chronological order, or
 - B) by retaining this copy with the individual medical record.
- i) Reports
- 1) Each hospital that provides maternity service shall submit a monthly perinatal activities report on forms provided for this purpose by the Department. This report shall be signed by a representative of the department preparing the document and shall be mailed not later than the 15th of the following month.
 - 2) Maternal Death Report
 - A) The hospital shall submit an immediate report of the occurrence of a maternal death to the Department, in accordance with the Department's rules titled Maternal Death Review (77 Ill. Adm. Code 657). Maternal death is the death of any woman dying of any cause whatsoever while pregnant or within one year after termination of the pregnancy, irrespective of the duration of the pregnancy at the time of the termination or the method by which it was terminated. A death shall be reported regardless of whether the death occurred in the maternity division or any other section of the hospital, or whether the patient was delivered in the hospital where death occurred, or elsewhere.
 - B) The filing of this report shall in no way preclude the necessity of filing a death certificate or of including the death on the Maternity Activities Report.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 3) The hospital shall comply with the laws of the State and the regulations of the Department as regards the preparation and filing of birth, stillbirth, and death certificates.
- 4) Epidemic and Communicable Disease Reporting
 - A) The hospital shall develop a protocol for the management and reporting of infections consistent with the Control of Communicable Diseases Code and with Guidelines for Perinatal Care and Guidelines for Women's Health Care and as approved by the Infection Control Committee. These policies shall be known to maternity and nursery personnel.
 - B) The facility shall particularly address those infections specifically related to mothers and infants, including but not limited to methicillin-resistant Staphylococcus Aureus occurring in infants under 61 days of age, ophthalmia neonatorum, and perinatal hepatitis B infection~~diarrhea of the newborn, staphylococcal infections occurring in infants younger than 28 days of age, and ophthalmia neonatorum.~~
- j) Formula
 - 1) If pasteurized, commercially prepared formula is used exclusively and no formula is prepared by the hospital, a formula room and formula room equipment are not required. However, adequate space, equipment and procedures acceptable to the Department for processing, handling and storing of commercially prepared formula shall be provided. Procedures and aseptic techniques shall be established and enforced. Provisions shall be made for the preparation of special formula.
 - 2) All hospitals providing maternity or pediatric services that prepare their own formula shall provide a well-ventilated and well-lighted formula room, which shall be adequately supervised and used exclusively for the preparation of formulas.
 - 3) Equipment shall include hand-washing facilities with hot and cold running water with knee, foot or elbow controlled valves; a double-section sink for

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

washing and rinsing bottles; facilities for storing cleaning equipment, refrigeration facilities; utensils in good condition for preparation of formulas; cupboard and work space and a work table; an autoclave and a supply of individual formula bottles, nipples and protecting caps, adequate to prepare a 24-hour supply of formula and water for each infant. Procedures shall be established by the hospital and enforced.

k) Visiting regulations

- 1) The visiting regulations set forth in Subpart B shall apply to maternity departments, except as modified in this subsection.
- 2) It is recommended that visitors be limited to two per patient at any one time.
- 3) Contact with the infant shall be restricted to the father, or one other adult selected by the mother, except as provided in subsection (k)(4) of this Section or as part of a rooming-in program as provided in Section 250.1850.
- 4) Siblings and grandparents may have contact with the infant only if the hospital has established specific policies and procedures for such a program. The program shall include:
 - A) Approval of the program by the hospital's Infection Control Committee and Governing Board;
 - B) A requirement for written consent of the mother for visitation by specific siblings or grandparents;
 - C) A procedure for hand washing by visitors prior to having contact with the infant; and
 - D) A policy on the location where visitation will occur.
- 5) The presence of the father or individual selected by the mother in the delivery room shall be discretionary with the individual hospital. If the father or the individual selected by the mother of the baby is to be admitted to the delivery room of any hospital, the hospital shall first have

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

adopted a policy statement on the matter that includes the following conditions:

- A) Written consent of both the mother and the attending physician;
 - B) Prior orientation preparation of the father of the baby or the selected individual and mother to this experience; and
 - C) Application of safeguards against the introduction of infection or other hazard by the father of the baby or selected individual.
- ~~6) Smoking shall be prohibited in the delivery rooms, nurseries, corridors and other areas in accordance with hospital policy. (See Section 250.250(g).)~~
- ~~6)7) Visiting hours shall not correspond with periods during which infants are with the mothers or with periods during which mothers are receiving nursing care, nor interfere with the care of patients.~~
- ~~7)8) Visitors shall neither sit nor place their clothing upon the beds.~~
- l) *Every hospital shall demonstrate to the Department that the following have been adopted:*
- 1) *Procedures designed to reduce the likelihood that an infant patient will be abducted from the hospital. The procedures may include, but need not be limited to, architectural plans to control access to infant care areas, video camera observation of infant care areas, and procedures for identifying hospital staff and visitors.*
 - 2) *Procedures designed to aid in identifying allegedly abducted infants who are recovered. The procedures may include, but need not be limited to, footprinting infants by staff who have been trained in that procedure, photographing infants, and obtaining and retaining blood samples for genetic testing. (Section 6.15 of the Act)*

(Source: Amended at 34 Ill. Reg. _____, effective _____)