Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 133. Hospital Licensing
Subchapter A. General Provisions.
New §§133.1 - 133.2
Repeal §§133.1 - 133.2
Subchapter B. Hospital License.
New §§133.21 - 133.26
Repeal §§133.21 - 133.26
Subchapter C. Operational Requirements.
New §§133.41 - 133.48
Repeal §§133.41 - 133.48
Subchapter D. Voluntary Agreements.
New §§133.61 - 133.62
Repeal §§133.61 - 133.62
Subchapter E. Waivers.
New §133.81
Repeal §133.81
Subchapter F. Inspection and Investigation Procedures.
New §§133.101 - 133.102
Repeal §§133.101 - 133.102
Subchapter G. Enforcement.
New §§133.121
Repeal §§133.121 - 133.122
Subchapter H. Fire Prevention and Safety Requirements.
New §§133.141 - 133.143
Repeal §§133.141 - 133.143
Subchapter I. Physical Plant and Construction Requirements.
New §§133.161 - 133.169
Repeal §§133.161 - 133.169

Adoption Preamble

The Executive Commissioner of the Health and Human Services Commission (commission) on behalf of the Department of State Health Services (department) adopts new §§133.1 - 133.2, 133.21 - 133.26, 133.41 - 133.48, 133.61 - 133.62, 133.81, 133.101 - 133.102, 133.121, 133.141 - 133.143, 133.161 - 133.169 and the repeal of §§133.1 - 133.2, 133.21 - 133.26, 133.41 - 133.48, 133.61 - 133.62, 133.81, 133.101 - 133.102, 133.121 - 133.122, 133.141 - 133.143, 133.161 - 133.169, concerning the regulation of hospitals. The new §§133.2, 133.21, 133.23, 133.26, 133.41, 133.42, 133.45, 133.162 – 133.163, 133.166, and 133.169 are adopted with changes to the proposed text as published in the December 15, 2006 issue of the *Texas Register* (31 TexReg 9961). The new §§133.1, 133.22, 133.24 - 133.25, 133.43 – 133.44, 133.46 – 133.48, 133.61 – 133.62, 133.81, 133.101 – 133.102, 133.121, 133.141 – 133.143, 133.161, 133.164 – 133.165, 133.167 – 133.168 and the repeal of §§133.1 - 133.2, 133.21 - 133.26, 133.41 - 133.48, 133.61 - 133.62, 133.81, 133.101 - 133.102, 133.121 - 133.122, 133.141 -

133.143, 133.161 - 133.169 are adopted without changes, and therefore, the sections will not be republished.

BACKGROUND AND PURPOSE

The repeals and new sections are necessary to update, reorganize and clarify the rules and to implement legislation by the 79th Legislature, Regular Session, 2005, specifically, the amendments to Health and Safety Code (HSC), Chapter 161, Subchapter T (Senate Bill (SB) 316) relating to information provided to parents of newborn children; Occupations Code, §164.052 (SB 419) relating to parental consent for abortion; Occupations Code, §162.052 (SB 872) relating to certain disclosure requirements regarding niche hospitals; HSC, §161.0052 (SB 1330) relating to the immunization of elderly persons; HSC, Chapter 256 (SB 1525) relating to safe patient handling and movement practices of nurses in hospitals; HSC, Chapter 322 (House Bill (HB) 677) relating to emergency services for sexual assault survivors; Occupations Code, §301.353 (HB 1718) relating to the regulation of certain nursing practices, including circulating duties in an operating room; HSC, §241.023 (HB 2471) relating to the issuance of a single license for multiple hospitals; and HSC, §241.022 (HB 3357) relating to information required on a hospital license application.

Government Code, §2001.039, requires that each state agency review and consider for readoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 133.1 - 133.2, 133.21 - 133.26, 133.41 - 133.48, 133.61 - 133.62, 133.81, 133.101 - 133.102, 133.121, 133.141 - 133.143, and 133.161 - 133.169 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

Proposed new §§133.1 - 133.2, 133.21 - 133.26, 133.41 - 133.48, 133.61 - 133.62, 133.81, 133.101 - 133.102, 133.121, 133.141 - 133.143, and 133.161 - 133.169 provide clarification to the rules, update references to statutes and rules, and change the name of the department and its programs. The new §133.2 adds definitions and deletes definitions not used in the rules and those that were moved to a specific section when the use was confined to that section. The new §133.21 sets out conditions under which multiple hospital locations may be licensed under one license number. New §133.22 and §133.23 include a proposal to collect additional ownership information on hospital license applications. The new §133.41 requires all hospitals to document all approvals or delegations of anesthesia services and include the training, experience, and qualifications of the person who provided the service; to have an emergency department with staff on duty and available to initiate immediate appropriate lifesaving measures; to participate in the local emergency medical service system; to develop, implement and enforce policies relating to survivors of sexual assault, workplace safety, and safe patient handling and movement practices by nurses in hospitals; to require a registered nurse be on duty in each licensed hospital location at all times; to comply with certain requirements for renal dialysis services; and to require direct supervision by a qualified registered nurse circulator of licensed vocational nurses and surgical technologists assisting in circulatory duties in the operating room. The new §133.45 requires hospitals to develop, implement and enforce policies (1) to implement an all-hazard

disaster preparedness plan; (2) to ensure that parents of newborn children receive information concerning postpartum depression and other emotional trauma associated with pregnancy and parenting, including the prevention of shaken baby syndrome, immunizations, and newborn screening; (3) to ensure compliance with statutory provisions relating to abortion and informed consent and parental consent for abortion; and (4) to provide influenza and pneumococcal vaccines for elderly persons. The repeal of §133.62 deletes procedural language for submission and approval of cooperative agreements deemed unnecessary because it is duplicative of statutory language. New §133.62 indicates current information regarding cooperative agreements.

New §§133.141 - 133.143 and 133.161 - 133.165 change the requirement for compliance with the National Fire Protection Association's (NFPA) Life Safety Code (LSC) from the 2000 edition to the 2003 edition, and provide new edition dates and section numbers for NFPA and other standards referenced in the sections. New §133.143 establishes conditions for the use of alcohol-based products when used for surgical skin preparation; new §133.162 clarifies prohibitions relating to hospital construction in designated 100-year flood plains, and requires a hospital to consider the provisions of HSC Chapter 256 relating to safe patient handling and movement practices; new §133.163 clarifies spatial requirements for patient multiple-bed rooms, establishes signage specifications for the emergency entrance to a hospital, and sets out standards for a decontamination room, intermediate care suite, and universal care suite when hospitals provide the services; new §133.165 clarifies that all spaces in a hospital must be contiguous when the building is shared with other hospitals or non-hospital occupancies, and clarifies the services and facilities that must be provided directly by the hospital and those that may be shared; and new §133.166 clarifies requirements for mobile, relocatable and transportable units when the units are permanently attached to a hospital. New §133.169 updates existing tables and provides two new tables for clarity of requirements relating to the nurses calling systems and multiple-bed room configurations.

The department, on behalf of the commission, has reviewed and prepared a response to the comments received regarding the proposed rules during the comment period, which the commission has reviewed and accepts. The commenters were individuals, associations, and/or groups, including the following: Baylor Medical Center at Trophy Club, Baylor Specialty Health Centers, Children's Memorial Hermann Hospital, CHRISTUS Health Care, CHRISTUS Santa Rosa Health Care, Coalition for Nurses in Advanced Practice, Cook Children's Health Care System, El Paso County Hospital District (R. E. Thomason General Hospital), Greater Houston Anesthesiology, P.A., HillCo Partners, Mary Shiels Hospital, Medical Multiplex, Inc., National Surgical Hospitals, North Hills Hospital, PageSoutherlandPage Architects, Seton Family of Hospitals, Smith Seckman Reid, Inc., Sterling Barnett Little, Inc., Sugar Land Surgical Hospital, Sweeny Hospital, Texas Association of Nurse Anesthetists, Inc., Texas Commission on Environmental Quality, Texas Hospital Association (THA), Texas Nurses Association, Texas Organization of Rural and Community Hospitals (TORCH), Texas Society of Anesthesiologists, Texas Society of Health-System Pharmacists, Texas State Board of Pharmacy, The Methodist Hospital System, The Physicians Centre, Travis County Healthcare District, University Health System. The commenters were not against the rules in their entirety; however, the commenters suggested recommendations for changes as discussed in the summary of comments.

Comment: Concerning §133.2(3), a commenter supports the rules, but recommended modifying the definition of "advanced practice nurse (APN)" to include advanced practice nurses who are not licensed in Texas but hold a license in another state party to the Nurse Licensure Compact. This would bring the definition of "advanced practice nurse (APN)" into conformity with the definition of "registered nurse (RN)" proposed in these rules. The commenter suggested removing the portion of the definition that refers to the educational grounds upon which the Board of Nurse Examiners for the State of Texas (BNE) authorizes APNs, as that seems unnecessary for this definition. The commenter also suggested changing the word "approved" to "authorized" to describe the action taken by the BNE, and changing the word "and" to "or" in the list of the types of nurses.

Response: The commission agrees with the commenter and has made the recommended changes.

Comment: Concerning §133.2(40), a commenter recommended that, in this section, the word "inpatient" be changed to the word "patient". The definition of "premises" relates only to inpatient facilities. Hospitals serve many outpatients in various capacities, but many older, smaller facilities have been unable to build outpatient facilities such as outpatient therapy facilities, certain types of imaging, and other outpatient treatment areas within the hospital inpatient building. The definition is too restrictive.

Response: The commission disagrees with the commenter. The rule at §133.21(c)(2) states that a hospital license shall not include off-site outpatient facilities. A hospital may provide outpatient services that are not included in the hospital license. The definition of premises is statutory language describing that the department may issue a license only for the premises of a hospital and person or governmental unit named in the application, and the department may issue one license for multiple hospitals if all the requirements in the definition are met. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.21(c)(2), a commenter requested that "off-site" be changed to "off-premises". This is similar in substance to the comment on "premises". "Off-site" has never been defined, but it is presumed by surveyors to mean "off-premises." Because small hospitals may not have enough space in the hospital, an outpatient facility, such as an outpatient therapy center, may be, by necessity, located across the street. Several member hospitals have been required by surveyors to relocate outpatient services (particularly outpatient physical therapy services) into the inpatient hospital, at great expense.

Response: The commission disagrees with the commenter. A hospital may provide outpatient services that are not included in the hospital license. The rules at §133.163(v) describe the architectural requirements for an outpatient suite. Outpatient services that the hospital provides to patients under the hospital license shall be within the hospital. If the outpatient suite is located in an office building or other building, that portion shall be physically connected to the hospital and become contiguous to the hospital. In no case may one leave the hospital, traverse the other occupancies, and then reenter the hospital to access the remaining portion of the hospital. To insure these rules are enforced correctly, all staff were notified on 06/01/06 that the patient quality care unit manager must be contacted to participate in the enforcement, if a hospital is

required to relocate a department. The department, THA and TORCH have jointly developed instructions on outpatient facilities. When finalized these instructions will be distributed to all licensed hospitals. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.21(c)(5), two commenters requested deletion as some hospitals currently have a free standing ambulatory surgical center (ASC) on their campus; other hospitals are considering such an arrangement. From a patient safety standpoint, placement of a hospital's ASC on the hospital's campus or premises ensures a more rapid and safer transfer of an ASC patient who may develop complications and require hospitalization. In addition, prohibiting placement of a hospital and its freestanding ASC on the same premises or campus likely will limit a hospital's ability to compete with other ASC owners in the hospital's service area.

Response: The commission disagrees with the commenters that the rule should be deleted. "Premises" is defined in the rules. The rule does not prohibit a licensed ASC being placed on a hospital's campus. The rule does prohibit any part of the campus being dually licensed as a hospital and as an ambulatory surgical center. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.26(f), a commenter recommended that the amount of the subscription and convenience fees be clarified and that a statement be added that the fee is in addition to the license fee at each renewal application. It is unclear as to how much these fees will add to the amounts paid and whether hospitals will be required to use TexasOnline.

Response: The commission agrees with the commenter and has added that at each renewal application, in addition to the license fee, there shall be a $20 TexasOnline subscription fee. The use of TexasOnline is optional, and hospitals are not required to use it.

Comment: Concerning §133.41(a)(1), a commenter recommended the deletion of the word "qualified" as it is unclear from the context whether "qualified' is defined by the text that follows, "who have been approved by the facility to provide anesthesia services" or may be defined elsewhere in the Texas Administrative Code.

Response: The commission agrees with the commenter and has deleted the word "qualified".

Comment: Concerning §133.41(a), a commenter supported the proposed anesthesia changes, especially the deletion of the wording in the current §133.41(a)(1)(D). The commenter commended the recognition that it is the department's responsibility to regulate hospitals and the responsibility of the respective licensing boards to regulate the health care professionals working in hospitals. The commenter recommended adding "licensed" to describe personnel in §133.41(a)(1), as it is not clear if every anesthesia provider is to be authorized by law.

Response: The commission disagrees with the commenter. The Texas Medical Board regulates medical practice. The Medical Practice Act does give physicians the authority to delegate certain medical acts. This includes delegation of the administration of anesthesia to anesthesiologist assistants. Anesthesiologist assistants are not licensed in the state of Texas. This addition would regulate medical practice by limiting the ability of a physician to

appropriately delegate the administration of anesthesia. The commission does regulate licensed hospitals, but does not regulate medical practice. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(a)(2)(C), a commenter stated that requiring an evaluation of patient color is ambiguous. It is not clear if the evaluation is to measure perfusion or oxygen saturation, or to record the racial color of the patient.

Response: The commission agrees with the commenter and has changed "patient color" to "patient's oxygen saturation level".

Comment: Concerning §133.41(c)(5)(C), (e)(1)(A), (n)(2), and (u)(3), a commenter recommended clarifying that the director is a medical director or clinical director who is a physician. Since physicians are normally not employed by the hospital, a hospital staff member has usually been designated as the administrative director. Because this wording indicates that only a physician may be designated as a director, the surveyors have required that the hospital staff be re-designated with another title.

Response: The commission agrees with the commenter and has clarified that the director shall be a medical director or a clinical director who is a physician.

Comment: Concerning §133.41(d)(2)(E)(vi), a commenter questioned the necessity of maintaining a four-day, rather than a three-day, supply of food.

Response: At §133.163(e)(1)(B)(iii), the current and proposed rules require the facility to provide storage of food for emergency use for a minimum of four calendar days. The requirement to ensure there is a four-day food supply on hand at all times, was added to the proposed rules at §133.41(d)(2)(E)(vi) for clarity. During one of the stakeholder meetings, the number of days was discussed. However, this meeting was held after hurricane Rita. Based on the lessons learned during the hurricane, it was decided to maintain the requirement of a four-day supply of food. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(e), a commenter supported the requirement that all hospital locations have an emergency suite.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(e)(2)(C)(i), a commenter stated that per this legislation, all have to have at least one full time board certified emergency room physician 24/7. So, some hospitals may have emergency room doctors who are not board certified, and they are going to be looking for a physician on each shift to meet this requirement. They estimated that the cost to their hospital would be $1,000,000.

Response: The commission disagrees with the commenter. The proposed rule does not require all hospitals to have at least one full time board certified emergency room physician on duty in

the emergency treatment area at all times. The proposed rule does require general hospitals, except for comprehensive medical rehabilitation hospitals and pediatric and adolescent hospitals that generally provide care that is not administered for or in expectation of compensation, located in counties with a population of 100,000 or more to have a physician qualified to provide emergency medical care on duty in the emergency treatment area at all times. The governing body is responsible for the appointment of the medical staff and to determine, in accordance with state law and with the advice of the medical staff, which categories of practitioners are eligible candidates for appointment to the medical staff. The medical staff bylaws must describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(e)(2)(C)(i), three commenters recommended all general hospitals in Texas be required to have a licensed health care provider trained in emergency medical care on duty in the facility at all times. A licensed health care provider, in this case, includes an emergency nurse practitioner (ENP). ENPs are already used throughout the state to provide emergency and urgent health care services to individuals of all ages. These advanced practice nurses' training focuses on the management of acute illnesses, trauma, and/or chronic unstable illnesses requiring immediate attention, stabilizing the individual's condition, and determining appropriate referral and follow-up care. ENPs in Texas currently provide care in ambulatory, urgent care, and emergency department settings. No general hospitals in Texas should be excluded. All citizens of Texas deserve access to facilities that provide this level of emergency services. Emergency care should not be confused with trauma care staffing.

Response: The commission disagrees with the commenters. The rules at §133.41(e)(2)(A) require that there shall be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the hospital. Except for comprehensive medical rehabilitation hospitals and pediatric and adolescent hospitals that generally provide care that is not administered for or in expectation of compensation, there shall be on duty and available at all times at least one person qualified as determined by the medical staff to initiate immediate appropriate lifesaving measures. The commission acknowledges the value of mid-level practitioners, including physician assistants (PAs) and advanced practice nurses (APNs), for patients with a variety of medical problems, and appreciates that non-physician providers can enhance the ability of both rural and urban health care facilities to provide a broader range of patient care services to their population base. The physical presence of PAs and APNs in general hospitals in Texas counties with a population greater than 100,000 does not meet the essential criterion that requires the physical presence of on-duty physicians to care for patients with critical medical or surgical conditions. General hospitals in counties with a population greater than 100,000 that elect to utilize PAs and APNs in their facilities must ensure that the scope of practice of these mid-level practitioners is clearly delineated and consistent with state regulations. This delineation should include the types of patients with critical medical or surgical conditions that require referral to the on-duty physician qualified to provide emergency medical care. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(e)(2)(C)(i) and (ii), two commenters recommended exempting hospitals designated as critical access hospitals (CAHs) by the Centers for Medicare & Medicaid

Services (CMS) from the requirement to have a physician qualified to provide emergency medical care on duty in the emergency treatment area at all times. This requirement would be cost prohibitive for a very limited number of cases. The commenters recommended requiring CAHs to be required to have a physician on-call and able to respond in person, or by radio or telephone within 30 minutes.

Response: The commission agrees with the commenters and has made the recommended changes.

Comment: Concerning §133.41(e)(2)(C)(i) and (ii), a commenter urged the withdrawal of the proposed rule and study of the issue in greater detail before placing the additional requirement on all hospitals in the state because the proposed rule is arbitrary and capricious in that it does not provide a tangible benefit; the proposed rule will raise the costs of providing emergency care services statewide and unnecessarily wastes hospital resources; and the proposed rule exceeds the rulemaking authority granted under HSC §214.026.

Response: The commission disagrees with the commenter. The current rule at §133.41(e)(1)(B)(iii) requires the hospital to provide that one or more physicians shall be available at all times for emergencies. The proposed rule clarifies that in larger counties, the available physician must be an on-duty physician. The proposed rule is not arbitrary or capricious because it will provide a tangible benefit to the people of Texas by requiring immediate access to a physician in emergency rooms located in larger counties, further serving and protecting the health needs of Texans. The new rule clearly is within the scope of statutory authority. HSC §241.026 requires adoption and enforcement of rules to further the purpose of this chapter. HSC §241.002 states the purpose of this chapter is to protect and promote the public health and welfare by providing for the development, establishment, and enforcement of certain standards in the construction, maintenance, and operation of hospitals. HSC §241.026 requires the rules at a minimum to address minimum requirements for staffing by physicians and nurses. The new rule was proposed by a large group of stakeholders who also considered the Medicare conditions of participation (CoPs) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards when proposing the rule. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(e)(5), a commenter agreed with the requirement that all emergency departments participate in their local emergency medical service (EMS) system.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(e)(6), a commenter supported the requirement that all emergency departments ensure the provision of emergency services for survivors of sexual assault.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(e)(6)(A)(ii), a commenter recommended that the term "community-wide" be amended to read "community-wide or regional" plan. "Community-wide" is not defined, and many small and rural hospitals are the only health care provider in the community, as that term is commonly used. The requirements of this section are beyond the capability of many small hospitals.

Response: The commission agrees with the commenter that the definition of "community-wide plan" is not in the proposed rules, has added the statutory definition from Health and Safety Code, Chapter 322, to the definitions in the rules, and renumbered the definitions.

Comment: Concerning §133.41(f)(4)(C)(i)(II), a commenter agreed that physicians should have the ability to require hospitals to participate in mediation.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(f)(4)(C)(i)(IV), a commenter appreciated the inclusion of the provision that allows hospital to require the provision of documentation of current clinical competency and professional training and experience.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(j)(1), a commenter recommended that the term "employ" be revised to read "employ or contract with" adequate personnel. Many medical records functions are often provided by independent contractors.

Response: The commission agrees with the commenter and has made the recommended change.

Comment: Concerning §133.41(j)(6), a commenter requested a definition of "as soon as possible".

Response: The commission has added, "As soon as possible would be the next time the prescriber or another practitioner who is responsible for the care of the patient and has been credentialed by the medical staff and granted privileges which are consistent with the written orders provides care to the patient, assesses the patient, or documents information in the patient's medical record."

Comment: Concerning §133.41(j)(7), two commenters requested that the proposed rule be revised to comply with the Medicare CoPs effective January 26, 2007.

Response: The commission agrees with the commenters and has deleted the phrase "promptly as specified by hospital policy" and has added "within 48 hours". This was the language in the 03/02/06 proposed rules that the council recommended the Executive Commissioner's approval for publication in the Texas Register. As new issues arose, those rules were not published. During the review of that set of rules, stakeholders recommended the language be changed from

"within 48 hours" to "promptly as specified by hospital policy" as there was no similar requirement in the CoPs at the time of the review. The Texas Hospital Licensing Law requires the consideration of the CoPs and the attempt to achieve consistency with those conditions. Most hospitals are Medicare certified and will be required to comply with the revised Medicare rule as there is no state law that designates a specific timeframe. Since the goal is to be as consistent as possible with the CoPs, this change has been made.

Comment: Concerning §133.41(j)(8)(C), two commenters agreed with the proposed language changing the history and physical exam requirement to be consistent with the JCAHO standards and the CMS regulations.

Response: The commission agrees with the commenters. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(k)(3)(F), a commenter stated that the change from seven days prior to admission to 30 days prior to admission will eliminate the conflict between state and federal regulations.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.41(n)(5)(B), a commenter requested clarification of this provision. It could be read as requiring retention of records for an indefinite period.

Response: The commission agrees with the commenter and has added "in accordance with §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material" for clarity. This is typically done when the facility requests termination of their radioactive material license.

Comment: Concerning §133.41(o)(2)(D), three commenters recommended revision as the term "location" is not defined, and it is unclear how this provision will be interpreted and applied by the department. Two of these commenters recommended a lesser requirement for CAHs. One of these commenters recommended CAHs have the same nurse staffing requirements as required by CMS under the CAH designation.

Response: The commission agrees with the commenters that the term "location" is not defined, and has added the phrase "building of a licensed hospital that contains at least one nursing unit where patients are present", and deleted the phrase "licensed hospital location at all times". The commission disagrees with the commenters that there should be a lesser requirement for CAHs as the rule has been clarified. The commission disagrees with the commenter that CAHs should have the same nurse staffing requirements as required by CMS under the CAH designation. The federal rules allow a registered nurse, clinical nurse specialist, or licensed practical nurse be on duty whenever the CAH has one or more inpatients. Changing the requirement from a registered nurse to a licensed practical nurse would be a substantive change and would require public notice and comment.

Comment: Concerning §133.41(o)(2)(H)(i), a commenter requested the rule be amended to increase the minimum number of direct care nurses on the hospital nurse staffing advisory committee from one-third to one-half to enhance the effectiveness of the committee.

Response: The commission agrees with the commenter and has made the requested change.

Comment: Concerning §133.41(o)(3(B)(ii)), two commenters requested that the proposed rule be revised to comply with the Medicare Conditions of Participation (CoPs) effective January 26, 2007, and to be consistent with the language in §133.41(j)(7).

Response: The commission agrees with the commenters and has deleted the phrase "promptly as specified by hospital policy" and has added "within 48 hours".

Comment: Concerning §133.41(o)(4)(D), a commenter supports the rules, but suggested moving the reference to prescribing to §133.41(o)(4)(A) as it would be more logical. The commenter also suggested changing the phrase "administered under medical direction" to "in accordance with hospital policy", as "administered under medical direction" is not defined, and seems inappropriate since the phrase usually indicates that a physician must be present.

Response: The commission agrees with the commenter and has made the recommended changes.

Comment: Concerning §133.41(w)(1)(C), a commenter recommended that direct supervision be defined to mean that an RN is available to assist licensed vocational nurses (LVNs) and surgical technologists with duties. If direct means one-to-one supervision, it appears to duplicate efforts of the circulator.

Response: During one of the stakeholder meetings for these rule revisions, THA requested that the statutory language be used in this rules, as this was a highly negotiated law and the rules should not expand the language cited in the statute. THA's comments and the department response have been on the department web site since 07/26/06. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.42(b), a commenter was not clear whether these additional provisions apply to all hospital patients admitted for any service if the hospital also has comprehensive medical rehabilitation services available or only inpatients admitted for medical rehabilitation services.

Response: The commission agrees with the commenter that the rule was not clear, and has added "applicable to patients who receive such services" to §133.42(b), (c) and (d) to clarify what is required of hospitals.

Comment: Concerning §133.44(b)(1), a commenter stated that the requirement to identify staff that has authority to represent that hospital and the physician is much needed.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.44(b)(2), a commenter stated that the inclusion of state mental hospitals in transfer agreements is long overdue.

Response: The commission agrees with the commenter. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(3), a commenter recommended that the regulation designate the local public health authority rather than the local disaster management authority.

Response: The commission disagrees with the commenter. Local disaster management authority is not defined. The local disaster management authority may be public health, if that is who the community commonly understands to be in control. Generally it is the City Emergency Management Office. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(A), a commenter objected to the all-hazard disaster plan being sent to the board of managers or the governing body.

Response: The commission disagrees with the commenter. The rule requiring developing the plan through a joint effort of the hospital governing body, administration, medical staff, and hospital personnel has been in effect since 08/13/98. The proposed rule adds the participation of the emergency medical services partners. The level of participation is not defined and is left to the members of the group to decide. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(C), a commenter recommended that hospitals be required to consider the availability of sources of potable water and/or water to flush toilets under emergency conditions. The commenter recommended, at the very least, that the hospital's emergency plan include emergency contact information for their water supplier.

Response: The commission agrees with the commenter and has added "and the hospital water supplier" to §133.45(c)(4)(C). The provision of an emergency water supply is required by §133.162(d)(4)(A)(i)(VIII).

Comment: Concerning §133.45(c)(4)(D), a commenter objected to a rule requiring the after action report be available for review by the local emergency management authority and the Department of State Health Services (DSHS). The responsibility for a hospital's after action reports rests with the hospital authorities within the institution. Reports are provided for review during state level inspections and during accreditation visits. A more appropriate way to phrase this is to have hospitals participate in local exercises and the follow-up after-action review on a community wide basis.

Response: The commission disagrees with the commenter. The plan is required to be developed through a joint effort of the hospital governing body, administration, medical staff, hospital personnel and emergency medical services partners. All members of the group need to participate in testing the all-hazard plan, identifying deficiencies, and taking corrective actions to continuously improve the effectiveness of the plan. The commenter stated that reports are provided for review during state level inspections. These inspections are conducted by DSHS staff. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(F), a commenter objected to this being a licensing rule. This should be a recommendation, not a requirement. Hospitals have back up generators that are tested regularly and this is reviewed by the JCAHO. The facility tests radios monthly; however, the decision on how the hospital communicates with the local utility company is better left to the hospital.

Response: The commission disagrees with the commenter. During a disaster, there may be a limited supply of fuel available for generators. During hurricane Rita, it was identified that hospitals need to have a plan for and to be given priority for the restoration of utility and phone services. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(G)(ii), a commenter recommended replacing the comma with “and” to clarify that there are two reporting categories rather than three.

Response: The commission agrees with the commenter and has replaced the comma with “and”, deleted “and” and added “that are”.

Comment: Concerning §133.45(c)(4)(H)(i)(I), a commenter objected to this being a licensing requirement. This is better handled locally. Employees have identification (ID) badges they can show the police and access should be granted without further action. A statement to that effect is on the back of the employee ID.

Response: The commission agrees with the commenter that this meets the intent of the rule, but disagrees with the commenter that this should not be a licensing requirement. During hurricane Rita, hospital staff had problems accessing their delivery care sites even with ID badges. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(H)(i)(II), a commenter objected to this being a licensing requirement. Hospitals already have personal protection equipment and the staff uses it daily. The decision should be a local one based upon the situation. The immunization of staff already occurs but staff can refuse to be vaccinated. Volunteers and families should see their personal physician or public health to receive vaccinations.

Response: The commission agrees with the commenter that this meets the intent of the rule, but disagrees with the commenter that this should not be a licensing requirement. During hurricane Rita, it was identified that hospitals need to include these requirements in the all-hazard disaster preparedness plan. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(H)(i)(II), two commenters recommended the rule be revised to give hospitals the discretion to determine which staff, volunteers or others are provided equipment or are immunized. In the development of the disaster plan a hospital must consider its needs, priorities and potential resources that are available in these situations and must have the flexibility to make decisions on resource allocation.

Response: The commission agrees with the commenters and has added "appropriate" to describe the provision of personal protection equipment.

Comment: Concerning §133.45(c)(4)(H)(i)(III), a commenter objected to this being a licensing requirement. It should be a recommendation. Not every hospital has a preparation area, not every hospital has staff to prepare food (contract pre-made meals for example) and some hospitals may have very limited storage capability.

Response: The commission disagrees with the commenter. During hurricane Rita, it was identified that a critical component of the all-hazard disaster preparedness plan must be a plan to provide food and shelter for staff and volunteers as needed throughout the duration of the response. Such an approach will aid the hospital in developing a scalable response capability, and in defining the timing and criteria for decisions involving sheltering in place, patient transfer, facility closing, or evacuation. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(H)(ii)(II), a commenter objected to this being a licensing requirement. "Evacuation" evokes the image of a disaster situation and in such a matter, the situation will dictate processes outside the control of the hospital. Patients are transferred on a daily basis and procedures are set up. However, in a disaster situation it may not be possible to know where the patients are going, what means of conveyance will be available or what the capabilities of the receiving facility may be.

Response: The commission disagrees with the commenter. The rule recognizes that this part of the evacuation component of the all-hazard disaster preparedness plan is when within control of the hospital. Planning must address managing and maintaining the hospital, but also must consider evacuation of the entire facility when the environment is no longer deemed safe. To transport patients safely during an emergency, the planning process must consider advance communication with the alternate care site or sites. The plan should also recognize that a contingency plan may be necessary in a disaster. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(H)(ii)(III), a commenter objected to this being a licensing requirement. It should be a recommendation. In a disaster situation, the phones could be down and the patients may need to be evacuated immediately. There would not be time for someone to go through the medical records and call each patient's family. And the destination may not be known.

Response: The commission disagrees with the commenter. The rule does not include a time frame or the method of notification of patient emergency contacts of an evacuation and the

patient's destination. During hurricane Rita, it was identified that a plan is needed to accomplish this notification. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.45(c)(4)(H)(ii)(IV), a commenter objected to this being a licensure requirement. It should be a recommendation. It is understood that these records should go with the patient. Wrist bands are shower proof already. In a disaster it may not be feasible to send all this information. Copy machines and computers may be down. A one page hand written summary of care may be all that time permits.

Response: The commission disagrees with the commenter. During hurricane Rita, it was identified that, when the environment cannot support adequate care, treatment, and services, to transport patients safely during an emergency, the evacuation component of the all-hazard disaster preparedness plan must include these items.

Comment: Concerning §133.161(a)(1)(B), a commenter recommended that it be clarified that existing hospitals are allowed to continue to meet requirements in effect at the time of construction. The proposed wording seems to require older existing facilities to comply with the 2003 edition of the NFPA 101, Chapter 19. This requirement could be cost prohibitive to bring a pre-1967 building up to the 2003 NFPA Code, causing hospitals to close.

Response: The commission disagrees with the commenter. CMS requires existing hospitals to comply with NFPA 101, LSC, Chapter 19 (Existing Health Care Occupancies), 2000 edition. The proposed rules adopt NFPA 101, Chapter 19, 2003 edition. The proposed rules clearly state that existing hospitals must comply with life safety code requirements that were in affect at the time the hospital was constructed. However, NFPA 101, Chapter 19, 2003 edition does incorporate code requirements from previous years' editions of the NFPA 101, which basically enables existing facilities to comply with all life safety code requirements. This requirement will not be cost prohibitive causing hospitals to close. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.162, a commenter recommended that, before the new construction requirements are adopted in final form, a cost analysis should be performed, and greater flexibility should be incorporated into the requirements. It was the general opinion of members that the new construction requirements, in general that increased spatial requirements, particularly in the emergency suite and the obstetrical suite, could increase space needed by 20–30%. In addition, in the rehabilitation therapy suite, there are requirements for separate offices for physical and occupational therapists, which in small hospitals are usually shared work areas. There are other instances of designating spaces for "exclusive use" which in small hospitals may not warrant exclusive use areas due to the low volume of patients or staffing needs. Members believe that the sharing of space for a variety of purposes should be allowed, as long as the effective, efficient, and safe delivery of care can be demonstrated by the hospital. It appears to members that the new construction requirements may be unnecessary, unduly burdensome and may prevent small hospitals from being able to undergo new construction due to rigid increased space specifications.

Response: The commission disagrees with the commenter. The proposed rules track and follow closely, the spatial requirements of the American Institute of Architects Academy of Architecture for Health, Guidelines for Design and Construction of Health Care Facilities, 2006 edition (AIA Guidelines). The workgroup's focus was to assure minimal requirements and to follow national standards and trends for healthcare facilities. Spatial increases were included in the proposed rules in order to accommodate the use of more healthcare equipment during the delivery of care and services to patients and to ensure an adequate work environment. Throughout the rules, "when" language is utilized to address situations that result in a hospital providing a certain type of service that is beyond the requirements of a minimal hospital. When a hospital elects to provide a specific type of service, then the requirements for that particular service is defined in the rules. The rules do not prohibit individuals such as a physical therapist and an occupational therapist from sharing the same office space. If one individual "wears many hats", then one office is probably appropriate. One major difference between the licensing rules and the AIA Guidelines is that the AIA Guidelines will require all future constructed patient sleeping rooms to be private. The reason the healthcare industry is enlarging the private room and making it suitable for only single occupancy is for infection control purposes and to meet handicap requirements. The proposed rules still allow for the construction of semiprivate rooms in new hospitals. The "exclusive" language in the proposed rules is used primarily for infection control purposes and closely mirrors national standards such as the AIA Guidelines. There would be no benefit gained by conducting a cost analysis because every hospital in Texas is unique in its size, scope, and location. The square foot costs continue to increase each year in hospitals. There are no two hospitals alike, and each year the size and spatial environment for new construction has increased in order to meet market demands. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.162(d)(4)(A)(i)(VIII), two commenters generally support the need for hospitals to have an appropriate emergency water supply, however, the prohibition on the use of bottled water is unnecessary and will limit hospitals' ability to address their water needs in emergency situations. The commenters requested deletion of the sentence that disallows the use of bottled water.

Response: The commission agrees with the commenters and is therefore modifying the language at §133.162(d)(4)(A)(i)(VIII). The department's primary concern is that a hospital has an adequate water supply to meet the needs of patients during an emergency situation. Each hospital is required to provide not less than 500 gallons or 12 gallons of water per licensed patient bed. For example, a hospital with 100 patient beds is required to have 1,200 gallons of water on site at all times for emergency purposes. The hospital must ensure that it maintains an adequate supply of bottled water at all times, maintains an inventory record which reflects the rotation and replacement of expired bottled water, and have adequate storage space on site that is readily accessible by staff in the event of an emergency. The hospital must ensure the continued availability and delivery of bottled water until the emergency situation has concluded.

Comment: Concerning §133.162(d)(4)(A)(iii)(IV), two commenters requested deletion of the qualifications of the personnel who will conduct the verification tests and inspections until the impact of this requirement can be assessed. This proposed requirement was not included in prior drafts of the rules, and the commenters are concerned that this personnel standard may not be

attainable by hospitals, particularly those hospitals located in rural areas of the state. The personnel required by this proposed rule to verify proper installation of these systems may not be available to rural and small community hospitals in their community or surrounding area. Bringing such personnel to hospitals in rural areas may be cost prohibitive, and may create an unfair financial burden on hospitals in those rural areas where such experts are not available.

Response: The commission disagrees with the commenters. In the 03/02/06 proposed rules that the council recommended the Executive Commissioner's approval for publication in the Texas Register, the NFPA 99 reference was updated from §4-3 to §5.1 in §133.162(d)(4)(A)(iii). NFPA 99, Chapter 5, 2002 edition, requires professional qualifications for medical gas verifiers to meet American Society of Safety Engineers (ASSE) Personnel Standard 6030, Professional Qualifications Standard for Medical Gas Systems. It was critical for this language to be incorporated in the proposed rules for clarity. A third party qualified to do the testing did all previous gas verification. Verifiers are now required to meet ASSE Personnel Standard 6030 qualification and to carry the certification card. The verification testing is necessary to assure patient safety and that medical gas systems have been tested by a qualified individual. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.163(c)(1)(B)(iii), a commenter asked if it is mandatory to have a locker room in a small facility.

Response: It is not mandatory to have a locker room in the central sterile supply suite. However, if the hospital chooses to provide a locker room in the central sterile supply suite, compliance with this rule is required. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.163(c)(1)(B)(iv), a commenter questioned whether the housekeeping room in the central sterile supply suite should be on the decontamination/soiled side and/or on the sterile supply/clean side, as it was not mentioned in the rules.

Response: The commission agrees with the commenter and has clarified that the housekeeping room shall be located on the decontamination/soiled side of the central sterile supply suite.

Comment: Concerning §133.163(d)(1)(B)(v) and §133.163(d)(1)(D)(ii), a commenter indicated that the distance requirements are in conflict.

Response: The commission disagrees with the commenter. The rule at §133.163(d)(1)(B)(v) applies to open ward environments in adult and pediatric units. The rule at §133.163(d)(1)(D)(ii) applies to a multiple-bassinet/crib (sleeping unit) room/ward. The two specific sleeping unit types constitute the differences in the requirements. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.163(k), a commenter recommended eliminating the proposed language and requiring that hyperbaric facilities conform either to the specific language of the Associates of the Undersea and Hyperbaric Medical Society, Hyperbaric Facility Design Guidelines, Version 1.0, July 2004, or the American Institute of Architects 2006 Guidelines for

Design and Construction of Health Care Facilities standard for hyperbaric suites. The commenter stated that the current standard and proposed changes contain ambiguous language with respect to hyperbaric chambers, ignore one entire class of hyperbaric chamber, and require inter-chamber spacing distances that have essentially no impact on patient care, yet increase the cost of facility construction.

Response: The commission disagrees with the commenter that the proposed language should be eliminated and that hyperbaric facilities should be required to conform either to the specific language of the Associates of the Undersea and Hyperbaric Medical Society, Hyperbaric Facility Design Guidelines, Version 1.0, July 2004, or the American Institute of Architects 2006 Guidelines for Design and Construction of Health Care Facilities standard for hyperbaric suites. The AIA Guidelines recommend in the appendix that the standard for hyperbaric suites should meet the requirements of the Associates of the Undersea and Hyperbaric Medical Society, Hyperbaric Facility Design Guidelines, Version 1.0, July 2004. The AIA Guidelines have not adopted the Associates of the Undersea and Hyperbaric Medical Society, Hyperbaric Facility Design Guidelines. The AIA Guidelines only recommend that it be reviewed in its appendix. The proposed rules have adopted the NFPA 99, Chapter 20, Hyperbaric Facilities, 2002 edition. The department has added, "Multiple occupancy chambers (Class A) shall be in accordance with NFPA 99, Chapter 20" in §133.163(k)(1)(A) This standard for Class A chambers was inadvertently left out of the proposed rules. The department has reworded the next sentence to clarify that the minimum clearance is from the side of a chamber to a wall/partition, and reduced the distance requirement from five feet to three feet as the distance was excessive. The phrase "foot of the chamber" was changed to "chamber entry" to clarify the configuration of the chamber entry point.

Comment: Concerning §133.163(u)(1)(Q)(iv) and §133.163(ee)(1)(G)(iii), **a** commenter questioned the requirement of providing viewing panels from the scrub area into the caesarean section (c-section) room and the operating room. The commenter has been asked by hospitals to remove existing viewing panels from scrub areas into operating rooms because of the privacy law.

Response: The commission disagrees with the commenter. The requirement for a viewing panel into the c-section room has been a requirement since 1985. New language has been added to require the viewing panel into operating rooms. The workgroup concurs with the AIA Guidelines, which require there to be a viewing panel from the scrub area into the operating room. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.163(v)(1)(F)(iii), a commenter stated that the requirement for the clearance between a side of lounger/gurney and a wall/partition to be a minimum of three feet six inches in each secondary recovery station conflicts with Diagram D in §133.169(h).

Response: The commission agrees with the commenter and has corrected three feet six inches to three feet.

Comment: Concerning §133.163(x), two commenters recommended requiring pharmacies to be in compliance with the rules of the Texas State Board of Pharmacy, as the proposed rules may be

in conflict with 22 Texas Administrative Code, §291.26 (relating to Pharmacies Compounding Sterile Pharmaceuticals) and the United States Pharmacopoeia, Chapter 797, Pharmaceutical Compounding-Sterile Preparations.

Response: The commission agrees with the commenters and has made the recommended changes to comply with 22 Texas Administrative Code, §291.26, (relating to Pharmacies Compounding Sterile Pharmaceuticals) and the United States Pharmacopoeia, Chapter 797, Pharmaceutical Compounding-Sterile Preparations. New language has been added for clarification purposes and to conform to the United States Pharmacopoeia, Chapter 797, Pharmaceutical Compounding-Sterile Preparations.

Comment: Concerning §133.163(ee)(1)(D), a commenter indicated that in facilities with two or more operating rooms the rule was silent as to a requirement for the number of preoperative patient holding area(s) or rooms. The commenter also indicated that the rule does not indicate that preoperative beds can swing to recovery beds.

Response: The commission agrees with the commenter. The workgroup indicated that each facility would determine the number of preoperative holding areas(s) or room(s) based on the workload of that facility. The workgroup also determined that these rooms should not be used as post-anesthesia care unit(s) (PACU), since the requirements for recovery and preoperative care are different. A patient coming out of anesthesia and a patient being prepared for surgery should not be in the same area. It was determined by the workgroup that the preoperative patient holding area(s) or room(s) could be used for secondary recovery. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.165, ten commenters requested the deletion of the section until the various architectural and operational issues relating to multiple hospitals within the same facility can be appropriately reviewed and an alternative rule can be developed. This is a new section of the rules that was not included in prior drafts of changes to the licensing rules. Based on input received from member hospitals, there are numerous concerns with this section and how it might be interpreted and applied by the department. Many hospitals are utilizing the hospital within a hospital concept in an effort to expand the scope of services provided within their community. This concept also can be very cost-effective if the guest hospital as described in the proposed rules is allowed to obtain certain services from the host hospital. However, this proposed section will require the guest hospital to separately provide services, such as, imaging/diagnostic services, dietary services and laboratory services; thus, prohibiting the guest hospital from obtaining these services for its patients from the host hospital. In addition, this proposed section establishes unnecessary restrictions on the movement of patients between the guest and host hospitals.

Response: The commission disagrees with the commenters. Most guest hospitals are licensed as special hospitals. A special hospital is already mandated by the HSC, §241.003(15), to provide clinical laboratory facilities, diagnostic x-ray facilities, treatment facilities or other definitive medical treatment. The 03/02/06 proposed rules that the council recommended the Executive Commissioner's approval for publication in the Texas Register included the requirement for each hospital to provide imaging and other diagnostic services and facilities and laboratory services

and a laboratory suite. The proposed rule requires each hospital also to provide dietary services and dietary suite, including staff dining facilities. The department determined this new requirement was necessary due to the sudden closure of several host hospitals over the past few years. Guest hospitals were left in a huge dilemma and unable to provide even minimal dietary services to inpatients. This proposed rule is only applicable to new construction. The new rule only requires the guest hospital to meet minimal dietary requirements. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.166(c)(1)(D), two commenters requested deletion of the requirement to provide a covered walkway or enclosure from the hospital to a mobile, transportable, or relocatable unit where inpatient services are provided. Based on comments received from member hospitals, it is the understanding of the commenters that measures currently are taken to protect inpatients from the elements when services are provided in these units. Strict compliance with this proposed section will unnecessarily increase hospital costs and will be cost prohibitive for small or rural hospitals. The strict enforcement of this proposed requirement is highly likely to cause hospitals to be unable to comply, which would result in the cessation of certain services in the rural areas, thus denying patients access to these services.

Response: The commission agrees with the commenters that, as long as a mobile, transportable or relocatable unit is utilized for outpatient purposes only, connection to the hospital is not required. The rule at §133.21(c)(2) states, "A hospital license shall not include off-site outpatient facilities." When a hospital wants outpatient services or any service to be part of the hospital license, a hospital shall be in a single building where inpatients and outpatients can receive hospital services as defined under "Premises" in §133.2(40). By providing a covered walkway or enclosure from a mobile, transportable or relocatable unit to a hospital, the mobile, transportable or relocatable unit can be considered as part of the hospital license. No change has been made to the proposed language based on this comment.

Comment: Concerning §133.166(c)(1)(F), two commenters requested deletion of the requirement for the unit to be provided certain equipment and systems connected to the hospital, when a mobile, transportable, or relocatable unit is permanently connected appropriately for the climate to the hospital or the unit does not move on a regular basis. These mobile units provide access to care for many rural Texans, and this care has been safe. The units typically provide for fire safety and electrical back-up power independently. Many of the units provide only services which do not require a patient to have access to a medical gas system or nurse call system. Based on comments received from member hospitals, one of these commenters believes that the cost to comply with this proposed rule will range from $75,000 to $100,000. Compliance with this proposed section also will unnecessarily increase hospital costs and this requirement will be cost prohibitive for small or rural hospitals.

Response: The commission agrees with the commenters that, as long as a mobile unit provides outpatient services only, the requirement for equipment system connection to the hospital is not necessary. The rule at §133.21(c)(2) states, "A hospital license shall not include off-site outpatient facilities." When a hospital wants outpatient services or any service to be part of the hospital license, then the hospital shall be in a single building where inpatients and outpatients can receive hospital services as defined under "Premises" in §133.2(40). Once a mobile unit is

providing services under the hospital license, it is considered a building and, therefore, required to be contiguous to the main building. For example, NFPA 72, which is the fire alarm code, requires the fire alarm to be one system in a hospital. The hospital licensing rules and NFPA 99, Standard for Health Care Facilities, require all medical gases to be a piped in single system and connected to the master alarm. NFPA 101, Life Safety Code, requires a hospital to have a wet sprinkler system and to be monitored at all times at a central location. NFPA 101 also requires the mobile unit to be connected to the emergency essential electrical system. All these physical equipment connections are necessary to assure the safety and protection of patients under one system. The commission has increased the number of days to describe a regular basis from every 30 days or less to every 90 days or less.

Comment: Concerning §133.169(c), a commenter requested that for x-ray (surgical/critical care, catheterization) the minimum air changes of outdoor air per hour not be increased from 3 to 4, and the minimum total air changes per hour not be increased from 15 to 20, as AIA and American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) still require 3 and 15.

Response: The commission agrees with the commenter and has maintained the requirements as in the current rules to reflect what is required by the AIA Guidelines and ASHRAE.

Comment: Concerning §133.169(c), two commenters recommended that the exhaust requirement be removed from the fluoroscopy room.

Response: The commission agrees with the commenters and has deleted the requirement. There is no qualitative reason to exhaust all the air in this room. Prohibiting the recirculation by means of room units should not be a factor in providing quality air.

Comment: Concerning §133.169(c), Note 7, a commenter recommended a correction to the description of the temperature in relation to the humidity.

Response: The commission agrees with the commenter and has corrected the sentence to read, "The relative humidity is expected to be at the lower end of the range when the temperature is also at the higher end, and vice versa."

Comment: Concerning §133.169(f), a commenter could not find the minimum requirement of medical gas station outlets for a continuing care nursery.

Response: The commission disagrees with the commenter. Table 6 does contain the number of medical gas station outlets for each bassinet. No change has been made to the proposed Table 6 based on this comment.

The department staff and the commission have made the following changes that will correct errors, clarify the intent, and improve the accuracy of the chapter.

Concerning §133.21(c)(4)(A), the reference to §133.2(40) was revised to §133.2(41) due to renumbering.

Concerning §133.23(b)(1)(B), the phrase “that is dated no earlier than one year prior to the application date;” was deleted and added the sentence “The hospital fire safety survey shall be conducted annually and both surveys shall be submitted.” This clarifies what is required of hospitals.

Concerning §133.41(i)(1)(C), the term "(HBV)-containing" was hyphenated to be consistent.

Concerning §133.41(j)(8)(C), the sentence “The medical history and physical examination must be placed in the patient’s medical record within 24 hours after admission.” was added. This clarifies what is required of hospitals and is consistent with the Medicare CoPs.

Concerning §133.41(j)(8)(D), the rule text “an updated medical record entry documenting an examination for any changes in the patient’s condition when the medical history and physical examination are completed within 30 days before admission. This updated examination must be completed and documented in the patient’s medical record within 24 hours after admission.” was inserted. This clarifies what is required of hospitals and is consistent with the Medicare CoPs. Subsequent subparagraphs were relettered.

Concerning §133.41(k)(3)(F), the sentence “The medical history and physical examination must be placed in the patient’s medical record within 24 hours after admission.” was added. This clarifies what is required of hospitals and is consistent with the Medicare CoPs.

Concerning §133.41(o)(7)(B), the spelling of policies was corrected.

Concerning §133.41(q)(5)(B), the sentence “Drugs and biologicals shall be kept in a locked storage area.” was deleted. The sentence “All drugs and biologicals must be kept in a secure area, and locked when appropriate.” was added. This new language is consistent with the Medicare CoPs for Hospitals effective January 26, 2007. Since the goal is to be as consistent as possible with the CoPs, the change has been made. Section 241.026(b) requires us to consider the CoPs in adopting rules and attempt to achieve consistency with those conditions. This change is less stringent than the proposed language.

Concerning §133.41(q)(5)(B)(ii), the sentence “Dangerous drugs as well as controlled substances shall be secure from unauthorized use.” was added. The sentence “Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area was added. This new language is consistent with the Medicare CoPs for Hospitals effective January 26, 2007. Since the goal is to be as consistent as possible with the CoPs, the change has been made. Section 241.026(b) requires us to consider the CoPs in adopting rules and attempt to achieve consistency with those conditions. This change is less stringent than the proposed language.

Concerning §133.162(d)(4), the title of the code was corrected to “National Standard Plumbing Code Illustrated” and corrected the year of the code from "2000" to "2003".
Concerning §133.162(d)(4)(A)(iii)(IV), the title of the standard and the contact information was corrected.

Concerning §133.163(f)(1)(A)(i)(II), the department has clarified that a multiple-bed emergency treatment room is not required by adding “When . . .is provided."

Concerning §133.163(f)(1)(B)(i)(IV), the word “room” was added after the words “patient toilet”.

Concerning §133.163(f)(3), language was added to clarify that when performing surgery in a trauma room, the ventilation requirement is no different than in an operating room.

Concerning §133.163(k)(1), the chapter reference was corrected from “19” to “20”.

Concerning §133.163(n)(3)(C)(iv), the number “twenty-four” was corrected to “24-hour”.

Concerning §133.163(o), the word “may” was corrected to “shall” as the hospital is required to provide laundry service.

Concerning §133.163(r)(1)(A), the phrase “for a general hospital” was added. This had been discussed with the workgroup, and it was not changed in the proposed rules.

Concerning §133.163(t)(1)(C)(iv), the text “and in surgical suite post-anesthesia care units” was added after “CCU suites” as the requirements are the same and the wording had been inadvertently left out in the proposed rules.

Concerning §133.163(u)(1)(N)(i), the observation windows are to permit the viewing of infants from public areas for full-term nurseries and from workroom(s) into adjacent nurseries, and added that windows between nurseries may be provided for convenience of staff observation.

Concerning §133.163(u)(1)(O)(xx), the word ”convenient” was changed to the word “conveniently”.

Concerning §133.163(u)(1)(Q)(vi), the words “small style D or E” were added to define the medical gas cylinder size.

Concerning §§133.163(u)(1)(Q)(xii), (dd)(1)(B)(iv) and (C)(vi), the word “appropriate” was changed to the word “appropriately”.

Concerning §133.163(u)(2)(A)(v) and (vi), the word “an” was corrected to the word “a”.

Concerning §133.163(u)(2)(B)(iii), the rule was corrected by adding “isolation and anteroom” as this was inadvertently left out in the proposed rules.

Concerning §133.163(u)(4)(B)(iii), the word “provide” to “provided in”.

Concerning §133.163(v)(1)(A), to clarify the rule language was added,"To be included in the hospital license,” and the words “If”, ‘is” and “that portion” were deleted. The word “contains”

was corrected to “contain”. The sentence, “When an outpatient facility is not located contiguous to the hospital and does not provide services for the hospital patients, it is not considered part of the licensed hospital and will not need to comply with these licensing rules” was deleted because of redundancy.

Concerning §133.163(y)(2)(A)(ii), the repetitive phrase “in design or shielding” was deleted.

Concerning §133.163(ff)(2)(A)(ii), the sentence was corrected to read as “shall have” hardware that minimizes jamming possibilities is required.

Concerning §133.169(c), the spelling of hospital was corrected in the title, changed "IV preparation room" to "preparation/anteroom," changed "chemo-hood room" to "chemotherapy room-fume hoods," changed the exhaust requirement for the preparation/anteroom, and added the IV hood room to comply with the United States Pharmacopoeia, Chapter 797, Pharmaceutical Compounding-Sterile Preparations.

Concerning §133.169(e), the temperature was changed from “110” to “105-120” in the hot water use table to provide a minimum and a maximum range of temperature for clinical areas in lieu of a fixed temperature, which is extremely hard to attain at all times. This is also the range indicated in the AIA guidelines.

Concerning §133.169(f), the medical gas station outlet headings for oxygen and vacuum was corrected by adding the numerical note “4” as it had been inadvertently left out in the proposed rules.

Concerning §133.169(g), "Note 10" was added to clarify the quantities of code blue devices required where there are multi-beds in an open ward. Note 10 was also added in the appropriate areas in the staff emergency assistance calling system (code blue) column. Corrections have been made to location titles to be consistent with the rules and intermediate care suite was moved to be in the same order as the rules.

LEGAL CERTIFICATION

The Department of State Health Services Deputy General Counsel, Lisa Hernandez, certifies that the rules, as adopted, have been reviewed by legal counsel and found to be a valid exercise of the agencies’ legal authority.

STATUTORY AUTHORITY

The repeal and new sections are adopted under the Health and Safety Code, §241.026, which requires the department to develop, establish, and enforce standards for the construction, maintenance, and operation of hospitals; Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001; and implements Government Code, §2001.039.

Repeal.

§133.1. Purpose.
§133.2. Definitions.
§133.21. General.
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