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How to Use the Texas Register

Information Available: The 11 sections of the ***Texas Register*** represent various facets of state government. Documents contained within them include:

Governor - Appointments, executive orders, and proclamations.

Attorney General - summaries of requests for opinions, opinions, and open records decisions.

Secretary of State - opinions based on the election laws.

Texas Ethics Commission - summaries of requests for opinions and opinions.

Emergency Rules- sections adopted by state agencies on an emergency basis.

Proposed Rules - sections proposed for adoption.

Withdrawn Rules - sections withdrawn by state agencies from consideration for adoption, or automatically withdrawn by the Texas Register six months after the proposal publication date.

Adopted Rules - sections adopted following a 30-day public comment period.

Tables and Graphics - graphic material from the proposed, emergency and adopted sections.

Open Meetings - notices of open meetings.

In Addition - miscellaneous information required to be published by statute or provided as a public service.

Specific explanation on the contents of each section can be found on the beginning page of the section. The division also publishes cumulative quarterly and annual indexes to aid in researching material published.

How to Cite: Material published in the ***Texas Register*** is referenced by citing the volume in which the document appears, the words "TexReg" and the beginning page number on which that document was published. For example, a document published on page 2402 of Volume 19 (1994) is cited as follows: 19 TexReg 2402.

In order that readers may cite material more easily, page numbers are now written as citations. Example: on page 2 in the lower-left hand corner of the page, would be written "19 TexReg 2 issue date," while on the opposite page, page 3, in the lower right-hand corner, would be written "issue date 19 TexReg 3."

How to Research: The public is invited to research rules and information of interest between 8 a.m. and 5 p.m. weekdays at the ***Texas Register*** office, Room 245, James Earl Rudder Building, 1019 Brazos, Austin. Material can be found using ***Texas Register*** indexes, the ***Texas Administrative Code***, section numbers, or TRD number.

Texas Administrative Code

The *Texas Administrative Code* (*TAC*) is the official compilation of all final state agency rules published in the ***Texas Register***. Following its effective date, a rule is entered into the ***Texas Administrative Code***. Emergency rules, which may be adopted by an agency on an interim basis, are not codified within the ***TAC***. West Publishing Company, the official publisher of the ***TAC***, publishes on an annual basis

The ***TAC*** volumes are arranged into Titles (using Arabic numerals) and Parts (using Roman numerals). The Titles are broad subject categories into which the agencies are grouped as a matter of convenience. Each Part represents an individual state agency. The ***Official TAC*** also is available on WESTLAW, West's computerized legal research service, in the TX-ADC database.

To purchase printed volumes of the ***TAC*** or to inquire about WESTLAW access to the ***TAC*** call West: **1-800-328-9352.**

The Titles of the ***TAC***, and their respective Title numbers are:

1. Administration
4. Agriculture
7. Banking and Securities
10. Community Development
13. Cultural Resources
16. Economic Regulation
19. Education
22. Examining Boards
25. Health Services
28. Insurance
30. Environmental Quality
31. Natural Resources and Conservation
34. Public Finance
37. Public Safety and Corrections
40. Social Services and Assistance
43. Transportation

How to Cite: Under the ***TAC*** scheme, each section is designated by a ***TAC*** number. For example in the citation 1 TAC §27.15:

1 indicates the title under which the agency appears in the ***Texas Administrative Code***; ***TAC*** stands for the ***Texas Administrative Code***; §27.15 is the section number of the rule (27 indicates that the section is under Chapter 27 of Title 1; 15 represents the individual section within the chapter).

How to update: To find out if a rule has changed since the publication of the current supplement to the ***Texas Administrative Code***, please look at the ***Table of TAC Titles Affected***. The table is published cumulatively in the blue-cover quarterly indexes to the ***Texas Register*** (January 21, April 15, July 12, and October 11, 1994). In its second issue each month the ***Texas Register*** contains a cumulative ***Table of TAC Titles Affected*** for the preceding month. If a rule has changed during the time period covered by the table, the rule's ***TAC*** number will be printed with one or more ***Texas Register*** page numbers, as shown in the following example.

TITLE 40. SOCIAL SERVICES AND ASSISTANCE
Part I. Texas Department of Human Services
40 TAC §3.704.....950, 1820

The ***Table of TAC Titles Affected*** is cumulative for each volume of the ***Texas Register*** (calendar year).

Update by FAX: An up-to-date ***Table of TAC Titles Affected*** is available by FAX upon request. Please specify the state agency and the TAC number(s) you wish to update. This service is free to ***Texas Register*** subscribers. Please have your subscription number ready when you make your request. For non-subscribers there will be a fee of $2.00 per page (VISA, MasterCard). (512) 463-5561.

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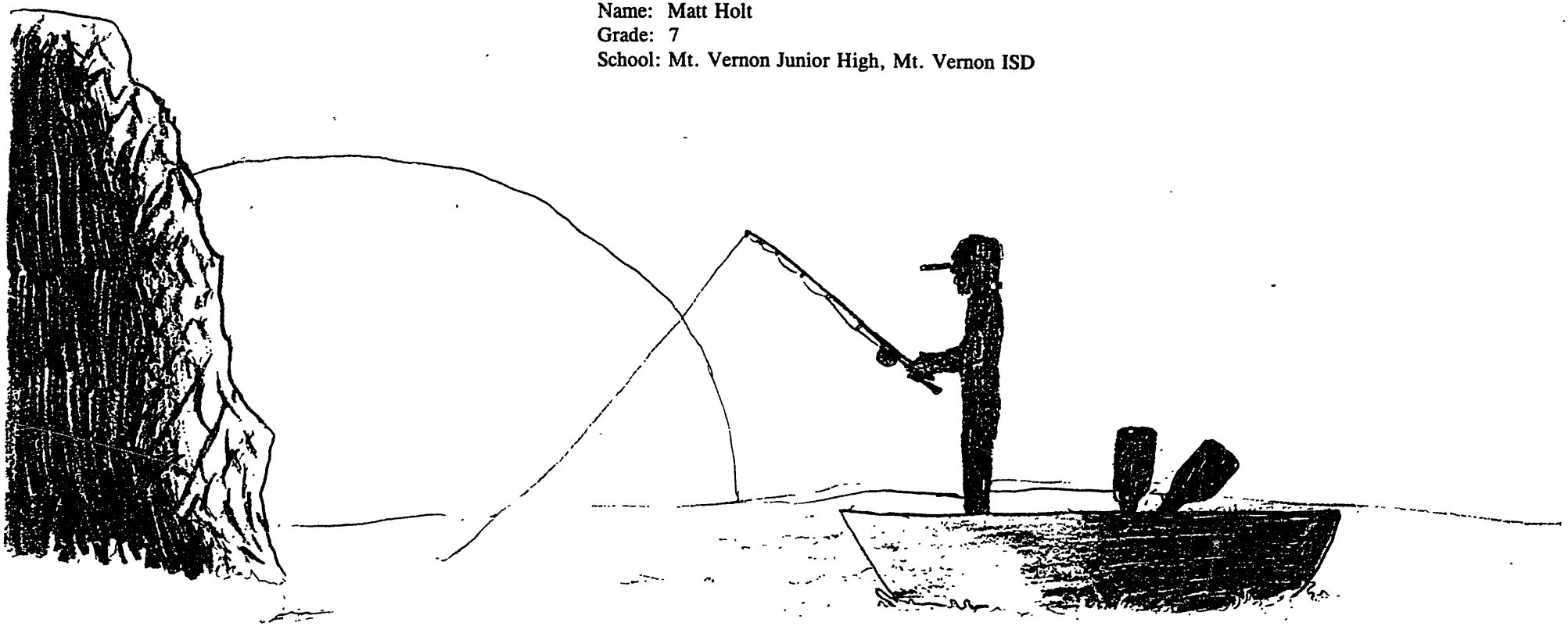

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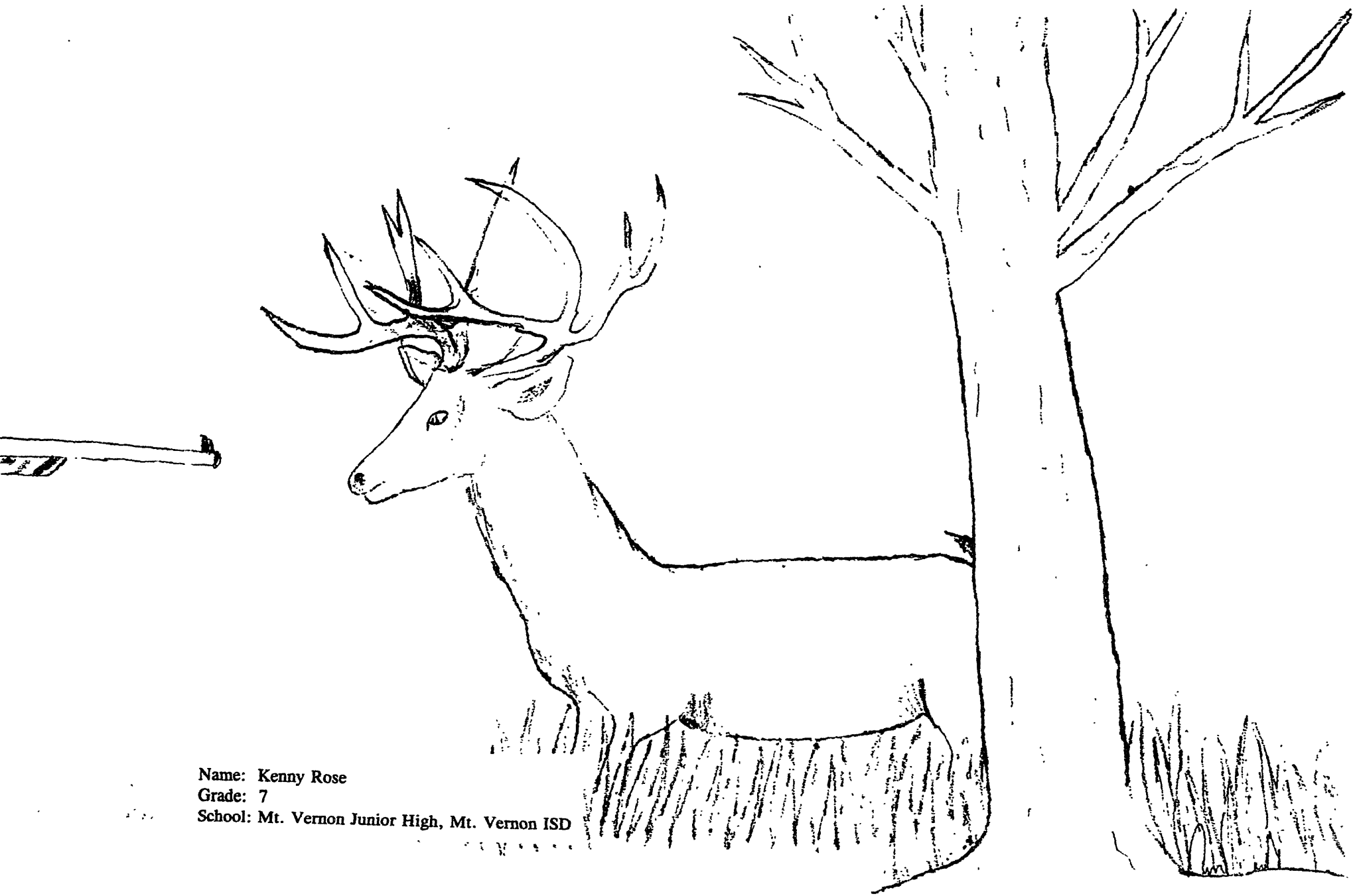
School: Mt. Vernon Junior High, Mt. Vernon ISD



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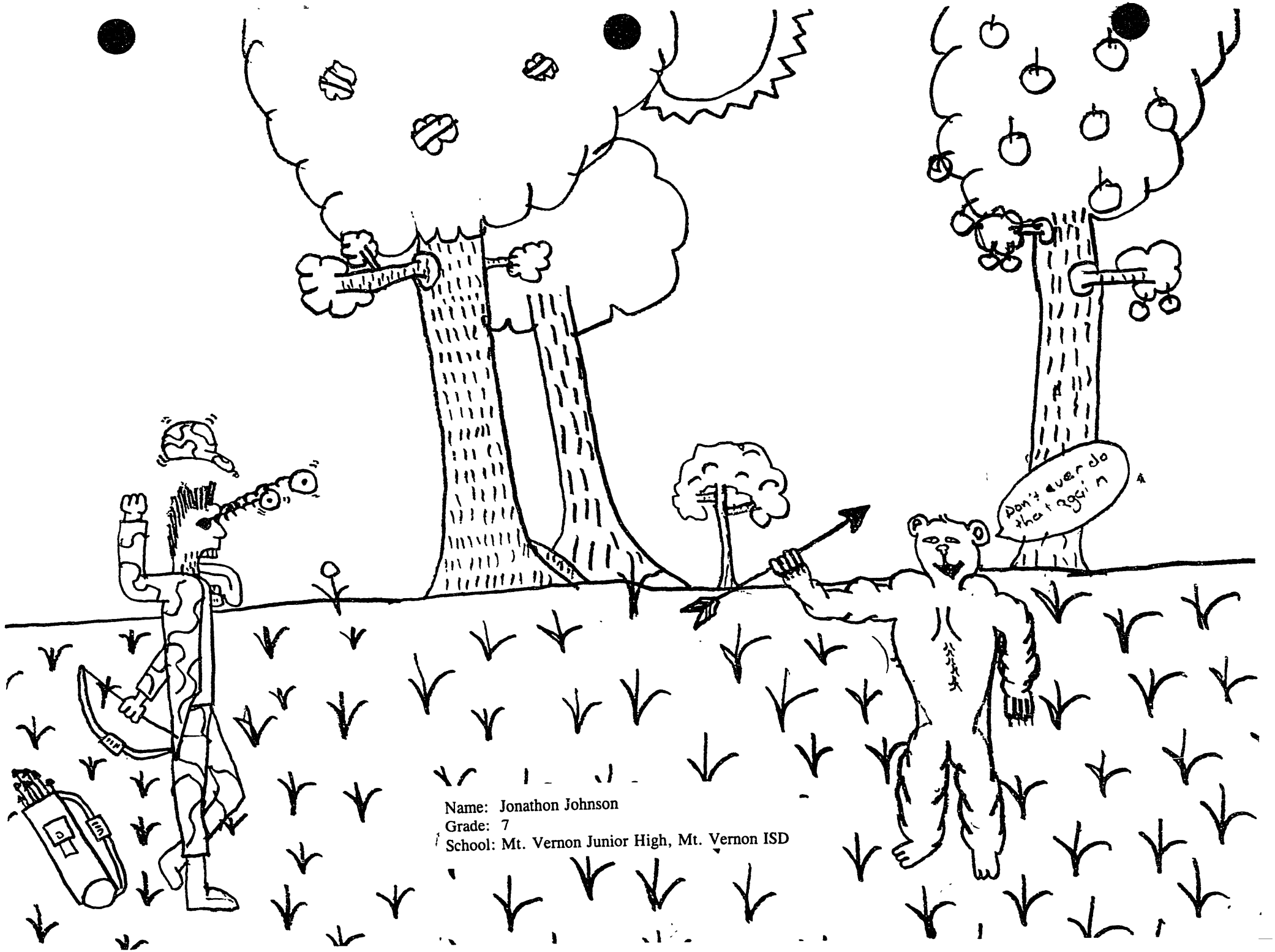

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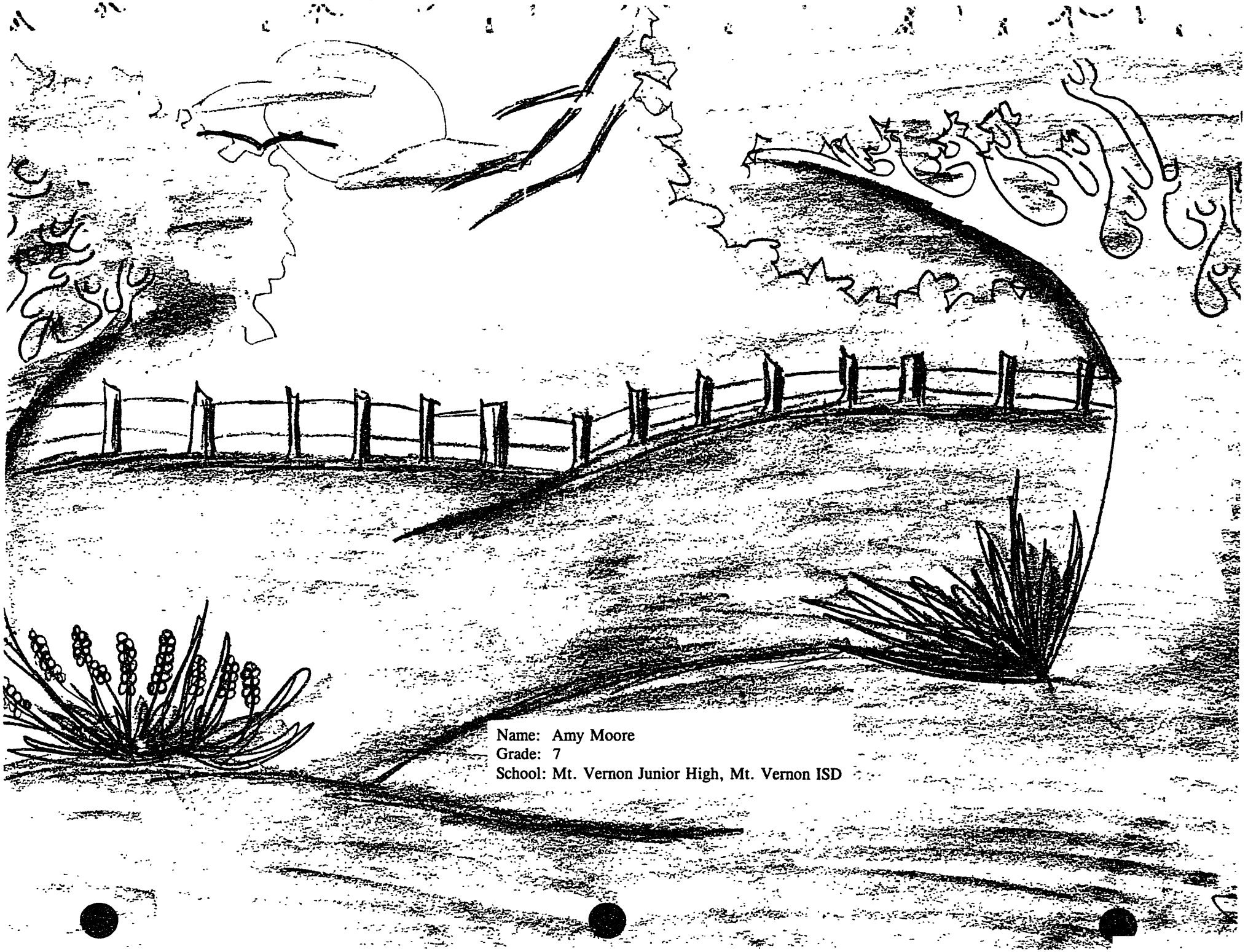

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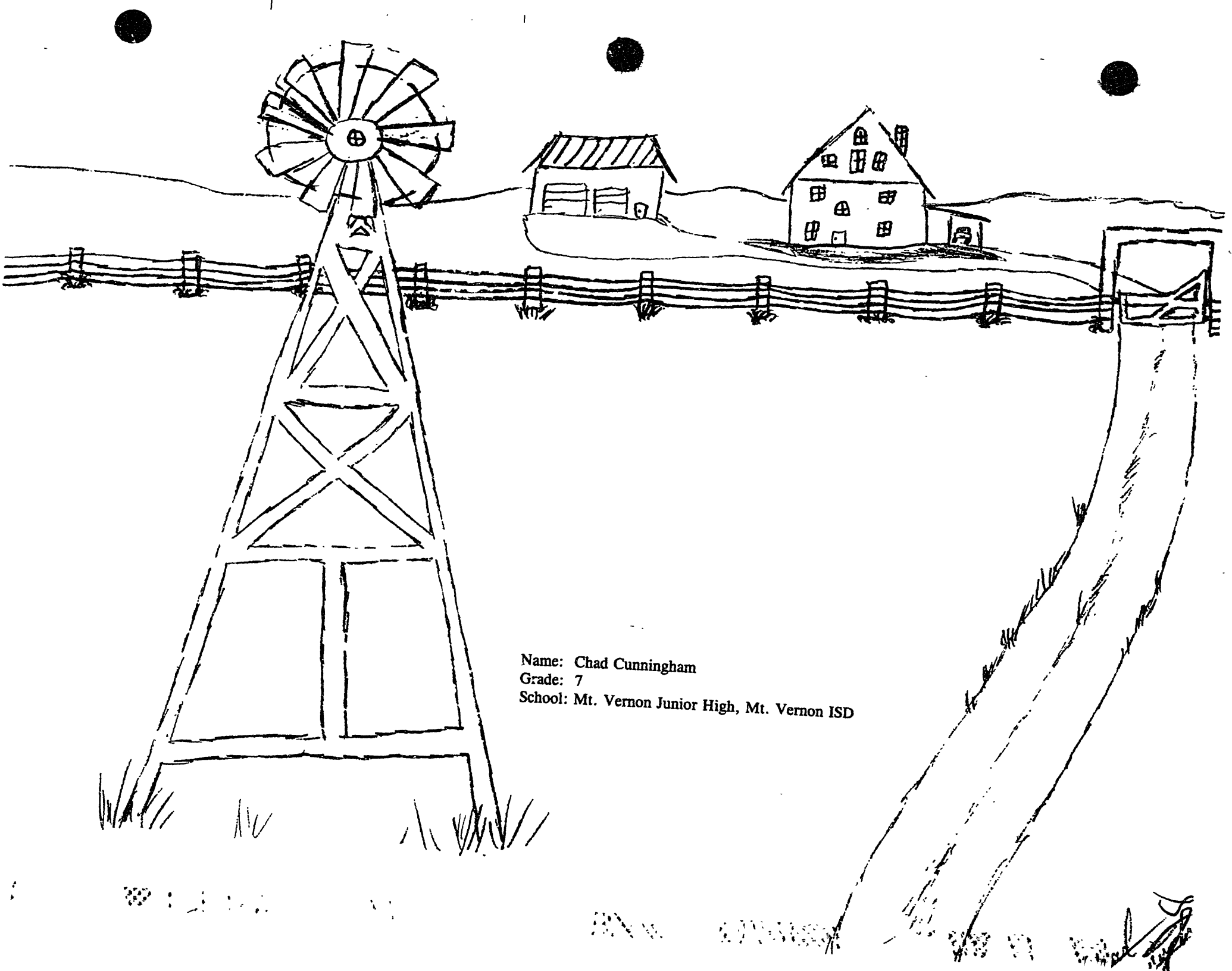

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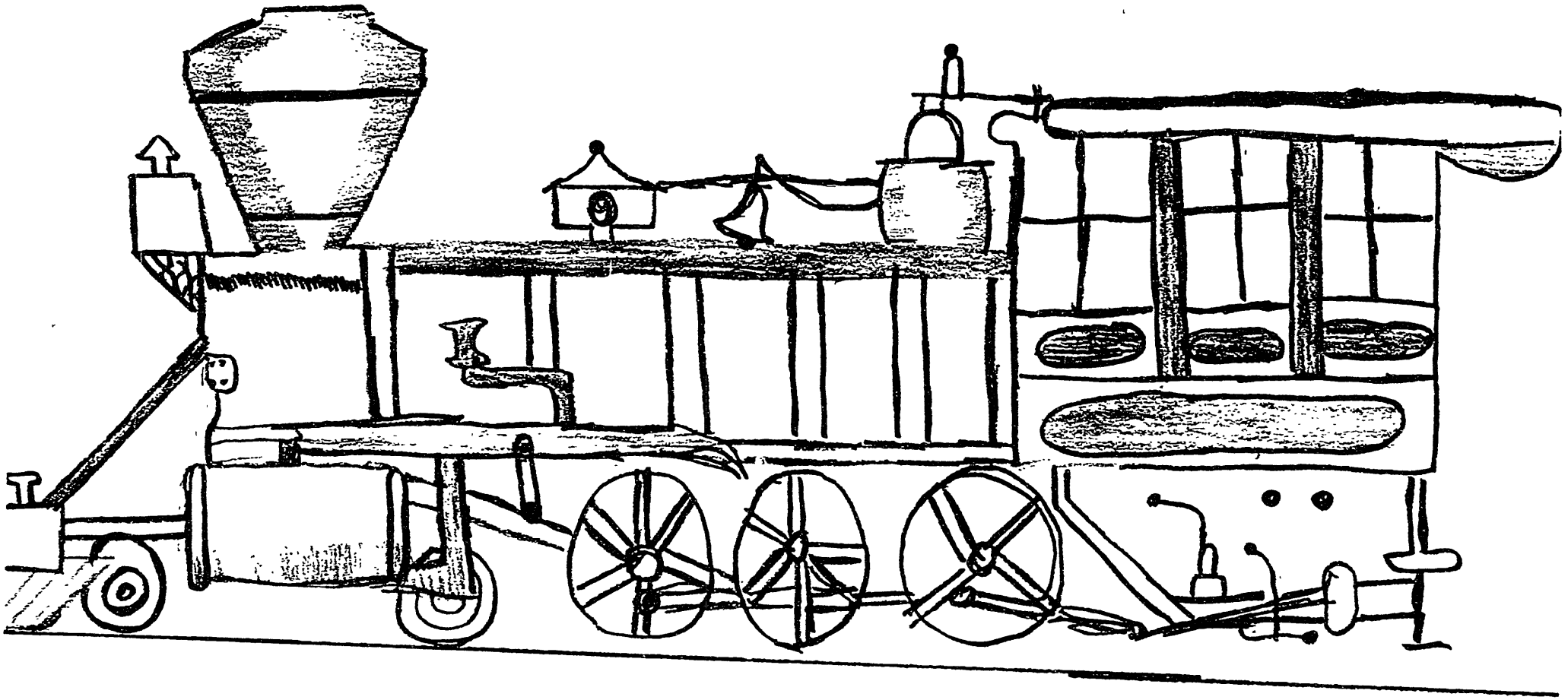

PROPOSED RULES

Before an agency may permanently adopt a new or amended section or repeal an existing section, a proposal detailing the action must be published in the ***Texas Register*** at least 30 days before action is taken. The 30-day time period gives interested persons an opportunity to review and make oral or written comments on the section. Also, in the case of substantive action, a public hearing must be granted if requested by at least 25 persons, a governmental subdivision or agency, or an association having at least 25 members.

Symbology in proposed amendments. New language added to an existing section is indicated by the use of **bold text.** [Brackets] indicate deletion of existing material within a section.

TITLE 25. HEALTH SERVICES

Part I. Texas Department of Health

Chapter 133. Hospital Licensing

Subchapter A. General Provisions

The Texas Department of Health (department) proposes the repeal of existing 25 Texas Administrative Code §§133.1-133.3, 133.11-133.14, 133.21, 133.22, 133.51-133.54, 133.71, 133.72, 133.101, 133.102, 133.111-133.113, 133. 121, and 133.131; and proposes new §§133.1-133.4, 133.11-133.14, 133. 21-133.23, 133.31-133.33, 133.41-133.49, 133.61-133.64, 133.71-133.73, 133. 91-133.101, 133.111, 133.112, 133.121-133.124, 133.131, and 133.141 concerning Hospital Licensing Rules. The sections proposed for repeal cover general provisions, application and issuance of a hospital license, operational requirements for all hospitals, special service requirements, physical plant and fire safety requirements, patient transfers, enforcement, internal investigation, and cooperative agreements. The proposed new sections cover general provisions which include purpose, definitions, fees, and applicability of the rules to all facilities; application and issuance of a hospital license; general requirements for all hospitals; requirements for general hospitals; requirements for special hospitals; requirements for hospital services; operational requirements for all hospitals; physical plant and construction; patient transfers; enforcement; internal investigation; and cooperative agreements. This is a proposal to repeal existing rules and adopt new rules concerning licensing requirements for general and special hospitals. Initially all hospital licensing standards were adopted by reference. The existing hospital licensing rules reflect the first conversion phase to *Texas Register* format and are partially adopted by reference and partially written in *Texas Register* format. In the effort to complete the conversion of the existing standards that are presently adopted by reference (Chapters 1-3 and 6-10 of the Hospital Licensing Standards adopted by reference in §133.21) to *Texas Register* format, all of the existing hospital licensing rules must be repealed. Incorporation of these standards vastly expands the existing sections making it necessary to reorganize and renumber every section. In addition, there is new language in §133.2 for definitions; new language in §§133.31-133.33 for requirements for general hospitals; new language in §133.41 for requirements for special hospitals; new language in §133.45 for requirements for a special hospital-convalescent, non-comprehensive rehabilitation and extended care; new language in §133.61 for requirements for hospital services, new language in §133.95 for skilled nursing facilities and bone marrow and organ transplantation units; and new language in §133.124 for administrative penalty. Existing language in all sections is being amended by revising, deleting, and updating with new language for clarity and for the purpose of reorganizing Chapter 133.

A conversion table is published in the "In Addition" section of this issue of the *Texas Register* that shows existing rules proposed for repeal and where they are being moved. Some of the existing rules were relocated throughout the new rules. This chart may only indicate the general area in the new rules rather than the specific location.

Bernie Underwood, chief of staff services for Health Care Quality and Standards Associateship has determined that for the first five-year period the repealed sections and proposed new sections are in effect, there will be significant fiscal implications for state government as the result of administering and enforcing the new sections. Additional costs to the state will arise from the statutory duty for the department to enforce the new sections and from the added administrative, investigative, and enforcement responsibilities. Costs associated with this fiscal note will be recovered by proposed new revenue that will be generated by an increase in the hospital licensure fee.

The department proposes to increase the hospital licensure fee from $4.00 to $7.00 per bed in order to obtain the funds necessary to administer and enforce the Texas Hospital Licensing Law, Health and Safety Code, Chapter 241.

Revenue to the department is estimated to increase due to an increase in licensing fees. At the rate proposed in these rules, the department projects licensing fees will increase by approximately $210,936 annually. The fiscal implications to local government will be discussed in conjunction with the fiscal implications to small and large businesses in the following paragraph

Bernie Underwood also has determined that for each year of the first five-year period the proposed rules will be in effect, the anticipated public benefit is that the rules will be strengthened in order to provide for better care of hospital patients, the rules will be easier to understand, the rules will more closely track the statutory mandate under the Health and Safety Code, Chapter 241, and publication of these rules concerning hospitals in the *Texas Register* will facilitate public access and review. Bernie Underwood has further determined that there will be a fiscal impact on hospitals operated by local governments and large and small businesses. Statute allows the department to increase fees for hospital licenses. The hospital license fees will increase from $4.00 per bed with a minimum fee of $200 and a maximum fee of $10,000, to $7.00 per bed with a minimum fee of $200 and a maximum fee of $10,000. There is no anticipated cost to persons affected by the proposal nor anticipated effect on local employment.

Comments on the proposal may be submitted to John M. Evans, Jr., MHA, RN, Hospital Licensing Director, Health Care Quality and Standards Associateship, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199, (512) 834-6648. Comments will be accepted for a period of 30 days after publication of this proposal in the *Texas Register.*

- **25 TAC §§133.1-133.3**

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the offices of the Texas Department of Health or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter

222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health, Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81 172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code, Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act, 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed action.

§133.1 Purpose.

§133.2 Definitions.

§133.3 Fees.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 15, 1995.

TRD-9503191 Susan K Steeg
General Counsel
Texas Department of Health

Earliest possible date of adoption: April 21, 1995

For further information, please call: (512) 458-7236

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• 25 TAC §§133.1-133.4

The new sections are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5 105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed new action

§133.1. Purpose.

(a) The purpose of this chapter is to implement the Health and Safety Code, Chapters 161, 164, 222, 241, 311, 313, and 321 relating to abuse, neglect and unprofessional or unethical conduct in health care facilities; treatment facilities' marketing and admission practices; health care facility surveys, construction, inspection, and regulation; general and special hospitals to be licensed by the Texas Department of Health (department); powers and duties of hospitals; cooperative agreements; and provision of mental health, chemical dependency, and rehabilitation services.

(b) This chapter provides procedures for granting, denying, suspending, or revoking a license; minimum requirements for licensing of hospitals; patient care; construction; patient transfers; audits of billing; commissioner of health's emergency orders; administrative penalties; complaints against the department; and cooperative agreements among hospitals.

§133.2. Definitions. The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

Abuse-Abuse includes:

(A) any act or failure to act by an employee, contract personnel, and volunteer of a hospital which was performed, or which was failed to be performed, knowingly, recklessly, or intentionally, and which caused, or may have caused, injury or death to a patient, and includes acts such as:

(i) the rape, sexual assault or sexual exploitation of a patient;

(ii) the striking of a patient;

(iii) the use of excessive force when placing a patient in bodily restraints; and

(iv) the use of bodily or chemical restraints on a patient which are not in compliance with federal and state laws and regulations; and

(B) verbal abuse, coercive or restrictive actions that are illegal or not justified by the patient's condition and that are in response to the patient's request for discharge or refusal of medication, therapy or treatment.

Act-The Texas Hospital Licensing Law, Health and Safety Code, Chapter 241.

Advance directive-Written instructions recognized under state law relating to the provision of health care when individuals are unable to communicate their wishes regarding medical treatment. The advance directive may be a written document authorizing an agent or surrogate to make decisions on an individual's behalf (a durable power of attorney for health care), a written or oral statement (a living will), or some other form of instruction recognized under state law specifically addressing the provisions of health care. Advance directives do not apply to children's hospitals.

Affiliate-With respect to an applicant or owner which is:

(A) a corporation-Each officer, director, stockholder with a direct ownership of at least 10%, subsidiary, and parent company;

(B) a limited liability company-Each officer, member, and parent company;

(C) an individual-Any of the following:

(i) the individual's spouse;

(ii) each partnership and each partner thereof of which the individual or any affiliate of the individual is a partner; and

(iii) each corporation in which the individual is an officer, director, or stockholder with a direct ownership of at least 10%,

(D) a partnership-Each partner and any parent company; and

(E) a group of co-owners under any other business arrangement-Each officer, director, or the equivalent under the specific business arrangement and each parent company.

Applicant-A person who seeks a hospital license from the department.

Attorney general-The attorney general of Texas or any assistant attorney general acting under the direction of the attorney general of Texas.

Biological indicator-Commercially-available microorganisms (e.g., United States Food and Drug Administration (FDA) approved strips or vials of Bacillus species endospores) which can be used to verify the performance of waste treatment equipment and processes (or sterilization equipment and processes).

Board-The Texas Board of Health.

Chemical dependency-Dependency resulting from:

(A) the abuse of alcohol or a controlled substance;

(B) psychological or physical dependence on alcohol or a controlled substance; or

(C) addiction to alcohol or a controlled substance.

Comprehensive medical rehabilitation-The provision of rehabilitation services that are designed to improve or minimize a person's physical or cognitive disabilities, maximize a person's functional ability, or restore a person's lost functional capacity through close coordination of services, communication, interaction, and integration among several professions that share responsibility to achieve team treatment goals for the person.

Cooperative agreement-An agreement among two or more hospitals for the allocation or sharing of health care equipment, facilities, personnel, or services.

Council-The Hospital Licensing Advisory Council.

Department-The Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199.

Designated provider-A provider of health care services, selected by a health maintenance organization, a self-insured business corporation, a beneficial society, the Veterans Administration, CHAMPUS, a business corporation, an employee organization, a county, a public hospital, a hospital district, or any other entity to provide health care services to a patient with whom the entity has a contractual, statutory, or regulatory relationship that creates an obligation for the entity to provide the services to the patient.

Dietitian-A person who is currently licensed by the Texas State Board of Examiners of Dietitians as a licensed dietitian or provisional licensed dietitian, or who is a registered dietitian.

Director-The director of the Health Facility Licensure and Certification Division, Texas Department of Health.

Disciplinary action-Denial, suspension, or revocation of a license, issuance of an emergency order or imposition of an administrative penalty.

Division-The Health Facility Licensure and Certification Division, Texas Department of Health.

Emergency medical condition-A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in one or all of the following:

(A) placing the health of the individual (or with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

(B) serious impairment to bodily functions;

(C) serious dysfunction of any bodily organ or part; or

(D) with respect to a pregnant woman who is having contractions:

(i) that there is inadequate time to effect a safe transfer to another hospital before delivery; or

(ii) that transfer may pose a threat to the health or safety of the woman or the unborn child.

Emergency medical services-Services used to respond to an emergency medical condition or to an individual's perceived need for immediate medical care and to prevent death or aggravation of physiological or psychological illness or injury.

Fast-track projects-A construction project in which it is necessary to begin initial phases of construction before later phases of the construction documents are fully completed in order to establish other design conditions or because of time constraints such as mandated deadlines.

Garbage-Solid waste that is putrescible animal and vegetable waste materials from the handling, preparation, cooking, or consumption of food, including waste materials from markets, storage facilities, and the handling and sale of produce and other food products.

General hospital-An establishment that:

(A) offers inpatient and emergency services, facilities, and beds for use for more than 24 hours for two or more unrelated individuals requiring diagnosis, treatment, or care for illness, injury, deformity, abnormality, or pregnancy;

(B) regularly maintains, at a minimum, clinical laboratory services, diagnostic X-ray services, a licensed pharmacy, treatment facilities including surgery or obstetrical care or both, and other definitive medical or surgical treatment of similar extent;

(C) has a medical staff in regular attendance;

(D) maintains records of the clinical work performed for each patient; and

(E) offers optional outpatient services on the premises of the hospital.

Governmental unit-A political subdivision of the state, including a hospital district, county, or municipality, and any department, division, board, or other agency of a political subdivision.

Governing body-The governing authority of a hospital which is responsible for a hospital's organization, management, control, and operation, including appointment of the medical staff; includes the owner or partners for hospitals owned or operated by an individual or partners.

Hospital-A general hospital or a special hospital.

Hospital administration-Administrative body of a hospital headed by an individual who has the authority to represent the hospital and who is responsible for the operation of the hospital according to the policies and procedures of the hospital's governing body.

Hospital licensing director-The director of hospital licensing, Texas Department of Health.

Illegal conduct-A conduct prohibited by federal or state law.

Inpatient-An individual admitted for an intended length of stay of 24 hours or greater.

Inpatient services-Services provided to an individual admitted to a hospital for an intended length of stay of 24 hours or greater.

Interdisciplinary team-A group of at least two health and allied health professionals which is directed by a physician and which works in collaboration to develop and implement the patient's treatment plan.

Learning disability-A severe discrepancy which exists when the individual's assessed intellectual ability is above the mentally retarded range, but where the individual's assessed educational achievement in areas specified is more than one standard deviation below the individual's intellectual ability.

Legally reproduced form-A medical record retained in hard copy, microfilm, microfiche, or computer diskette.

Licensed vocational nurse-A person who is currently licensed under the Vocational Nurse Act by the Board of Vocational Nurse Examiners for the State of Texas as a licensed vocational nurse (LVN).

Licensee-The premises, person, or governmental unit named in the application for issuance of a hospital license.

Managers of the applicant-A person having a contractual relationship to provide management services to a hospital for the overall operation of a hospital, including administration, staffing, or delivery of services. Examples of contracts for services that will not be considered to be contracts for management services shall include contracts solely for maintenance, laundry, or food services.

Mandated provider-A person who provides health care services, is selected by a county, public hospital, or hospital district, and agrees to provide health care services to eligible residents.

Medical staff-A physician or group of physicians or a podiatrist or group of podiatrists who by action of the governing body of a hospital are privileged to work in and use the facilities of a hospital for, or in connection with, the observation, care, diagnosis, or treatment of an individual who is or may be suffering from mental or physical disease or disorder, or a physical deformity or injury.

Medical waste-Waste generated by health care related facilities which is associated with health care activities not including garbage or rubbish generated from offices, kitchens, or other non-health care activities.

Medical waste, other regulated-Medical waste which is not included within special waste from health care related facilities but which is subject to special handling requirements within the generating facility by other federal or state agencies, excluding medical waste which is subject to Chapter 289 of this title (relating to Radiation Control).

Mental health services-All services concerned with research, prevention, and detection of mental disorders and disabilities and all services necessary to treat, care for, control, supervise, and rehabilitate persons who have a mental disorder or disability, including persons whose mental disorders or disabilities result from alcoholism or drug addiction.

Mental illness-An illness, disease, or condition, other than epilepsy, senility, alcoholism, or mental deficiency that:

(A) substantially impairs a person's thought, perception of reality, emotional process, or judgement; or

(B) grossly impairs behavior as demonstrated by recent disturbed behavior.

Mental retardation-Significantly subaverage general intellectual functioning that is concurrent with deficits in adaptive behavior and originates during the developmental period.

Neglect-A negligent act or omission by any individual responsible for providing services in a hospital which caused or may have caused injury or death to a patient or which placed a patient at risk of injury or death, and includes an act or omission such as the failure to establish or carry out an appropriate individual program plan or treatment plan for a patient, the failure to provide adequate nutrition, clothing, or health care to a patient, or the failure to provide a safe environment for a patient, including the failure to maintain adequate numbers of appropriately trained staff.

Organ-A human kidney, liver, heart, lung, or pancreas.

Outpatient-An individual who presents for diagnostic or treatment services for an intended length of stay of less than 24 hours.

Outpatient services-Medical services, including psychiatric, which are provided in a clinic operating on the hospital's premises under the hospital's license and meeting hospital licensure rules. Such services are provided to patients whose medical needs can be met in less than 24 hours and without inpatient care and are necessary for the diagnosis or treatment of the individual's condition, expected to improve or maintain the individual's condition and functional level, and to prevent relapse or hospitalization.

Owner-One of the following persons or governmental unit which will hold or does hold a license issued under the statute in the person's name or the person's assumed name:

(A) a corporation;

(B) a governmental unit;

(C) a limited liability company;

(D) an individual;

(E) a partnership if a partnership name is stated in a written partnership agreement or an assumed name certificate;

(F) all partners in a partnership if a partnership name is not stated in a written partnership agreement or an assumed name certificate; or

(G) all co-owners under any other business arrangement.

Patient-An individual who presents for diagnosis or treatment.

Person-An individual, firm, partnership, corporation, association, or joint stock company, and includes a receiver, trustee, assignee, or other similar representative of those entities.

Physician-A physician licensed by the Texas State Board of Medical Examiners.

Podiatrist-A podiatrist licensed by the Texas State Board of Podiatry Examiners.

Political subdivision-A county, municipality, or hospital district in this state but does not include a department, board, or agency of the state that has statewide authority and responsibilities.

Premises-Contiguous buildings at the same physical location and street address and under common direction.

Presurvey conference-A conference held with department staff and the applicant or his or her representative to review licensure rules and survey documents and provide consultation prior to the on-site licensure inspection

Psychiatric disorder-A clinically significant behavioral or psychological syndrome or pattern that occurs in an individual and that is associated with present distress (e.g., a painful syndrome) or disability (i.e , impairment in one or more important areas of functioning) or with a significantly increased risk of suffering death, pain, disability, or an important loss of freedom. This syndrome or pattern must not be merely an expectable and culturally sanctioned response to a particular event, for example, the death of a loved one. Neither deviant behavior (e.g., political, religious, or sexual) nor conflicts that are primarily between the individual and society are psychiatric disorders unless the deviance or conflict is a symptom of a dysfunction in the individual. This definition includes patients diagnosed as chemically dependent.

Psychiatric unit-A distinct part of the hospital providing, by or under the supervision of a psychiatrist, psychiatric ser-

vices for the diagnosis and treatment of mentally ill persons, and in compliance with relevant licensing rules for a psychiatric and chemical dependency unit.

Registered nurse–A person who is currently licensed by the Board of Nurse Examiners for the State of Texas as a registered nurse (RN).

Rehabilitation unit–An identifiable part of a hospital which provides comprehensive medical rehabilitation services to patients admitted to the unit

Rehabilitation hospital–A hospital which primarily provides comprehensive medical rehabilitation services.

Rubbish–Nonputrescible solid waste, excluding ashes, that consists of:

(A) combustible waste materials, including paper, rags, cartons, wood, excelsior, furniture, rubber, plastics, yard trimmings, leaves, and similar materials, and

(B) non-combustible waste materials, including glass, crockery, tin cans, aluminum cans, metal furniture, and similar materials that do not burn at ordinary incinerator temperatures (1,600 degrees Fahrenheit to 1,800 degrees Fahrenheit).

Rural area–A non-metropolitan county as defined by the United States Census Bureau in its most recent census.

Rural community–A municipality in a rural area

Special hospital–An establishment that:

(A) offers services, facilities, and beds for use for more than 24 hours for two or more unrelated individuals who are regularly admitted, treated, and discharged, and who require services more intensive than room, board, personal services, and general nursing care;

(B) has clinical laboratory facilities, X-ray facilities, a licensed pharmacy, treatment facilities, or provides other definitive medical treatment(s);

(C) has a medical staff in regular attendance; and

(D) maintains records of the clinical work performed for each patient.

Special waste from health care related facilities–Waste as defined in §1.132 of this title (relating to Definitions), which includes animal waste, bulk human blood, blood products, and body fluids, microbiological waste, pathological waste, and sharps; but does not include the items listed as exemptions in §1.133(a) of this title (relating to Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of Health).

Stabilize–The adequate evaluation and initiation of treatment to assure that transfer of a patient will not, within reasonable medical probability, result in death or loss or serious impairment of bodily functions, parts, or organs

Transfer–The movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who has been declared dead, or leaves the facility without the permission of any such person.

Under common direction–The hospital administration and governing body are responsible for all services covered by a single hospital license.

Unethical conduct–Conduct prohibited by the ethical standards adopted by state or national professional organizations for their respective professions or by rules established by the state licensing agency for the respective profession.

Unprofessional conduct–Conduct prohibited under rules adopted by the state licensing agency for the respective profession.

Vector–An agent, such as an insect, snake, rodent, bird, or animal capable of mechanically or biologically transferring a pathogen from one organism to another.

Violation–Failure to comply with hospital licensing rules. Each rule in noncompliance resulting in one patient adversely affected or each potential for or each adverse outcome counts as one violation for the assessment of administrative penalties.

§133.3. Fees.

(a) General.

(1) Non-refundable. All fees paid to the Texas Department of Health (department) are non-refundable with the exception of inspection fees for inspections that were not conducted.

(2) Payable to the department. All fees shall be paid by check or money order made payable to the Texas Department of Health.

(b) License fees.

(1) Temporary initial or renewal license fee. The fee for a temporary initial license or a renewal license is $7.00 per bed based upon the design bed capacity of the hospital. The total fee may not be less than $200 or more than $10,000.

(2) First annual license. The temporary initial license fee includes the fee for the first annual license.

(3) Additional fee. A hospital shall submit an additional fee with the notarized affidavit for final construction approval for an increase in the number of beds resulting from an approved construction project and an additional plan review fee if the construction cost increases to the next higher fee schedule according to subsection (c)(4) of this section.

(4) Refund. A hospital will not receive a refund of previously submitted fees should the hospital's bed capacity decrease as a result of an approved construction project.

(c) Plan review fees. This subsection outlines the fees which must accompany the application for plan review and all proposed plans and specifications covering the construction of new buildings or alterations to existing buildings which must be submitted for review and approval by the department in accordance with §133.91 of this title (relating to Construction Plans, Specifications, and Inspections).

(1) Architectural plans. Architectural plans will not be reviewed or approved until the required fee and an application for plan review are received by the department.

(2) Fee basis. Plan review fees are based upon the estimated construction project costs which are the total expenditures required for a proposed project from initiation to completion, including at least the following items.

(A) Physical assets. Construction project costs shall include expenditures for physical assets such as:

(i) site acquisition;

(ii) soil tests and site preparation;

(iii) construction and improvements required as a result of the project;

(iv) building, structure, or office space acquisition;

(v) renovation;

(vi) fixed equipment; and

(vii) energy provisions and alternatives.

(B) Professional services. Construction project costs shall include expenditures for professional services including:

(i) planning consultants;

(ii) architectural fees;

(iii) fees for cost estimation;

(iv) legal fees;

(v) managerial fees; and

(vi) feasibility study.

(C) Financing. Construction project costs shall include expenditures or costs associated with financing, excluding long-term interest, but including:

(i) financial advisor;

(ii) fund-raising expenses;

(iii) lender's or investment banker's fee; and

(iv) interest on interim financing.

(D) Contingencies. Construction project costs shall include expenditure allowances for contingencies including:

(i) inflation;

(ii) inaccurate estimates;

(iii) unforeseen fluctuations in the money market; and

(iv) other unforeseen expenditures.

(3) Fair market value. Regarding purchases, donations, gifts, transfers, and other comparable arrangements whereby the acquisition is to be made for no consideration or at less than the fair market value, the project cost shall be determined by the fair market value of the item to be acquired as a result of the purchase, donation, gift, transfer, or other comparable arrangement.

(4) Fee schedule. The plan review fee schedule based on cost of construction is:

(A) $600,000 or less: $500;

(B) $600,001 to 2,000,000: $1,000;

(C) $2,000,001 to 5,000,000: $1,500;

(D) $5,000,001 to 10,000,000: $2,000; and

(E) $10,000,001 and over: $3,000.

(5) Estimated cost. If an estimated construction cost cannot be established, the estimated cost shall be based on $105 per square foot. No construction project shall be increased in size, scope, or cost unless the appropriate fees are submitted with the proposed changes.

(d) Construction inspection fees. A fee of $400 and an application for construction inspection for each inspection shall be submitted in writing to the department at least three weeks prior to the anticipated inspection date. Construction inspections will not be conducted until all required fees are received by the department. If additional construction inspections of the proposed project are required by the department or requested by the hospital, the appropriate additional fees shall be submitted prior to any inspections conducted by the staff of the department.

§133.4. Applicability of This Chapter for All Facilities.

(a) License. Each license shall be issued only for the premises and persons or governmental units named in the application. A license shall not be extended to other locations for inpatient services, outpatient services, or any other services. One license shall be issued for one location only.

(b) Applicability. All existing buildings, in which health care services are provided for hospital inpatients and hospital outpatients, that are part of the required hospital's health care delivery system, and are licensed by the Texas Department of Health (department) shall comply with this chapter.

(c) Buildings containing more than one hospital. Hospital services not provided directly shall be provided through written contractual arrangements as needed to meet the requirements of this chapter.

(d) New and existing conditions. This chapter shall apply equally to new and to existing conditions except that existing conditions not in strict compliance with this chapter may be permitted to continue where the exceptions do not constitute, in the opinion of the department, any significant hazard to life or property.

(e) Psychiatric provisions. As a minimum requirement, all hospitals shall have at least one room in which patients who may become mentally disturbed can be cared for until such time as the patient can be transferred to a hospital providing psychiatric care. This requirement may also be satisfied by a special provision, such as additional staff, or other measures appropriate to meet the needs of the patients.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 14, 1995.

TRD-9503179 Susan K. Steeg
General Counsel
Texas Department of Health

Earliest possible date of adoption: April 21, 1995

For further information, please call: (512) 458-7236

Subchapter B. Application and Issuance of a Hospital License

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the offices of the Texas Department of Health or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

• 25 TAC §§133.11-133.14

The repeals are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health. Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed action.

§133.11. Application and Issuance of Temporary Initial License for First-Time Applicants.

§133.12. Issuance and Renewal of Annual License.

§133.13. Time Periods for Processing and Issuing Hospital Licenses.

§133.14. Change of Ownership or Services.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 14, 1995.

TRD-9503192 Susan K. Steeg
General Counsel
Texas Department of Health

Earliest possible date of adoption: April 21, 1995

For further information, please call: (512) 458-7236

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The new sections are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed new action.

§133.11. Application and Issuance of Temporary Initial License for First-time Applicants.

(a) General. The first application for a hospital license is an application for a temporary initial license issued by the Texas Department of Health (department). The application for a temporary initial license is also the application for the first annual license.

(b) Application submittal. Upon written request, the department shall furnish a person with an application form for a hospital license. The applicant shall submit the following to the department no more than 60 calendar days prior to the projected opening date of the hospital and shall retain a copy of all documentation that is submitted to the department.

(1) Application form. An accurate and complete application form shall be submitted.

(2) Transfer policy. The hospital shall submit a copy of the hospital's patient transfer policy which is developed in accordance with §133.111 of this title (relating to Hospital Patient Transfer) and is signed by both the chairman and secretary of the governing body attesting to:

(A) the date the policy was adopted by the governing body; and

(B) the effective date of the policy.

(3) Memorandum of transfer. A copy of the hospital's memorandum of transfer form which contains at a minimum the information described in §133.111(b)(11) of this title (relating to Hospital Patient Transfer) shall be submitted.

(4) Transfer agreements. Copies of any existing patient transfer agreements entered into between the hospital and another hospital in accordance with §133.112 of this title (relating to Hospital Patient Transfer Agreements) shall be submitted unless there is a written waiver by the hospital licensing director. If waived, the hospital shall submit a list and dates of any existing agreements.

(5) Fire inspection report. For existing facilities, a copy of an approved fire safety inspection report from the local fire authority in whose jurisdiction the hospital is based that is dated no earlier than one year prior to the hospital opening date shall be submitted. For new construction, addition, and renovation projects, written approval by the local building department and local fire authority shall be submitted during the final construction inspection by the department.

(6) License fee. The license fee shall be submitted as required in §133.3 of this title (relating to Fees).

(7) Corporation standing or tax report. If the applicant is a corporation, a current letter from the state comptroller's office stating the corporation is in good standing or a notarized certification on the license application that the tax owed to the state under the Tax Code, Texas Codes Annotated, Chapter 171, is not delinquent or that the corporation is exempt from the payment of the tax and is not subject to the Tax Code, Texas Codes Annotated, Chapter 171 shall be submitted.

(8) Accreditation. If the hospital applicant is accredited by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association, a copy of documentation from the accrediting body showing that the hospital is currently accredited shall be submitted.

(c) Disclosure requirements. An applicant shall disclose the following information for the two-year period preceding the application date, data concerning the applicant, and the real property lessors, affiliates, and managers of the applicant, without regard to whether the data required relates to current or previous events:

(1) denial, suspension, or revocation of a hospital license, a private psychiatric hospital license, or a license for any health care facility in any state;

(2) federal Medicare or state Medicaid sanctions or penalties;

(3) federal or state criminal convictions which imposed incarceration;

(4) federal or state tax liens;

(5) unsatisfied final judgements;

(6) operation of a hospital that has been decertified in any state under federal Medicare or state Medicaid;

(7) debarment, exclusion, or contract cancellation in any state from federal Medicare or state Medicaid;

(8) eviction involving any property or space used as a hospital in any state;

(9) unresolved final federal Medicare or state Medicaid audit exceptions; or

(10) injunctive orders from any court.

(d) Ownership and management information required.

(1) Disclosure. Each applicant for a hospital license shall disclose to the

department the name and business address of the following.

(A) Partnership. Each limited partner and general partner shall be disclosed if the applicant is a partnership.

(B) Corporation. Each director and officer shall be disclosed if the applicant is a corporation.

(2) Licensed hospital. If the applicant has held or holds a hospital license or has been or is an affiliate of another licensed hospital, the applicant shall disclose to the department the relationship, including the name and current or last address of the other hospital and the date such relationship commenced and, if applicable, the date it was terminated.

(3) Subsidiary. If the applicant is a subsidiary of another organization, the information shall include the names and addresses of the parent organization and the names and addresses of the officers and directors of the parent organization.

(4) Management contract. If the facility is operated by or proposed to be operated under a management contract, the names and addresses of any person and organization having an ownership interest of 5.0% or more in the management company shall be disclosed to the department.

(e) Exemptions. The provisions of subsections (c) and (d) of this section shall not apply to an applicant who is a bank, trust company, financial institution, title insurer, escrow company, or underwriter title company to which a license will be issued in a fiduciary capacity except for provisions that require disclosure relating to the manager of the hospital.

(f) Review of application. Upon receipt of the application material, the department shall review the material to determine whether it is complete. The time periods for processing an application shall be in accordance with §133.13 of this title (relating to Time Periods for Processing and Issuing Hospital Licenses). Prior to the department's issuance of a temporary initial license, the following shall be completed.

(1) Plan review and approval. The department shall have reviewed and approved preliminary and final architectural plans and specifications in accordance with §133.91 of this title (relating to Construction Plans, Specifications, and Inspections).

(2) Construction inspections. The department shall have conducted necessary preliminary inspections and a final construction inspection to determine that the hospital is constructed in accordance with this chapter.

(3) Receipt of fees. The department shall have received all plan review and construction inspection fees.

(4) Approval for occupancy. The department shall have received a copy of the approval for occupancy, a certificate of occupancy approved by the local fire authority, and issued by the city building inspector, if applicable.

(5) Final construction approval. The department shall have received a complete, accurate, and notarized affidavit for final construction approval form and the letter from the Texas Department of Licensing and Regulation approving project plans and specifications.

(6) Presurvey conference. The applicant shall have attended a presurvey conference at the office designated by the department. The designated survey office may waive the presurvey conference requirement.

(g) Issuance of temporary initial license. When the hospital has submitted the information described in subsections (b)-(d) and (f) of this section, the department shall issue the temporary initial license effective the date the hospital is determined to be in compliance with this chapter. The effective date of the temporary initial license shall not be prior to the date of the final construction inspection conducted by the department. The admission of patients for hospital services shall not commence until the hospital has been issued a temporary initial license.

(1) Duration. The department shall issue a temporary initial license which is valid for six months from the date of issuance and is not renewable. The department shall mail the temporary initial license to the licensee.

(2) Posting. The hospital shall prominently and conspicuously post for display the temporary initial license in a public area of the licensed premises that is readily visible to patients, residents, employees, and visitors.

(3) Alteration. A temporary initial license shall not be materially altered.

(4) Compliance. Continuing compliance with the minimum requirements and the provisions of this chapter is required during the temporary licensing period in order for an annual license to be issued.

(h) Withdrawal of application. If an applicant decides not to continue the application process for a temporary initial license, first annual license, or renewal of an annual license, the application may be withdrawn. If a temporary or annual license has been issued, the applicant shall return the temporary or annual license to the department with its written request to withdraw. The department shall acknowledge receipt of the request to withdraw.

(i) Denial of a license. Denial of a license shall be governed by §133.123 of this title (relating to Disciplinary Action and Emergency Order).

§133.12. Issuance and Renewal of Annual License.

(a) Issuance of first annual license. The Texas Department of Health (department) shall issue a first annual license to a hospital which meets the minimum requirements for a license contained in this chapter as determined through a health inspection to assess compliance with the provisions of this chapter relating to patient health, safety and rights or through the hospital's successful completion of an on-site inspection conducted after issuance of the temporary initial license to determine compliance with 42 Code of Federal Regulations (CFR), Part 482 (relating to Medicare Conditions of Participation for Hospitals). A hospital shall have admitted and be providing services to at least one patient in the hospital at the time of the health inspection.

(b) Duration. The first annual license supersedes the temporary initial license and shall expire one year from the date of issuance of the temporary initial license.

(1) Expiration date for license issued first day of month. If the temporary initial license was issued effective the first day of a month, the first annual license expires on the last day of the month preceding the issuance month (e.g. if a temporary initial license is effective September 1, the first annual license expires on August 31 of the next year and every year thereafter unless a change of ownership occurs).

(2) Expiration date for license issued any subsequent day of month. If the temporary initial license was issued effective the second or any subsequent day of a month, the first annual license expires on the last day of the month of issuance of the next year (e.g. if the temporary initial license is effective September 2, the first annual license expires on September 30 of the next year and every year thereafter unless a change of ownership occurs).

(c) Expiration notice. The department shall send notice of expiration to a hospital at least 60 calendar days before the expiration date of an annual license. If the hospital has not received notice of expiration from the department within 45 calendar days prior to the expiration date, it is the duty of the hospital to notify the department and request a renewal application for a license. If the hospital fails to submit the application and fee within 15 calendar days

prior to the expiration date of the license, the department shall send by certified mail to the hospital a letter advising that unless the license is renewed, the hospital must cease operations upon the expiration of the hospital's license.

(d) Renewal license. The department shall issue a renewal license to a hospital which meets the minimum requirements for a license, and which submits the following to the department postmarked no later than 30 calendar days prior to the expiration date of the license.

(1) Renewal application form. A completed and accurate renewal application form shall be submitted by the hospital.

(2) Fire inspection report. A copy of an approved fire safety inspection report from the local fire authority in whose jurisdiction the hospital is based that is dated no earlier than one year prior to the application date shall be submitted by the hospital.

(3) Renewal fee. The renewal license fee shall be submitted by the hospital.

(4) Corporation standing or tax report. If the applicant is a corporation, a current letter from the state comptroller's office stating the corporation is in good standing or a notarized certification on the licensure application that the tax owed to the state under the Tax Code, Texas Codes Annotated, Chapter 171, is not delinquent or that the corporation is exempt from the payment of the tax and is not subject to the Tax Code, Texas Codes Annotated, Chapter 171 shall be submitted.

(5) Accreditation. If the applicant is accredited by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association, the applicant shall submit a copy of documentation from the accrediting body showing the current accreditation status of the hospital.

(6) Change of ownership or services. Any changes to the information relating to the disclosure, ownership, and management requirements in §133. 11(c) and (d) of this title (relating to Application and Issuance of Temporary Initial License for First-time Applicants) shall be submitted by the hospital. The information provided shall address all changes during the most recent annual license period.

(e) Notice to cease operation and return license. If a hospital fails to submit the application, documents, and fee by the expiration date of the hospital's license, the department shall notify the hospital that it must cease operation and immediately return the license by certified mail to the department. If the hospital wishes to provide services after the expiration date of the license, it shall apply for a temporary initial license under §133.11 of this title.

(f) Altered license. An annual license shall not be materially altered.

(g) Posting. A hospital license shall be prominently and conspicuously posted for display in a public area of the licensed premise that is readily visible to patients, residents, employees, and visitors.

§133.13. Time Periods for Processing and Issuing Hospital Licenses.

(a) General.

(1) Application date. The date an application for a license, temporary initial, annual, renewal, or change of ownership is the date the application is received by the Texas Department of Health (department).

(2) Complete application for temporary initial license. An application for a temporary initial license is complete when the department has received, reviewed, and found acceptable the information described in §133.11(b)-(d) and (f) of this title (relating to Application and Issuance of Temporary Initial License for First-time Applicants).

(3) Complete application for renewal license. An application for a renewal license is complete when the department has received, reviewed, and found acceptable the information described in §133.12(d) of this title (relating to Issuance and Renewal of Annual License).

(4) Complete application for change of ownership. An application for change of ownership is complete when the department has received, reviewed, and found acceptable the information described in §133.14 of this title (relating to Change of Ownership or Services).

(b) Time periods. An application for a hospital license shall be processed in accordance with the following time periods.

(1) First time period. The first time period begins on the date the application is received. The first time period ends on the date the hospital license is issued, or, if the application is received incomplete, the period ends on the date the hospital is issued a written notice that the application is incomplete. The written notice shall describe the specific information that is required before the application is considered complete. The time period is 20 calendar days for each of the following categories: application for a temporary initial and first annual hospital license; application for change of ownership; and application for renewal of annual license.

(2) Second time period. The second time period begins on the date the last item necessary to complete the application is received and ends on the date the hospital license is issued. The time period is 20 calendar days for each of the following categories: application for temporary initial and first annual hospital licenses; application for change of ownership; and application for renewal of annual license.

(c) Reimbursement of fees.

(1) Violation of established time period. In the event the application is not processed in the time periods as stated in subsection (b) of this section, the applicant has the right to request the department to reimburse in full all filing fees paid in that particular application process. If the department does not agree that the established periods have been violated or finds that good cause existed for exceeding the established periods, the request shall be denied.

(2) Cause for exceeding time period. The following shall be considered good cause for exceeding the period established.

(A) Number of applications. The number of applications for licenses to be processed exceeds by 15% or more the number processed in the same calendar quarter the preceding year;

(B) Public or private entity. Another public or private entity utilized in the application process caused the delay.

(C) Other conditions. Other conditions existed which gave good cause for exceeding the established periods.

(d) Appeal. If the request for full reimbursement authorized by subsection (c) of this section is denied, the applicant may then appeal to the commissioner of health (commissioner) for a resolution of the dispute. The applicant shall give written notice to the commissioner requesting full reimbursement of all filing fees paid because the application was not processed within the adopted time period. The division shall submit a written report of the facts related to the processing of the application and good cause for exceeding the established time periods. The commissioner shall make the final decision and provide written notification of the decision to the applicant and the division.

(e) Contested case hearing. If at any time during the processing of the application during the second time period, a contested case hearing becomes involved, the time periods in §1.34 of this title (relating to Time Periods for Conducting Contested Case Hearing) are applicable.

§133.14. Change of Ownership or Services.

(a) Transfer or assign. No license shall be transferred or assigned.

(1) Change of ownership. A change of ownership of a hospital occurs when the name of the licensee as reflected on the original application is changed.

(2) Submission of license application. A person who desires to receive a license in its name for a hospital currently licensed under the name of another person or to change the ownership of any hospital shall submit a license application 60 calendar days prior to the desired date of change of licensure. The application shall be in accordance with §133.11 of this title (relating to the Application and Issuance of Temporary Initial License for First-time Applicants) and shall include the effective date of the new ownership.

(3) Waiver of inspection(s). The on-site construction and health inspections required by §133.11 of this title and §133.12 of this title (relating to Issuance and Renewal of Annual License) may be waived by the Texas Department of Health (department).

(4) Issuance of license. When the person has complied with the provisions of §133.11 of this title, the department shall issue a temporary initial license which shall be effective the date of the change of ownership unless the department waives the inspections in accordance with paragraph (3) of this subsection. If the inspections are waived, the department shall issue an annual license, in lieu of the temporary initial license, effective the date of the change of ownership.

(5) Surrender of license. The previous license shall be void on the effective date of the new temporary initial license or annual license and must be surrendered to the department.

(6) Corporation name change. If a corporate licensee amends its articles of incorporation to revise its name, this subsection does not apply, except that the corporation shall notify the department within five business days after the effective date of the name change.

(7) Sale of stock. The sale of stock of a corporate licensee does not cause this subsection to apply.

(8) Additional regulations. The provisions of this subsection are in addition to any applicable federal law or regulations relating to change of ownership or control.

(b) Change of telephone number. A hospital shall notify the department in writing of any change in the hospital's main telephone number within 10 calendar days.

(c) Notification requirements. A hospital shall notify the department in writing prior to, or, at the time of, the occurrence of any of the following:

(1) addition or deletion of services provided;

(2) addition or deletion of beds;

(3) request to change license classification;

(4) cessation of operation of the hospital. The temporary initial license or annual license shall be mailed or returned to the department at the end of the day hospital services are terminated;

(5) any change in certification or accreditation status; and

(6) any construction, renovation, or modification of the hospital buildings.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 14, 1995.

TRD-9503180 Susan K. Steeg
General Counsel
Texas Department of Health

Earliest possible date of adoption: April 21, 1995

For further information, please call: (512) 458-7236

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Subchapter C. Operational Requirements for All Hospitals

• 25 TAC §133.21, §133.22

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the offices of the Texas Department of Health or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeal of existing rules is proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and Section 12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395l(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed action.

§133.21. Standards-Adoption by Reference.

§133.22. Licensure Requirements and Standards for All Hospitals.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 15, 1995.

TRD-9503193 Susan K. Steeg
General Counsel
Texas Department of Health

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For further information, please call: (512) 458-7236

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Subchapter C. General Requirements for All Hospitals

• 25 TAC §§133.21-133.23

The new sections are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation ser-

vices; and Section 12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed new action.

§133.21. Patient Rights For All Hospitals.

(a) Prohibition of physical or verbal abuse, sexual exploitation, or neglect. Physical or verbal abuse, sexual exploitation, or neglect of a patient receiving hospital inpatient services or outpatient services shall be prohibited and shall be reported to the Texas Department of Health (department) .

(b) Reporting abuse or neglect. Abuse or neglect of minor patients, disabled patients, or elderly patients which occurs in the hospital shall be reported to the department immediately as required in the Family Code, Chapter 34, and the Human Resources Code, Chapter 48.

(c) Patient rights policy. A hospital shall adopt, implement, and enforce a policy to ensure the patient's rights. The written policy shall include the following.

(1) Communication with the patient. The written policy shall include a written procedure which the hospital shall follow to ensure effective communication between the patient and the physician and other hospital personnel (e.g., telecommunications device for the deaf, sign-language interpreter for the hearing impaired, taped or braille materials for the visually impaired, translators to communicate in the patient's primary language for persons with limited English proficiency).

(A) A hospital shall meet applicable requirements of the federal Rehabilitation Act of 1973, §504, which requires program accessibility as well as facility accessibility.

(B) A hospital shall comply with the United States Department of Health and Human Services, Office of Civil Rights, Requirements for Program Accessibility and Facility Accessibility, as required by the Americans with Disabilities Act (ADA), 42 United States Code, Chapter 126.

(2) Hospital's response to requests and needs of the patient. The written policy shall include the right of the patient to the hospital's reasonable response to his or her requests and needs for treatment or service, within the hospital's capacity, its stated mission, and applicable law and regulation.

(3) Considerate and respectful care. The written policy shall include the right of the patient to considerate and respectful care.

(A) Psychosocial, spiritual, and cultural consideration. The care of the patient includes consideration of the psychosocial, spiritual, and cultural variables that influence the perceptions of illness.

(B) Care of dying patient. The care of the dying patient optimizes the comfort and dignity of the patient through:

(i) treating primary and secondary symptoms that respond to treatment as desired by the patient or surrogate decision maker;

(ii) effectively managing pain; and

(iii) acknowledging the psychosocial and spiritual concerns of the patient and the family regarding dying and the expression of grief by the patient and family.

(4) Patient health care decisions. The written policy shall include the right of the patient, in collaboration with his or her physician, to make decisions involving his or her health care, to include the following.

(A) Acceptance or refusal of care or treatment. The right of the patient to accept medical care or to refuse treatment to the extent permitted by law and to be informed of the medical consequences of such refusal shall be included.

(B) Advance directives. The right of the adult patient or the patient's guardian, next of kin, or legally responsible person to formulate advance directives and to appoint a surrogate to make health care decisions on his or her behalf to the extent permitted by law shall be included. (Advance directives do not apply to children's hospitals).

(i) In formulating an advance directive, a hospital shall have in place a mechanism to ascertain the existence of and assist in the development of advance directives at the time of the patient's admission.

(ii) The provision of care shall not be conditioned on the existence of an advance directive.

(iii) If the patient has executed an advance directive, a copy shall be in the patient's medical record and shall be reviewed periodically with the patient or surrogate decision maker.

(5) Patient treatment decisions. The written policy shall include the right of the patient or the patient's guardian, next of kin, or legally responsible person to the information necessary to enable him or her to make treatment decisions that reflect his or her wishes. A policy on informed decision making shall be developed by the medical staff and governing body and shall be consistent with any legal requirements.

(6) Receipt of patient rights policy. The written policy shall include the right of the patient or the patient's guardian, next of kin, or legally responsible person to receive, at the time of admission, information about:

(A) the hospital's patient rights policies and the mechanism for the initiation, review, and when possible, resolution of patient complaints concerning the quality of care; and

(B) patient's rights for the elderly when patients are 55 years of age or older.

(7) Ethical issues. The written policy shall include the right of the patient or the patient's designated representative to participate in the consideration of ethical issues that arise in the care of the patient. The hospital shall have a mechanism for the consideration of ethical issues arising in the care of patients and to provide education to caregivers and patients on ethical issues in health care.

(8) Human experimentation or research. The written policy shall include the right of the patient or the patient's guardian, next of kin, or legally responsible person to be informed of any human experimentation or other research or educational projects affecting his or her care or treatment.

(9) Patient privacy and confidentiality. The written policy shall include the right of the patient, within the limits of law, to personal privacy and confidentiality of information.

(10) Patient access to medical records. The written policy shall include the right of the patient or the patient's legally designated representative, within the limits of the law, to access the information contained in the patient's medical record.

(11) Rights of patient's legal representative. The written policy shall include the right of the patient's guardian, next of kin, or legally authorized responsible person to exercise, to the extent permitted by law, the rights delineated on behalf of the patient if the following occurs.

(A) Incompetent. The patient's guardian, next of kin, or legally authorized responsible person shall exercise, to the extent permitted by law, the rights delineated on behalf of the patient if the patient has been adjudicated incompetent in accordance with the law.

(B) Medically incapable. The patient's guardian, next of kin, or legally responsible person shall exercise, to the extent permitted by law, the rights delineated on behalf of the patient if the patient is found by his or her physician to be medically incapable of understanding the proposed treatment or procedure.

(C) Unable to communicate. The patient's guardian, next of kin, or legally responsible person shall exercise, to the extent permitted by law, the rights delineated on behalf of the patient if the patient is unable to communicate his or her wishes regarding treatment.

(D) Minor. The patient's guardian, next of kin, or legally responsible person shall exercise, to the extent permitted by law, the rights delineated on behalf of the patient if the patient is a minor

(d) Posting requirements for patient bill of rights. The hospital's patient bill of rights shall be posted next to the hospital's license.

§133.22. Discrimination or Retaliation.

(a) Posting requirements for employees and staff protection for reporting a violation of law. Each hospital shall prominently and conspicuously post for display in a public area of the hospital that is readily visible to patients, residents, employees, and visitors a statement that employees and staff are protected from discrimination or retaliation for reporting a violation of law. The statement shall be in English and in a second language appropriate to the demographic makeup of the community served.

(b) Posting requirements for non-employees protection for reporting a violation of law. Each hospital shall prominently and conspicuously post for display in a public area of the hospital that is readily visible to patients, residents, employees, and visitors a statement that non-employees are protected from discrimination or retaliation for reporting a violation of law. The statement shall be in English and in a second language appropriate to the demographic makeup of the community served The sign may be combined with the sign required by subsection (a) of this section.

(c) Discrimination relating to employee reporting a violation of law. A hospital may not suspend or terminate the employment of, discipline, or otherwise discriminate against an employee for reporting to the employee's supervisor, an administrator of the hospital, a state regulatory agency, or a law enforcement agency a violation of law, including a violation of the Act or this chapter.

(d) Retaliation relating to non-employee reporting a violation of law. A hospital may not retaliate against a person who is not an employee for reporting a violation of law, including a violation of the Act or this chapter.

§133.23. Posting, Reporting, Investigating, and Training Requirements for Comprehensive Medical Rehabilitation, Mental Health, or Chemical Dependency Services.

(a) Posting requirements. A hospital providing comprehensive medical rehabilitation, mental health, or chemical dependency services shall prominently and conspicuously post for display in a public area or the unit of the hospital providing such services that is readily visible to patients, residents, volunteers, employees, and visitors a statement of the duty to report abuse and neglect, or illegal, unprofessional, or unethical conduct. The statement shall be in English and in a second language appropriate to the demographic makeup of the community served and contain the number of the Texas Department of Health (department) hospital patient information and complaint line at 1-800-228-1570.

(b) Reporting requirements.

(1) Reporting abuse and neglect. A person, including an employee, volunteer, or other person associated with a hospital that provides comprehensive medical rehabilitation, mental health, or chemical dependency services who reasonably believes or who knows of information that would reasonably cause a person to believe that the physical or mental health or welfare of a patient of the hospital who is receiving comprehensive medical rehabilitation, mental health, or chemical dependency services has been, is, or will be adversely affected by abuse or neglect by any person shall as soon as possible report the information supporting the belief to the department or to the appropriate state health care regulatory agency.

(2) Reporting illegal, unprofessional, or unethical conduct. An employee of or other person associated with a hospital that provides comprehensive medical rehabilitation, mental health, or chemical dependency services, including a health care professional, who reasonably believes or who knows of information that would reasonably cause a person to believe that the hospital or an employee or health care professional associated with the hospital, has, is, or will be engaged in conduct that is or might be illegal, unprofessional, or unethical and that relates to the operation of the hospital or comprehensive medical rehabilitation, mental health, or chemical dependency services provided in the hospital shall as soon as possible report the information supporting the belief to the department or to the appropriate state health care regulatory agency.

(3) Physical or verbal abuse or sexual exploitation. A complaint may include physical or verbal abuse or sexual exploitation.

(4) Additional requirements. The requirement prescribed by this section is in addition to the requirements provided by the Family Code, Chapter 34, and the Human Resources Code, Chapter 48.

(c) Investigation. Investigation of reports of abuse and neglect, or of illegal, unprofessional, or unethical conduct.

(1) Submission of complaints. A complaint made under subsection (a) of this section may be submitted in writing or verbally to the Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199, telephone, 1-800-228-1570.

(2) Other complaints. A complaint containing allegations which are a violation of the Act or this chapter shall be investigated by the department.

(3) Complaints not in violation of the Act or this chapter. The Act or this chapter not violated. A complaint containing allegations which are not a violation of the Act or this chapter will not be investigated by the department but shall be referred to law enforcement agencies or other agencies, as appropriate.

(4) Notification. The department shall inform in writing a complainant who identifies himself by name and address of the following:

(A) the receipt of the complaint;

(B) if the complainant's allegations are potential violations of the Act or this chapter warranting an investigation;

(C) whether the complaint will be investigated by the department;

(D) whether and to whom the complaint will be referred; and

(E) the findings of the complaint investigation.

(5) Referral report. The department shall request a report from each referral agency of the action taken by the agency six months after the referral

(6) Reporting health care professional to licensing board. A health care professional who fails to report abuse and neglect or illegal, unprofessional, or unethical conduct shall be referred by the department to the individual's licensing board for appropriate disciplinary action.

(d) Treatment methods advisory committee. The department shall report or forward a copy of a complaint relating to an abusive treatment method to the Treatment Methods Advisory Committee with the Texas Department of Mental Health and Mental Retardation.

(e) Memorandum of understanding (MOU) on inservice training.

(1) Inservice training requirements. The Texas Board of Mental Health and Mental Retardation, Texas Board of Health, and Texas Commission on Alcohol and Drug Abuse shall adopt a joint memorandum of understanding that requires each inpatient mental health facility, chemical dependency treatment facility, or hospital that provides comprehensive medical rehabilitation, mental health services, or chemical dependency services to annually provide as a condition of continued licensure a minimum of eight hours of inservice training designed to assist employees and health care professionals associated with the facility in identifying patient abuse and neglect, or of illegal, unprofessional, or unethical conduct by or in the facility.

(2) Compliance A hospital providing any of these services shall comply with the memorandum of understanding as specified in §401 57 of this title (relating to Training Requirements for Identifying Abuse, Neglect, and Unprofessional or Unethical Conduct in Health Care Facilities) as amended July 25, 1994.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 15, 1995.

TRD-9503181 Susan K Steeg
General Counsel
Texas Department of Health

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For further information, please call: (512) 458-7236

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Subchapter D. Requirements for General Hospitals

• 25 TAC §§133.31-133.33

The new sections are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and Section 12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note, 42 USC, Sections 1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed new action.

§133.31. All General Hospitals.

(a) Compliance. Each general hospital shall meet all requirements in this chapter and exceptions and additional requirements specified in this subchapter.

(b) Hospital location. Each general hospital shall be located in a separate building or portions of a building provided the entire building complies with the construction rules in this chapter.

(c) Emergencies Each general hospital shall have an emergency service with appropriate facilities. Each general hospital shall provide all facilities specified in §133.95(b)(6)(B) of this title (relating to Hospital Units-Spatial Requirements). Each general hospital shall comply with the provisions in §133.111 of this title (relating to Hospital Patient Transfer)

(d) Surgical services or obstetrical services. Each general hospital shall provide surgical services and surgical facilities or obstetrical services and obstetrical facilities or both When obstetrical services are provided, a newborn nursery unit shall be required.

§133.32 Hospital Services

(a) Required services. Each general hospital shall provide all services specified in this section. These services shall meet the requirements in §133 61 of this title (relating to Hospital Services) Each general hospital shall provide the following services as a minimum

(1) administrative services-governing body,

(2) anesthesia services;

(3) blood transfusion services;

(4) emergency services,

(5) food and dietetic services;

(6) infection control;

(7) laboratory services;

(8) linen and laundry services;

(9) medical record services,

(10) medical staff;

(11) nursing services;

(12) pharmacy services,

(13) physical environment,

(14) quality assurance;

(15) radiology services,

(16) social services;

(17) sterilization and sterile supplies;

(18) surgical services or obstetrical services or both; and

(19) waste and waste disposal.

(b) Optional Services A general hospital may also elect to provide optional services If a general hospital provides services specified in §133. 61 of this title, the requirements in that section for those services shall be met

§133.33. Hospital Units-Spatial Requirements.

(a) Unit requirements. Each general hospital shall contain all elements and spatial requirements specified in this section. A general hospital shall also contain facilities for surgery or obstetrical care or both. Elements and spatial requirements shall meet the requirements in §133.95 of this title (relating to Hospital Units-Spatial Requirements). A general hospital shall contain the following elements and spatial requirements as a minimum:

(1) administration and public areas;

(2) facilities for cleaning and sanitizing carts;

(3) central supply department when surgical services or obstetrical services are provided;

(4) dietary facilities;

(5) emergency department or treatment room;

(6) employee facilities;

(7) engineering service and equipment areas;

(8) general stores;

(9) janitor closets;

(10) laboratory suite;

(11) laundry;

(12) medical records unit;

(13) morgue or ventilated room;

(14) newborn nursery unit when obstetrical services are provided;

(15) nursing unit;

(16) pharmacy suite;

(17) radiology suite;

(18) surgical facilities or obstetrical facilities or both; and

(19) waste processing and storage facilities.

(b) Optional units. A general hospital may also elect to provide optional services and facilities in addition to those specified as minimum requirements. When facilities specified in §133.95 of this title are provided within the general hospital, elements and spatial requirements in that section for those facilities shall be met.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 15, 1995.

TRD-9503182 Susan K. Steeg
General Counsel
Texas Department of Health

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Subchapter E. Requirements for Special Hospitals

• 25 TAC §§133.41-133.49

The new sections are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and Section 12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395lt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed new action.

§133.41. All Special Hospitals.

(a) Compliance. Each special hospital shall meet all requirements in this chapter and exceptions and additional requirements specified in this subchapter.

(b) Hospital location. Each special hospital shall be located in a separate building or portions of a building provided the entire building complies with the construction rules in this chapter.

(c) Essential electrical system. Essential electrical distribution systems in each special hospital shall conform to requirements of a Type II system described in National Fire Protection Association (NFPA) 99 which the department adopts by reference in §133.100(b)(1)(M) of this title (relating to Codes and Standards).

(d) Emergencies. Each special hospital shall have an emergency service with appropriate facilities. As a minimum, at least one room which the requirements in §133.95(b)(6)(B)(iv) of this title (relating to Hospital Units-Spatial Requirements) shall be designated for the reception, examination, and initial treatment of emergency patients. Each special hospital shall comply with the provisions in §133.111 of this title (relating to Hospital Patient Transfer).

(e) Surgical services. A special hospital shall not provide surgical services or surgical facilities.

(f) Hospital services. Each special hospital shall provide all services specified in this section. These services shall meet the requirements in §133.61 of this title (relating to Hospital Services). Exceptions and additional requirements specified in this subchapter shall be met. A special hospital may also elect to provide optional services. If a special hospital provides services specified in §133.61 of this title, the requirements in that section for those services shall be met. Each special hospital shall provide the following services as a minimum:

(1) administrative services-governing body;

(2) blood transfusion services;

(3) emergency services;

(4) food and dietetic services;

(5) infection control;

(6) laboratory services;

(7) linen and laundry services;

(8) medical record services;

(9) medical staff;

(10) nursing services;

(11) pharmacy services;

(12) physical environment;

(13) quality assurance;

(14) radiology services;

(15) social services;

(16) sterilization and sterile supplies; and

(17) waste and waste disposal.

(g) Unit requirements. Each special hospital shall contain all elements and spa-

tial requirements specified in this section. Elements and spatial requirements shall meet the requirements in §133.95 of this title. Exceptions and additional requirements specified in this subchapter shall be met. A special hospital may also elect to provide optional services and facilities in addition to those specified as minimum requirements. When facilities specified in §133.95 of this title are provided within the special hospital, elements and spatial requirements in that section for those facilities shall be met. Each special hospital shall contain the following elements and spatial requirements as a minimum:

(1) administration and public areas;

(2) facilities for cleaning and sanitizing carts;

(3) dietary facilities;

(4) emergency department or treatment room;

(5) employee facilities;

(6) engineering service and equipment areas;

(7) general stores;

(8) janitor closets;

(9) laboratory suite;

(10) laundry;

(11) medical records unit;

(12) morgue or ventilated room;

(13) nursing unit;

(14) pharmacy suite;

(15) radiology suite; and

(16) waste processing and storage facilities

§133.42. Special Hospital-College Infirmary. A hospital operated by a college or university for the exclusive use of students enrolled in that college or university, shall comply with the following.

(1) Staff. The hospital shall have on the staff one or more physicians qualified by training and experience in internal medicine or family medicine.

(2) Radiology services. Radiology services shall be provided to meet the needs of patients. Radiology services may be provided on-site within the infirmary or through a written contractual arrangement. Portable X-ray equipment may be acceptable as a minimum requirement when radiology services are provided in the infirmary.

(3) Transfer agreement. The hospital shall have an agreement in writing with an appropriately licensed general hospital permitting the prompt transfer to and the admission by the receiving hospital of any patient when special services are needed but are unavailable at the college infirmary.

(4) Ancillary services. Ancillary services (such as, but not limited to, dietary, pharmacy, laboratory) shall be provided within the infirmary or on the campus of each college.

(5) Nursing units. Multipurpose room(s) for staff and patient conferences, education, demonstrations, and consultation may be omitted.

(6) Code classification. College infirmaries shall conform to the requirements of an Ambulatory Health Care Center listed in National Fire Protection Association (NFPA) 101, Chapter 12, for new facilities and Chapter 13 for existing facilities. The following exceptions shall be met.

(A) Corridors. The minimum corridor width shall be five feet in all public, patient sleeping, and outpatient areas.

(B) Doors. Doors in means of egress and doors to treatment rooms and sleeping rooms shall be not less than 36 inches in width.

(7) Electrical requirements. Stand-by electrical services supplied by an engine-driven generator set(s) may be deleted if provisions of NFPA 101, Chapter 12, §12-6.2.9. Emergency Lighting and Essential Electrical Systems, are met.

§133.43. Special Hospital-Comprehensive Medical Rehabilitation. A hospital providing primarily comprehensive medical rehabilitation services shall comply with all requirements in §133.62 of this title (relating to Comprehensive Medical Rehabilitation Services).

§133.44. Special Hospital-Contagious Disease and Terminally Ill Patients. Hospitals specializing exclusively in the care of persons who have, or are suspected of having, infectious, contagious, communicable, or terminal disease shall have on staff one or more physicians qualified by training and experience in the diagnosis and treatment of diseases and terminally ill patients in accordance with medical staff bylaws.

§133.45. Special Hospital-Convalescent, Non-comprehensive Rehabilitation and Extended Care. A hospital providing only specialized medical and nursing care for patients convalescing from illness or injury or requiring extended care or rehabilitation, which is not comprehensive, from illness or injury, and excluding surgical or maternity patients shall comply with the following.

(1) Staff.

(A) The hospital shall have on the staff one or more physicians qualified by training and experience in internal medicine or family medicine in accordance with medical staff bylaws.

(B) The hospital shall have on the staff or on a consultative basis one or more licensed physical therapists.

(2) Physical therapy facilities and equipment. There shall be adequate physical therapy facilities and equipment to meet the needs of those patients requiring physical therapy, including as a minimum:

(A) wheel chairs;

(B) crutches;

(C) walking bars; and

(D) heat therapy equipment.

(3) Radiology services. The hospital shall provide radiology services. Portable X-ray equipment may be acceptable as a minimum requirement.

(4) Transfer agreement. The hospital shall have an agreement in writing with an appropriately licensed general hospital permitting the prompt transfer to and the admission by the receiving hospital of any patient when special services are needed but are unavailable at the special convalescent, non-comprehensive rehabilitation, extended care hospital.

(5) Special provision for psychiatric patients. Psychiatric patients shall be housed in a separate unit meeting licensure rules if psychiatric disordered patients are admitted. At the minimum, each hospital shall have at least one room equipped as a psychiatric unit in which patients who may become mentally disturbed can be cared for until such time as the patient can be transferred to a hospital providing psychiatric care.

§133.46. Special Hospital-Essential Access Community Services. Hospitals providing rural health care services as a designated essential access community hospital under 42 United States Code (USC), §1395i-4 shall comply with the following.

(1) Location.

(A) Rural area. The hospital shall be located in a rural area, as defined in 42 USC, §1395ww(d)(2)(D).

(B) Distance. The hospital shall be more than 35 miles from any other hospital or any hospital that either:

(i) has been designated as an essential access community hospital,

(ii) is classified by the Secretary of the United States Department of Health and Human Services (secretary) as a rural referral center under 42 USC, §1395ww(d)(5)(C); or

(iii) is located in an urban area that meets the criteria for classification as a regional referral center under 42 Code of Federal Regulations (CFR) Part 400, §412.96.

(C) Geographic location. The hospital shall be at a location which meets such other criteria relating to geographic location as the state may impose with the approval of the secretary.

(2) Beds. The hospital shall have at least 75 inpatient beds.

(3) Emergency services agreement. The hospital shall have in effect an agreement to provide emergency and medical backup services for rural primary care hospitals participating in the rural health network of which it is a member and throughout its service area.

(4) Transfer agreement. The hospital shall have in effect an agreement with each rural primary care hospital participating in the rural health network of which it is a member to accept patients transferred from the primary care hospital, to receive data from and transmit data to the primary care hospital, and to provide medical staff membership and privileges to physicians providing care at the primary care hospital through the hospital's credential and peer review process.

(5) Other requirements. The hospital shall meet any other requirements imposed by the state with the approval of the secretary.

§133.47. Special Hospital-Medical Only. Hospitals providing only specialized services for diagnosis, treatment, and therapy, exclusive of admissions of actually injured or surgical patients, shall comply with the following.

(1) Staff. The hospital shall have on the staff one or more physicians qualified by training and experience in internal medicine or family medicine in accordance with medical staff bylaws.

(2) Radiology services. The hospital shall provide radiology services. Portable X-ray equipment may be acceptable as a minimum requirement.

(3) Transfer agreement. The hospital shall have an agreement in writing with an appropriately licensed hospital permitting the prompt transfer to and the admission by the receiving hospital of any patient when special services are needed but are unavailable at the special hospital.

§133.48. Special Hospital-Pediatric and Adolescent Only Hospitals providing specialized services for the diagnosis and treatment of pediatric and adolescent patients shall have on staff one or more physicians qualified by training and experience in the diagnosis and treatment of diseases of children in accordance with medical staff bylaws.

§133.49. Special Hospital-Rural Primary Care Services. Hospitals providing rural primary care services as a designated rural primary care hospital under 42 United States Code (USC), §1395i-4 shall comply with the following.

(1) Location. The hospital shall be located in one of the following areas.

(A) Rural area. The hospital shall be located in a rural area, as defined in 42 USC, §1395ww(d)(2)(D).

(B) Geographic area. The hospital shall be located in a county whose geographic area is substantially larger than the average geographic area for urban counties in the United States and whose hospital service area is characteristic of service areas of hospitals located in rural areas.

(2) Medicare agreement. The hospital shall have entered into a Medicare participation agreement (or, in the case of a hospital that closed during the 12-month period that ends on the date the hospital applies for such designation, at the time the hospital closed) and not been found to be in violation of any Medicare hospital condition of participation.

(3) Inpatient care agreement. The hospital shall have ceased, or agrees, upon approval of its request to be designated a rural primary care hospital, to cease providing inpatient care except as required by paragraph (6) of this section.

(4) Network communications system agreement. The hospital shall have in effect an agreement to participate with other hospitals and facilities in a communications system, including electronic sharing of patient data, telemetry, and medical records, if the hospital is a member of a rural health network and the network has a communications system in operation.

(5) Emergency services. The hospital shall make available 24-hour emergency care.

(6) Inpatient services. The hospital shall provide not more than six inpatient beds for providing inpatient care for a period not to exceed 72 hours, unless a longer period is required because transfer to another hospital is precluded because of inclement weather or other emergency conditions, to patients requiring stabilization before discharge or transfer to another hospital.

(7) Staffing. The hospital shall meet the staffing requirements applicable to rural hospitals under 50 beds under 42 USC, §1395x(e), except the following.

(A) Hours of operation. The hospital need not meet hospital rules relating to the number of hours during a day, or days during a week, in which the hospital must be open, except as required to provide emergency care on a 24-hours a day basis under paragraph (5) of this section.

(B) Ancillary services. The hospital may provide any services otherwise required to be provided by a full-time, on-site dietitian, pharmacist, laboratory technician, medical technologist, and radiological technologist on a part-time, off-site basis.

(C) Staff providing inpatient services. The inpatient care may be provided by a physician's assistant or nurse practitioner, subject to the supervision by a physician. A registered nurse or licensed vocational nurse shall be on duty when the hospital has one or more inpatients.

(8) Federal requirements. The hospital shall meet the requirements of subparagraphs (C)-(J) of 42 USC §1395x(aa).

(A) Medical records. The hospital shall maintain medical records on all patients.

(B) Transfer agreement. The hospital shall have arrangements with one or more hospitals, having agreements in effect under 42 USC §1395cc, for referral and admission of patients requiring inpatient services or such diagnostic or other specialized services which are not available at the special hospital.

(C) Written policies. The hospital shall have written policies which are developed with the advice of (and with provision for review of such policies from time to time by) a group of professional personnel, including one or more physicians and one or more physician assistants or nurse practitioners, to govern rural health clinic services described in 42 USC §1395x(aa).

(D) Execution of policies. The hospital shall have a physician, physician assistant, or nurse practitioner responsible for the execution of policies described in subparagraph (C) of this paragraph and relating to the provision of the hospital's services.

(E) Diagnostic services. The hospital shall directly provide routine diagnostic services, including clinical laboratory services, as prescribed in regulations by the United States Secretary of Health and Human Services (secretary), and have prompt access to additional diagnostic services from facilities meeting requirements under Title XVIII of the Social Security Act (42 USC §§1395 et seq). A hospital that provides laboratory services shall comply with federal Public Law 100-578, CLIA 1988, in accordance with the requirements specified in 42 Code of Federal Regulations (CFR) Part 493. CLIA 1988 applies to all hospitals with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. The requirements of §133. 61(g) of this title (relating to Hospital Services) shall also be met.

(F) Evaluation and quality assurance.

(i) The hospital shall have appropriate procedures for review, at least annually, of utilization of hospital services furnished to patients by the institution and by members of the medical staff.

(ii) The hospital shall have an effective quality assurance (QA) program to evaluate the quality and appropriateness of diagnosis and treatment furnished by the institution and by members of the medical staff, and services furnished by contractors. Nosocomial infections and medication therapy shall be evaluated. The QA program shall be on-going and have a written plan of implementation. The hospital shall take and document appropriate remedial action to address deficiencies found through the QA program. The hospital shall document the outcome of remedial action.

(G) Drugs and biologicals. The hospital shall maintain compliance with federal and state laws, have available for administering to patients of the hospital at least such drugs and biologicals as are determined to be necessary for the treatment of emergency cases, and have appropriate procedures or arrangements for storing, administering, and dispensing any drugs and biologicals.

(H) Blood and blood products. The hospital shall provide, either directly or under written arrangements, the following:

(i) services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on 24 hours a day basis;

(ii) blood storage facilities that meet the requirements of 42 CFR Part 493, Subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement shall be approved by the hospital's medical staff and by the persons directly responsible for the operation of the facility; and

(iii) the requirements in §133.61(c) of this title shall be met.

(I) Credentialed staffing requirements. The hospital shall have a nurse practitioner, a physician assistant, or a certified nurse-midwife as defined in 42 USC §1395x(gg) available to furnish patient care services not less than 50% of the time the hospital is in operation.

(J) Medicare billing agreement. The hospital shall have filed an agreement by which the hospital agrees not to charge any individual or other person for items or services for which such individual is entitled to have payment made under Title XVIII of the Social Security Act (42 USC §1395 et seq) except for the amount of any deductible or coinsurance amount imposed with respect to such items or services (not in excess of the amount customarily charged for such items and services by such hospital), pursuant to 42 USC §1351(a) and (b).

(K) Rehabilitation and psychiatric services. The hospital shall not be a rehabilitation facility or a facility which is primarily for the care and treatment of mental diseases.

(L) Health care services. The hospital shall provide hospital and other health care services, as determined appropriate by the hospital governing board, including but not limited to:

(i) outpatient diagnostic and therapeutic services;

(ii) rural health clinic services;

(iii) swing-bed services;

(iv) long-term care; or

(v) home health services.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt

Issued in Austin, Texas, on March 15, 1995.

TRD-9503183 Susan K. Steeg
General Counsel
Texas Department of Health

Earliest possible date of adoption: April 21, 1995

For further information, please call: (512) 458-7236

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Subchapter D. Special Service Requirements

• 25 TAC §§133.51-133.54

(Editor's note. The text of the following sections proposed for repeal will not be published. The sections may be examined in the offices of the Texas Department of Health or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, Sections 1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886,

1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395l(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed action

§133.51. Standard for the Provision of Comprehensive Medical Rehabilitation Services.

§133.52. Standards for the Provision of Mental Health Services in an Identifiable Part of Hospital.

§133.53. Standards for the Provision of Chemical Dependency Services in an Identifiable Part of a Hospital.

§133 54. Standards for Hospitals Providing Comprehensive Medical Rehabilitation, Mental Health, or Chemical Dependency Services.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt

Issued in Austin, Texas, on March 15, 1995.

TRD-9503194 Susan K Steeg
General Counsel
Texas Department of Health

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For further information, please call: (512) 458-7236

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Subchapter F. Requirements for Hospital Services

• 25 TAC §§133.61-133.64

The new sections are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and Section 12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed new action.

§133.61. Hospital Services.

(a) Administrative services-governing body. The hospital shall have an effective governing body legally responsible for the conduct of the hospital as an institution. However, if a hospital does not have an organized governing body, the person(s) legally responsible for the conduct of the hospital shall carry out the functions that pertain to the governing body. Written records of governing body meetings shall be maintained.

(1) Medical staff.

(A) Eligible practitioners. The governing body shall determine, in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff.

(B) Appointments. The governing body shall appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.

(C) Approve and ensure bylaws. The governing body shall ensure that the medical staff has current bylaws, rules, and regulations which are implemented and enforced. The governing body shall approve medical staff bylaws and other medical staff rules and regulations.

(D) Accountability. The governing body shall ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

(E) Criteria. The governing body shall ensure that criteria for selection are individual character, competence, training, experience, and judgment.

(F) Professional privileges. The governing body shall ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society.

(2) Hospital administration. The governing body shall appoint a chief executive officer (CEO) or hospital administrator who is responsible for managing the hospital.

(3) Care of patient. In accordance with hospital policy, the governing body shall ensure that the following are met.

(A) Patient care. As appropriate, every patient shall be under the care of:

(i) a doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under state law or the state's regulatory mechanism);

(ii) a doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the state and who is acting within the scope of his or her license; or

(iii) a doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the state to perform.

(B) Admissions. Patients shall be admitted to the hospital only on the recommendation of a licensed practitioner permitted by the state to admit patients to a hospital.

(C) Physician on-call. A doctor of medicine or osteopathy shall be on duty or on-call at all times.

(D) Scope of practice. A doctor of medicine or osteopathy shall be responsible for the care of each patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization and that is not specifically within the scope of practice, as defined by the medical staff and permitted by state law, of any of the practitioners specified in subparagraph (A)(ii) or (iii) of this paragraph.

(4) Determination of death and autopsy reports. The hospital shall establish written protocols to be used in determining death and for filing autopsy reports which comply with Health and Safety Code (HSC), Title 8, Subtitle A, Chapter 671 (relating to Determination of Death and Autopsy Reports).

(5) Organ and tissue donors. The hospital shall establish a written protocol to identify potential organ and tissue donors which is in compliance with the Texas Anatomical Gift Act, HSC, Chapter 692. The hospital shall make its protocol available to the public during the hospital's normal business hours.

(A) Hospital protocol. The hospital's protocol shall include all requirements in HSC, Chapter 692, §692.103 (relating to Hospital Protocol).

(B) Network. In the case of a hospital in which organ transplants are performed, the hospital shall be a member of the Organ Procurement and Transplantation Network.

(6) Institutional plan and budget. The institution shall have an overall institutional plan that meets the following conditions.

(A) Annual budget. The plan shall include an annual operating budget that is prepared according to generally accepted accounting principles.

(B) Income and expenses. The budget shall include all anticipated income and expenses. This provision does not require that the budget identify item-by-item the components of each anticipated income and expense.

(C) Capital expenditures. The plan shall provide for capital expenditures for at least a three-year period including the year in which the operating budget specified in subparagraph (B) of this paragraph is applicable.

(D) Objective and source of financing. The plan shall include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 that related to any of the following:

(i) acquisition of land;

(ii) improvement of land, building and equipment; or

(iii) the replacement, modernization and expansion of building and equipment.

(E) Annual review. The plan shall be reviewed and updated annually.

(F) Plan preparation. The plan shall be prepared:

(i) under the direction of the governing body; and

(ii) by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.

(7) Contracted services. The governing body shall be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body shall ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable rules and standards for contracted services.

(A) Provision of services. The governing body shall ensure that the services performed under a contract are provided in a safe and effective manner.

(B) List. The hospital shall maintain a list of all contracted services, including the scope and nature of the services provided.

(8) Emergency services.

(A) Compliance. The hospital shall comply with the requirements of subsection (d) of this section (relating to Emergency Services).

(B) Appraisal and referral. The governing body shall ensure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

(9) Disaster preparedness. A hospital shall adopt, implement, and enforce a written policy for publicly known natural disaster preparedness for the reception, treatment, and disposition of casualties from a single catastrophe.

(A) The written policy shall be developed through a joint effort of the hospital governing body, administration, medical staff, and hospital personnel.

(B) The written policy shall include a plan for the reasonable mechanism for triaging patients, the notification of appropriate personnel and patients in the event of a disaster, the identification of appropriate community resources, and the identification of possible evacuation procedures.

(C) The written policy shall include the applicable information contained in the National Fire Protection Association (NFPA) 99, Annex 1, Health Care Emergency Preparedness, which the department adopts by reference in §133.100(b)(1)(M) of this title (relating to Codes and Standards) and the State of Texas Emergency Management Plan and applicable annexes and appendices which the department adopts by reference in §133.100(b)(3)(U) of this title. (Information regarding the State of Texas Emergency Management Plan is available from the city or county Emergency Management Coordinator).

(10) Illegal remuneration. The governing body shall adopt, implement, and enforce a policy to ensure that the hospital shall not violate the Health and Safety Code (HSC), Chapter 161, Subchapter I (relating to Illegal Remuneration).

(11) Itemized statements of billed services. The governing body shall adopt, implement, and enforce a policy to ensure that the hospital shall comply with the HSC, Chapter 311, §§311.002-311.0025 (relating to Powers and Duties of Hospitals).

(b) Anesthesia services. If the hospital furnishes anesthesia services, these services shall be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The services are responsible for all anesthesia administered in the hospital.

(1) Organization and staffing. The organization of anesthesia services shall be appropriate to the scope of the services offered. Anesthesia shall be administered only by:

(A) a qualified anesthesiologist;

(B) a doctor of medicine or osteopathy (other than an anesthesiologist);

(C) a dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under state law; or

(D) a certified registered nurse anesthetist who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed.

(2) Delivery of services. Anesthesia services shall be consistent with needs and resources. Policies on anesthesia procedures shall include the delineation of

pre-anesthesia and post-anesthesia responsibilities. The policies shall ensure that the following are provided for each patient.

(A) Pre-anesthesia evaluation. A pre-anesthesia evaluation by an individual qualified to administer anesthesia under paragraph (1) of this subsection shall be performed within 48 hours prior to surgery.

(B) Intraoperative record. An intraoperative anesthesia record shall be provided which includes any complications or problems occurring during the anesthesia including time, description of symptoms, review of affected systems, and treatments rendered. The intraoperative anesthesia record shall correlate with the controlled substance administration record.

(C) Post-anesthesia report. A post-anesthesia follow-up report shall be written by the person administering the anesthesia before transferring the patient from the recovery room and shall include evaluation for recovery from anesthesia, level of activity, respiration, blood pressure, level of consciousness, and patient color.

(D) Post-anesthesia evaluation

(i) Inpatients. With respect to inpatients, a post-anesthesia evaluation for proper anesthesia recovery shall be performed after transfer from recovery and within 48 hours after surgery by the person administering the anesthesia, registered nurse (RN), or physician in accordance with policies and procedures approved by the medical staff and using criteria written in the medical staff bylaws for post-operative monitoring of anesthesia

(ii) Outpatients. With respect to outpatients, immediately prior to discharge, a post-anesthesia evaluation for proper anesthesia recovery shall be performed by the person administering the anesthesia, RN, or physician in accordance with policies and procedures approved by the medical staff and using criteria written in the medical staff bylaws for post-operative monitoring of anesthesia.

(c) Blood transfusion services.

(1) For emergencies on a 24-hours a day basis, the hospital shall:

(A) directly provide a minimum supply of blood or blood products;

(B) contract with blood banks or other institutions to obtain blood or blood products in the most expedient manner available;

(C) in the absence of an immediately available blood or blood products supply, have written policies for obtaining blood or blood products in a reasonable time frame; or

(D) in the absence of blood or blood products, have a supply of plasma expanders available.

(2) Blood storage facilities shall meet the requirements of 42 Code of Federal Regulations (CFR) Part 493, Subpart K, and shall be under the control and supervision of a pathologist or other doctor of medicine or osteopathy qualified by experience or training or both in immunohematology, transfusion services, and bloodbanking.

(3) A hospital that provides blood transfusion services shall comply with the American Association of Blood Banks, Technical Manual and Standards for Blood Banks and Transfusion Services, Fifteenth Edition, 1993 which the department adopts by reference in §133.100(b)(1)(B) of this title.

(4) A hospital that provides blood transfusion services shall comply with federal Public Law 100-578, Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988), in accordance with the requirements specified in 42 CFR Part 493.

(5) A hospital that contracts with a blood bank or other institution shall ensure that all transfusion services and laboratory services are performed in a facility certified in the appropriate specialties and subspecialties of service in accordance with the requirements in 42 CFR Part 493 to comply with CLIA 1988.

(6) If bloodbanking and transfusion services are provided under a written contractual arrangement, the arrangement shall be approved by the hospital medical staff and by the person(s) directly responsible for the operation of the facility.

(d) Emergency services. The hospital shall meet the emergency needs of patients in accordance with acceptable standards of practice.

(1) First aid and emergency care.

(A) Facilities. Hospitals shall have an emergency service with appropriate facilities. At least one room shall be designated for the reception, examination, and initial treatment of emergency patients. This room shall be independent of the operating room suite.

(B) Supplies and equipment Adequate supplies and equipment shall be available and in readiness for use. Facilities shall be available for the administration of blood, blood products, and intravenous medications as well as facilities for the control of bleeding and emergency splinting of fractures. The emergency equipment shall be periodically tested according to the policy established by the hospital.

(C) Required emergency equipment. At a minimum, the emergency equipment and supplies shall include the following:

(i) emergency call system;

(ii) oxygen;

(iii) mechanical ventilatory assistance equipment, including airways, manual breathing bag, and mask;

(iv) cardiac defibrillator;

(v) cardiac monitoring equipment;

(vi) laryngoscopes and endotracheal tubes;

(vii) suction equipment;

(viii) emergency drugs and supplies specified by the medical staff; and

(ix) supplies and equipment for obstetrical emergencies.

(2) Psychiatric services. Psychiatric services provided in the emergency department shall conform to the standards identified in §133.63 of this title (relating to Mental Health Services in an Identifiable Part of the Hospital).

(3) Organization and direction. The organization of the emergency services shall be appropriate to the scope of the services offered.

(A) Direction. The services shall be organized under the direction of a qualified member of the medical staff.

(B) Integration. The services shall be integrated with other departments of the hospital.

(C) Medical care. The policies and procedures governing acceptance of emergency patients and medical care provided in the emergency service or department shall be established by and shall be a continuing responsibility of the medical staff.

(D) Medical records. Medical records indicating patient identification,

complaint, physician, nurse, time admitted to the emergency room, treatment, time discharged, and disposition shall be maintained for all emergency patients.

(4) Personnel.

(A) Physicians. The hospital shall provide that one or more physicians shall be available at all times for emergencies.

(B) Emergency services supervision. The emergency services shall be supervised by a qualified member of the medical staff.

(C) Medical and nursing personnel.

(i) There shall be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the hospital.

(ii) There shall be on duty at all times at least one person qualified to initiate immediate appropriate lifesaving measures.

(D) Schedules. Schedules, names, and telephone numbers of all physicians and others on emergency call duty, including alternates, shall be maintained. Schedules shall be retained for no less than one year.

(e) Food and dietetic services. The hospital shall have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this requirement if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum requirements specified in this section, and provides for constant liaison with the hospital medical staff for recommendations of dietetic policies affecting patient treatment. The hospital shall ensure that there are sufficient personnel to respond to the dietary needs of the patient population being served.

(1) Organization.

(A) Full-time employee. The hospital shall have a full-time employee who:

(i) serves as director of the food and dietetic service;

(ii) is responsible for the daily management of the dietary services; and

(iii) is qualified by experience or training.

(B) Dietitian. There shall be a qualified dietitian, full-time, part-time, or on a consultant basis. If by consultation, such services shall occur at least once per month for not less than eight hours. The dietitian shall:

(i) be currently licensed under the laws of this state to use the titles of licensed dietitian or provisional licensed dietitian, or be a registered dietitian;

(ii) maintain standards for professional practice;

(iii) supervise the nutritional aspects of patient care;

(iv) make an assessment of the nutritional status and adequacy of nutritional regimen;

(v) provide diet counseling and teaching;

(vi) document nutritional status and pertinent information in patient medical records;

(vii) approve menus; and

(viii) approve menu substitutions.

(C) Administrative and technical personnel. There shall be administrative and technical personnel competent in their respective duties. The administrative and technical personnel shall:

(i) participate in established departmental or hospital training pertinent to assigned duties;

(ii) conform to food handling techniques as adopted by reference in paragraph (2)(E)(vii) and (viii) of this subsection;

(iii) adhere to clearly defined work schedules and assignment sheets; and

(iv) comply with position descriptions which are job specific.

(2) Director.

(A) Comply. The director shall comply with a position description which is job specific.

(B) Delineate. The director shall clearly delineate responsibility and authority.

(C) Participate. The director shall participate in conferences with administration and department heads.

(D) Establish. The director shall establish, implement, and enforce policies and procedures for the overall operational components of the department to include, but not limited to:

(i) quality assurance program;

(ii) frequency of meals served;

(iii) non-routine occurrences; and

(iv) identification system for patient trays.

(E) Maintain authority. The director shall maintain authority and responsibility for the following, but not limited to:

(i) orientation and training;

(ii) performance evaluations;

(iii) work assignments;

(iv) supervision of work and food handling techniques;

(v) procurement of food, paper, chemical, and other supplies, to include implementation of first-in first-out rotation system for food items in the dry and canned food areas;

(vi) menu planning;

(vii) ensuring compliance with §§229.161-229.171 of this title (relating to Food Service Sanitation); and

(viii) ensuring compliance with United States Department of Health and Human Services, Public Health Service, Food and Drug Administration, Food Service Sanitation Manual, Department of Health, Education, and Welfare Publication Number (FDA) 78-2081, 1976 edition which the department adopts by reference in this section.

(3) Diets. Menus shall meet the needs of the patients.

(A) Therapeutic. Therapeutic diets shall be prescribed by the practitioner or practitioners responsible for the care of the patients. The dietary department of the hospital shall:

(i) establish procedures for the processing of therapeutic diets to include, but not limited to:

(I) accurate patient identification;

(II) transcription from nursing to dietary services;

(III) diet planning by a dietitian;

(IV) regular review and updating of diet when necessary; and

(V) written and verbal instruction to patient and family in the patient's primary language prior to discharge;

(ii) ensure that therapeutic diets are planned in writing by a qualified dietitian;

(iii) ensure that menu substitutions are approved by a qualified dietitian;

(iv) document pertinent information about the patient's response to a therapeutic diet in the medical record; and

(v) evaluate therapeutic diets for nutritional adequacy.

(B) Nutritional needs. Nutritional needs shall be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients. The following requirements shall be met.

(i) Menus shall provide a sufficient variety of foods served in adequate amounts at each meal to satisfy the Recommended Dietary Allowances (RDA) in compliance with the following publications which the department adopts by reference in this section:

(I) Food and Nutrition Board, National Research Council, Tenth Edition, 1989 (relating to Recommended Dietary Allowances);

(II) The Food Guide Pyramid, 1993 Revision (relating to Dietary Guidelines); and

(III) Nutrition and Your Health: Dietary Guidelines for Americans, Third Edition, 1990.

(ii) A different written menu shall be followed each day of the week with at least three meals per day, seven days per week. The menu shall be posted in the food preparation area.

(iii) A maximum of 15 hours shall not be exceeded between the last meal of the day (i.e. supper) and the breakfast meal, unless a substantial snack is provided. The hospital shall adopt, implement, and enforce a policy on the definition of "substantial" to meet each patient's varied nutritional needs.

(iv) Current and previous menus shall meet the recommended allowances as addressed in The Food Guide Pyramid adopted by reference in clause (i) of this subparagraph that include:

(I) fats, oils, and sweets used sparingly;

(II) 2-3 servings of the milk, yogurt, and cheese group;

(III) 2-3 servings of the meat, poultry, fish, dry beans, eggs, and nuts group;

(IV) 3-5 servings of the vegetable group;

(V) 2-4 servings of the fruit group; and

(VI) 6-11 servings of the bread, cereal, rice, and pasta group.

(C) Therapeutic diet manual. A current therapeutic diet manual approved by the dietitian and medical staff shall be readily available to all medical, nursing, and food service personnel. The therapeutic manual shall:

(i) be revised as needed, not to exceed 5 years;

(ii) be appropriate for the diets routinely ordered in the hospital;

(iii) have standards in compliance with the RDA;

(iv) contain specific diets which are not in compliance with RDA; and

(v) be used as a guide for ordering and serving diets.

(f) Infection control. The hospital shall provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There shall be an active program for the prevention, control, and investigation of infections and communicable diseases.

(1) Organization and policies. A person or persons shall be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

(A) System. The infection control officer or officers shall develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

(B) Log. The infection control officer or officers shall maintain a log of incidents related to infections and communicable diseases.

(C) Reporting. The infection control officer or officers shall report all reportable diseases to the Infectious Disease Epidemiology and Surveillance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199.

(2) Responsibilities of the CEO, medical staff, and director of nursing (DON). The CEO, the medical staff, and the DON shall be responsible for the following.

(A) Quality assurance. The hospital-wide quality assurance program and training programs shall address problems identified by the infection control officer or officers.

(B) Corrective actions. Successful corrective action plans in affected problem areas shall be implemented.

(3) Universal precautions. The hospital shall adopt, implement, and enforce a written policy to monitor compliance of the hospital and its personnel and medical staff with universal precautions in accordance with the HSC, Chapter 85, Subchapter I of this title (relating to the Prevention of Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV) by Infected Health Care Workers).

(4) Preventing tuberculosis transmission. The hospital shall comply with the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis (TB) in Health Care Facilities, Morbidity and Mortality Weekly Report (MMWR), October 28, 1994, Volume 40, Number RR-13 which the department adopts by reference in §133.100(b)(2)(T) of this title.

(5) Exposure to infectious diseases. The hospital shall adopt, implement, and enforce written policies and procedures to manage, minimize, or eliminate the risks of infection of hospital personnel and medical staff as a result of exposure to infectious diseases regardless of source. The hospital policies and procedures shall include, but not be limited to, the following:

(A) identification of tasks and procedures in which exposure to an infectious disease(s) may occur during the normal course of job performance to include a written list of all jobs identified in which employees performing those jobs have exposure;

(B) appropriate infection control strategy:

(i) immunization policy for provision or availability of vaccines, biologicals, and TB skin testing;

(ii) post exposure management process; and

(iii) appropriate selection, provision, and use of:

(I) work practice controls (e.g., handwashing, procedures for handling sharps, work area restrictions);

(II) engineering controls (e.g., sharps containers, resuscitation bags, self-sheathing needles); and

(III) personal protective equipment (e.g., gloves, gowns and other outerwear, goggles or glasses with solid side shields, face shields or masks);

(C) communication of hazards to employees (e.g., warning labels depicting the universal biohazard symbol, color-coding);

(D) provision of information and training to employees:

(i) relevant disease information;

(ii) training at initial assignment to tasks where exposure may take place and when changes such as modification of tasks or procedures or institution of new tasks and procedures affect the employee's exposure; and

(iii) annual inservices;

(E) appropriate housekeeping procedures:

(i) identification of surfaces and equipment to be cleaned, disinfected, and sterilized, written schedules for cleaning, disinfecting, and sterilizing surfaces and equipment, and products and methods to be utilized in cleaning, disinfecting, and sterilizing surfaces and equipment;

(ii) procedures to decontaminate spills of blood and other body substances;

(iii) procedures for cleaning and laundering personal protective equipment and for handling contaminated laundry; and

(iv) disposal of regulated medical waste in compliance with the applicable requirements in subsection (bb) of this section; and

(F) recordkeeping:

(i) medical records. The hospital shall establish and maintain accurate records for each employee with exposure. The period of retention for employee medical records shall be determined by the hospital, and the retention period shall be clearly stated in the exposure control plan. The record shall include:

(I) name and social security number of the employee;

(II) a copy of the employee's hepatitis B vaccination status including the dates of all hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination;

(III) a copy of all results of examinations, medical testing, and follow-up procedures resulting from post-exposure evaluations; and

(IV) the hospital's copy of the health care professional's written opinion, if any;

(ii) confidentiality of medical records. The hospital shall ensure that an employee's medical records are:

(I) kept confidential; and

(II) not disclosed or reported without the employee's written consent to any person within or outside the workplace as may be required by law; and

(iii) training records. Records documenting training received by employees with exposure shall be maintained and retained for three years. Training records shall include:

(I) dates of training sessions;

(II) content or a summary of the training session;

(III) names and qualifications of persons conducting the training; and

(IV) names and job titles of all persons attending the training sessions.

(g) Laboratory services. The hospital shall maintain directly, or have available through a contractual agreement, adequate laboratory services to meet the needs of its patients.

(1) Hospital laboratory services. A hospital that provides laboratory services shall comply with CLIA 1988, in accordance with the requirements specified in 42 CFR, §§493.1-493.2001. CLIA 1988 applies to all hospitals with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(2) Contracted laboratory services. The hospital shall ensure that all laboratory services provided to its patients through a contractual agreement are performed in a facility certified in the appropriate specialties and subspecialties of service in accordance with the requirements specified in 42 CFR Part 493 to comply with CLIA 1988.

(3) Adequacy of laboratory services. The hospital shall ensure the following.

(A) Emergency services. Emergency laboratory services shall be available 24 hours a day.

(B) Written description. A written description of services provided shall be available to the medical staff.

(C) Receipt and reporting of tissue specimens. The laboratory shall make provision for proper receipt and reporting of tissue specimens.

(D) Tissue specimen examination. The medical staff and a pathologist shall determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examination.

(4) Chemical hygiene. A hospital that provides laboratory services shall adopt, implement, and enforce written policies and procedures to manage, minimize, or eliminate the risks to laboratory personnel of exposure to potentially hazardous chemicals in the laboratory which may occur during the normal course of job performance. The policies and procedures shall include, but not be limited to, the following:

(A) identification of potentially hazardous chemicals (any chemical which is a health hazard or physical hazard) present in the workplace to include a written list of hazardous chemicals identified. The list shall specify whether the hazardous chemical is listed in the National Toxicology Program Annual Report on Carcinogens or has been found to be a potential carcinogen in the International Agency for Research on Cancer Monographs or by the Occupational Safety and Health Administra-

tion;

(B) identification of tasks and procedures in which exposure to a hazardous chemical may occur during the normal course of job performance to include a written list of all jobs identified in which employees performing those jobs have exposure;

(C) appropriate exposure control plan;

(D) post exposure management process;

(E) appropriate selection, provision, and use of:

(i) work practice controls (e.g., handwashing, work area restrictions, fume hoods);

(ii) engineering controls (e.g., continuous monitoring devices, ventilation); and

(iii) personal protective equipment (e.g., gloves, gowns and other outerwear, goggles or glasses with solid side shields, face shield or masks, respirators);

(F) communication of hazards to employees (e.g., warning signs and labels, Material Safety Data Sheets);

(G) provisions of information and training to employees:

(i) relevant information about the hazardous chemicals:

(I) physical and chemical characteristics of the hazardous chemicals (e. g., potential for fire, explosion, reactivity, corrosivity);

(II) health hazards (e.g., carcinogenic, toxic, irritant) of the hazardous chemicals, including signs and symptoms of exposure, target organ effects, any medical conditions which are generally recognized as being aggravated by exposure to the chemicals, and types of exposure (acute, chronic) ;

(III) permissible exposure limits;

(IV) primary routes of entry (e.g., inhalation, ingestion, absorption);

(V) any generally applicable precautions for safe handling and use;

(VI) methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area (monitoring devices, visual appearance or odor of hazardous chemicals when released);

(VII) warning signs and labels and the labeling system on containers of chemicals; and

(VIII) information contained in material safety data sheets;

(ii) training at initial assignment to tasks where exposure may take place and when changes such as modification of tasks or procedures or institution of new tasks and procedures affect the employee's exposure; and

(iii) annual inservices;

(H) appropriate housekeeping procedures:

(i) procedures for decontamination and clean-up of chemical spills);

(ii) appropriate storage of chemicals; and

(iii) disposal of hazardous waste in compliance with applicable requirements in subsection (bb) of this section;

(I) emergency and first aid procedures; and

(J) recordkeeping. The hospital shall establish and maintain accurate medical records and training records for each employee with exposure which meet the requirements described in subsection (f)(5)(F) of this section.

(h) Linen and laundry services.

(1) Linen provided. The hospital shall provide sufficient linen to ensure the comfort of the patient and to provide a safeguard from infectious or communicable disease transmitted via linen.

(2) Laundry services. The hospital, whether it operates its own laundry or uses commercial service, shall ensure the following.

(A) Personnel.

(i) Supervision. Laundry supervision shall be provided by an institutional or commercial laundry operator qualified for the position by education, training, and experience.

(ii) Inservice training. Employees of a hospital involved in transporting, processing, or otherwise handling clean or soiled limen shall be given initial and follow-up inservice training to ensure a safe product for patients and to safeguard employees in their work.

(iii) Continuing education. Employees of healthcare linen and laundry service providers shall participate in a relevant continuing education program.

(B) Transportation of linen. Clean linen shall be handled, transported, and stored by methods that will ensure its cleanliness.

(i) Delivery methods. Clean linen shall be transported by any of the following methods:

(I) placing clean linen in containers used exclusively for this purpose;

(II) placing clean linen in a hamper lined with an unused plastic liner or a clean reusable liner. The hamper shall be covered with a disposable cover or clean reusable cover or the liner closed to cover the linen;

(III) placing clean linen in a cart, covering it with disposable plastic or clean reusable material, and securing the cover. Carts shall be moved to the doors of patient rooms during routine bed making; or

(IV) placing clean linen on a linen rack and covering it with a suitable cover.

(ii) Separation of clean and soiled linen. Separation shall be maintained if:

(I) the container which is used to transport soiled linen is properly cleaned before it is used to transport clean linen;

(II) bundles of clean linen are wrapped in plastic or other suitable material and sealed or taped; or

(III) transportation of clean and soiled linen is done in separate containers.

(iii) Cleaning containers and covers.

(I) Containers and

covers shall be properly cleaned in order to maintain separation Properly cleaned shall mean steam cleaned or cleaned with soap and water solution.

(II) In all cases, containers and covers shall be treated with a germicidal agent.

(C) Soiled linen collection, handling, and processing.

(i) Identification of soiled linen. All soiled and contaminated linen shall be clearly identified for the safety of those persons transporting, handling, or processing laundry.

(ii) Universal precautions and protective apparel

(I) The use of protective apparel shall be based on the likelihood of contact of exposed skin and clothing with soiled linen

(II) Laundry workers who handle soiled linen shall not handle clean linen unless proper biosafety techniques and universal precautions are observed

(III) If and when soiled linen is sorted in the laundry, gloves and other appropriate protective apparel shall be worn by laundry personnel.

(iii) Handling and sorting. Soiled linen shall be handled as little as possible and with minimum agitation to prevent gross microbial contamination of the air and of persons handling the linen. Soiled linen shall not be sorted or prerinsed in patient-care areas.

(iv) Collection. All soiled linen shall be bagged or put into carts at the location where it was used. Loose or unprotected soiled linen shall not be permitted.

(I) The collection bags or containers shall be of sufficient quality to functionally contain wet or soiled linen to prevent contamination of the environment during collection, transportation, and storage prior to processing. (A single bag should be acceptable in most cases).

(II) If bags are used, the bag shall have a drawstring or flap closure. The bag shall be filled and then closed immediately to await transfer to the laundry.

(III) Soiled linen from nurseries and from infectious areas, including isolation patients and dirty surgery, shall not be intermingled with linen from other patients before laundry processing Linen from these areas shall be placed in color-coded bags within the infectious area.

(IV) Linen soiled with blood or body fluids shall be deposited and transported in bags that prevent leakage.

(V) All soiled linen placed in laundry chutes shall be bagged. Linen from infectious areas shall not be placed in chutes.

(VI) If chutes are not used to convey soiled linen to a central receiving or sorting room, then adequate space shall be allocated on the various nursing wings for holding the bagged soiled linen.

(v) Processing.

(I) Soiled linen from nurseries and from infectious areas, including isolation patients and dirty surgery, shall go through one preliminary washing at 180 degrees Fahrenheit before being sorted. Isolation linen shall be washed last.

(II) Soiled nondisposable diapers and other nursery linen shall be considered as infected linen and shall be washed separately from each other and from other hospital linen.

(III) If hot water is used, soiled linen shall be washed with detergent in water with a temperature of at least 71 degrees Centigrade (160 degrees Fahrenheit) for 25 minutes. The wash cycle shall include a bleach cycle of 50-150 parts per million (ppm) of chlorine bleach to ensure removal of significant quantities of microorganisms from large quantities of grossly contaminated linen. Hot water requirements specified in Table 5 in §133. 101(a) of this title (relating to Tables and Figures) shall be met.

(IV) If low temperature (less than or equal to 70 degrees Centigrade) (158 degrees Fahrenheit) laundry cycles are used, chemicals suitable for low-temperature washing at proper use concentration shall be used.

(V) Commercial dry cleaning of fabrics soiled with blood also renders these items free of the risk of pathogen transmission.

(VI) Flammable liquids shall not be used in the laundry.

(D) Linen quality control Clean linen from the laundry shall be of a quality required for comfort and safety of the patient. Tests shall be conducted for bacteria count, texture, appearance, and odor as needed for quality control

(E) Plant facilities

(i) Safety measures. The laundry facilities shall be planned, equipped, and ventilated so as to minimize the dissemination of contaminants The ventilation system shall include adequate intake, filtration, exchange rate, and exhaust in accordance with federal, state, and local requirements.

(ii) Separate processing areas. The soiled linen area shall be separated from the clean linen processing area. Functional separation of clean and soiled may be obtained by any one or more of the following methods:

(I) physical barrier,

(II) negative air pressure system in the soiled linen area; or

(III) positive air flow from clean to soiled.

(iii) Laundry location. When the laundry (operation) is in the hospital, it shall be separated from patient rooms, area of food preparation and storage, and from areas in which clean supplies and equipment are stored.

(iv) Employee facilities. Adequate handwashing facilities and protective apparel shall be available to laundry personnel.

(F) Housekeeping.

(i) Adequate procedures shall be developed and implemented for:

(I) the use, cleaning, and care of equipment;

(II) the selection, measurement, and proper use of cleaning supplies;

(III) the maintenance of cleaning schedules;

(IV) the evaluation of cleaning effectiveness; and

(V) the maintenance of liaison with the Infection Control Committee.

(ii) Disinfectant fogging shall not be used as a method of decontaminating air.

(i) Medical record services. The hospital shall have a medical record service that has administrative responsibility for medical records. A medical record shall be maintained for every individual who presents to the hospital for evaluation or treatment.

(1) Organization and staffing. The organization of the medical record service shall be appropriate to the scope and complexity of the services performed. The hospital shall employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

(2) Form and retention of record.

(A) General. Medical records shall be accurately written, promptly completed, properly filed and retained, and accessible.

(B) Security. The hospital shall use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all entries to the records.

(C) Length of retention. Medical records (reports and printouts) shall be retained in their original or legally reproduced form for a period of at least ten years. Films, scans, and other image records shall be retained for a period of at least five years.

(D) Disposal of records of minors. If a patient was less than 18 years of age at the time he was last treated, the hospital shall authorize the disposal of medical records relating to the patient on or after the date of his 20th birthday or on or after the 10th anniversary of the date on which he was last treated, whichever date is later.

(E) Litigation. The hospital shall not destroy medical records that relate to any matter that is involved in litigation if the hospital knows the litigation has not been finally resolved.

(F) Coding and indexing. The hospital shall have a system of coding and indexing medical records. The system shall allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(G) Confidentiality. The hospital shall have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals, and the hospital shall ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records shall be released by the hospital only in accordance with federal or state laws, court orders, or subpoenas.

(H) Hospital closure. If a licensed hospital should close, the hospital shall notify the department within 30 calendar days of the closure of the disposition of the medical records, including the location of the records storage and the identity of the custodian of the records.

(3) Content of record. The medical record shall contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

(A) Authentication. All entries shall be legible and complete and shall be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.

(i) The author of each entry shall be identified and shall authenticate his or her entry.

(ii) Authentication shall include signatures, written initials, or computer entry.

(iii) Use of signature stamps by physicians shall be allowed in hospitals when the signature stamp is authorized by the individual, whose signature the stamp represents. The administrative offices of the hospital shall have on file a signed statement to the effect that he or she is the only one who has the stamp and uses it. Delegation of use to another individual shall not be acceptable.

(iv) A list of computer codes and written signatures shall be readily available and shall be maintained under adequate safeguards.

(v) Faxed signatures shall be acceptable. If received on a thermal machine, the faxed document shall be copied onto regular paper.

(B) Medical records to be retained. For retention purposes, medical records that shall be preserved for ten years include:

(i) identification data;

(ii) the medical history of the patient;

(iii) evidence of a physical examination, including a health history, performed no more than seven days prior to admission or within 48 hours after admission;

(iv) admitting diagnosis;

(v) diagnostic and therapeutic orders;

(vi) properly executed informed consent forms for procedures and treatments specified by the medical staff, or by federal or state laws if applicable, to require written patient consent;

(vii) clinical observations, including the results of therapy and treatment, all practitioner's orders, nursing notes, medication records, vital signs, and other information necessary to monitor the patient's condition;

(viii) reports of procedures, tests, and their results, including laboratory, pathology, and radiology reports;

(ix) results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient;

(x) documentation of hospital acquired infections, complications, and unfavorable reactions to drugs and anesthesia;

(xi) discharge summary with outcome of hospitalization, disposition of care, and provisions for follow-up care; and

(xii) final diagnosis with completion of medical records within 30 calendar days following discharge.

(j) Medical staff.

(1) Composition. The medical staff shall be composed of doctors of medicine or osteopathy and, in accordance with state law, may also be composed of other practitioners appointed by the governing body.

(A) Appraisals. The medical staff shall periodically conduct appraisals of its members according to medical staff bylaws.

(B) Appointments. The medical staff shall examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidate.

(2) Organization and accountability. The medical staff shall be well-organized and accountable to the governing body for the quality of the medical care provided to patients.

(A) Organization. The medical staff shall be organized in a manner approved by the governing body.

(B) Executive committee. If the medical staff has an executive committee, a majority of the members of the committee shall be doctors of medicine or osteopathy.

(C) Records of meetings. Written records of medical staff meetings shall be maintained.

(D) Director. The responsibility for organization and conduct of the medical staff shall be assigned only to an individual doctor of medicine or osteopathy.

(3) Medical staff bylaws. The medical staff shall adopt, implement, and enforce bylaws to carry out its responsibilities.

(A) Approval. The bylaws shall be approved by the governing body.

(B) Duties and privileges. The bylaws shall include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, consultant)

(C) Organization. The bylaws shall describe the organization of the medical staff.

(D) Qualifications. The bylaws shall 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.

(E) History and physical. The bylaws shall include a requirement that a physical examination and medical history be done no more than seven days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with state law.

(F) Criteria for privileges. The bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

(4) Autopsies. The medical staff shall attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy shall be defined. There shall be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

(k) Nuclear medicine services. If the hospital provides nuclear medicine services, these services shall meet the needs of the patients in accordance with acceptable standards of practice.

(1) Organization and staffing. The organization of the nuclear medicine services shall be appropriate to the scope and complexity of the services offered.

(A) Director. There shall be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

(B) Nuclear medicine personnel. The qualifications, training, functions, and responsibilities of nuclear medicine personnel shall be specified by the services director and approved by the medical staff.

(2) Delivery of services. Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice and in accordance with state laws concerning radiation control.

(A) Preparation of radiopharmaceuticals. In-house preparation of radiopharmaceuticals shall be by, or under, the direct supervision of an appropriately trained registered pharmacist or doctor of medicine or osteopathy.

(B) Storage and disposal. There shall be proper storage and disposal of radioactive material in accordance with the Texas Regulations for Control of Radiation adopted in Chapter 289 of this title (relating to Radiation Control).

(C) Laboratory tests. If clinical laboratory tests are performed by the nuclear medicine services staff, the nuclear medicine staff shall comply with CLIA 1988 in accordance with the requirements specified in 42 CFR Part 493.

(D) Monthly radiation exposure checks. Nuclear medicine workers shall be checked at least monthly, by the use of exposure meters or badge tests, for amount of radiation exposure. Exposure reports and documentation shall be available for review.

(E) Compliance. Adequate protection against radioactive isotope radiation shall conform to Chapter 289 of this title and all amendments as adopted by the Texas State Board of Health.

(3) Equipment and supplies. Equipment and supplies shall be appropriate for the types of nuclear medicine services offered and shall be maintained for safe and efficient performance.

(A) Safe. The equipment shall be maintained in safe operating condition.

(B) Inspected, tested, calibrated. The equipment shall be inspected, tested, and calibrated at least annually by qualified personnel.

(4) Records. The hospital shall maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(A) Retention. The hospital shall maintain copies of nuclear medicine reports for at least ten years.

(B) Signed interpretations. The practitioner approved by the medical staff to interpret diagnostic procedures shall sign and date the interpretations of these tests.

(C) Receipt and disposal records. The hospital shall maintain records of the receipt and disposition of radiopharmaceuticals.

(D) Orders. Nuclear medicine services shall be ordered only by a practitioner whose scope of federal or state licensure and whose defined staff privileges allow such referrals.

(l) Nursing services. The hospital shall have an organized nursing service that provides 24-hour nursing services. The nursing services shall be furnished or supervised by a registered nurse (RN).

(1) Nursing Practice Act. The hospital shall comply with the Nursing Practice Act, Texas Civil Statutes, (TCS), Articles 4513-4528c.

(2) Vocation Nurse Act. The hosptial shall comply with the Vocational Nurse Act, TCS, Article 4528c.

(3) Organization. The hospital shall have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care.

(A) Director qualifications. The DON shall be a licensed RN.

(B) Director responsibilities. The DON shall be responsible for the operation of the services, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(4) Staffing and delivery of care. The nursing services shall have adequate numbers of RNs, licensed vocational nurses (LVNs), and other personnel to provide nursing care to all patients as needed. There shall be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of an RN for bedside care of any patient.

(A) Provision of services. The hospital shall provide 24-hour nursing services furnished or supervised by an RN and have an LVN or RN on duty at all times.

(B) Licensure. The nursing services shall have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(C) Supervision. An RN shall supervise and evaluate the nursing care for each patient.

(D) Patient assessment. An RN shall assess the patients and assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

(E) Nursing care plan. The hospital shall ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient which addresses the patient's needs.

(F) Non-employee nurses. Non-employee licensed nurses who are working in the hospital shall adhere to the policies and procedures of the hospital. The DON shall provide for the adequate orientation, supervision, and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing services.

(5) Drugs and biologicals. Drugs and biologicals shall be prepared and administered in accordance with federal and state laws, the orders of the practitioner or practitioners responsible for the patient's care as specified by law, and accepted standards of practice.

(A) Administration. All drugs and biologicals shall be administered by, or under supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing rules, and in accordance with the approved medical staff policies and procedures.

(B) Orders. All orders for drugs and biologicals shall be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under subsection (a)(3)(A) of this section. When telephone or oral orders must be used, they shall be:

(i) accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with federal and state laws;

(ii) signed or initialed by the prescribing practitioner in accordance with medical staff bylaws, rules, and regulations; and

(iii) used infrequently.

(C) Transfusions and intravenous medications. Blood transfusions and intravenous medications shall be administered in accordance with state law and approved hospital policies. If blood transfusions and intravenous medications are administered, the personnel shall have special training for this duty and shall have demonstrated an acceptable level of skill in these procedures.

(D) Reactions and errors. There shall be a hospital procedure for immediately reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs to the attending physician and if appropriate, to the hospital-wide quality assurance program.

(m) Obstetrical services. If the hospital provides obstetrical services, the services shall meet the needs of the patients in accordance with acceptable standards of practice.

(1) Organization. The organization of the services shall be appropriate to the scope and complexity of the services offered.

(2) Personnel.

(A) Director. The director of the services shall have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(B) Physicians. The hospital shall have on staff one or more physicians qualified by training and experience in obstetrics and gynecology or family practice in accordance with medical staff bylaws.

(C) Professional and nonprofessional staff. The hospital shall have appropriate professional and nonprofessional personnel available.

(n) Orthopedic services. If the hospital provides orthopedic services, the services shall meet the needs of the patients in accordance with acceptable standards of practice.

(1) Organization. The organization of the services shall be appropriate to the scope and complexity of the services offered.

(2) Personnel.

(A) Director. The director of the services shall have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(B) Physicians. The hospital shall have on the staff one or more physicians qualified by training and experience in the diagnosis and treatment of orthopedic conditions in accordance with medical staff bylaws.

(C) Professional and nonprofessional staff. The hospital shall have appropriate professional and nonprofessional personnel available.

(3) Physical therapy. The hospital shall have adequate physical therapy facilities and equipment to meet the needs of those patients requiring physical therapy.

(A) Physical therapy equipment. Equipment utilized for physical therapy shall include as a minimum:

(i) wheelchairs;

(ii) crutches;

(iii) walking bars; and

(iv) heat therapy equipment.

(B) Physical therapy supervision. Physical therapy facilities shall be under the supervision of one or more physicians and licensed physical therapists, which can be on a consultative basis.

(o) Outpatient services. If the hospital provides outpatient services, the services shall meet the needs of the patients in accordance with acceptable standards of practice.

(1) Location. Outpatient services operated under the hospital's license shall be located on the premises of the

hospital (i.e., at the same physical location and street address) and shall meet the requirements in this chapter.

(2) Services. Outpatient services may include medical, surgical, or psychiatric services provided the needs of such patients can be met in less than 24 hours and without inpatient care and shall include diagnosis or treatment of the individual's condition expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization

(3) Organization. Outpatient services shall be appropriately organized and integrated with inpatient services.

(4) Personnel.

(A) Responsibility for outpatient services. The hospital shall assign an individual to be responsible for outpatient services.

(B) Professional and non-professional staff. The hospital shall have appropriate physicians on staff and other professional and non-professional personnel available.

(p) Pastoral services.

(1) The hospital shall provide or have available pastoral services to meet the needs of the patients.

(2) There shall be a director of pastoral services who monitors and evaluates the quality and appropriateness of pastoral services furnished. The services shall be furnished in accordance with accepted standards of practice and established policies and procedures.

(q) Pediatric and adolescent services. If the hospital provides pediatric and adolescent services the services shall meet the needs of the patients in accordance with acceptable standards of practice.

(1) Organization. The organization of the services shall be appropriate to the scope and complexity of services offered.

(2) Personnel.

(A) Director. The director of the services shall have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(B) Physicians. The hospital shall have on staff one of more physicians qualified by training and experience in the diagnosis and treatment of diseases of children in accordance with medical staff bylaws.

(C) Professional and non-professional staff. The hospital shall have appropriate professional and non-professional personnel available.

(r) Pharmacy services. The hospital shall provide pharmaceutical services that meet the needs of the patients.

(1) Compliance. Pharmacy services shall comply with the following rules.

(A) Texas Pharmacy Act, Texas Civil Statutes, (TCS), Article 4542a-1, and 22 Texas Administrative Code, (TAC), Chapter 281 (relating to Texas State Board of Pharmacy Rules of Procedure) shall be met.

(B) Texas Dangerous Drug Act, HSC, Chapter 483 shall be met.

(C) Texas Controlled Substances Act, HSC, Chapter 481, and 37 TAC, Chapter 13 (relating to Texas Controlled Substances Regulations) shall be met.

(D) Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 CFR, Part 1300 to end (relating to Drug Enforcement Administration, Department of Justice), shall be met.

(2) Organization. The institution shall have a pharmacy directed by a registered pharmacist.

(3) Medical staff.

(A) Responsibilities. The medical staff shall be responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical services.

(B) Consistency. The policies and procedures shall be consistent with those of other hospital departments and with actual practices in the hospital.

(4) Pharmacy management and administration. The pharmacy or drug storage area shall be administered in accordance with accepted professional principles.

(A) Standards of practice. Standards of practice as defined by state law shall be followed regarding the provision of pharmacy services.

(B) System. The hospital shall utilize either a unit dose system, individual prescription, floor stock system, or a combination of these systems.

(C) Personnel. The pharmaceutical services shall have an adequate number of personnel to ensure quality pharmaceutical services including emergency services.

(i) The staff shall be sufficient in number and training to respond to the pharmaceutical needs of the patient population being served. There shall be an arrangement for emergency services.

(ii) Employees shall provide pharmaceutical services within the scope of their license and education.

(D) Storage. Drugs and biologicals shall be properly stored to ensure ventilation, light, security, and temperature controls.

(E) Records. Records shall have sufficient detail to follow the flow of drugs from entry through dispensation.

(F) Controls. There shall be adequate controls over all drugs and medications including the floor stock. Drug storage areas shall be approved by the pharmacist, and floor stock lists shall be established.

(G) Inspections. Inspections of drug storage areas shall be conducted monthly throughout the hospital under pharmacist supervision.

(H) Drug recall. There shall be a drug recall procedure.

(I) Supervision. A full-time, part-time, or consulting pharmacist shall be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

(i) Direction of pharmaceutical services may not require on premises supervision but may be accomplished through regularly scheduled visits in accordance with state law.

(ii) A job description or other written agreement shall clearly define the responsibilities of the pharmacist.

(J) Receipt and disposition of drugs. Current and accurate records shall be kept of the receipt and disposition of all scheduled drugs.

(i) There shall be a record system in place that provides the information on controlled substances in a readily retrievable manner which is separate from the patient record.

(ii) Records shall trace the movement of scheduled drugs throughout the services, documenting utilization or wastage.

(iii) The pharmacist shall be responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled with physician orders.

(5) Delivery of services. In order to provide patient safety, drugs and biologicals shall be controlled and distributed in accordance with applicable standards of practice, consistent with federal and state laws.

(A) Compounding, packaging, and dispensing. All compounding, packaging, and dispensing of drugs and biologicals shall be under the supervision of a pharmacist and performed consistent with federal and state laws.

(B) Locked storage. Drugs and biologicals shall be kept in a locked storage area.

(i) A policy shall be established for the safeguarding, transferring, and availability of keys to the locked storage area.

(ii) Dangerous drugs as well as controlled substances shall be secure from unauthorized use.

(C) Unusable drugs. Outdated, mislabeled, or otherwise unusable drugs and biologicals shall not be available for patient use.

(D) Designated personnel. When a pharmacist is not available, drugs and biologicals shall be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with federal and state laws.

(i) There shall be a current list of individuals identified by name and qualifications who are designated to remove drugs from the pharmacy.

(ii) Only amounts sufficient for immediate therapeutic needs shall be removed.

(E) Stop orders. Drugs and biologicals not specifically prescribed as to time or number of doses shall automatically be stopped after a reasonable time that is predetermined by the medical staff.

(i) Stop order policies and procedures shall be consistent with those of the nursing staff and the medical staff rules and regulations.

(ii) A protocol shall be established by the medical staff for the implementation of the stop order policy, in order that drugs shall be reviewed and renewed, or automatically stopped.

(iii) A system shall be in place to determine compliance with the stop order policy.

(F) Reporting errors, reactions, and incompatibilities.

(i) Drug administration errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

(ii) There shall be a mechanism in place for capturing, reviewing, and tracking medication errors and adverse drug reactions.

(G) Reporting abuses and losses of controlled substances. Abuses and losses of controlled substances shall be reported, in accordance with applicable federal and state laws, to the individual responsible for the pharmaceutical services, and to the CEO, as appropriate.

(H) Information. Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be available to the professional staff.

(i) The hospital shall have immediately available sufficient texts and other resources on drug therapy.

(ii) A pharmacist shall be readily available by telephone or other means to discuss drug therapy, interactions, side effects, dosage with practitioners to assist in drug selection and with nursing personnel to assist in the identification of drug induced problems.

(iii) There shall be staff development programs on drug therapy available to facility staff to cover such topics as new drugs added to the formulary, how to resolve drug therapy problems, and other general information as the need arises.

(I) Formulary system. A formulary system shall be established by the medical staff to ensure quality pharmaceuticals at reasonable costs.

(s) Physical environment. The hospital shall be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(1) Safety and quality. The condition of the physical plant and the overall hospital environment shall be developed and maintained in such a manner that the safety and well-being of patients are ensured.

(A) Emergency power and lighting. There shall be emergency power and lighting as required by NFPA 99 which the department adopts by reference in §133.100(b)(1)(M) of this title. Examples include, but are not limited to, stairwells and the operating, recovery, intensive care, and emergency rooms. In all areas not serviced by the emergency supply source, battery lamps and flashlights shall be available.

(B) Emergency gas and water. There shall be facilities for emergency gas and water supply.

(2) Facilities. The hospital shall maintain adequate facilities for its services.

(A) Diagnostic and therapeutic. Diagnostic and therapeutic facilities shall be located for the safety of patients.

(B) Supplies and equipment. Facilities, supplies, and equipment shall be maintained to ensure an acceptable level of safety and quality.

(C) Extent and complexity. The extent and complexity of facilities shall be determined by the services offered.

(D) Ventilation, light, and temperature. There shall be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

(t) Quality assurance. The governing body shall ensure that there is an effective, hospital-wide quality assurance (QA) program to evaluate the provision of patient care.

(1) Clinical plan. The organized, hospital-wide QA program shall include outpatient services operated under the hospital's license. The hospital-wide QA program shall be on-going and have a written plan of implementation.

(A) Evaluation. All organized services related to patient care, including services furnished by a contractor, shall be evaluated for effectiveness and quality.

(B) Infections and medications. Nosocomial infections and medication therapy shall be evaluated.

(C) Appropriateness. All medical, surgical, rehabilitative, and psychiatric services performed in the hospital shall be evaluated as they relate to appropriateness of diagnosis and treatment.

(2) Medically-related patient care services. The hospital shall have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically-related needs of its patients. The hospital also shall have an effective, ongoing discharge planning program that facilitates the provision of follow-up care.

(A) Discharge planning. Discharge planning shall be initiated at the time of admission for all patients.

(B) Follow-up care. Patients, along with necessary medical information, shall be transferred or referred to appropriate facilities, agencies, or outpatient services, as needed for follow-up or ancillary care.

(3) Implementation. The hospital shall take and document appropriate remedial action to address deficiencies found through the QA program. The hospital shall document the outcome of the remedial action.

(u) Radiology services. The hospital shall maintain, or have available, diagnostic radiologic services according to needs of the patients. If therapeutic services are also provided, the services, as well as the diagnostic services, shall meet professionally approved standards for safety and personnel qualifications.

(1) Safety for patients and personnel. The radiology services, particularly ionizing radiology procedures, shall be free from hazards for patients and personnel.

(A) Safety precautions. Proper safety precautions shall be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials in accordance with Texas Regulations for the Control of Radiation in Chapter 289 of this title.

(B) Annual equipment inspections. Inspection of equipment shall be made at least annually. Defective equipment shall be promptly repaired or replaced.

(C) Unit output. Output of each fluoroscopic and therapeutic X-ray unit shall serve as the basis for establishing the time of the X-ray exposure.

(D) Posting exposure time schedules. Exposure time schedules shall be posted at each X-ray control booth.

(E) Monthly radiation exposure checks. Radiation workers shall be checked at least monthly, by the use of exposure meters or badge tests, for amount of radiation exposure. Exposure reports and documentation shall be available for review

(F) Orders. Radiology services shall be provided only on the order of practitioners with clinical privileges, or, consistent with state law, of other practitioners authorized by the medical staff and the governing body to order the services.

(G) Compliance. Adequate protection against X-ray and radioactive isotope radiation shall conform to the Texas Regulations for Control of Radiation in Chapter 289 of this title.

(2) Personnel.

(A) Radiologist. A qualified full-time, part-time, or consulting radiologist shall supervise the ionizing radiology services and shall interpret only those radiology tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology in accordance with medical staff bylaws.

(B) Designated personnel. Only personnel designated as qualified by the medical staff shall use the radiology equipment and administer procedures.

(3) Records Records of radiology services shall be maintained.

(A) Signed reports. The radiologist or other practitioner who performs radiology services shall sign reports of his or her interpretations.

(B) Retention. The hospital shall maintain the following.

(i) copies of reports and printouts for at least ten years; and

(ii) films, scans, and other image records for at least five years.

(v) Respiratory care services. The hospital shall meet the needs of the patients in accordance with acceptable standards of practice. The following apply if the hospital provides respiratory care services.

(1) Organization and staffing. The organization of the respiratory care services shall be appropriate to the scope and complexity of the services offered.

(A) Director. There shall be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the services properly. The director may serve on either a full-time or part-time basis.

(B) Respiratory staff. There shall be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with the state law.

(2) Delivery of services. Services shall be delivered in accordance with medical staff directives.

(A) Designated personnel. Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures shall be designated in writing.

(B) Blood gases. If blood gases or other clinical laboratory tests are performed by the respiratory care services staff, the respiratory care staff shall comply with CLIA 1988 in accordance with the requirements specified in 42 CFR, Part 493.

(C) Orders. Services shall be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.

(w) Social services.

(1) The hospital shall provide or have available social services to meet the needs of the patients.

(2) There shall be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services shall be furnished in accordance with accepted standards of practice and established policies and procedures.

(A) The director of the social work department or services shall have a master's degree from an accredited school of social work or shall be qualified by education and experience in the social services needs of the patients.

(B) Social service staff responsibilities shall include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

(x) Sterilization and sterile supplies.

(1) Supervision The sterilization of all supplies and equipment shall be under the supervision of a person qualified by training and experience to carry out safe and efficient service

(2) Equipment and procedures.

(A) Sterilization. Every facility covered by this chapter shall provide equipment adequate for sterilization and disinfection of supplies and equipment. Equipment shall be maintained and operated to perform, with accuracy, sterilization and disinfection of the various materials required.

(B) Written policy. Policies and procedures for sterilization and disinfection shall be written, implemented, reviewed at least annually, and be readily available within the practice setting. These policies and procedures shall be reviewed and approved by the infection control officer or committee.

(C) Separation of clean and soiled supplies and equipment. Where cleaning, preparation, and sterilization functions are performed in the same room or unit, the physical facilities, equipment, and the policies and procedures for their use, shall be such as to effectively separate soiled or contaminated supplies and equipment from the clean or sterilized supplies and equipment. A sink shall be provided for safe disposal of liquid waste. Separate handwashing facilities shall be provided.

(D) Labeled containers. All containers for solutions, drugs, flammable solvents, ether, alcohol, and medicated supplies shall be clearly labeled to indicate contents. Those which are sterilized by the hospital shall be labeled so as to be identifiable both before and after sterilization.

(E) Preparation for sterilization.

(i) All items to be sterilized shall be prepared to reduce the bioburden All items shall be thoroughly cleaned and prepared in a clean, controlled environment.

(ii) All articles to be sterilized shall be arranged so all surfaces will be directly exposed to the sterilizing agent for the prescribed time and temperature.

(F) Packaging.

(i) All wrapped articles to be sterilized shall be packaged in materials recommended for the specific type of sterilizer or autoclave and material to be sterilized.

(ii) Every package shall be imprinted or labeled with a load control number which indicates the sterilizer used, the cycle or load number, the date of sterilization, and an expiration date.

(G) Chemical indicators.

(i) Chemical indicators, also known as sterilization process indicators, shall be used to indicate that items have been exposed to the sterilization process.

(ii) The indicator results shall be interpreted according to manufacturer's written instructions and indicator reaction specifications.

(iii) A log shall be maintained with the load identification, indicator results, and identification of the contents of the load.

(H) Biological indicators.

(i) The efficacy of the sterilizing process shall be monitored with reliable biological indicators appropriate for the type of sterilizer used (e. g., Bacillus stearothermophilus for steam sterilizers and Bacillus subtilis variant (var.) niger or var. globigii for ethylene oxide sterilizers).

(ii) Biological indicators shall be included in at least one run each day of use.

(iii) Biological indicators shall be included in every load that contains implantable objects.

(iv) A log shall be maintained with the load identification, biological indicator results, and identification of the contents of the load.

(v) Placement of biological indicators in the sterilizer shall comply with the following criteria.

(I) Spore carriers shall be placed in the center of the largest pack in the largest load or in an area of the load that is least likely to reach sterilizing temperature or to receive adequate exposure to EO.

(II) Biological indicators shall not be placed on an open shelf or on the peripheral exterior surface of a pack.

(III) Biological indicators shall be systematically rotated within the sterilizer to ensure all areas of the sterilizer are monitored.

(vi) If a test is positive, the sterilizer shall immediately be checked for proper use and function and the test repeated.

(vii) A policy and procedure shall be written, implemented, and reviewed at least annually to ensure that items from suspect loads shall be recalled and reprocessed. The policy shall include, but not be limited to, the following.

(I) Implantable items shall be recalled and reprocessed if a biological indicator test (spore test) is positive.

(II) All available items shall be recalled and reprocessed if a sterilizer malfunction is found.

(III) A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer's recommendations.

(I) Sterilizers.

(i) Steam sterilizers (saturated steam under pressure) shall be utilized for sterilization of heat and moisture stable items. Steam sterilizers shall be used according to manufacturer's written instructions.

(ii) Ethylene oxide (EO) sterilizers shall be used for processing heat and moisture sensitive items. EO sterilizers and aerators shall be used and vented according to the manufacturer's written instructions.

(iii) Flash sterilizers shall be used for emergency sterilization of clean, unwrapped instruments and porous items only.

(J) Disinfectants.

(i) A high-level disinfectant shall be used if an item is to be disinfected rather than sterilized.

(ii) Products selected for disinfection shall:

(I) be registered as a sporicide with the United States Environmental Protection Agency (EPA); or

(II) have demonstrated efficacy as disinfectants of equipment or supplies. Scientific literature, papers presented at scientific meetings, scientific data provided by manufacturers, and guidelines of professional organizations (e.g., the Association for Practitioners for Infection Control and the Centers for Disease Control and Prevention), in addition to EPA registration, may be acceptable as documentation of the efficacy for intended use as a high-level disinfectant. This documentation shall be available for review.

(iii) The manufacturer's written instructions shall be followed for use.

(iv) An expiration date, determined according to manufacturer's written recommendations, shall be marked on the container of disinfection solution currently in use.

(v) Disinfection solutions shall be kept covered and shall be used in a well ventilated area.

(K) Performance records.

(i) Performance records for all sterilizers shall be maintained for each cycle. These records shall be retained and available for review.

(ii) Each sterilizer shall be monitored continuously during operation for pressure, temperature, and time at desired temperature and pressure. Each EO sterilizer shall also be monitored for gas concentration and relative humidity. A record shall be maintained and shall include:

(I) the sterilizer identification;

(II) sterilization date;

(III) cycle number;

(IV) contents of each load;

(V) duration and temperature of exposure phase (if not provided on sterilizer recording charts);

(VI) identification of operator(s);

(VII) results of biological tests and dates performed;

(VIII) time-temperature recording charts from each sterilizer;

(IX) gas concentration and relative humidity (if applicable); and

(X) any other test results.

(L) Preventive maintenance. Preventive maintenance of all sterilizers shall be performed according to individual policy on a scheduled basis by qualified personnel, using the sterilizer manufacturer's service manual as a reference. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least two years and shall be available for review.

(M) Employee safety.

(i) Due to the toxic and potential carcinogenic effects of some sterilants and disinfectants, the hospital shall provide:

(I) gloves, masks, goggles, outerwear, and other appropriate protective equipment;

(II) adequate local exhaust ventilation;

(III) fume hoods, as appropriate;

(IV) appropriate warning signs and labels; and

(V) appropriate training in the use, handling, storage, and disposal of sterilants and disinfectants. Training records shall be maintained and retained for at least three years.

(ii) The hospital shall adopt, implement, and enforce written policies and procedures for exposure of hospital personnel to ethylene oxide. The policies and procedures shall include, but not be limited to, the following:

(I) an exposure control plan;

(II) post exposure management process;

(III) appropriate selection, provision, and use of work practice controls (e.g., work area restrictions); engineering controls (e.g., ventilation, monitoring devices); and personal protective equipment (e.g., gloves, gowns and other outerwear, face shields or masks, respirators);

(IV) communications of hazards to employees (e.g., warning signs and labels, Material Safety Data Sheets);

(V) provisions of information and training to employees initially when assigned to an area where potential exposure to ethylene oxide may occur and annually thereafter; and

(VI) recordkeeping. Medical records for each employee with exposure shall be maintained. The period of retention for employee medical records shall be determined by the hospital, and the retention period shall be clearly stated in the exposure control plan. Confidentiality of employee medical records shall be ensured. Records documenting training received by employees shall be maintained and retained for three years.

(y) Surgical services. If the hospital provides surgical services, the services shall be well-organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services shall be consistent in quality with inpatient care in accordance with the complexity of services offered.

(1) Organization and staffing. The organization of the surgical services shall be appropriate for the scope of the services offered.

(A) Operating room. The operating rooms shall be supervised by an experienced RN or doctor of medicine or osteopathy.

(B) Scrub nurses or technologists. LVNs and surgical technologists (operating room technicians) may serve as scrub nurses or technologists under the supervision of an RN.

(C) Circulating duties. Qualified RNs may perform circulating duties in the operating room. In accordance with applicable state laws and approved medical staff polices and procedures, LVNs and surgical technologists may assist in circulatory duties under the supervision of a qualified RN who is immediately available to respond to emergencies.

(D) Surgical privileges. Surgical privileges shall be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical services shall maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(2) Delivery of service. Surgical services shall be consistent with needs and resources. Written policies governing surgical care shall be designed to ensure the achievement and maintenance of high standards of medical practice and patient care.

(A) History and physical. There shall be a complete medical history and physical examination in the medical record of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's

medical record, there shall be a statement to that effect and an admission note in the record by the practitioner who admitted the patient.

(B) Informed consent. A properly executed informed consent form for the operation shall be in the patient's medical record before surgery, except in emergencies.

(C) Equipment. The following equipment shall be available in the operating room suites:

(i) communication system;

(ii) cardiac monitor;

(iii) resuscitator;

(iv) defibrillator;

(v) aspirator; and

(vi) tracheotomy set.

(D) Post-operative care. There shall be adequate provisions for immediate post-operative care.

(E) Register. The operating room register shall be complete and up-to-date. The register shall contain, but not be limited to, the following:

(i) patient identification;

(ii) procedure scheduled;

(iii) procedure performed;

(iv) operating physician;

(v) anesthesiologist;

(vi) time surgery began and ended;

(vii) time anesthesia began and ended;

(viii) disposition of specimens;

(ix) identification of surgical assistants;

(x) unusual occurrences; and

(xi) disposition of the patient.

(F) Operative report. An operative report describing techniques, findings, and tissue removed or altered shall be written or dictated immediately following surgery and signed by the surgeon.

(z) Therapy services. If the hospital provides physical therapy, occupational therapy, audiology, or speech pathology services, the services shall be organized and staffed to ensure the health and safety of patients.

(1) Organization and staffing. The organization of the services shall be appropriate to the scope of the services offered.

(A) Director. The director of the services shall have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(B) Staff qualifications. Physical therapy, occupational therapy, speech therapy, or audiology services, if provided, shall be provided by staff who meet the qualifications specified by the medical staff, consistent with state law.

(2) Delivery of services. Services shall be furnished in accordance with a written plan of treatment. Services shall be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders shall be incorporated in the patient's medical record.

(aa) Transplantation services. If the hospital provides transplantation services such a bone marrow and organ transplantation, the services shall meet the needs of the patients in accordance with acceptable standards of practice.

(1) Organization. The organization of the services shall be appropriate to the scope and complexity of the services offered.

(2) Personnel.

(A) Director. The director of the services shall have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(B) Physicians. The hospital shall have on staff appropriate physicians qualified by training and experience to provide the necessary services according to medical staff bylaws.

(C) Professional and non-professional staff. The hospital shall have appropriate professional and non-professional personnel available.

(bb) Waste and waste disposal.

(1) Special waste from health care-related facilities (SWFHCRF).

(A) Definition of SWFHCRF, including exemptions.

(i) SWFHCRF, as defined in §1.132 of this title (relating to Definitions) consists of five major categories, including:

(I) animal waste;

(II) bulk human blood and body fluids;

(III) microbial waste;

(IV) pathological waste; and

(V) sharps.

(ii) With the exception of the category of "bulk human blood and body fluids," each category of SWFHCRF is further divided into subcategories as outlined in §1.132 of this title.

(iii) The following waste items are exempted from SWFHCRF as outlined in §1.133 of this title (relating to Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of Health):

(I) teeth;

(II) human tissue, including fetal tissue, donated for research or teaching purposes under those conditions outlined in §1.133(a)(2)(B) of this title;

(III) placentas designated for sale;

(IV) *in vitro* tissue cultures that have not been intentionally exposed to pathogens;

(V) any material included in the definition of SWFHCRF which has been sold, donated, or in any way transferred from one health care related facility to a subsequent facility(ies) and other entities specified in §1.133(a)(2)(B) of this title for research or teaching purposes until it is discarded; and

(VI) fetal remains of a single pregnancy, body parts, or tissue (including bulk blood), transferred for disposition to a licensed funeral director in accordance with the Health & Safety Code, Chapter 711, and Chapter 181 of this title (relating to Vital Statistics), with the consent of the person or persons authorized to consent to the disposition of the fetal remains, body parts, or tissue (including bulk blood).

(iv) SWFHCRF shall be considered as treated or untreated for the

purposes of waste management as the waste is scheduled to leave the facility or the grounds thereof en route to final disposition.

(B) Definition of on-site. For the purposes of this chapter, on-site shall be as defined in 30 TAC §330.1004(f) (relating to Generators of Medical Waste) enforced by the Texas Natural Resource Conservation Commission (TNRCC), and includes the following settings:

(i) any contiguous structures, or portion thereof, which are operated by one entity;

(ii) any structures located on contiguous properties which are operated by one entity;

(iii) any combination of structures operating as a single entity under a license issued by the department; or

(iv) any structure owned and managed by a single entity operated under a license by the department, and meeting the following provisions:

(I) general waste management is provided by the licensee to facilities within the structure;

(II) individual generators within the structure shall maintain records in accordance with 30 TAC, §330.1004(h) (enforced by TNRCC);

(III) waste shall be identified and packaged in accordance with 30 TAC, §330.1004(i) (enforced by TNRCC);

(IV) waste which must be transported over public roadways (excluding crossing a public roadway) shall comply with 30 TAC §330.1005 (relating to Transporters of Medical Waste);

(V) waste from any source other than a facility in such structure shall not be accepted as on-site generated waste; and

(VI) if the waste is not to be treated on site, it shall be released only to a registered medical waste transporter. The licensee shall provide the transporter with a list of the waste collected, including the identity of the waste generator.

(C) Untreated SWFHCRF.

(i) The hospital may provide for the off-site treatment and disposal of untreated SWFHCRF through a written contractual arrangement with a registered medical waste transporter. The hospital shall ensure through the procurement and retention of documentation that the SWFHCRF was:

(I) processed or treated in accordance with the provisions in §1.136 of this title (relating to Approved Methods of Treatment and Disposition) administered by the Texas Department of Health, Bureau of Environmental Health;

(II) transported, stored, and disposed of in accordance with 30 TAC, Chapter 330 (relating to Municipal Solid Waste) (administered by TNRCC).

(ii) The hospital shall comply with the provisions in 30 TAC, §330.1004 (enforced by TNRCC) as they relate to the generator's management of untreated SWFHCRF, including:

(I) identifying and segregating SWFHCRF from other wastes;

(II) proper packaging and labeling of SWFHCRF; and

(III) securing appropriate signed receipts and documentation for the registered medical waste transporter in accordance with 30 TAC, Chapter 330. This documentation shall be available for review.

(iii) Prior to releasing untreated SWFHCRF to a registered medical waste transporter, the hospital shall store said wastes as necessary in a secure manner in accordance with 30 TAC, §330.1009(a) (relating to Storage of Medical Waste) (enforced by TNRCC).

(iv) Hospitals may elect to transport their own untreated SWFHCRF to a registered medical waste collection station, a transfer station, a storage facility, or a Type V processing facility in accordance with 30 TAC, §330.1005(p) (enforced by TRNCC).

(v) Disposal of untreated SWFHCRF released to a registered medical waste transporter shall be the responsibility of the transporter, who in turn shall provide the hospital with documentation as to final disposition of the waste in accordance with 30 TAC, §330.1005 (enforced by TRNCC). This documentation shall be available for review.

(D) Treated SWFHCRF.

(i) The hospital may elect to treat SWFHCRF on-site prior to its discharge from the facility or from the grounds thereof. Treatment is accomplished through the use of:

(I) equipment at a fixed location within the facility or on the grounds or premises thereof; or

(II) on-site treatment equipment or processes on mobile vehicles.

(ii) If the hospital elects to utilize an on-site treatment process on a mobile vehicle, then:

(I) if the provider of the on-site treatment on mobile vehicles is not the generator of the waste, the provider shall register with the TNRCC and comply with the provisions of 30 TAC, §330.1010 (relating to Mobile On-site Treatment Services) (enforced by TNRCC); the provider shall treat the waste in accordance with the provisions of §1.136 of this title; and the hospital shall obtain from the provider documentation of any treatment performed on-site. This documentation shall be available for review; or

(II) if the provider of the on-site treatment process on a mobile vehicle is the generator of the waste, the generator shall comply with the provisions of 30 TAC, §330.1010 (enforced by TRNCC) as appropriate. If the on-site treatment equipment or process on a mobile vehicle is jointly owned by several entities, a statement about said joint ownership shall be provided in accordance with 30 TAC, §330.1010(q) (enforced by TRNCC).

(iii) Treatment of SWFHCRF.

(I) All categories and subcategories of SWFHCRF shall be treated in accordance with §1.136 of this title.

(II) Approved technologies as described in §1.133 of this title or alternate treatment technologies approved in accordance with §1.135 of this title (relating to Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care Related Facilities) shall be operated in accordance with the minimum parametric standards as specified in their respective sections.

(III) Previously approved treatment technologies include steam sterilization, incineration, chemical disinfection, thermal inactivation, encapsulation (only for sharps in containers), chlorine disinfection and maceration, moist heat disinfection, and interment (only for patho-

logical waste).

(IV) The hospital may elect to purchase a commercially-available alternate treatment technology, equipment, or process designed or intended for treating SWFHCRF. Except for those technologies meeting the provisions of §1. 133 of this title, it shall be the responsibility of the manufacturer of said commercially-available alternate treatment technology, equipment, or process to obtain departmental approval in accordance with §1.135 of this title.

(iv) The hospital shall comply with the provisions of 30 TAC, §330.1004 (enforced by TRNCC) as they relate to the management of SWFHCRF treated on-site which includes:

(I) utilizing the appropriate treatment for the categories and subcategories of SWFHCRF in accordance with §1.136 of this title; and

(II) maintaining records and documentation of storage, treatment, quality assurance, and routine performance monitoring of the equipment, technology, or process as appropriate based on the quantity of SWFHCRF produced per month. This documentation shall be available for review.

(v) Treatment of SWFHCRF converts the waste into a routine solid waste which shall be disposed of in accordance with 30 TAC, Chapter 330 (enforced by TRNCC).

(2) Other regulated medical waste. Other regulated medical waste, as per 30 TAC, §330.2 (relating to Definitions) (enforced by TRNCC), which is not included with the definition of SWFHCRF, but which is subject to special handling requirements within the generating facility by other federal or state agencies, excluding medical waste which is subject to Chapter 289 of this title (relating to Radiation Control), shall be contained in receptacles appropriately identified according to the specifications outlined in the functional program, and disposed of as routine solid waste in accordance with 30 TAC, Chapter 330 (enforced by TRNCC), provided that these wastes have not been commingled with SWFHCRF.

(3) Radioactive waste. Waste materials which are radioactive are subject to the rules in Chapter 289 of this title. Where a SWFHCRF is also subject to the rules in Chapter 289 of this title, the sections in Chapter 289 of this title shall prevail over the rules governing the management of SWFHCRF.

(4) Liquid waste. Liquid wastes resulting from the cleaning of utensils, floors, toilets, and lavatories shall be disposed of in a public sanitary sewer or, in the absence of a public sanitary sewer, by a method approved in accordance with local discharge ordinances. Grease traps are recommended where grease is discharged. The design and location of grease traps shall be in accordance with the National Association of Plumbing, Heating, Cooling Contractors (PHCC) National Standard Plumbing Code which the department adopts by reference in §133.100(b)(1)(K) of this title.

(5) Other municipal solid waste. Other municipal solid waste, as per 30 TAC, §330.2, shall be disposed of by suitable means approved in accordance with 30 TAC, Chapter 330 (enforced by TRNCC).

(A) If a city garbage collection system is available, this waste stream shall be disposed of through that collection system

(B) All other municipal solid waste throughout the hospital shall be stored in a manner that will not create a nuisance or provide conditions for harborage, feeding, and propagation of animals and vectors.

(6) Hazardous waste. Hazardous wastes shall be managed in accordance with 30 TAC, Chapter 335 (relating to Solid Waste and Municipal Hazardous Waste) (enforced by TRNCC) and applicable federal regulations.

(7) Mixing of wastes. SWFHCRF shall not be mixed or commingled with wastes from other categories. If such mixing occurs within the same container, then the entire contents of that container shall be considered as SWFHCRF requiring treatment prior to final disposal as per 30 TAC, §330.1004(b) (enforced by TRNCC). The sections of 30 TAC, Chapter 335 (enforced by TRNCC) and applicable federal regulations shall prevail in the event that SWFHCRF is mixed with a hazardous waste. The sections of Chapter 289 of this title shall prevail if SWFHCRF is mixed with a radioactive waste.

(8) Waste receptacles.

(A) Waste receptacles shall be conveniently available in all toilet rooms, patient areas, staff work areas, and waiting rooms. Receptacles shall be routinely emptied of their contents at a central location(s) into closed containers.

(B) Waste receptacles shall be properly cleaned with soap and hot water, followed by treatment of inside surfaces of the receptacles with a germicidal agent.

(C) All containers for other municipal solid waste shall be leak-resistant, have tight-fitting covers, and be rodent-proof.

(D) Non-reusable containers shall be of suitable strength to minimize animal scavenging or rupture during collection operations.

(9) Incineration.

(A) Incineration process. If an incinerator, as defined in 30 TAC, §101.1 (relating to Definitions), is utilized by the hospital, the facility shall comply with the provisions in 30 TAC, Chapter 111 (relating to Control of Air Pollution From Visible Emissions and Particulate Matter) (enforced by TRNCC). Existing units shall be operated in accordance with the permit or exemption granted by the Office of Air Quality, Texas Natural Resource Conservation Commission. New units shall comply with the requirements found in 30 TAC, Chapter 116 (relating to Control of Air Pollution by Permits for New Construction or Modification) (enforced by TRNCC).

(B) Incinerator capacity. The incinerator capacity required shall vary with the type and quantity of waste to be processed.

(C) Incinerator location. The incinerator shall be in a separate room or placed outdoors except that incinerators with a capacity of less than 50 pounds per hour may be located in a separate area within the boiler room. Rooms and areas containing incinerators shall have adequate space and facilities for charging and cleaning as well as clearances necessary for work and maintenance. Provisions shall be made for operation, temporary storage, and disposal of materials so that odors and fumes do not drift back into occupied areas.

(D) Design and construction of incinerators and trash chutes. The design and construction of incinerators and trash chutes shall be in accordance with National Fire Protection Association (NFPA) 82 which the department adopts by reference in §133.100(b)(1)(M) of this title.

(E) Air pollution. Incinerators shall be designed and equipped to conform to requirements prescribed by federal regulation and state air pollution regulations in 30 TAC, Chapters 111 and 116 administered by the Office of Air Quality, TNRCC.

(F) Ash. Ash from an incinerator shall be disposed of in accordance with 30 TAC §330.136 (relating to Disposal

of Special Waste), administered by TNRCC.

(G) Incinerator installation and arrangement. Installation and arrangement shall minimize hazards to staff while handling waste (broken glass, sharps) for incineration.

§133.62. Comprehensive Medical Rehabilitation Services

(a) Purpose. The purpose of this section is to improve the care and treatment of patients receiving comprehensive medical rehabilitation services in hospitals

(b) License required. Unless a person, as defined in §133.2 of this title (relating to Definitions) has a hospital license, a person other than an individual may not provide inpatient comprehensive medical rehabilitation services to a patient who requires medical services that are provided under the supervision of a physician and that are more intensive than nursing facility care and minor treatment.

(c) Notice. A hospital shall notify the Texas Department of Health (department) of its intent to initiate the provision of comprehensive medical rehabilitation services before the provision of these services has begun.

(d) Equipment.

(1) Implement the treatment plan. The hospital shall have the necessary equipment and sufficient space to implement the treatment plan described in subsection (j)(3) of this section and allow for adequate care. Necessary equipment is all equipment necessary to comply with all parts of the written treatment plan. The equipment shall be on-site or available through an arrangement with another provider. Sufficient space is the physical area of a hospital which in the aggregate, constitutes the total amount of the space necessary to comply with the written treatment plan.

(2) Radiology services. The hospital shall have an X-ray department, portable X-ray equipment, or written contractual arrangements with another facility for radiology services. The provision of radiology services by arrangements shall be performed in a timely manner so as not to jeopardize the patient's health.

(3) Emergency equipment. Emergency equipment, supplies, and medications for hospitals providing comprehensive medical rehabilitation services shall be as follows.

(A) Emergency care. A hospital which provides comprehensive medical rehabilitation services shall have emergency equipment, supplies, medications, and designated personnel assigned for providing emergency care to patients and visitors.

(B) Maintenance and accessibility. The emergency equipment, supplies, and medications shall be properly maintained and immediately accessible to all areas of the hospital. The emergency equipment shall be periodically tested according to the policy established by the hospital.

(C) Required emergency equipment. At a minimum, the emergency equipment and supplies shall include the following:

(i) emergency call system;

(ii) oxygen,

(iii) mechanical ventilatory assistance equipment, including airways, manual breathing bag, and mask;

(iv) cardiac defibrillator;

(v) cardiac monitoring equipment;

(vi) laryngoscopes and endotracheal tubes;

(vii) suction equipment; and

(viii) emergency drugs and supplies specified by the medical staff.

(D) Personnel providing emergency care. The personnel providing emergency care in accordance with this section shall be staffed for 24-hour coverage and accessible to all areas of the hospital. The personnel providing the 24-hour coverage shall be licensed and qualified by training to perform advanced cardiac life support (ACLS) and administer emergency drugs.

(E) Cardiopulmonary resuscitation (CPR) requirements. All direct patient care licensed personnel of the hospital shall maintain current certification in CPR.

(e) Rehabilitation units. A patient admitted to a general hospital to receive comprehensive medical rehabilitation services shall be housed in the rehabilitation unit which has been approved by the department as meeting the requirements in this section.

(f) Rehabilitation hospitals.

(1) Transfer agreement. A rehabilitation hospital shall have an agreement in writing with a licensed general hospital for the transfer of a patient when services are needed but are unavailable at the rehabilitation hospital. This requirement applies only to transfers not covered by Subchapter H of this chapter (relating to Patient Transfers).

(2) Emergencies A rehabilitation hospital shall have an emergency service with appropriate facilities As a minimum, at least one room which meets the requirements in §133.95(b)(6)(B)(iv) of this title (relating to Hospital Units-Spatial Requirements) shall be designated for the reception, examination, and initial treatment of emergency patients A rehabilitation hospital shall comply with the provisions in §133.111 of this title (relating to Hospital Patient Transfer).

(g) Medications. A rehabilitation hospital's governing body shall adopt and enforce policies and procedures that require all medications to be administered by licensed nurses, licensed physicians, or other licensed professionals authorized by law to administer medications.

(h) Staffing.

(1) Organization and staffing. A hospital providing comprehensive medical rehabilitation services shall be organized and staffed to ensure the health and safety of the patients.

(A) Provided services. All provided services shall be consistent with accepted professional standards and practice.

(B) Organization of services. The organization of the services shall be appropriate to the scope of the services offered.

(C) Patient care policies. The hospital shall have written patient care policies that govern the services it furnishes.

(2) Medical supervision. The provision of comprehensive medical rehabilitation services in a hospital shall be under the medical supervision of a licensed physician who is on duty and available, or who is on-call 24 hours each day.

(3) Director. A hospital providing comprehensive medical rehabilitation services shall have a director who supervises and administers the provisions of comprehensive medical rehabilitation services.

(A) Licensed. The director shall be a physician licensed by the State of Texas.

(B) Board certified. The director shall be board certified or eligible for board certification in physical medicine and

rehabilitation, orthopedics, neurosurgery, internal medicine, or rheumatology as appropriate for the rehabilitation program.

(C) Training and experience. The director shall be qualified by training or at least two years training and experience to serve as medical director. A person is qualified under this subsection if the person has training and experience in the treatment of rehabilitation patients in a rehabilitation setting.

(i) Admission criteria. A hospital providing comprehensive medical rehabilitation services shall have written admission criteria that are applied uniformly to all patients.

(1) Admission of minors. The hospital's admission criteria shall include procedures to prevent the admission of a minor for a condition which is not generally recognized as responsive to treatment in an inpatient setting for comprehensive medical rehabilitation services.

(A) Conditions not responsive to inpatient rehabilitation services. The following are not generally recognized as responsive to treatment in an inpatient setting for comprehensive medical rehabilitation services unless the minor to be admitted is qualified because of other disabilities:

(i) persons with cognitive disabilities due to mental retardation;

(ii) learning disabilities; or

(iii) psychiatric disorders.

(B) Other disabilities. A minor may be qualified for admission based on other disabilities which would be responsive to comprehensive medical rehabilitation services.

(2) Preadmission examination. The hospital shall have a preadmission examination procedure under which each patient's condition and medical history are reviewed by a qualified physician to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(j) Care and services.

(1) Interdisciplinary team director. A hospital providing comprehensive medical rehabilitation services shall use a coordinated interdisciplinary team which shall be directed by a licensed physician.

(A) Interdisciplinary team composition. The interdisciplinary team for comprehensive medical rehabilitation services shall have available to it, at the hospital at which the services are provided or by contract, members of the following professions as necessary to meet the treatment needs of the patient:

(i) physical therapy;

(ii) occupational therapy;

(iii) speech-language pathology;

(iv) therapeutic recreation;

(v) social services and case management;

(vi) dietetics;

(vii) psychology;

(viii) respiratory therapy;

(ix) rehabilitative nursing;

(x) certified orthotics;

(xi) certified prosthetics; and

(xii) pharmaceutical care.

(B) Documentation. The coordinated interdisciplinary team approach used in the rehabilitation of each patient shall be documented by periodic entries made in the patient's medical record to denote:

(i) the patient's status in relationship to goal attainment; and

(ii) that team conferences are held at least every two weeks to determine the appropriateness of treatment.

(C) Interdisciplinary team composition for minors. In the case of a minor patient, the interdisciplinary team shall include persons who have specialized training in emotional, mental health, chemical dependency problems, and treatment of minors.

(2) Initial assessment. An initial assessment and preliminary treatment plan shall be performed or established by the physician within 24 hours of admission.

(3) Written treatment plan. The physician in coordination with the interdisciplinary team shall establish a written treatment plan for the patient within seven working days of the date of admission.

(A) Medical rehabilitation. Comprehensive medical rehabilitation shall be provided in accordance with the written treatment plan.

(B) Written qualifications for services provided. The treatment provided under the written treatment plan shall be provided by staff who are qualified to provide services under state law. The hospital shall establish written qualifications for services provided by each discipline for which there is no applicable state statute for professional licensure or certification.

(C) Orders for services. Services provided under the written treatment plan shall be given in accordance with the orders of practitioners who are authorized by the governing body, hospital administration, and medical staff to order the services, and the orders shall be incorporated in the patient's record.

(D) Content and time frame for written treatment plan.

(i) The written treatment plan shall delineate anticipated goals and specify the type, amount, frequency, and anticipated duration of service to be provided.

(ii) Within ten working days of the date of admission, the written treatment plan shall be provided in the person's primary language, if practicable. What is or would have been practicable shall be determined by the facts and circumstances of each case. The written treatment plan shall be provided to:

(I) the patient;

(II) a person designated by the patient; and

(III) upon request, a family member, guardian, or individual who has demonstrated on a routine basis responsibility and participation in the patient's care or treatment, but only with the patient's consent unless such consent is not required by law.

(E) Review of treatment plan.

(i) The written treatment plan shall be reviewed by the interdisciplinary team at least every two weeks.

(ii) The written treatment plan shall be revised by the interdisciplinary team if a comprehensive reassessment of the patient's status or the results of a patient case review conference indicates the need for revision.

(iii) The revision shall be incorporated into the patient's record within seven working days after the revision.

(iv) The revised treatment plan shall be reduced to writing in the person's primary language, if practicable, and provided to:

(I) the patient;

(II) a person designated by the patient; and

(III) upon request, a family member, guardian, or individual who has demonstrated on a routine basis responsibility and participation in the patient's care or treatment, but only with the patient's consent unless such consent is not required by law.

(k) Discharge and continuing care plan. The patient's interdisciplinary team shall prepare a written continuing care plan that addresses the patient's needs for care after discharge.

(1) Contents. The continuing care plan for the patient shall include recommendations for treatment and care and information about the availability of resources for treatment or care.

(2) Time frame. If the patient's interdisciplinary team deems it impracticable to provide a written continuing care plan prior to discharge, the patient's interdisciplinary team shall provide the written continuing care plan to the patient within two working days of the date of discharge.

(3) Availability. Prior to discharge or within two working days of the date of discharge, the written continuing care plan shall be provided in the person's primary language, if practicable, to:

(A) the patient;

(B) a person designated by the patient; and

(C) upon request to a family member, guardian, or individual who has demonstrated on a routine basis responsibility and participation in the patient's care or treatment, but only with the patient's consent unless such consent is not required by law.

(l) Bill of rights.

(1) Minors. A patient receiving comprehensive medical rehabilitation services shall have a patient's bill of rights which complies with §133.21 of the title (relating to Patient Rights for All Hospitals) which shall address the rights of minors and provide that a minor is entitled to the following.

(A) Treatment setting. A minor patient is entitled to appropriate treatment in the least restrictive setting available.

(B) Medication. A minor patient is entitled to not receive unnecessary or excessive medication.

(C) Treatment plan. A minor patient is entitled to an individualized treatment plan and to participate in the development of the plan.

(D) Environment. A minor patient is entitled to a humane treatment environment that provides reasonable protection from harm and appropriate privacy for personal needs.

(E) Location. A minor patient is entitled to separation from adult patients.

(F) Communication. A minor patient is entitled to regular communication between the minor patient and the patient's family, subject only to a restriction by the minor patient's physician in accordance with Chapter 404, Subchapter E of this title (relating to Rights of Persons Receiving Mental Health Services) administered by Texas Department of Mental Health and Mental Retardation (TXMHMR).

(2) Bill of rights provided. Prior to admission or acceptance for evaluation, a written copy of the patient's bill of rights in the patient's primary language, if possible, shall be given to each patient, and, as appropriate, to the patient's parent, managing conservator, or guardian.

(3) Witnessed presentation of bill of rights. If the patient cannot comprehend the information because of illness, age, or other factors, or an emergency exists that precludes immediate presentation of the information, or the patient refused to sign the written copy of the patient's bill of rights, the presentation of the document shall be witnessed by two members of the hospital staff, and the unsigned patient's bill of rights shall be placed in the clinical record along with a note signed by the witnesses indicating the reasons for their signatures.

(4) Explanation. The hospital shall ensure that within 24 hours after the patient is admitted to the hospital, the rights described in this subsection are explained to the patient and, if appropriate, to the patient's parent, managing conservator, or guardian in the following manner:

(A) orally, in simple, nontechnical terms in the person's primary language, if possible; or

(B) other reasonable means calculated to communicate with a person who has an impairment of vision or hearing, if applicable.

(5) Signed. The hospital shall obtain a signed copy of the patient's bill of rights from each patient, or, if appropriate, from the patient's parent, managing conservator, or guardian. The signed copy shall include a statement that the patient, patient's parent, managing conservator, or guardian has read the document and understands the rights specified in the document. The signed copy shall be made a part of the patient's medical record.

§133.63. Mental Health Services in an Identifiable Part of a Hospital.

(a) Admission criteria. A hospital providing mental health services shall have written admission criteria that are applied uniformly to all patients.

(1) Admission of minors. The hospital's admission criteria shall include procedures to prevent the admission of minors for a condition which is not generally recognized as responsive to treatment in an inpatient setting for mental health services.

(A) The following are not generally recognized as responsive to treatment in a hospital unless the minor to be admitted is qualified because of other disabilities:

(i) persons with cognitive disabilities due to mental retardation; or

(ii) learning disabilities.

(B) A minor may be qualified for admission based on other disabilities which would be responsive to mental health services.

(C) A minor patient shall be separated from adult patients.

(2) Admission consent. The medical record shall contain evidence that admission consent was given by the patient or the patient's legal guardian or managing conservator, if applicable.

(3) Preadmission examination. The hospital shall have a preadmission examination procedure under which each patient's conditions and medical history are reviewed by a qualified physician to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(4) Voluntary admission A voluntarily admitted patient shall sign an admission consent form prior to admission to a psychiatric or chemical dependency unit which includes verification that the patient has been informed of the services to be provided and the estimated charges.

(b) Compliance. A hospital providing mental health services shall comply with the following rules administered by the Texas Mental Health and Mental Retardation board (TXMHMR). These rules apply immediately upon diagnosis of the patient as having a psychiatric disorder.

(1) Standards of care. Chapter 401, Subchapter J of this title (relating to Standards of Care and Treatment in Psychiatric Hospitals) shall be met.

(2) Patient rights. Chapter 404, Subchapter E of this title (relating to Rights of Persons Receiving Mental Health Services) shall be met. The hospital shall prominently and conspicuously post for display a copy of the patient's bill of rights in a public area of the hospital that is readily visible to patients, residents, employees, and visitors. The patient's bill of rights posted for display shall be in English and in a second language appropriate to the demographic makeup of the community served.

(3) Electroconvulsive therapy. Chapter 405, Subchapter E of this title (relating to Electroconvulsive Therapy) shall be met.

(4) Psychoactive medication. Chapter 405, Subchapter FF of this title (relating to Consent to Treatment with Psychoactive Medication) shall be met. This subchapter applies in cases in which a patient is committed to care that is funded by the state.

(5) Restraint and seclusion. Chapter 405, Subchapter F of this title (relating to Restraint and Seclusion in Mental Health Facilities) shall be met.

§133.64. Chemical Dependency Services in an Identifiable Part of a Hospital.

(a) Admission criteria. A hospital providing chemical dependency services shall have written admission criteria that are applied uniformly to all patients.

(1) Admission of minors. The hospital's admission criteria shall include procedures to prevent the admission of minors for a condition which is not generally recognized as responsive to treatment in an inpatient setting for chemical dependency services.

(A) The following are not generally recognized as responsive to treatment in a treatment facility for chemical dependency unless the minor to be admitted is qualified because of other disabilities:

(i) persons with cognitive disabilities due to mental retardation;

(ii) learning disabilities; or

(iii) psychiatric disorders.

(B) A minor may be qualified for admission based on other disabilities which would be responsive to chemical dependency services.

(C) A minor patient shall be separated from adult patients.

(2) Preadmission examination. The hospital shall have a preadmission examination procedure under which each patient's condition and medical history are reviewed by a qualified physician to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(3) Voluntary admission. A voluntarily admitted patient shall sign an admission consent form prior to admission to a psychiatric or chemical dependency unit which includes verification that the patient has been informed of the services to be provided and the estimated charges.

(b) Compliance. A hospital providing chemical dependency services shall comply with 40 Texas Administrative Code (TAC), Chapter 148 (relating to Licensure) administered by the Texas Commission on Alcohol and Drug Abuse (TCADA) under the Health and Safety Code, (HSC), Title 6, Subtitle B, Chapter 464. The rules in 40 TAC, Chapter 148 apply immediately upon diagnosis of the patient as chemically dependent and include rules relating to the following:

(1) patient's bill of rights;

(2) marketing, admission, and referral services; and

(3) standards of care for chemical dependency.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

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Susan K. Steeg
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Texas Department of Health

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For further information, please call: (512) 458-7236

Subchapter E. Physical Plant and Fire Safety Requirements

• 25 TAC §133.71, §133.72

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the offices of the Texas Department of Health or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed action.

§133.71. Construction Plans, Specifications, and Inspections.

§133.72. Waiver Provisions.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 15, 1995.

TRD-9503195 Susan K. Steeg
General Counsel
Texas Department of Health

Earliest possible date of adoption: April 21, 1995

For further information, please call: (512) 458-7236

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Subchapter G. Operational Requirements for All Hospitals

• 25 TAC §§133.71-133.73

The new sections are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and Section 12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed new action.

§133.71. Fire Prevention and Protection.

(a) Fire inspections.

(1) Annual inspection. It shall be the duty of the chief of the fire department to inspect, or cause to be inspected, at least annually, all hospitals within the jurisdiction of fire department services.

(2) Purpose of inspection. The purpose of these inspections shall be to ascertain and to cause to be corrected any conditions liable to cause fire or violations of any of the provisions or intents of these rules, or of any other applicable ordinances, which affect fire safety in any way.

(3) Hazardous or dangerous conditions or materials. Whenever any of the officers, members, or inspectors of the fire department or bureau of fire prevention find in any building or upon any premises dangerous or hazardous conditions or materials, removal or remedy of dangerous conditions or materials shall be ordered in a manner specified by the head of the local fire department.

(4) Access for inspection. At all reasonable hours, the chief of the fire department, the chief of the bureau of fire prevention, or any of the fire inspectors may enter any building or premises for the purpose of making an inspection or investigation which, under the provisions of these rules, may be deemed necessary.

(b) Compliance. Compliance with standards of the National Fire Protection Association (NFPA) shall be deemed evidence of compliance with the fire safety provisions of the rules for existing facilities. Further, nothing in these rules shall prevent the abatement of fire hazards not specifically mentioned. The Texas Department of Health adopts by reference the various NFPA standards referenced in this section in §133.100(b)(1)(M) of this title (relating to Codes and Standards).

(c) Fire reporting. All occurrences of fire shall be reported to the local fire authority and shall be reported in writing to the Director of the Health Facility Licensure and Certification Division of the Texas Department of Health.

(d) Fire protection.

(1) Provision of fire protection. Fire protection shall be provided in accordance with the requirements of NFPA 101 and §133.96(b) of this title (relating to Physical Plant-Existing Hospitals) and §133.99(a), (b), and (d) of this title (relating to Construction Requirements).

(2) Fire department approval. Approval of the fire protection of a hospital by the local fire department shall be a prerequisite for licensure.

(e) Smoking rules. Each hospital shall establish and enforce a smoking policy. The policy shall include the minimal provisions of NFPA 101, Section 31-4.4,

and NFPA 99 and, if allowed, shall provide for smoking in designated areas only.

(1) Smoking policies. The smoking policies for the hospital shall be prominently displayed at all entrances of each hospital.

(2) "No Smoking" signs.

(A) Posting requirements in restricted areas. "No Smoking" signs shall be posted in corridors of operating, delivery, and emergency room suites, in all areas where inhalation therapy is in use, and in all areas where smoking is restricted by policy.

(B) Posting requirements in storage areas. "No Smoking" signs shall be prominently displayed in areas where flammable liquids or gases are stored and in areas where combustibles are stored.

(f) Fire extinguishing systems.

(1) Inspection, testing, and maintenance of fire-fighting equipment.

(A) Standpipes shall be inspected and tested at least once each year.

(B) Sprinkler systems shall be tested, inspected, and maintained in accordance with NFPA 13A.

(C) Fire hoses shall be inspected annually.

(D) Fire extinguishing systems for commercial cooking equipment, such as at range hoods, shall be inspected and maintained in accordance with NFPA 96.

(2) Portable fire extinguishers.

(A) Recharging and tagging extinguishers Fire extinguishers shall be refilled when necessary and kept in condition for instant use. A tag indicating the date of the last inspection and the name, address, and telephone number of the person who recharged the unit shall be attached to each extinguisher at all times.

(B) Installation and maintenance. Every portable fire extinguisher located in a hospital or upon hospital property shall be installed and maintained in accordance with NFPA 10 and NFPA 101. The hose, nozzle, gaskets, and all other parts shall be maintained in good repair at all times. Defective hoses shall be replaced immediately.

(C) Location of fire extinguishers. All buildings shall be provided with approved fire extinguishing equipment adequate for the conditions involved and suitably located so that a person shall not have to travel more than 75 feet from any point to reach a fire extinguisher.

(g) Fire protection and evacuation plan. An approved plan for the protection of patients in the event of fire and their evacuation from the building when necessary shall be formulated by the management. Copies of the plan shall be available to all staff.

(1) Posting requirements. This plan shall be reduced to a written plan with an evacuation floor plan which shall be prominently and conspicuously posted for display throughout the hospital in public areas that are readily visible to patients, residents, employees, and visitors.

(2) Employee duties. All employees shall be instructed and kept informed regarding their duties under the fire protection and evacuation plan. All personnel shall be familiar with the locations of fire-fighting equipment.

(3) Annual training. Each hospital and institution shall formulate an annual training program for instruction of all personnel in the location and use of fire-fighting equipment.

(h) Fire drills. As required by NFPA 101, at least 12 fire drills shall be conducted each year, one fire drill per shift per quarter, which shall include communication of alarms, simulation of evacuation of patients and other occupants, and use of fire-fighting equipment.

(i) Fire alarm system. Every hospital and building used for patient care shall have an approved fire alarm system.

(1) System for communicating an alarm of fire. A reliable telephone system shall be provided as a means of communicating an alarm of fire to the fire department. This is in addition to the automatic alarm transmission to the fire department required by NFPA 101, Emergency Forces Notification.

(2) Installation and testing of alarms. All fire alarms shall be installed and tested as required by NFPA 72 and NFPA 101.

(j) Fire department access. As an aid to fire department services, every hospital shall provide the following.

(1) Driveways. The hospital shall maintain proper driveways, free from all obstructions, to main buildings for fire department apparatus use.

(2) Submission of building plans. Upon request, the hospital shall submit a copy of the plans of the building to the local fire department officials.

(3) Outside identification. The hospital shall place proper identification on the outside of the main building showing the locations of siamese connections and standpipes as required by the local fire department services.

(k) Fire department protection. When a hospital is located outside of the service area or range of the public fire protection, arrangements shall be made to have the nearest fire department respond in case of a fire.

§133.72. General Safety.

(a) Safety committee. Each hospital shall have a multi-disciplinary safety committee. The Chief Executive Officer (CEO) shall appoint the chairman and members of the safety committee.

(1) Safety director or officer. The CEO shall appoint a safety director or safety officer who is knowledgeable in safety practices in health care facilities. The safety director shall be a member of the safety committee, and shall be ensured of time to carry out the functions of the safety program.

(2) Safety meetings. The safety committee shall meet as required by the chairman, but not less than quarterly. Written minutes of each meeting shall be maintained.

(3) Safety activities.

(A) Incident reports. An incident reporting system shall be established which includes a mechanism to ensure that all incidents recorded in safety or quality assurance committee minutes are investigated, evaluated, and documentation provided to show follow-up and corrective actions.

(B) Safety policies and procedures. Safety policies and procedures for each department or service, including outpatient services operated under the hospital's license, shall be developed and implemented.

(C) Safety training and continuing education. Safety training shall be established as part of new employee orientation and in the continuing education of all employees, including outpatient services personnel.

(4) Written authority. The authority of the safety committee, through the action of the chairman or director, to take action when conditions exist that are a possible threat to life, health, or building damage, shall be defined in writing and approved by the governing body or CEO, as applicable, and by the medical staff.

(b) Safety manual. Each department or service, including outpatient services operated under the hospital's license, shall have a safety policy and procedure manual within their own area that becomes a part of the overall facility safety manual.

(c) Hazard communications.

(1) Private hospitals shall comply with Health and Safety Code, (HSC), Chapter 507 and related §295.183 of this title (relating to Nonmanufacturing Facilities Community Right-To-Know) administered by the Texas Department of Health (department), Occupational Safety and Health Division.

(2) Public hospitals shall comply with the Hazard Communications Act, HSC, Chapter 502 and related §§295.1-295.8 of this title (relating to Hazard Communications) administered by the department's Occupational Safety and Health Division.

(3) Public hospitals shall comply with the Public Employer Community Right-To-Know Act, HSC, Chapter 506 and related §295.182 of this title (relating to Public Facilities Community Right-To-Know) administered by the department's Occupational Safety and Health Division.

(d) Disaster plans.

(1) Written plans. The hospital shall have written plans for the timely care of casualties arising from both external and internal disasters.

(2) References. National Fire Protection Association (NFPA) 99, Annex 1 and the State of Texas Emergency Management Plan and applicable annexes and appendices shall be used as references to establish the disaster plans. The department adopts by reference the various NFPA standards referenced in §133. 100(b)(1)(M) of this title (relating to Codes and Standards). The department adopts by reference the State of Texas Emergency Management Plan and applicable annexes and appendices in §133.100(b)(3)(U) of this title. (Information regarding the State of Texas Emergency Management Plan is available from the city or county Emergency Management Coordinator).

(3) Annual rehearsal. The hospital shall practice the disaster plans at least one time per year.

(4) Documentation The hospital shall document the rehearsal of the plans.

§133.73. Handling and Storage of Gases, Anesthetics, and Flammable Liquids.

(a) Flammable germicides. Flammable germicides shall not be used for preoperative preparation of the surgical field.

(b) Flammable and nonflammable gases and liquids. When stored within the hospital, nonflammable gases (examples include, but are not limited to, oxygen and nitrous oxide) and flammable gases or liquids shall be stored in rooms conforming to the applicable rules for such storage rooms as required in National Fire Protection Association (NFPA) 99 and NFPA 101 and applicable requirements by the Compressed Gas Association (CGA) in Pamphlet G-8.1, 1979, Nitrous Oxide Systems at Consumer sites, CGA Pamphlet P-1, Characteristics of Safe Handling of Compressed Gases, and CGA Pamphlet P-2, Characteristics of Safe Handling of Medical Gases. The Texas Department of Health adopts by reference the various NFPA standards in §133.100(b)(1)(M) of this title (relating to Codes and Standards) and CGA standards in §133.100(b)(1)(F) of this title.

(1) Exception-flammable liquid. One day's supply of flammable liquid may be stored in approved safety cans in laboratories or other places where used.

(2) Exception-alcohol. Alcohol may be kept in plastic containers of one gallon or less.

(c) Nonflammable medical gas installation. Nonflammable medical gas systems shall be installed in accordance with the rules in §133.99(e)(3)(F) of this title (relating to Construction Requirements).

(d) Fire prevention. No motor vehicle, gasoline-powered equipment, or other devices which may cause or communicate fire, and which are not necessary for patient treatment or care, shall be stored within a hospital or institution building. All such devices and materials which are necessary shall be used within the building only with precautions which ensure a reasonable degree of safety from fire.

(e) Transfer of flammable liquids. Transfer of flammable liquids shall be handled in accordance with NFPA 99. Containers being filled shall be effectively bonded to the container from which the transfer is being made.

(f) Handling of gases. Gases shall be handled in accordance with the requirements in NFPA 99, CGA Pamphlet G-8.1, 1979, CGA Pamphlet P-1, and CGA Pamphlet P-2.

(g) Oxygen. Oxygen shall be administered only in locations in which every effort has been made to reduce the possibility of accidental combustion. The use of unapproved nurse call systems, unapproved electric beds, or any other unapproved equipment which would be a possible source of ignition, is prohibited in areas used for the administration of oxygen.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 15, 1995.

TRD-9503185 Susan K. Steeg
General Counsel
Texas Department of Health

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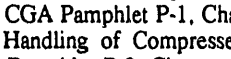
For further information, please call: (512) 458-7236



Subchapter H. Physical Plant and Construction

• 25 TAC §§133.91-133.101

The new sections are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and Section 12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed new action.

§133.91. Construction Plans, Specifications, and Inspections.

(a) Submission of plans and specifications and fees. Before construction is begun, plans and specifications covering the construction of new buildings or alterations, additions, conversions, modernizations, or renovations to existing buildings, shall be submitted to the Texas Department of Health (department) for review and approval. These plans and specifications must be accompanied by an Application for Plan Review, and the appropriate plan review fee as required by §133.3 of this title (relating to Fees). The cost of submitting plans and specifications shall be borne by the sender.

(1) Preliminary and final stages. The submission of plans and specifications shall be made in preliminary and final stages.

(2) Preliminary (stage one) plans. Preliminary (stage one) plans shall be submitted in accordance with subsection (b)(1) of this section.

(3) Correction of stage one deficiencies. All deficiencies noted in the preliminary (stage one) plan review shall be satisfactorily resolved prior to proceeding with final plans and specifications (stage two). This paragraph also applies to fast-track projects.

(4) Final (stage two) plans. The final working plans and specifications shall be submitted to the department for review and approval prior to construction. Any contract modifications which affect or change the function, design, or designated use of an area shall be submitted to the department for approval prior to authorization of the modifications. Final (stage two) plans shall be submitted in accordance with subsection (b)(2) of this section.

(5) Minor remodeling or alterations. Minor remodeling or alterations which do not involve alterations to load bearing members or partitions, change functional operation, affect fire safety, and add beds or services over those for which the hospital is licensed may be requested for approval without submittal of contract documents and specifications. Approval shall be requested in writing with a brief description of the proposed changes and accompanied by a sketch of the area being remodeled.

(6) Installation, alteration, or extension approval. No system of mechanical, electrical, plumbing, fire protection, or medical gases shall be installed, or any such existing system shall be materially altered or extended, until complete plans and specifications for the installation, alteration, or extension have been submitted to the department for review and approval in accordance with this subchapter.

(7) TDLR approval. Project plans and specifications shall be submitted to the Texas Department of Licensing and Regulation (TDLR), Elimination of Architectural Barriers section, for review and approval. Written approval by TDLR shall be submitted to the department.

(b) Preparation of plans and specifications.

(1) Stage one. One complete set of the preliminary plans and outline specifications shall be submitted and contain sufficient information to establish the project scope, project location, required fire safety and exiting criteria, building construction type, compartmentation showing fire and smoke barriers, bed count and services, and the assignment of all spaces, areas, and rooms for each floor level including the basement.

(A) Scale. The plans shall be drawn at a scale sufficiently large to clearly present the proposed design.

(B) Floor area and bed distribution. The total floor area and proposed bed distribution shall be computed and shown on the drawings.

(C) Floor plan. Each floor plan shall indicate the type and location of all fire protection rated partitions, fire and smoke compartments including the gross area at each compartment, and means of egress.

(D) Existing floor plan. An overall floor plan showing existing spaces, smoke partitions, smoke compartments, and exits and their relationship to the new construction shall be submitted on all renovations or additions to an existing facility. Plans for remodeling of spaces above the level of discharge shall include the level of discharge floor plan showing all exits at that level.

(E) Construction type and fire rating. A building section(s) shall be required to establish construction type and fire protection rating. Section(s) shall be drawn at a scale sufficiently large to clearly present the proposed construction system.

(F) Site plan. A site plan shall be submitted and shall indicate the location of the building(s) in relation to property lines, existing buildings or structures, access and approach roads, and parking areas and drives. Any overhead or underground utilities or service lines and building structures or other conditions which may impair or adversely affect the construction shall be indicated.

(G) Outline specifications. Outline specifications shall provide a general description of the construction, materials, and finishes that are not shown on the drawings.

(2) Stage two. One complete set of construction documents (final drawings and specifications) shall be submitted. All working drawings shall be well prepared so that clear and distinct prints may be obtained and accurately dimensioned and shall include all necessary explanatory notes, schedules, and legends. Final drawings shall be complete and adequate for contract purposes. All final plans and specifications shall be appropriately sealed and signed by a registered architect and professional engineer licensed by the State of Texas. Compliance with model building codes and this chapter shall be indicated. Type of construction, as classified by NFPA 220 shall be provided for existing and new facilities. Rooms shall be indicated on all plans submitted. Separate drawings shall be prepared for each of the following branches of work.

(A) Architectural drawings. Architectural drawings shall include the following:

(i) site plan showing all new topography, newly established levels and grades, existing structure on the site (if any), new buildings and structures, roadways, walks, and the extent of the areas to be landscaped. All structures which are to be removed under the construction contract and improvements shall be shown;

(ii) plan of each floor and roof to include fire and smoke separation, means of egress, and identification of all spaces;

(iii) separate fire safety plan of each floor and roof (preferably one floor plan per sheet) shall indicate smoke partitions, the type (one and two hour) and location of fire protection rated walls and partitions, designated smoke compartments, and the required means of egress (corridors, stairs, exit passageways);

(iv) schedules of doors, windows, and finishes;

(v) elevations of each facade;

(vi) sections through building; and

(vii) scaled details as necessary.

(B) Equipment drawings. Equipment drawings shall include the following:

(i) all equipment necessary for the operation of the hospital as planned. The design shall indicate provisions for the installation of large and special items of equipment and for service accessibility;

(ii) fixed equipment (equipment which is permanently affixed to the building or which must be permanently connected to a service distribution system designed and installed during construction for the specific use of the equipment). The term "fixed equipment" includes items such as laundry extractors, walk-in refrigerators, communication systems, and built-in casework (cabinets);

(iii) movable equipment (equipment not described in clause (ii) of this subparagraph as fixed). The term "moveable equipment" includes wheeled equipment, plug-in type monitoring equipment, and relocatable items such as operating tables and obstetrical tables; and

(iv) equipment which is not included in the construction contract but which requires mechanical or electrical service connections or construction modifications. The equipment described in this clause shall be identified on the drawings to ensure its coordination with the architectural, mechanical, and electrical phases of construction.

(C) Structural drawings. Structural drawings shall include:

(i) plans for foundations, floors, roofs, and all intermediate levels;

(ii) a complete design with sizes, sections, and the relative location of the various members;

(iii) a schedule of beams, girders, and columns;

(iv) dimensioned floor levels, column centers, and offsets;

(v) details of all special connections, assemblies, and expansion joints; and

(vi) special openings and pipe sleeves dimensioned or otherwise noted for easy reference.

(D) Mechanical drawings. Mechanical drawings shall include:

(i) complete ventilation systems (supply, return, exhaust), all fire and smoke partitions, locations of all dampers, registers, and grilles, air volume flow at each device, and identification of all spaces (i.e. corridor, patient room, operating room);

(ii) boilers, chillers, heating and cooling piping systems (steam piping, hot water, chilled water), and associated pumps;

(iii) cold and warm water supply systems, water heaters, storage tanks, circulating pumps, plumbing fixtures, emergency water storage tanks, and special piping systems such as for deionized water;

(iv) non-flammable medical gas piping (oxygen, compressed medical air, vacuum systems, nitrous oxide), emergency shut-off valves, pressure gages, alarm modules, gas outlets;

(v) drain piping systems (waste and soiled piping systems, laboratory drain systems, roof drain systems);

(vi) fire protection piping systems (sprinkler piping systems, fire standpipe systems, water or chemical extinguisher piping system for cooking equipment); and

(vii) piping riser diagrams, equipment schedules, control diagrams, or narrative description of controls, filters, and location of all duct mounted smoke detectors.

(E) Electrical drawings. Electrical drawings shall include:

(i) all electrical wiring, receptacles, light fixtures, and equipment which require electrical connections;

(ii) electrical service entrance with service switches, service feeders to the public service feeders, and characteristics of the light and power current. Transformers and their connections shall be included, if located in the building;

(iii) schematic diagram showing main switchboard, power panels, light panels, and equipment. Feeder and conduit sizes shall be shown with schedule of feeder breakers or switches;

(iv) telephone and communication, fixed computers, terminals, connections, outlets, and equipment;

(v) nurse call system showing all stations, signals, and annunciators on the plans and one-line diagram of the complete system;

(vi) fire alarm system showing the location of all system components and fire zones on the plans and a one-line diagram of the complete system;

(vii) a one-line diagram showing the complete essential electrical system including the on-site generator, transfer switch(es), equipment system, and emergency system (life safety branch and critical branch), panels, subpanels, all panel schedules, connected load of each panel, transformers, conduit, and wire sizes;

(viii) light fixtures shall be marked distinctly to indicate connection of critical life safety at normal lighting circuits; and

(ix) schedules of all panels indicating connection to life safety branch, critical branch, equipment system or normal system, and connected lead at each panel.

(c) Special submittal.

(1) Fast-track projects.

(A) Approval and submittal. Fast-track projects shall have prior approval by the department and shall be submitted in a maximum of four separate packages.

(B) Fast-track packages. Fast-track packages shall be submitted for the following:

(i) site work, foundation, structural, underslab mechanical, electrical, and plumbing work, and related specifications;

(ii) complete architectural plans and specifications;

(iii) all mechanical, electrical, and plumbing plans and specifications; and

(iv) equipment and furnishings.

(2) Automatic sprinkler systems. One set of approved sprinkler system shop drawings, specifications, and calculations, prepared by the licensed installer, shall be submitted to the department for recordkeeping. Sprinkler requirements in §133.99(e)(4) of this title (relating to Construction Requirements) shall be met.

(3) Radiation protection. Prior to installment of radiology equipment relating to a project, a hospital shall include in the project submission one set of plans, specifications, and radiation shielding criteria prepared by a qualified radiation physicist experienced in the field of radiation protection.

(d) Construction and inspections.

(1) Major construction. Construction, of other than minor alterations, shall not be commenced until stage two plan review deficiencies have been satisfactorily resolved, the appropriate plan review fee according to the plan review schedule in §133.3 of this title (relating to Fees) has been paid, and the department has issued a letter granting approval to begin construction. Such authorization does not constitute release from the requirements contained in this chapter. If the construction takes place in or near occupied areas, adequate provision shall be made for the safety and comfort of patients.

(2) Written notification. The architect or licensee shall provide written no-

tification to the department when construction is commenced. The department shall be notified in writing of any change in the completion schedules.

(3) Progress reports. After construction has commenced, progress reports shall be submitted by the hospital as required by the department to monitor the construction work

(4) Completion. Construction shall be completed in compliance with the construction documents including all addenda or modifications approved for the project.

(5) Determination of the number of construction inspections. The department shall determine the number of required inspections necessary to complete all proposed construction projects. All hospitals including those which maintain certification under Title XVIII of the Social Security Act (42 United States Code §1395 et seq) and those which maintain accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or by the American Osteopathic Association (AOA) are subject to construction inspections.

(6) Inspections. A minimum of two construction inspections of the project in the hospital shall normally be scheduled for the purpose of verifying compliance with this subchapter and the approved plans and specifications.

(A) Intermediate inspection. The intermediate construction inspection shall be scheduled at approximately 80% completion. All major work above the ceiling shall be completed.

(B) Final inspection. The final construction inspection shall be scheduled at 100% completion when the project is ready to be occupied. All electrical, mechanical, and fire safety systems shall have been verified to operate properly in accordance with the design.

(7) Approval for occupancy. A facility shall not occupy a new structure or alteration, addition, conversion, modernization, or renovation space until the appropriate approval has been received from the local building and fire authorities and the department.

(8) Time frame for construction commencement. A construction project shall commence within one year of the construction approval date. A project not meeting this requirement shall be resubmitted to the department for approval.

(9) Project cancellation. A facility shall notify the department in writing when a project has been cancelled or abandoned.

§133.92. Waiver Provisions.

(a) Written request for a waiver. Upon submission of a written request by a particular special hospital or a particular general or special hospital serving a rural community to the Texas Department of Health's (department) hospital licensing director, and upon recommendation by the hospital licensing director, the commissioner of health (commissioner) may waive or modify the requirement of a particular provision of the Texas Hospital Licensing Act (Act) or a minimum requirement in this chapter, except fire safety requirements, for the requesting hospital if the commissioner determines that the waiver or modification will facilitate the creation or operation of the hospital and is in the best interests of the individuals served or to be served by the hospital.

(b) Waived sections. The written request shall specify the section(s) of the Act or this chapter for which a waiver is requested.

(c) Consideration. In considering the waiver or modification request, the hospital licensing director shall consider whether the waiver or modification:

(1) will adversely effect the health and safety of the hospital patients, employees, or the general public;

(2) will adversely impact the hospital's participation in the federal Medicare program or accreditation by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association;

(3) if not granted, would impose an unreasonable hardship on the hospital in providing adequate care for patients;

(4) will facilitate the creation or operation of the hospital; and

(5) is appropriate when balanced against the best interests of the individuals served or to be served by the hospital.

(d) Supporting documentation. The hospital licensing director may request written documentation from the hospital to support the waiver or modification including, but not limited to:

(1) a statement addressing each of the criteria in subsection (c) of this section;

(2) approval by the local building and fire authorities;

(3) evidence of provisions in the Act or this chapter which will mitigate any adverse effect of the waiver or modification; and

(4) evidence of any mitigating act in excess of the Act or this chapter which will be used by the hospital to offset any adverse effect of the waiver or modification.

(e) Written recommendation. A recommendation of the hospital licensing director shall be in writing and shall address each of the criteria in subsection (c) of this section.

(f) Granting order. If the hospital licensing director recommends that the waiver or modification should be granted, the commissioner may issue a written order granting the waiver or modification.

(g) Denial order. If the hospital licensing director recommends that the waiver or modification be denied, the commissioner may issue a written order denying or approving the waiver or modification.

(h) Hospital licensing file contents. If a waiver or modification is granted, the licensing file of the hospital shall contain a copy of the order, the request, the written recommendation of the hospital licensing director, and the documents requested in subsection (d) of this section.

§133.93. Construction and Building. Compliance with this chapter does not constitute release from the requirements of other applicable federal, state, or local codes and ordinances. This section shall be followed where it exceeds other codes and ordinances.

(1) Design for the handicapped. A hospital shall comply with design for the handicapped.

(A) Architectural barriers. A hospital shall be designed in accordance with the Architectural Barriers Act (ABA), Texas Civil Statutes, Article 9102; 16 Texas Administrative Code (TAC), Chapter 68 (relating to Architectural Barriers Administrative Rules); and Texas Accessibility Standards of the ABA, 19 TexReg 167, administered by the Texas Department of Licensing and Regulation (TDLR). Special design features for the handicapped shall be provided for all buildings.

(i) These special considerations shall benefit handicapped staff, visitors, and patients.

(ii) All provisions for handicapped persons shall be in accordance with standards and specifications and other applicable regulations administered by the TDLR.

(iii) The building owner and appointed designee shall comply with the TDLR instructions, rules, and regulations for the plan and specification review process and shall be responsible for com-

pleting the necessary forms and for obtaining final approval from TDLR.

(B) Rehabilitation Act. A hospital shall meet applicable requirements of the federal Rehabilitation Act of 1973, §504, which requires program accessibility as well as facility accessibility. When federal funds are used for construction, for program requirements, or for client services, the handicapped requirements of §504 shall apply. In such cases, all facilities constructed after June 3, 1977 shall be designed and constructed to conform with the American National Standards Institute (ANSI) A.117.1 requirements for handicapped individuals which the Texas Department of Health (department) adopts by reference in §133.100(b)(1)(E) of this title (relating to Codes and Standards). The United States Department of Health and Human Services, (USDHHS) Office of Civil Rights enforces the ANSI standards, pursuant to 45 Code of Federal Regulations (CFR) §84.22 and §84.23.

(C) Americans with Disabilities Act. A hospital shall comply with the USDHHS, Office of Civil Rights, Requirements for Program Accessibility and Facility Accessibility, as required by the Americans with Disabilities Act (ADA), Public Law 101-336, 42 United States Code, Chapter 126 and Appendix to Part 1191-ADA Accessibility Guidelines for Buildings and Facilities, Federal Register, Volume 56, Number 144, July 26, 1991, Rules and Regulations, pages 35455-35542.

(2) Physical environment. A hospital shall provide a physical environment that protects the health and safety of patients, personnel, and the public. The physical premises of the hospital and those areas of the hospital's surrounding physical structure that are used by the patients (including all stairwells, corridors, and passageways) shall meet the local building and fire safety codes and this chapter.

(3) Hazardous to health and safety. No building may be converted for use as a hospital which, because of its location, physical condition, state of repair, or arrangement of facilities, would be hazardous to the health and safety of the patients who would be housed in such a building. Prior to licensure by the department, the hospital shall meet all requirements for new construction.

(4) Fire safety. The hospital shall comply with the requirements found at 42 CFR §482(b)(1)(i) which the department adopts by reference in this section as the fire safety requirements for all hospitals which have been vacated or used for an occupancy other than as a hospital. These requirements are that the hospitals shall meet the applicable provisions of the 1991 edition of the National Fire Protection Association's Life Safety Code (NFPA 101) which the department adopts by reference in §133.100(b)(1)(M) of this title, unless such hospitals are in compliance and continue to remain in compliance with the 1967, 1973, 1981, or 1985 edition of NFPA 101, which the department adopts by reference in this section, that was in effect when the hospital was constructed, modified, or expanded.

(5) Exceeding minimum requirements. Nothing in this subchapter shall be construed to prohibit a better type of building construction, more exits, or otherwise safer conditions than the minimum requirements specified in this subchapter.

(6) Equivalency. Nothing in this subchapter is intended to prevent the use of systems, methods, or devices of equivalent or superior quality, strength, fire resistance, effectiveness, durability, and safety to those prescribed by this subchapter, providing technical documentation is submitted to the department to demonstrate equivalency and the system, method, or device is approved for the intended purpose.

(7) Modification. The specific requirements of this subchapter for existing buildings may be modified by the department to allow alternate arrangements that will secure as nearly equivalent safety to life from fire as practical, but in no case shall the modification afford less safety to life than compliance with the corresponding provisions contained in this subchapter for existing buildings.

(8) Other regulations. Certain projects may be subject to other regulations, including those of federal, state, and local authorities.

(A) Verification. Verification of compliance with other regulations, when applicable, is required.

(B) Medicare. In addition to the provisions of this subchapter, a project submitted by a hospital certified under Title XVIII of the Social Security Act (42 United States Code, §1395 et seq), is subject to the applicable requirements contained in the Medicare Conditions of Participation for Hospitals, 42 CFR, §§482.2-482.66.

(C) More stringent requirement. The more stringent standard or requirement shall apply when a difference in program requirements for construction exists.

(9) New construction or addition. All new construction, including additions to existing hospitals, shall comply with Chapter 12, New Health Care Occupancies, NFPA 101; and the hospital licensing rules.

(10) Conversion. An existing building may be converted to a hospital if the construction complies with Chapter 12, New Health Care Occupancies, NFPA 101; and the hospital licensing rules.

(11) Renovation. Existing hospital buildings may be modernized or renovated for health services; however, no construction shall diminish the fire safety features of the hospital currently in effect.

(A) Renovation-compliance. When an existing hospital is modernized or renovated, that portion of the hospital affected by the work shall comply with provisions of Chapter 12, New Health Care Occupancies, NFPA 101 and the hospital licensing rules.

(B) Existing hospital-compliance. An existing hospital shall at least maintain the level of fire safety required in NFPA 101 and the requirements of the Hospital Licensing Rules under which the facility was constructed.

(C) Existing building-noncompliance. An existing hospital which does not comply with all provisions of NFPA 101 and the Hospital Licensing Rules under which the facility was constructed may continue temporarily in service subject to approval of the department. A limited but reasonable amount of time shall be allowed for compliance with the life safety requirements of the "Fire Safety Evaluation System for Health Care Facilities" contained in NFPA 101M, "Alternative Approaches to Life Safety."

(12) Plan submission. Plans and specifications for buildings and facilities shall be submitted as required by §133.91 of this title (relating to Construction Plans, Specifications, and Inspections).

(13) Energy conservation. In the implementation of energy conservation initiatives and as a part of an overall energy conservation plan, each applicant shall use American Society of Heating, Refrigerating, and Air-conditioning Engineers (ASHRAE) Standard 90.1, Energy Efficiency Design of New Buildings which the department adopts by reference in §133.100(b)(1)(C) of this title, or equivalent criteria to improve the utilization of energy in new building design.

§133.94. Physical Plant.

(a) General. A hospital may be located in a separate building or in portions of a building provided the entire building complies with the construction requirements of this chapter.

(1) Building containing more than one hospital. A hospital located in a

building containing more than one hospital shall be separated with two-hour fire protection rated construction and contain all the architectural, mechanical, and electrical elements required for a hospital such as, but not limited to, administration, pharmacy, medical records, employee facilities, and nursing units. Other hospital services may be contracted as needed.

(2) Building shared with psychiatric hospitals and non-hospital occupancies. A hospital sharing a building with a psychiatric hospital and non-hospital occupancies shall be separated with two-hour fire protection rated construction from the remainder of the building and contain all the architectural, mechanical, and electrical elements required for a hospital.

(A) Separate entrances. Separate entrances to the hospital shall be provided and shall be identified with the name of each hospital.

(B) Ambulance entrance. Separate ambulance entrance to the emergency department shall be provided.

(C) Pedestrian entrance. Separate pedestrian entrance to the emergency department shall be provided from the exterior.

(D) Service entrance. Separate service entrance or dock shall be provided.

(E) Morgue entrance. When the hospital contains a morgue, an exterior entrance shall be provided.

(b) Cooking appliances.

(1) Electric cooking appliances. Electric cooking appliances shall be installed in accordance with NFPA 70. The Texas Department of Health (department) adopts by reference the various NFPA standards referenced in this section in §133.100(b)(1)(M) of this title (relating to Codes and Standards).

(2) Gas cooking appliances. Gas cooking appliances shall be installed in accordance with NFPA 54.

(3) Hoods and filters. Metal exhaust hoods with filters shall be provided over cooking appliances. Such hoods or canopies shall be equipped and designed in compliance with NFPA 96.

(4) Filters. Only listed filters shall be used in kitchen exhaust hoods. Filters shall be kept clean and in efficient working order.

(c) Gas appliances.

(1) General. The installation, use, and maintenance of gas fired appliances, heating equipment, and gas piping including venting shall comply with NFPA 54.

(2) Prohibited gas appliances. The use of the following gas appliances shall be prohibited:

(A) portable gas heaters;

(B) floor furnaces; and

(C) open flame heaters.

(3) Fresh air inlet and vent. A fresh air inlet and a vent directly to the outside of the building shall be provided in the hot water heater, boiler, or furnace room where gas-fired equipment is used.

(4) Hot water heater. All hot water heaters shall be equipped with an approved temperature pressure relief valve.

(5) Direct fuel-fired heating unit. All direct fuel-fired heating units shall be designed to discharge the products of combustion into an approved flue. All such flues shall be properly connected to a vertical flue or chimney leading to the outer air above the high point on the roof. Direct fuel-fired heating units shall not be permitted in any operating room or in any room where combustible vapors may be present.

(d) Heating, cooling, and ventilating systems.

(1) General. Heating shall be provided for all areas of the hospital to meet prevailing weather conditions and shall have the capability of maintaining a minimum temperature of 70 degrees Fahrenheit. All heating units and systems shall meet state and local regulations.

(2) Requirements. All heating, cooling, and ventilating systems shall conform to the requirements of §133.99(e)(2) of this title (relating to Construction Requirements).

(e) Lighting.

(1) General lighting.

(A) In hospitals having operating rooms or delivery rooms, there shall be adequate illumination of the operative field as well as general illumination.

(B) All means of egress such as hallways, corridors, stairways, exterior exit doors, inclines, ramps, and entrances shall be well lighted.

(C) Every room including storerooms and attics shall have sufficient artificial lighting so that all parts of the room shall be clearly visible.

(D) Lighting levels shall be as described by the Illumination Engineering Society of North America (IES) in Lighting for Health Care Facilities and in the IES Lighting Handbook which the department adopts by reference in §133.100(b)(1)(J) of this title.

(2) Patient room lighting. All patient rooms shall have, as a minimum, a night light, a patient's reading light, and general illumination. Switches for general illumination and night light fixtures shall be provided at the entrance to each patient room.

(f) Plumbing.

(1) General. New installations, correction of defects, and system maintenance shall follow the recommendations of the National Standard Plumbing Code (NSPC) which the department adopts by reference in §133.100(b)(1)(K) of this title.

(2) Compliance. The NSPC shall be used to determine satisfactory compliance of individual plumbing fixture installations.

(3) Bathroom and lavatory facilities. Bathroom and lavatory facilities shall be provided in numbers ample for use according to the number of personnel and patients of both sexes.

(4) Water testing. When a municipal water supply is not available to the hospital, the water shall be tested at monthly intervals in accordance with the rules administered by the department.

(5) Cross contamination. The plumbing system shall be free from cross-connections and interconnections between a safe water supply and one which is subject to contamination or between a safe water supply and sewage, waste water, drainage, condensates, previously used water, contents of plumbing fixtures, or any other contaminated material.

(6) Back flow or siphoning. All plumbing fixtures and equipment shall be designed and installed to prevent the back-flow or back-siphonage of any material into the water supply. The over-the-rim type water inlet shall be used wherever possible. Vacuum-breaking devices shall be properly installed when an over-the-rim type water inlet cannot be utilized.

(7) Drinking fountain. Each drinking fountain shall be designed so that the water issues at an angle from the vertical, the end of the water orifice is above the rim of the bowl, and a guard is located over the orifice to protect it from lip contamination.

(8) Hose position. No hose shall be affixed to any faucet if the end of the hose can become submerged in contaminated liquid unless the faucet is equipped with an approved, properly installed vacuum-breaker.

(9) Sterilizing equipment. All sterilizing equipment shall be designed and installed to prevent not only the contamination of the water supply but also the entrance of contaminating materials into the sterilizing units.

(10) Bedpan washers and sterilizers. Bedpan washers and sterilizers shall be designed and installed so that both hot and cold water inlets shall be protected against back-siphonage at maximum water level.

(11) Contaminated waste disposal. The plumbing and drainage or other arrangements for the disposal of excreta, infectious discharges, and household wastes shall be in accordance with the requirements of the NSPC.

(12) Sewage and liquid waste disposal. All sewage and liquid wastes shall be disposed of in a municipal or state approved sewerage system where such facilities are available. If such facilities are not available, septic tanks shall conform to the sizes and features as required in 30 TAC, Chapter 285 (relating to On-site Wastewater Treatment) administered by the Texas Natural Resources Conservation Commission (TNRCC).

(13) Radioactive waste. The disposal of all radioactive wastes shall comply with the rules in Chapter 289 of this title (relating to Radiation Control) administered by the Texas Department of Health, Division of Radiation Control.

(g) Roads and parking.

(1) Paved roads and walkways.

(A) Paved roads. Paved roads shall be provided within the lot lines to provide access to the main entrance, emergency entrance, entrances serving community activities, and to service entrances, including loading and unloading docks for delivery trucks.

(i) Hospitals having an organized emergency services department shall have the emergency entrance well marked to facilitate entry from the public roads or streets serving the site.

(ii) Access to the emergency entrance shall not conflict with other vehicular traffic or pedestrian traffic.

(iii) Access to emergency service shall be located so as not to be subject to damage from floods and other natural disasters.

(B) Walkways. Walkways shall be provided in accordance with federal, state, and local codes and ordinances.

(2) Parking.

(A) Off-street parking. Off-street parking shall be available for visitors, employees, and staff.

(i) In the absence of a formal parking study or local codes, each hospital shall provide not less than one parking space for each day shift employee plus one space for each patient bed.

(ii) This ratio may be reduced in an area convenient to a public transportation system or to public parking facilities on the basis of a formal parking study or local standards.

(B) Additional parking. Additional parking shall be required to accommodate outpatient and other services when such services are provided.

(C) Emergency and delivery parking. Parking spaces shall be provided for emergency and delivery vehicles.

(D) Handicapped parking. Parking spaces for handicapped persons shall be provided in accordance with the Architectural Barriers Act, Texas Civil Statutes (TCS), Article 9102, 16 Texas Administrative Code (TAC), Chapter 68 (relating to Architectural Barriers Administrative Rules), and the Texas Accessibility Standards (TAS), 19 Texas Register (TexReg) 167 administered by the Texas Department of Licensing and Regulation (TDLR).

(h) Storage and housekeeping.

(1) General storage. All storage space shall be kept clean and orderly at all times.

(A) Mattresses shall be stored in a small pile with sufficient access space to all sides.

(B) No storage shall extend higher than 18 inches below the bottom of ceiling, structure, or sprinkler heads.

(2) Combustible storage. When basements, storerooms, or attics are used for combustible storage, applicable requirements of NFPA 101 shall be met.

(3) Metal cabinets. Local supplies of paints, oils, and highly volatile combustible liquids shall be kept in metal cabinets having tight closing doors and drip pans. These cabinets shall be well ventilated at top and bottom.

(4) Storage of unapproved film. Storage and handling of other than approved safety film shall be in accordance with the NFPA 40.

(5) Excess combustibles. The entire premises shall be kept free from accumulations of combustible materials not necessary for immediate operation of the building.

(6) Waste paper receptacles. All waste paper receptacles shall be a metal or approved nonmetallic receptacle.

(i) Testing and maintenance.

(1) Maintenance and repair. The hospital structure, its component parts and facilities, shall be kept in good repair and maintained with consideration for the health and safety of the occupants of the building. Mechanical, plumbing, and electrical equipment shall be maintained in good repair and operating condition at all times. Physical plant equipment, medical, and surgical equipment shall be tested and maintained under a formal preventive maintenance and testing program and documentation kept for annual reviews and inspections.

(2) Air-conditioning and ventilation. All air-conditioning and ventilating systems and all duct work shall meet the requirements of NFPA 90A.

(3) Elevators. All elevator equipment shall be tested as required by Health and Safety Code (HSC), Chapter 754, Subchapter B (relating to Inspection and Certification of Elevators, Escalators, and Related Equipment) as specified in §133.99(c)(2) of this title.

(4) Casters. All patient beds and portable equipment affixed to patients, which is necessary to sustain life, shall be equipped with casters at each floor contact.

(j) Wiring and electrical appliances.

(1) General. All new installations, corrections of defects, and system maintenance shall follow the requirements of NFPA 70 and NFPA 99.

(A) New wiring. All new electrical wiring and installations shall be installed in accordance with the provisions of NFPA 70.

(B) Confined areas. Electric lamps and other appliances in closets or other confined locations shall be protected by wire guards if near woodwork, paper, clothing, or other combustible materials, or if subject to breakage.

(C) Working condition. All fixtures, switches, sockets, and other pieces of apparatus shall be maintained in a safe and working condition.

(D) Extension cords. Extension cords and cables shall not be used for permanent wiring.

(E) Multiple outlet plugs. Multiple outlet plugs shall not be used in patient care areas. Additional receptacles shall be installed where needed.

(F) Wire supports. Wire supports shall be non-combustible insulated knobs and cleats, or wire staples, or in metal or metallic raceways.

(G) Surface mounted wiring. Surface mounted wiring installed on walls or partitions shall be protected from mechanical injury to a height of seven feet above the floor.

(H) Penetrating wires. All wires through walls, floors, partitions, and building members shall be installed in approved metal sleeves or in approved conduit.

(I) Pilot light or temperature limiting device. All electrical heating devices shall be equipped with a pilot light to indicate when the device is in service, unless equipped with a temperature limiting device integral with the heater.

(2) Grounding. All equipment, fixtures, and appliances shall be properly grounded in accordance with NFPA 70.

(3) Emergency power. All hospitals shall have an approved stand-by emergency generator set capable of supplying essential electrical service, as required by NFPA 99 and §133.99(f)(4) of this title.

§133.95. Hospital Units-Spatial Requirements.

(a) General. The hospital shall ensure that all elements and spatial requirements specified in this section are met for all services and facilities provided.

(b) Hospital units-spatial requirements.

(1) Administration and public areas.

(A) Entrance. An entrance at grade level, sheltered from the weather, and able to accommodate wheelchairs shall be provided.

(B) Lobby. The lobby provided shall include:

(i) storage space for wheelchairs;

(ii) reception and information counter or desk;

(iii) waiting space(s);

(iv) public toilet facilities;

(v) public telephones; and

(vi) drinking fountain(s).

(C) Interview space(s). Space for private interviews relating to social service, credit, and admissions shall be provided.

(D) General or individual office(s). Office space for business transactions, medical and financial records, and administrative and professional staffs shall be provided.

(E) Multipurpose room(s). Room(s) for conferences, meetings, and health education purposes including provisions for showing visual aids shall be provided.

(F) Storage. Storage for office equipment and supplies shall be provided.

(2) Bone marrow transplantation unit. When bone marrow transplantation is provided, the bone marrow transplantation unit shall contain all spatial requirements specified in this paragraph.

(A) General. Units intended for bone marrow transplantation shall be designed to facilitate care of ambulatory, nonambulatory, and handicapped inpatients. Each bone marrow transplantation unit shall meet the requirements in paragraph (18) of this subsection.

(B) Patient rooms. A mix of general isolation patient rooms, reverse isolation patient rooms, and general patient rooms (complying with private room requirements specified in paragraph (10)(A)(i) of this subsection) shall be provided. The following requirements shall be met.

(i) Accommodations for overnight visitor or family member shall be provided in each isolation or general patient room.

(ii) Windows shall be provided to facilitate views of the outside.

(iii) Each isolation room shall meet the following requirements.

(I) Minimum floor area, exclusive of toilet room, closet, locker, wardrobe, alcove, or vestibule shall be 300 square feet.

(II) Entrance to an isolation room shall be through an anteroom which may serve more than one isolation room.

(III) Each isolation room shall be arranged for privacy and to permit view of each bed from the corridor and nurses station.

(IV) Isolation room finishes shall comply with isolation protocols. Walls and ceilings shall be monolithic, impervious (no lay-in ceilings), and washable. Floors shall be of the seamless or welded joint type. Drapes, curtains, or other wall hangings shall not be permitted.

(V) Restrictions on materials brought into the isolation room shall be implemented. Plants shall not be permitted in isolation rooms.

(C) Service areas. Service areas complying with paragraph (18)(B) of this subsection shall be provided. In addition, the following requirements shall be met.

(i) A satellite pharmacy shall be provided. Floor area of the pharmacy shall be not less than 50 square feet or eight square feet per bed, whichever is greater.

(ii) A consultation room, at least 80 square feet in floor area, shall be provided.

(iii) A lounge for visitors and family members shall be provided.

(iv) A lounge, library, or music room shall be provided for recovering patients.

(v) When pediatric procedures are performed, the following shall be provided.

(I) A dedicated area for visiting with recovering pediatric patients shall be provided.

(II) A play area for recovering pediatric patients shall be provided.

(3) Carts, facilities for cleaning and sanitizing.

(A) Cart storage and cleaning. Facilities shall be provided to clean and sanitize carts serving the central service department, dietary facilities, and linen services.

(B) Location. Cart facilities may be centralized or departmentalized.

(4) Central supply department. When obstetrical or surgical services are provided, the following rooms or areas shall be provided.

(A) Receiving and decontamination room. A receiving and decontamination room shall be provided and shall contain work space and equipment for cleaning medical and surgical equipment and for disposal of or processing unclean material. Handwashing facilities shall be provided. Lockers and toilets for staff employed in this area shall be provided if not available in convenient employee facilities serving other soiled areas.

(B) Clean workroom. A clean workroom shall be provided and shall contain handwashing facilities and work space and equipment for sterilizing and disinfecting medical and surgical equipment and supplies.

(C) Storage of supplies. Storage areas for clean supplies and for sterile supplies shall be provided. (May be in clean workroom).

(D) Equipment storage. An equipment storage room shall be provided.

(5) Dietary facilities.

(A) General. Construction, equipment, and installation shall comply with the standards specified in United States Department of Health and Human Services, Food and Drug Administration, publication number (FDA) 78-2081, Food Service Sanitation Manual and §§229.161-229.171 of this title (relating to Rules on Food Service Sanitation).

(B) Facilities. Food service facilities shall be provided on or off the site. These may consist of an on-site conventional food preparing system, a convenience food service system, or an appropriate combination of the two. The following facilities shall be provided regardless of type and location of dietary services:

(i) control station for receiving food supplies;

(ii) cold storage space for four calendar days supply of food. Total storage space shall be adequate to accommodate the minimum requirement for a seven calendar day cycle menu;

(iii) food preparation facilities. When conventional food preparation systems are provided, there shall be space and equipment for preparing, cooking, and baking. When convenience food service systems such as frozen prepared meals, bulk packaged entrees, and individual packaged portions, or systems using contractual commissary services are provided, there shall be space and equipment for thawing, portioning, cooking, and baking. The following shall be provided in all food preparation areas:

(I) handwashing facilities located in the food preparation area;

(II) patient meal service facilities. Examples are those required for tray assembly and distribution;

(III) dishwashing space located in a room separate from food preparation and serving area. Commercial-type dishwashing equipment shall be provided Space shall also be provided for receiving, scraping, sorting, and stacking soiled tableware and for transferring clean tableware to the using areas. A lavatory shall be located within the soiled dish wash area. There shall be no cross traffic between the dirty side and the clean side of dish wash areas and food handling areas;

(IV) pot-washing facilities, three-compartment sink minimum in new facilities;

(V) storage areas and sanitizing facilities for garbage or refuse cans, carts, and mobile tray conveyors. All containers for trash storage shall have tight-fitting lids;

(VI) waste storage facilities located in a separate room easily accessible to the outside for direct pickup or disposal;

(VII) office(s) or desk space(s) for dietitian(s) or the dietary service manager;

(VIII) toilets for dietary staff located convenient to dietary area and not open directly to the food preparation areas;

(IX) janitor closet located within the dietary department. It shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies;

(X) automatic icemaking facilities; and

(XI) grease trap or grease interceptor. The hospital shall comply with the requirements in the National Association of Plumbing-Heating-Cooling Contractors (PHCC), National Standard Plumbing Code which the department adopts by reference in §133.100(b)(1)(K) of this title (relating to Codes and Standards); and

(iv) dining space for ambulatory patients and staff.

(6) Emergency department or treatment room.

(A) General. Levels of emergency care range from elementary first aid to sophisticated surgical procedures such as repair of heart wounds. However, for these rules, emergency services are described in two broad categories: first aid and trauma.

(B) Emergency first aid services. The following minimum facilities shall be provided:

(i) an entrance at grade level, sheltered from the weather, and with separate provisions for ambulance and pedestrian access;

(ii) a reception and control area conveniently located near the entrance, waiting area(s), and treatment room(s);

(iii) public waiting space with toilet facilities, public telephone, and drinking fountain;

(iv) multipurpose treatment room, examination and treatment room(s). As a minimum requirement, a hospital shall provide a room to serve as an examination and treatment room to handle emergencies. The hospital may provide separate examination and treatment rooms. Examination room(s), treatment room(s), or multipurpose room(s) shall meet the following requirements.

(I) Rooms for a single patient shall be not less than 120 square feet clear with the smallest dimension not less than 10 feet in length and shall contain cabinets, medication storage, work counter, medical gases in accordance with Table 6 in §133.101(a) of this title (relating to Tables and Figures), X-ray film illuminators, and space for storage of required emergency equipment such as emergency treatment trays, defibrillator, cardiac monitor, and resuscitator.

(II) Rooms for more than one patient shall be not less than 80 square feet clear, per bed.

(III) Handwashing facilities shall be provided in each examination room, treatment room, or multipurpose room;

(v) observation room(s). An observation room for handling isolation, suspect, or disturbed patients shall be provided. The room shall be conveniently located to nurses station or other control station to permit close observation of patients and to minimize patient hiding, escape, injury, or suicide. Patient shall have access to a toilet room without entering the general corridor area.

(vi) storage area for stretchers and wheelchairs. It shall be located out of line of traffic;

(vii) staff work and charting area(s). These may be combined with reception and control area or located within the treatment room;

(viii) clean supply storage. This may be a separate room or located within the treatment room;

(ix) soiled workroom or area containing clinical sink, work counter, and sink equipped for handwashing, waste receptacle, and linen receptacles;

(x) patient toilet room(s) convenient to treatment room(s); and

(xi) access to poison control center (with data and antidotes).

(C) Trauma center. If provided, the trauma center shall comply with Guidelines for Construction and Equipment of Hospitals and Medical Facilities published by the American Institute of Architects (AIA) which the department adopts by reference in §133.100(b)(1)(A) of this title.

(D) Diagnostic facilities.

(i) Radiology facilities for diagnostic services shall be made available to the emergency suite. If a separate radiology unit is installed within the emergency suite, it shall comply with the requirements in paragraph (27) of this subsection.

(ii) Laboratory services shall be made available to the emergency suite. If a separate laboratory unit is installed within the emergency suite, it shall comply with the requirements in paragraph (12) of this subsection. All laboratory services provided on-site or by contractual arrangement shall be performed in a facility certified in the appropriate specialties and subspecialties of service in accordance with the requirements specified in 42 CFR, Part 493 to comply with federal Public Law 100-578, Clinical Laboratory Improvements Amendment of 1988 (CLIA 1988).

(7) Employee facilities.

(A) General. In addition to employee facilities such as locker rooms, lounges, toilets, or showers required in certain departments, a sufficient number of such facilities shall be provided to accommodate the needs of all personnel and volunteers.

(B) Physician locker rooms. If both male and female physicians are members of the hospital staff, then, in reasonable proportion to the ratio of male-to-female physicians on the hospital staff, properly labeled, equitable locker facilities including equipment, similar luxuries, and equal access to uniforms shall be provided for both sexes.

(8) Engineering service and equipment areas. The following maintenance facilities shall be provided.

(A) Boiler, mechanical, and electrical equipment facilities. Room(s) or separate building(s) for boilers, mechanical equipment, and electrical equipment shall be provided.

(B) Plant engineer facilities. Office or desk space for the plant engineer shall be provided.

(C) Maintenance facilities. Maintenance area or room shall be provided.

(D) Storage. Storage room for building maintenance supplies shall be provided.

(E) Yard equipment storage. A separate room or building for yard maintenance equipment and supplies shall be provided. Yard equipment or vehicles using flammable liquid fuels shall not be stored or housed within the general hospital building.

(9) General stores.

(A) General. Adequate storage shall be provided throughout the hospital.

(B) Minimum storage. The following minimum storage facilities shall be provided:

(i) off-street unloading facilities;

(ii) receiving area; and

(iii) general storage rooms. Rooms shall generally be concentrated in one area, but, in a multiple building complex, storage may be in separate concentrated areas located in one or more individual buildings.

(10) Intensive care unit. When an intensive care unit (ICU) is provided, the following requirements shall be met.

(A) Patient rooms. Each cardiac intensive care patient shall have a separate room for acoustical and visual privacy. Equipment for monitoring cardiac patients shall be provided by visual display both at the bed location and at the nurses station. Medical and surgical intensive care units may be set up as an open ward, with beds separated by curtains, or as a suite of separate enclosed rooms. If the open ward plan is used, there shall be at least one private room for every six ward beds to provide for medical isolation or psychological needs. All beds shall be arranged to permit direct visual observation by nursing staff. Patient rooms shall meet the following requirements.

(i) Single-bed rooms or cubicles shall have a minimum clear area of 120 square feet and a minimum dimension of 10 feet. Clearance between beds in open wards shall be not less than six feet, and clearance between a bed and a wall shall not be less than five feet. The arrangement of beds shall allow at least three feet between the bed headboard and the wall and provide passage space at the foot of each bed of not less than four feet wide to permit resuscitation procedures without restricting movement of beds and equipment.

(ii) Viewing panels shall be provided in doors and walls for nursing staff observation of patients. Curtains or other means shall be provided to cover the viewing panels when the patient requires visual privacy. Glazing in viewing panels shall be safety glass, wire glass, or clear plastic to reduce the hazard from accidental breakage except that wire glass may be required in glazed openings to corridors or passageways used as means of egress for fire safety purposes.

(iii) An intravenous solution support shall be provided for each patient. The intravenous solution shall not be suspended directly over the patient.

(iv) A lavatory equipped for handwashing shall be provided in each private patient room. In rooms with multiple beds, one lavatory for each two beds shall be provided.

(v) Each cardiac patient shall have access to a toilet directly from his or her room or cubicle. (Swivel type commodes may be utilized in lieu of individual toilets rooms, but provision must be made for patient privacy, servicing, and odor control). Toilet room exhaust rate of Table 3 in §133. 101(a) of this title shall apply in either case.

(vi) Each room or ward shall be located on an exterior wall and shall have a window. One window may serve more than one patient. The window sill height shall not exceed five feet above the floor. Otherwise, the window shall comply with §133.99(d)(2)(J) of this title (relating to Contstruction Requirements). In no case shall any patient bed be located more than 50 feet from an exterior window.

(B) Service area exceptions. The service areas listed in paragraph (18) (B) of this subsection shall be located in, or readily available to, each intensive care unit and may serve two or more adjacent intensive care units, with the exceptions listed in clauses (i)-(vi) of this subparagraph.

(i) Nurses station shall be located to permit direct visual observation of each patient served. Video cameras shall not be substituted for direct visual observation.

(ii) Nurses office may be omitted if room is located conveniently in another area.

(iii) Multipurpose room for conference may be omitted if room is located conveniently in another area.

(iv) An examination room is not required.

(v) Bathing facilities are not required.

(vi) A separate waiting room shall be provided for family members and others who may be permitted to visit the intensive care patients. A toilet room, public telephone, and seating accommodations for long waiting periods shall be provided.

(C) Combined medical, surgical, and cardiac intensive care.

(i) If medical, surgical, and cardiac intensive care services are combined in one intensive care unit, at least 50% of the beds shall be located in private rooms or cubicles. (NOTE: Medical or surgical patients may utilize open areas or private ICU rooms as needed and available, but cardiac patients shall not be accommodated in open ward areas).

(ii) When 50% of the beds are in private rooms within a combined unit, the requirements of subparagraph (A) of this paragraph for additional separate enclosed rooms do not apply.

(11) Janitor closets.

(A) In addition to the janitor closet(s) required in certain departments, sufficient janitor closets shall be provided throughout the hospital as required to maintain a clean and sanitary environment.

(B) Each janitor closet shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies.

(12) Laboratory suite.

(A) General. Laboratory facilities shall be provided for hematology, clinical chemistry, urinalysis, cytology, pathology, immunohematology, and bacteriology. These may be provided within the hospital or through an effective contract arrangement. All lab services provided on-site or by contractual arrangement shall be performed in a facility certified in the appropriate specialties and subspecialties of service in accordance with the requirements specified in 42 CFR, Part 493 to comply with CLIA 1988.

(B) Laboratory facilities. When laboratory services are provided by contractual arrangement, at least the following minimum facilities shall be provided within the hospital:

(i) laboratory work counter(s) with sink, vacuum, gas, and electric services as needed;

(ii) lavatory(ies) or counter sink(s) equipped for handwashing;

(iii) storage cabinet(s) or closet(s);

(iv) blood storage facilities. Blood storage facilities shall meet the requirements of 42 CFR, Part 493, Subpart K;

(v) specimen collection facilities. Urine collection toilet room(s) shall be equipped with a water closet and lavatory (a toilet room shall meet this requirement). Blood collection facilities shall have a work counter, handwashing facilities, and space for patient seating; and

(vi) each laboratory unit shall meet the requirements of National Fire Protection Association (NFPA) 99 and NFPA 101. The department adopts by reference the various NFPA standards reference in the section in §133.100(b) (1)(M) of this title.

(C) Special lab facilities for bone marrow transplantation services. A cryopreservation laboratory and a human leukocyte antigen laboratory (HLA lab) shall be provided in hospitals with bone marrow transplantation units. These laboratories need not be located on the bone marrow transplantation units but shall have access for specimen transport and access to the blood bank and blood donor areas.

(13) Laundry.

(A) General. The hospital, whether it operates its own laundry or uses a commercial service, shall ensure that laundry supervision is under a qualified institutional or commercial laundry operator and that the laundry is processed under the rules listed in §133.61(h) of this title (relating to Hospital Services).

(B) On-site processing. If linen is to be processed on the hospital site, the following shall be provided:

(i) laundry processing room with commercial-type equipment;

(ii) soiled linen receiving, holding, and sorting room with handwashing facilities. Lockers and toilets for staff employed in this area shall be provided if not available in adjacent employee facilities serving other soiled areas;

(iii) storage for laundry supplies with the following:

(I) clean linen inspection and mending room or area; and

(II) clean linen storage, issuing, and holding room or area;

(iv) janitor closet containing a floor receptor or service sink and storage space for housekeeping equipment and supplies; and

(v) cart storage and sanitizing.

(I) Cart sanitizing shall comply with paragraph (3) of this subsection.

(II) Arrangement of equipment and procedures shall be in a manner to prevent cross traffic of clean and soiled operations.

(C) Off-site processing. If linen is processed off the hospital site, the following shall be provided:

(i) soiled linen holding room;

(ii) clean linen receiving, holding, inspection, and storage room(s) ; and

(iii) cart storage and sanitizing. The hospital shall comply with the requirements in paragraph (3) of this subsection for cart sanitizing facilities.

(14) Medical records unit. The following minimum facilities shall be pro-

vided.

(A) Office space. Medical records administrator or technician office or space shall be provided.

(B) Dictation. Review and dictating rooms or spaces shall be provided.

(C) Work area. Work area for sorting, recording, or microfilming records shall be provided.

(D) Storage. Storage area for records shall be provided.

(15) Morgue.

(A) Location. The morgue shall be directly accessible to the outside and shall be located to avoid movement of bodies of deceased patients through public areas.

(B) Autopsy performed within hospital. When autopsies are performed within the hospital, the following shall be provided.

(i) refrigerated facilities for body-holding; and

(ii) autopsy room. This room shall contain.

(I) work counter with sink equipped for handwashing;

(II) storage space for supplies, equipment, and specimens;

(III) autopsy table;

(IV) a deep sink for washing specimens;

(V) clothing change area with shower, toilet, and lockers; and

(VI) janitor service sink or receptacle.

(C) Minimum requirements. When autopsy facilities are not provided within the hospital, a ventilated room in which bodies of deceased patients shall be kept prior to transport to a destination off the hospital premises shall be provided as a minimum requirement.

(16) Neonatal and pediatric intensive care units.

(A) Neonatal intensive care. When neonatal intensive care services are provided, the unit(s) shall meet the following requirements.

(i) General. The unit shall be conveniently located near obstetrical facilities and arranged to preclude unrelated traffic. Whenever possible neonatal units shall be located on an exterior wall and comply with paragraph (10)(A)(vi) of this subsection.

(ii) Patient rooms. Neonatal intensive care patients may be housed in a single-bed room or a room with multiple beds. There shall be at least one enclosed private room for every six bassinets or cribs. Each unit shall not exceed 24 bassinets or cribs. Each room shall meet the following requirements.

(I) Clearance between cribs or bassinets in rooms with multiple beds shall be not less than six feet, and clearance at the foot of each bassinet or crib shall not be less than four feet and shall not overlap with other patient care space or aisles. Single-bed rooms and cubicles shall have a minimum clear area of 100 square feet.

(II) A lavatory equipped for handwashing shall be provided in each single-bed room. In rooms with multiple beds, one lavatory for each four patient stations shall be provided. These shall be located convenient to infant stations and to the nurses station and medication preparation area.

(iii) Service areas in the neonatal intensive care units shall meet the following requirements.

(I) Workroom. Each neonatal intensive care unit shall be served by a connecting workroom. It shall contain gowning facilities at the entrance for staff and housekeeping personnel, a work space with counter, storage facilities, a lavatory or sink equipped for handwashing, and individual closets or lockers for the safekeeping of coats and personal effects of nursing personnel. Workrooms may serve two neonatal intensive care units provided the required services are convenient to each. Workrooms may open directly to the unit(s).

(II) Examination and treatment room. Examination and treatment room or space for infants shall contain a work counter, storage, and lavatory equipped for handwashing. The exam treatment space may be located within the neonatal unit.

(III) Infant formula facilities. The hospital shall comply with the requirements in paragraph (17)(B)(iv) of this subsection.

(IV) Janitor closet. The hospital shall comply with the requirements in paragraph (18)(B)(xxi) of this subsection.

(V) Storage. Storage space shall be provided for equipment storage, clean linen, and cart storage. The storage area shall have not less than 20 square feet for each patient station and be concentrated in one area.

(VI) Soiled workroom or soiled holding room. The hospital shall comply with the requirements in paragraph (18)(B)(xiii) of this subsection. The soiled workroom shall not have direct access into the neonatal unit.

(VII) Nurse emergency call system. The hospital shall provide a nurse emergency call system in compliance with the requirements in §133.99(f)(7)(E) of this title.

(B) Pediatric intensive care. When pediatric intensive care units are provided, the unit(s) shall meet the following requirements.

(i) Patient rooms. The pediatric intensive care unit (ICU) may be an open ward plan or may have all private patient rooms. If the open ward plan is used, one private room for each 10 beds shall be provided for seclusion or isolation. Not less than one private room for each unit shall be provided for seclusion or isolation.

(ii) In addition, each pediatric ICU shall include:

(I) space at each bedside for visiting parents;

(II) sleeping space for parents who may be required to spend long hours with the patient. This space may be within the patient room or separate from the patient area but shall be under control of, and in communication with, the pediatric ICU staff;

(III) consultation or demonstration room within, or convenient to, the pediatric ICU for private discussions. The multipurpose room noted in paragraph (10)(B)(iii) of this subsection will meet this requirement;

(IV) provision for infant formula preparation and storage. May be outside the pediatric ICU but shall be available for use at all times;

(V) adequate storage cabinets or closets for toys and games;

(VI) storage for cots, bed linens, and other items needed for overnight accommodation of parents (in the general location of sleeping accommodations);

(VII) clearances between bassinets, incubators, and warmers shall be the same as for adult beds in paragraph (10)(A)(i) of this subsection. Where bassinets, incubators, and warmers are grouped, work aisles at least eight feet wide shall be provided;

(VIII) examination area and work space; and

(IX) nurse emergency call system. The hospital shall comply with the requirements in §133.99(f)(7)(E) of this title.

(17) Newborn nursery unit. When obstetric services are provided, a nursery unit shall be required

(A) Nursery location. Nursery unit(s) shall be located and arranged to preclude unrelated traffic, shall be located near the postpartum nursing unit, and shall not open directly into another nursery. Each nursery unit shall meet the following requirements.

(i) Lavatory(ies) equipped for handwashing at the rate of one for each eight infant stations shall be provided.

(ii) Nurse emergency call system as specified in §133.99(f)(7)(E) of this title shall be provided.

(iii) Observation windows to permit viewing infants from public areas, from workrooms, and between adjacent nurseries shall be provided.

(iv) Full-term nursery shall be provided. A full-term nursery shall contain no more than 16 infant stations. The minimum floor area shall be 24 square feet for each infant station exclusive of auxiliary work areas There shall be at least four feet between bassinets. When a rooming-in program is used, the total number of bassinets provided in these units may be appropriately reduced, but the nursery shall not be reduced below one infant station or bassinet for each labor bed provided.

(v) Special care nursery shall be provided. A nursery to provide continuing care for infants requiring close observation is required in hospitals having 25 or more maternity beds. The minimum floor area per infant station shall be 40 square feet exclusive of auxiliary work areas and limited to 16 bassinets per nursery unit. There shall be at least four feet between bassinets. Additional area shall be provided to accommodate workroom functions if these are located within the nursery area as specified in subparagraph (B) (ii) of this paragraph.

(B) Service areas Service areas shall be located in, or readily available to, each nursery unit. Each service area may be arranged and located to serve more than one nursery unit if convenient to each. At least one such service area shall be provided on each floor. The following service areas shall be provided.

(i) Charting facilities shall be provided

(ii) A connecting workroom shall be provided which shall contain gowning facilities at the entrance for staff and housekeeping personnel, work space with counter, refrigerator, lavatory or sink equipped for handwashing, and storage. One workroom shall serve no more than two full-term nurseries provided that required services are convenient to each. The workroom which serves the special care nursery may be omitted if equivalent work area and facilities are provided within the nursery in which case the gowning facilities shall be located near the entrance to the nursery and shall be separated from the work area.

(iii) Examination and treatment room or space shall be provided and shall contain a work counter, storage, and lavatory equipped for handwashing.

(iv) Infant formula facilities shall be provided.

(I) On-site formula preparation. Where infant formula is prepared on the hospital site, the hospital shall provide cleanup facilities for washing and sterilizing supplies. These shall consist of a lavatory or sink equipped for handwashing, a bottle washer, work counter space, and an equipment sterilizer. A separate room for preparing infant formula shall be provided. The room shall contain a lavatory or sink equipped for handwashing, hot plate, refrigerator, work counter, formula sterilizer, and storage facilities. It may be located near the nurseries or at another appropriate place within the hospital. There shall be no direct access from the formula room to a nursery.

(II) Commercially prepared formula. If a commercial infant formula is used, the storage and handling may be done in the nursery workroom or in another appropriate room elsewhere in the hospital which has a work counter, sink equipped for handwashing, and storage facilities.

(v) Janitor closet for nursery use only shall be provided. The hospital shall comply with the requirements in paragraph (18)(B)(xxi) of this subsection.

(18) Nursing unit.

(A) Patient rooms. Each patient room shall meet the following requirements.

(i) Minor encroachments including columns and lavatories that do not interfere with functions may be ignored when determining space requirements for patient rooms. Exclusive of toilet room, closets, lockers, wardrobes, alcoves, or vestibules, minimum room areas shall meet the following requirements.

(I) Single-bed room. Minimum floor area provided shall be 100 square feet in a single-bed room.

(II) Room with multiple beds. Minimum floor area provided shall be 80 square feet per bed in a room with multiple beds. A clearance of three feet eight inches shall be available at the foot of each bed to permit the passage of equipment and beds. A minimum distance of three feet between any wall and bed plus four feet between beds shall be provided.

(III) Handicapped-single-bed room. Minimum floor area shall be 120 square feet in a single-bed room for use by the handicapped.

(IV) Handicapped-room with multiple beds. Minimum floor area shall be 100 square feet per bed in a room with multiple beds for use by the handicapped. A clearance of four feet shall be available at the foot of each bed to permit the passage of equipment and beds. A minimum of three feet between any wall and bed and at least five feet between beds shall be provided.

(ii) No room dimension shall be less than ten feet in patient sleeping area. Maximum room capacity shall be four patient beds.

(iii) Each room shall have a window in accordance with §133.99(d)(2)(J) of this title.

(iv) Nurse call system shall be provided in accordance with §133.99(f)(7) of this title.

(v) One lavatory shall be provided in each postpartum room proper. One lavatory shall be provided in other patient rooms, except that it may be omitted from a single-bed room or a two-bed room if a lavatory is located in an adjoining toilet room which serves these rooms

(vi) Each patient shall have access to a toilet room without entering the general corridor area. One toilet room shall serve no more than four beds and no more than two patient rooms. The toilet room shall contain a water closet and a lavatory. The lavatory may be omitted from a toilet room which serves single-bed and two-bed rooms if each patient room contains a lavatory.

(vii) Each patient shall have a wardrobe, locker, or closet that is suitable for handling full-length garments and for storing personal effects.

(viii) Visual privacy shall be provided each patient in rooms with multiple beds Design for privacy shall not restrict patient access to room, lavatory, or toilet.

(B) Service areas The service areas shall be located in, or readily available to, each nursing unit. Each service area may be arranged and located to serve more than one nursing unit, but at least one service area shall be provided on each nursing floor. The following service areas shall be provided.

(i) Nurses station. Administrative center or nurses station shall be provided.

(ii) Office. Nurses office shall be provided.

(iii) Storage Storage for administrative supplies shall be provided.

(iv) Handwashing. Handwashing facilities located near the nurses station and the drug distribution station shall be provided One lavatory may serve both areas.

(v) Charting. Charting facilities for nurses and doctors shall be provided.

(vi) Toilet. Toilet room(s) for staff shall be provided

(vii) Staff lounge. Staff lounge facilities shall be provided and may be centrally located on another floor.

(viii) Closets. Individual closets or compartments for the safekeeping of coats and personal effects of nursing personnel shall be provided. These shall be located convenient to the duty station of personnel or in a central location.

(ix) Ice machine. Each nursing unit shall have equipment to provide ice for treatments and nourishment. Ice making equipment may be in the clean work room or at the nourishment station under staff control. Ice intended for human consumption shall be from self-dispensing ice maker(s).

(x) Multipurpose room. Multipurpose room(s) for staff and patient conferences, education, demonstrations, and consultation shall be provided. Multipurpose rooms shall be conveniently accessible to each nursing unit. Multipurpose rooms may be on other floors if convenient for regular use. One such room may serve several nursing units or departments.

(xi) Examination and treatment room(s). This room may be omitted if all beds in the hospital are single-bed patient rooms. The examination and treatment room(s) may serve several nursing units and may be on a different floor if conveniently located for routine use. Examination room(s) shall have a minimum floor area of 120 square feet excluding space for vestibule, toilets, and closets. Each room shall contain a lavatory or sink equipped for handwashing, storage facilities, and a desk, counter, or shelf space for writing.

(xii) Clean workroom. Clean workroom or clean holding room shall be provided. The room shall contain a work counter, handwashing, and storage facilities and shall be part of a system for storage and distribution of clean and sterile supply materials.

(xiii) Soiled workroom. Soiled workroom or soiled holding room shall be provided. The room shall contain a clinical sink or equivalent flushing rim fixture, sink equipped for handwashing, work counter, waste receptacle, and linen receptacle and shall be part of a system for collection and disposal of soiled materials.

(xiv) Drug distribution station Distribution of drugs may be from a medicine preparation room or unit, a self-contained medicine dispensing unit, or by another approved system. If used, a medicine preparation room or unit shall be under the nursing staff's visual control and contain a work counter, refrigerator, and locked storage for biologicals and drugs and shall have a minimum of 50 square feet. A medicine dispensing unit may be located at the nurses station, in the clean workroom, or in an alcove or other space under direct control of the nursing or pharmacy staff. Access to a lavatory for handwashing shall be provided

(xv) Clean linen storage. A separate closet or a designated area within the clean workroom for clean linen storage shall be provided. If a closed cart system is used, storage may be in an alcove.

(xvi) Nourishment station or room. Nourishment station or room shall be provided and shall contain a sink equipped for handwashing, equipment for serving nourishment between scheduled meals, refrigerator, and storage cabinets. Nourishment station shall not be located in the clean work room.

(xvii) Equipment storage room. Appropriate room(s) for equipment such as intravenous stands, inhalators, air mattresses, cots, and walkers shall be provided. This may serve more than one floor when conveniently located for 24-hour access.

(xviii) Parking for stretchers and wheelchairs. A room or area shall be provided on each floor for parking stretchers and wheelchairs and shall be located out of the path of normal traffic.

(xix) Patient bathing facilities. Patient bathing facilities shall be provided.

(I) In postpartum units where individual bathing facilities are not provided in patient rooms, at least one shower for each 12 beds and one sitz bath unit (disposable or portable units may be substituted for this requirement) shall be provided.

(II) In other nursing units, bathtubs or showers shall be provided at the rate of one for each 12 beds which are not otherwise served by bathing facilities explicitly provided at each patient room. Each tub or shower shall be in an individual room or enclosure which provides space for the private use of the bathing fixture and for drying and dressing.

(III) At least one central bathing fixture on each patient floor with tub or shower, lavatory, water closet, and space for a wheelchair and an attendant shall be provided. Three feet clearance on each side and front of the water closet shall be provided.

(xx) Emergency equipment storage. Space for emergency equipment such as a crash cart shall be provided and shall be under direct control of the nursing staff, in close proximity to the nurses station, and out of traffic.

(xxi) Janitor closet. A closet for exclusive use of housekeeping staff in maintaining the nursing unit shall be provided. It shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies.

(C) Isolation room(s). One isolation room, designed to minimize infec-

tion hazards to or from the patient, shall be provided for each 30 acute care beds or fraction thereof. At least 10% of the isolation rooms shall be handicapped accessible. These may be located within individual nursing units and used for normal acute care when not required for isolation cases or grouped as a separate isolation unit. Each isolation room shall contain only one bed and shall comply with the patient room requirements in subparagraph (A) of this paragraph as well as the following.

(i) Entry into the room shall be through a work area that provides for aseptic control including facilities separate from patient areas for handwashing, gowning, and storage for clean and soiled materials. The work area entry may be a separate enclosed anteroom or a vestibule that is open to the room. The use of vestibule work space open to the room may provide flexibility for other use when not needed for isolation. At least 50% of all isolation rooms shall be designed for entry through an enclosed anteroom.

(ii) Viewing panel(s) shall be provided for observation of each patient by staff from any enclosed anteroom.

(iii) One separate anteroom may serve several isolation rooms.

(iv) Toilet, bathtub or shower, and handwashing facilities are required for each isolation room. These shall be arranged to permit access from the bed area without entering or passing through the work area of the vestibule or anteroom.

(v) In facilities offering specialized services such as those for organ transplants, burn patients, and patients receiving immunosuppressive treatments, special design provisions including environmental air control systems and spacial design shall be included as required to meet the needs of these specialized services.

(D) Room(s) for disturbed medical patients. Each hospital shall provide a minimum of one single-bed room for patients needing close supervision for medical and mental health care. This may be part of the psychiatric unit and chemical dependency unit described in paragraph (26) of this subsection, §133.63 of this title (relating to Mental Health Services in an Identifiable Part of a Hospital), and §133.64 of this title (relating to Chemical Dependency Services in an Identifiable Part of a Hospital). If the single-bed room is part of the acute care unit, provisions of subparagraph (A) of this paragraph shall apply, except that each bedroom shall be for single occupancy and shall be located so that the entrance is visible for direct supervision. Each room shall be designed to minimize potential for escape, hiding, injury, or suicide.

(19) Obstetrical facilities.

(A) General. When obstetrical services are provided, the obstetrical suite shall be located and arranged to preclude unrelated traffic through the suite. The obstetrical suite shall meet the following requirements.

(B) Delivery rooms. Each room shall have a minimum clear area of 300 square feet exclusive of fixed cabinets and built-in shelves. Delivery rooms that are used for Caesarean sections shall have not less than 360 square feet of clear area. An emergency communications system is required and shall comply with the requirements in §133.99(f)(7)(E) of this title. Resuscitation facilities (electrical outlets, oxygen, vacuum, and compressed air) shall be provided for newborn infants within each delivery room in addition to the facilities required for the mother.

(C) Labor rooms. These rooms shall be single-bed or two-bed rooms with a minimum clear area of 100 square feet per bed. Labor beds shall be provided at the rate of at least two for each delivery room. Labor, delivery, and recovery rooms (LDRs) may be substituted.

(i) In facilities having only one delivery room, two labor beds shall be provided. One labor room shall be large enough to function as an emergency delivery room with a minimum of 160 square feet and have at least two oxygen and two vacuum outlets.

(ii) Each labor room shall contain a lavatory equipped for handwashing. Each labor room shall have access to a toilet room. One toilet room may serve two labor rooms.

(iii) Labor rooms shall be arranged so that doors are visible from a nurses work station and shall also be directly accessible to facilities for medication, handwashing, charting, and storage for supplies and equipment.

(iv) At least one shower for each four labor room patients shall be provided. Shower controls shall be outside the wet area for use by nursing staff. A water closet shall be accessible to the shower facility.

(D) Birthing rooms-LDRs and labor, delivery, recovery, and postpartum (LDRPs). With appropriate finishes, and other environmental factors, delivery procedures in accordance with birthing concepts may be done in rooms that meet the basic provisions of subparagraphs (B) and (C) of this paragraph. If required by the functional program, separate birthing rooms may be substituted for labor and delivery rooms to accommodate the anticipated number of deliveries, except that not less than one delivery and two labor beds in accordance with subparagraphs (B) and (C) of this paragraph shall be provided for each delivery suite.

(i) Birthing rooms shall have controlled access and shall be located so that a patient may be transferred to the delivery room without need to pass through other functional areas.

(ii) Each designated birthing room shall be for single occupancy and have an adjoining toilet for the exclusive use of that room. Each birthing room shall have convenient access to a shower suitable for patient use with staff assistance. Showers may be shared by two or more birthing or labor rooms. A lavatory shall be provided in each birthing room proper.

(iii) Resuscitation facilities for newborn infants shall be provided. In addition, birthing rooms shall have utilities described in subparagraph '(B) of this paragraph and Table 6 in §133.101(a) of this title.

(iv) Room size shall be at least 160 square feet. Examination lights may be portable but shall be immediately available. Finishes shall be selected for ease of cleaning and resistance to strong detergents. Windows within a normal sightline that would permit observation into the room from the exterior shall be arranged or draped as necessary for patient privacy. LDRPs shall be located on an exterior wall and shall have operable windows.

(E) Recovery room(s). Recovery room(s) shall contain not less than two beds, charting facilities located to permit staff to have visual control of all beds, facilities for medicine dispensing, handwashing facilities, clinical sink with bedpan flushing device, and storage for supplies and equipment. The recovery room may be omitted in hospitals with fewer than 1500 annual births.

(F) Service areas. Individual rooms shall be provided when so noted; otherwise, alcoves or other open spaces which will not interfere with traffic may be used. Services, except the soiled workroom in paragraph (30)(F)(vi) of this subsection and the janitor closet in paragraph (30)(F)(xviii) of this subsection may be shared with the surgical facilities if the design reflects this sharing concept. Service areas shall be arranged to avoid direct traffic between the delivery and operating rooms. Service areas shall be provided as listed in paragraph (30)(F) of this subsection, except as follows.

(i) Control station. A control station located to permit visual surveillance of all traffic which enters the obstetrical suite shall be provided.

(ii) Sterilizing facilities. Sterilizing facility(ies) with high speed autoclave(s) conveniently located to serve all delivery rooms shall be provided

(iii) Scrub facilities. Two scrub stations shall be provided near entrance to each delivery room; however, two scrub stations may serve two delivery rooms if the scrub stations are located adjacent to the entrance of each delivery room. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts. Viewing panels to permit observation of delivery rooms from the scrub area shall be provided.

(iv) Lounge and toilet facilities for obstetrical staff. A nurses toilet room shall be provided near the labor rooms and recovery rooms(s).

(v) Stretcher storage alcove. The stretcher storage alcove shall be out of direct line of traffic.

(20) Occupational therapy suite.

(A) When occupational therapy services are furnished, the following rooms or areas shall be provided:

(i) office space;

(ii) activities area containing a sink or lavatory. Facilities for collection of waste products prior to disposal shall be provided;

(iii) storage for supplies and equipment; and

(iv) patient toilet room which shall meet the handicapped requirements in the Architectural Barriers Act (ABA), Texas Civil Statutes, Article 1902; 16 TAC, Chapter 68 (relating to Architectural Barriers Administrative Rules); and the Texas Accessibility Standards (TAS) of the (ABA) , 19 Texas Register (TexReg) 167, administered by the Texas Department of Licensing and Regulation (TDLR).

(B) Appropriate rooms or areas may be shared by physical therapy patients and staff.

(21) Organ transplantation unit. To be proposed and adopted at a later date pending further information.

(22) Outpatient clinic.

(A) General. When facilities for outpatient services operated under the hospital's license are provided, they shall be located on the premises of the hospital (i.e., at the same physical location and street address as the hospital). Outpatient facilities shall be constructed in accordance with NFPA 101, Chapter 26 which the department adopts by reference in §133.100(b)(1)(M) of this title and shall contain, but need not be limited to, all the elements described in subparagraph (C) of this paragraph. Each element provided in the outpatient facility shall meet the requirements outlined in this paragraph as a minimum. The planning of outpatient facilities shall provide for the privacy and dignity of the patient during interview, examination, and treatment. The facilities shall be located so that outpatients do not traverse inpatient areas. The following shall be provided or made available to the outpatient services.

(B) Administration and public areas. Administration and public areas shall meet the following:

(i) entrance shall be located at grade level, sheltered from weather, and able to accommodate wheelchairs;

(ii) lobby shall include:

(I) wheelchair storage space(s);

(II) reception and information counter or desk;

(III) waiting space(s);

(IV) public toilet facilities;

(V) public telephone(s); and

(VI) drinking fountain(s);

(iii) interview space(s) for private interviews relating to social service, credit, and admissions;

(iv) general or individual office(s) for business transaction, records, and administrative and professional staff;

(v) multipurpose room(s) for conferences, meetings, and health education purposes equipped for showing visual aids;

(vi) storage space for employees' personal effects; and

(vii) storage facilities for office supplies, sterile supplies, pharmaceutical supplies, splints and other orthopedic supplies, and housekeeping supplies and equipment.

(C) Clinical facilities.

(i) General purpose examination room(s). A general purpose examination room shall be provided for medical, obstetrical, and similar examinations. The room shall have a minimum floor area of 80 square feet excluding spaces such as vestibule, toilet, closet, and work counter (whether fixed or movable). Arrangement shall permit at least two feet eight inches clearance at each side and at the foot of the examination table. A lavatory or sink equipped for handwashing and a counter or shelf space for writing shall be provided.

(ii) Special purpose examination rooms. Room sizes for special clinics such as eye, dental, and ear, nose, and throat examinations shall be determined by types of equipment used but shall be not less than 80 square feet excluding spaces such as vestibule, toilet, closet, and work counter (whether fixed or movable). A lavatory or sink equipped for handwashing and a counter or shelf space for writing shall be provided.

(iii) Treatment room(s). A treatment room for minor surgical procedures and cast procedures shall be provided. The room shall have a minimum floor area of 120 square feet, excluding spaces such as vestibule, toilet, closet, and work counter (whether fixed or movable). The minimum room dimension shall be 10 feet. A work counter, storage cabinets, and lavatory or sink equipped for handwashing shall be provided.

(iv) Observation room(s). An observation room for handling isolation, suspect, or disturbed patients shall be provided. The room shall be conveniently located to nurses station or other control station to permit close observation of patients and to minimize patient hiding, escape, injury, or suicide. Patients shall have access to a toilet room without entering the general corridor area. A separate room is not required if an examination room is modified to accommodate this function.

(v) Facilities for charting and for clinical records, or nurses station. Work counter, communication system, and space for supplies shall be provided for charting and for clinical records, or nurses station. A separate space may be omitted if these functions are accommodated in each examination room and each treatment room.

(vi) Drug distribution station. The drug distribution station provided may be a medicine preparation room or unit, a self-contained medicine dispensing unit, or other approved systems. If used, a medicine preparation room or unit shall be under the nursing staff's visual control, contain a work counter, refrigerator, and locked storage for biologicals and drugs, and shall have a minimum area of 50 square feet. A medicine dispensing unit may be located at

the nurses station, in the clean workroom, or in an alcove or other space under direct control of the nursing or pharmacy staff. Access to a lavatory for handwashing shall be provided.

(vii) Clean workroom or clean holding room. The hospital shall comply with the requirements in paragraph (18)(B)(xii) of this subsection.

(viii) Soiled workroom or soiled holding room. The hospital shall comply with the requirements in paragraph (18)(B)(xiii) of this subsection.

(ix) Stretcher storage. Stretcher storage space located out of direct line of traffic shall be provided.

(D) Diagnostic facilities.

(i) Radiology facilities for diagnostic services shall be made available to the outpatient clinic. If a separate radiology unit is installed within the outpatient clinic, it shall comply with the requirements in paragraph (27) of this subsection.

(ii) Laboratory services shall be made available to the outpatient clinic. If a separate laboratory unit is installed within the outpatient clinic, it shall comply with the requirements in paragraph (12) of this subsection. All laboratory services provided within the outpatient clinic or by a written contractual arrangement shall be performed in a facility certified in the appropriate specialties and subspecialties of service in accordance with the requirements specified in 42 CFR, Part 493 to comply with CLIA 1988.

(23) Pediatric and adolescent nursing units. When a facility offers pediatric care services and the nursing unit(s) contains more than 15 patient beds, the unit(s) shall meet the following requirements.

(A) Patient rooms. The requirements noted in paragraph (18)(A) of this subsection shall be applied to a pediatric and adolescent nursing unit containing hospital beds or cribs, except that patient rooms used for cribs may contain a minimum of 60 square feet of clear area for each crib with no more than six cribs in a room.

(B) Nursery. Each nursery serving pediatric patients shall contain no more than eight bassinets. The minimum clear floor area per bassinet shall be 40 square feet. Each room shall contain a lavatory equipped for handwashing, nurses emergency call system as specified in §133.99(f)(7)(E) of this title, and glazed viewing windows for observing infants from public areas and workroom.

(C) Service areas. The service areas in the pediatric and adolescent nursing unit shall conform to the conditions listed in paragraph (18)(B) of this subsection and shall meet the following additional conditions.

(i) For nursery workrooms, the hospital shall comply with the requirements in paragraph (17)(B)(ii) of this subsection.

(ii) Examination and treatment room for nursery(ies) may be located in a separate room or a designated part of the workroom. It shall contain a work counter, storage facilities, and lavatory equipped for handwashing.

(iii) Multipurpose or individual room(s) shall be provided for dining, educational, and play purposes. Special provision shall be made to minimize the impact noise transmission through the floor of the multipurpose room(s) to occupied spaces below. Requirements in Table 1 in §133.101(a) of this title shall be met.

(iv) Space for preparation and storage of infant formula shall be provided in the unit or in a convenient location nearby.

(v) Patient toilet room(s) shall be provided convenient to multipurpose room(s) and central bathing facilities.

(vi) Storage closets or cabinets for toys and educational and recreational equipment shall be provided.

(vii) Storage space shall be provided for replacement of cribs and adult beds to provide flexibility for interchange of patient accommodations.

(24) Pharmacy suite.

(A) General. The pharmacy unit shall be located for convenient access, control, and security. Satellite pharmacy facilities, if provided, shall include those items required by the program.

(B) Functional area. Pharmacy unit or room shall provide the following functional areas:

(i) dispensing area with handwashing facilities separate from toilet facilities;

(ii) editing or order review area;

(iii) sterile products area. A sterile products area is required if intravenous admixture services are provided by the hospital pharmacy;

(iv) administrative areas. Office area for the chief pharmacist and any other offices required for the proper maintenance of records and reports and also for purchasing, accounting, and personnel activities;

(v) storage areas: bulk, active, refrigeration, controlled substances, volatile liquids;

(vi) drug information area;

(vii) packaging area;

(viii) bulk compounding area;

(ix) quality control area; and

(x) narcotic vault, safe, or securely constructed locked wall cabinet.

(25) Physical therapy suite. When physical therapy services are included, the following shall be provided:

(A) office space;

(B) waiting space;

(C) treatment area(s) for thermotherapy, diathermy, ultrasonics, and hydrotherapy which provide:

(i) cubicle curtains around each individual treatment area;

(ii) handwashing facilities;

(iii) one lavatory or sink (may serve more than one cubicle); and

(iv) facilities for collection of wet and soiled linen and other material;

(D) exercise area; and

(E) service areas which provide:

(i) storage for clean linen, supplies, and equipment;

(ii) patient dressing areas, showers, lockers, and handicapped designed and equipped toilet room(s) if outpatient service is offered;

(iii) janitor closet and service sink; and

(iv) wheelchair and stretcher storage.

(26) Psychiatric unit and chemical dependency unit. When psychiatric, alcohol, and drug abuse patient care services are provided, the unit(s) shall meet the following requirements.

(A) General. Units intended for psychiatric, alcohol, and drug abuse care shall be designed to facilitate care of ambu-

latory and nonambulatory inpatients. When psychiatric, alcohol, and drug abuse services are provided, each unit shall meet the requirements of paragraph (18) of this subsection. All areas of the psychiatric unit, including entrances to patient rooms, shall be visible from the nurses station(s). Observation by video cameras of seclusion rooms, entrances, hallways, and activity areas shall be acceptable.

(B) Patient rooms. In psychiatric and chemical dependency units housing detoxification treatment services and certain types of patients or having detention rooms or a security section, it may be necessary to provide detention screens to confine or protect building inhabitants. Where windows require the use of tools or keys for operation because of detention screens, the tools or keys shall be located on the floor or area involved at a prominent location accessible to staff. The hospital shall determine the degree of security required and the amount of window operation required in order to inhibit possible tendency for suicide or escape. Where glass fragments may create a hazard, safety glazing or other appropriate security features shall be incorporated. Windows may be fixed when the building is provided with an engineered smoke control system in accordance with NFPA 90A, is protected throughout with an automatic sprinkler system in accordance with NFPA 13, and meets applicable requirements in NFPA 101.

(i) A nurse call system is not required except for dependent patients. If a call system is included, it shall conform to requirements in §133.99(f)(7) of this title and shall include the following requirements.

(I) Provisions shall be made to permit removal of call buttons or use of blank plates as required for security.

(II) No nurse call cable shall be longer than 18 inches. An alarm shall activate at the nurses station if the call cable is unplugged.

(III) Desk or tap call bells shall not be acceptable.

(ii) No lamp cord shall be longer than 18 inches.

(iii) Electric beds shall be acceptable only for geropsychiatric patients and physically disabled adult psychiatric patients.

(iv) Clothes bars in wardrobes, lockers, or closets shall break-away to prevent patient injury.

(v) Wire coat hangers shall not be acceptable in psychiatric units.

(C) Service areas. Service areas shall meet the requirements of paragraph (18)(B) of this subsection, and the following additional spaces shall be included.

(i) Charting area shall be provided with separation needed for acoustical privacy as well as space required for the function. View window to permit observation of patient area by the charting nurse or physician may be used provided that it is located so that patient files cannot be read from outside the charting space.

(ii) A minimum of two separate social spaces, one appropriate for noisy activities and the other for quiet activities, shall be provided. The combined total area shall be not less than 40 square feet per bed with not less than 160 square feet for each of the two spaces, whichever is greater.

(iii) A room for group therapy shall be provided. The room shall not be less than 250 square feet. The group therapy room may be combined with the quiet space required in clause (ii) of this subparagraph provided that a space of not less than 370 square feet is available for both the quiet activity room and group therapy activities.

(iv) Patient laundry facilities with automatic washer and dryer shall be provided.

(v) There shall be a minimum of one consultation room for each 24 beds or any portion thereof. For each additional 24 beds or any portion thereof, one additional consultation room shall be provided. Each consultation room shall have a minimum floor space of 100 square feet. The room(s) shall be designed for acoustical and visual privacy.

(vi) Space for occupational therapy shall be provided at the rate of 15 square feet per occupant of the room and a minimum area of not less than 375 square feet, whichever is greater. Space shall include provisions for hand washing, work counter(s), storage, and displays. Where psychiatric facilities contain less than 25 beds, the occupational therapy functions may be performed within the noisy activities area required in clause (ii) of this subparagraph provided that a space of not less than 485 square feet is available for both the noisy activity area and occupational therapy activities.

(vii) Small kitchen for patient use shall be provided. This area may contain a sink, refrigerator, residential type dishwasher, kitchen cabinets, ice dispenser, range, oven (hot plate), and other equipment. The area is to provide nourishment for patients between scheduled meals.

(D) Seclusion room. There shall be a seclusion room for short-term occupancy by a single person requiring security and protection from either himself or others.

(i) The seclusion room(s) shall be located and designed in a manner affording direct supervision by nursing staff.

(ii) The seclusion room(s) shall be constructed to prevent patient hiding, escape, injury, or suicide.

(iii) The minimum room area shall be not less than 60 square feet. The minimum room dimension shall be six feet.

(iv) There shall be a minimum of one seclusion room for each 24 beds or any portion thereof. For each additional 24 beds or any portion thereof, one additional seclusion room shall be provided.

(v) Special fixtures, hardware, and tamper-proof screws shall be used.

(vi) The access door shall open out and permit staff observation of the entire room while maintaining privacy from the public and other patients.

(vii) The seclusion room shall be accessed by an anteroom or vestibule which also provides direct access to a toilet room. The toilet room shall be large enough to safely manage the patient.

(viii) Each seclusion room shall have natural light (skylight or window) in order to maintain a therapeutic environment. Skylight wells or windows shall be not less than 240 square inches in area.

(27) Radiology suite. As a minimum, each general hospital shall include or make provision for:

(A) equipment provided for diagnostic purposes as required;

(B) radiographic room(s). Shield design shall meet the requirements of §133.99(d)(2)(Z) of this title;

(C) film processing facilities;

(D) viewing and administration area(s);

(E) film storage facilities;

(F) toilet room with handwashing facilities. The toilet room

shall be directly accessible from each fluoroscopy room without entering the general corridor area;

(G) dressing area(s) with convenient access to toilets. At least one dressing area shall be provided to accommodate wheel chair patients;

(H) waiting room or alcove for ambulatory patients;

(I) holding area for stretcher patients out of the direct line of normal traffic; and

(J) handwashing facilities in each radiographic room unless the room is used only for routine diagnostic screening such as chest X-rays

(28) Respiratory therapy unit.

(A) General. Respiratory therapy services shall be required when intensive care service is provided.

(B) Unit requirements. The unit shall contain the following:

(i) office space including records file;

(ii) space for separation of clean and soiled supplies and equipment. Where cleaning, preparation, sterilization, and disinfection functions are performed in the same room or unit, the physical facilities, equipment, and the policies and procedures for their use, shall be such as to effectively separate soiled or contaminated supplies and equipment from the clean, sterilized, or disinfected supplies and equipment. A sink shall be provided for safe disposal of liquid waste. Separate handwashing facilities shall be provided;

(iii) storage for supplies and equipment, and

(iv) equipment services area.

(29) Skilled nursing facilities (SNF)-hospital based.

(A) SNF. When skilled nursing facilities are provided, the following requirements shall be met.

(i) Patient rooms. Patient bedrooms shall be grouped together as a unit and shall comply with requirements in paragraph (18)(A) of this subsection.

(ii) Hospital conversions. When a section of the acute care facility is converted, it may be necessary to reduce the number of beds to provide space for long-term care services. The design shall maximize opportunities for ambulation and self-care and minimize the negative aspects of institutionalization. The following requirements for bedrooms shall be met.

(I) Converted rooms. Not less than 10% of any existing bedroom and bath conversions to SNF use shall be designed to meet the handicapped provisions. This includes patient toilet rooms.

(II) New construction or reconstruction. Not less than 50% of newly constructed or reconstructed SNF patient bedrooms shall be designed for the handicapped. This includes patient toilet rooms.

(B) Nursing unit. Each nursing unit shall comply with all provisions found in paragraph (18) of this subsection. In addition, all corridors with a wall length exceeding two feet shall have graspable handrails. The handrails shall comply with NFPA 101 Section 5-2.2.4 and the provisions found in the TAS, 19 TexReg 167, Architectural Barriers Act, TCS, Article 1902. No handrail shall protrude more than 3 1/2 inches into the egress corridor. All handrail ends shall be returned to the wall.

(i) The required nurses station may be shared with other nursing units provided it is located between the shared nursing units.

(ii) A dedicated medication room (not a cabinet) shall be provided in the SNF, preferably at the nurses station.

(C) Service areas.

(i) Service areas may be arranged and located to serve more than one nursing unit, but at least one such service area shall be provided on each nursing floor. Service areas shall comply with those listed in paragraph (18) (B) of this subsection.

(ii) Resident bathing facilities shall be provided. Each unit shall have a minimum of one wheel chair bathing facility, tub or shower room or enclosure, for the private use of the fixture unit. The room shall be provided centrally and shall be directly accessible from the corridor. The room shall have space for drying, dressing, lavatory, and water closet with training facilities. One training toilet with three feet of clearance on both sides and front shall be provided for the handicapped. The room shall be designed to met TAS handicapped requirements.

(D) Resident support areas. A room shall be set aside on the same floor as the SNF for dining, resident lounges, and recreational activities. The room shall be at least 30 square feet per patient bed but shall be not less than 160 square feet. Additional space may be required for outpatient day care programs.

(E) Rehabilitation therapy. SNF which provide physical and occupational therapy services for rehabilitating long-term care residents shall have areas and equipment that conform to program intent.

(i) SNF may share services with other nursing units as appropriate.

(ii) Physical and occupational therapy shall be available on-site for patients of the SNF. Paragraphs (20) and (25) of this subsection shall be met.

(F) Fire wall. The SNF may be separated from the rest of the hospital with two-hour fire protection rated construction. This is recommended to facilitate inspections by other licensing agencies (Long-Term Care Division, Texas Department of Human Services).

(G) Telephone. A public telephone shall be provided in the SNF when telephones are not provided in individual patient rooms.

(30) Surgical facilities.

(A) General. The surgical suite shall be located and arranged to preclude unrelated traffic through the suite. The suite shall meet the following requirements.

(B) General operating room(s). A minimum of one operating room shall be provided and shall have a minimum clear area of 360 square feet exclusive of fixed and movable cabinets and shelves. The minimum dimension shall be 18 feet. There shall be no direct access between operating rooms.

(i) An emergency communications system shall be provided in accordance with §133.99(f)(7)(E) of this title.

(ii) At least two X-ray film illuminators shall be provided in each room.

(iii) Storage space for splints and traction equipment shall be provided for rooms equipped for orthopedic surgery.

(C) Special procedures room(s). Special procedures rooms are not

required, but if provided, these rooms shall have a minimum clear area of 250 square feet and minimum room dimension of 12 feet exclusive of fixed and movable cabinets and shelves. Additional clear space may be required to accommodate special functions in one or more of these rooms. Surgical cystoscopic, endoscopic, cardiac catheterization, and other similar special procedures requiring the use of general anesthesia or inhalation anesthetizing agents shall be performed in these rooms or the operating rooms.

(i) An emergency communications system connecting with the surgical suite control station shall be provided.

(ii) Facilities for the disposal of liquid wastes shall be provided.

(D) Minor operating rooms. When provided, rooms used for outpatient minor surgery shall meet the requirements of subparagraph (C) of this paragraph.

(E) Recovery room(s).

(i) Post-anesthesia recovery rooms for surgical patients shall contain: a drug distribution station, handwashing facilities, charting facilities, clinical sink, and storage space for supplies and equipment.

(ii) A minimum of four feet six inches clear between each patient bed and three feet between a wall and a patient bed shall be provided.

(iii) Special provisions shall be made to keep separate or isolate infectious patients during surgical recovery. An isolation room meeting the requirements in paragraph (18)(C) of this subsection shall meet this requirement if conveniently located near the operating room suite.

(F) Service areas. Service areas, except the soiled workroom and the janitor closet mentioned in clauses (vi) and (xviii) of this subparagraph, may be shared with, and organized as part of, the obstetrical facilities if the design reflects this shared concept. Service areas shall be arranged to avoid direct traffic between the operating and the delivery rooms. The following services shall be provided.

(i) Control station. Control station located to permit visual surveillance of all traffic which enters the operating suite shall be provided.

(ii) Office. Supervisor's office or station shall be provided.

(iii) Sterilizing facilities. Sterilizing facilities with high speed autoclave(s) conveniently located to serve all operating rooms shall be provided.

(iv) Drug distribution station. Provision shall be made for the storage and preparation of medication to be administered to patients.

(v) Scrub facilities. Two scrub stations shall be provided near the entrance to each operating room; however, two scrub stations may serve two operating rooms if the scrub stations are located adjacent to the entrance of each operating room. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts.

(vi) Soiled workroom. Soiled workroom for the exclusive use of the surgical suite staff for the collection and disposal of soiled materials and fluid waste shall be provided. The soiled workroom shall contain fluid waste disposal facilities such as a clinical sink or equivalent flushing type fixture, work counter, sink equipped for handwashing, waste receptacle, and linen receptacle.

(vii) Clean workroom. Clean workroom or a clean supply room shall be provided. The clean workroom shall contain a work counter, sink equipped for handwashing, and space for clean and sterile supplies.

(viii) Anesthesia storage facilities. Unless the official hospital board action prohibits in writing the use of flammable anesthetics, a separate room shall be provided for storage of flammable gases in accordance with the requirements detailed in NFPA 99

(ix) Anesthesia workroom. Anesthesia workroom for cleaning, testing, and storing anesthesia equipment shall be provided. It shall contain a work counter and sink.

(x) Medical gas storage Medical gas cylinder storage space for reserve nitrous oxide and oxygen cylinders shall be provided. (May be located in the anesthesia workroom if properly vented). The space shall comply with NFPA 99 and Compressed Gas Association (CGA) requirements in Pamphlet G-8.1, 1979, Nitrous Oxide Systems at Consumer Sites, Pamphlet P-1, Safe Handling of Compressed Gases, and Pamphlet P-2, Characteristics of Safe Handling of Medical Gases. The department adopts by reference the CGA standards in §133. 100(b)(1)(F) of this title.

(xi) Storage. Storage room(s) for equipment and supplies used in surgical suite shall be provided.

(xii) Staff clothing change areas. Appropriate areas shall be provided for male and female personnel working within the surgical suite. The areas shall contain lockers, showers, toilets, lavatories equipped for handwashing, and space to change into scrub suits and boots. These areas shall be arranged to provide a traffic pattern so that personnel entering from outside the surgical suite can shower, change, and move directly into the surgical suite.

(xiii) Outpatient surgery change areas. When outpatient services are provided, a separate area shall be provided where outpatients change from street clothing into hospital gowns and are prepared for surgery. This shall include a waiting room, lockers, toilets, and clothing change or gowning area with a traffic pattern similar to that of the staff clothing change area.

(xiv) Outpatient recovery. Where patients are not subjected to general anesthesia, provisions shall be made for separating inpatient and outpatient recovery. This requirement may be satisfied by separated rooms or by scheduling of procedures.

(xv) Patient holding area. In facilities with two or more operating rooms, a room or alcove shall be provided to accommodate stretcher patients waiting for surgery. This waiting area shall be under the visual control of the surgical suite control station.

(xvi) Stretcher storage alcove. The alcove provided for stretcher storage shall be located out of direct line of traffic.

(xvii) Lounge and toilet facilities for surgical staff. These facilities shall be provided in hospitals having three or more operating rooms and shall be located to permit use without leaving the surgical suite. A nurses toilet room shall be provided near the recovery room(s).

(xviii) Janitor closet. A closet containing a floor receptor or service sink and storage space for housekeeping supplies and equipment shall be provided exclusively for the surgical suite.

(xix) Cast room. A room equipped with handwashing facilities, plaster sink, storage, and other provisions required for cast procedures shall be provided. May be located in the emergency room.

(31) Waste processing and storage facilities. The hospital shall comply with applicable requirements in §133.61(bb) of this title.

§133.96. Physical Plant-Existing Hospitals.

(a) Compliance. All existing buildings in which health care services are provided for hospital inpatients, are attached to the hospital, are part of the required hospital's health care delivery system, and are licensed by the Texas Department of Health (department), shall comply with this chapter.

(b) Physical aspects. The existing building(s) shall meet the requirements for health care occupancies code, National Fire Protection Association (NFPA) 101, under which the building was constructed, or NFPA 101M, Fire Safety Evaluation System For Health Care Occupancies which the department adopts by reference in §133.100(b)(1)(M) of this title (relating to Codes and Standards). Other applicable requirements for existing conditions in a health care occupancy in Subchapter F of this title (relating to Operational Requirements for All Hospitals) shall be met. If psychiatric services are provided, seclusion room(s) shall meet the requirements in §133. 95(b)(26)(D) of this title (relating to Hospital Units-Spatial Requirements).

§133.97. Renovation.

(a) Construction phasing. Projects involving alterations of and additions to existing buildings shall be programmed and phased so that on-site construction will minimize disruptions of existing functions. Access, exit access, and fire protection shall be maintained so that the safety of the occupants will not be jeopardized during construction. Airtight dust and vapor barriers shall be provided to separate areas undergoing demolition and construction from occupied areas. Temporary sound barriers shall be provided where intense prolonged construction noises will disturb patients or staff in the occupied portions of the building.

(b) Minimum requirements. All requirements listed in this chapter relating to new construction projects are applicable to renovation projects involving additions or alterations, except that when existing conditions make changes impractical to accomplish, minor deviations from functional requirements may be permitted if the intent of the requirements is met and if the care and safety of patients will not be jeopardized.

(c) Nonconforming conditions. When doing renovation work, if it is found to be unfeasible to correct all of the nonconforming conditions in the existing facility in accordance with these rules, a conditional approval may be granted by the Texas Department of Health if the operation of the facility, necessary access by the handicapped, and safety of the patients are not jeopardized by the remaining nonconforming conditions.

§133.98. Physical Plant-All New Hospitals

(a) Hospital location.

(1) Accessibility. The site of any new hospital shall be easily accessible to the community and to service vehicles such as delivery trucks, ambulances, and fire protection apparatus.

(2) Flood protection. Construction of new hospitals shall be avoided in designated flood plains. Where such is un avoidable, consult the local flood control agencies for the latest applicable regulations pertaining to flood protection measures.

(b) Provision for natural disasters.

(1) Emergency communication system. An emergency communication system shall be provided in each facility The system shall be self-sufficient in time of emergency, capable of operating without reliance on the building's service or emergency power supply, and linked with the available community or state emergency communication network, including connections with police and fire systems.

(2) Hurricanes, tornadoes, and floods. Special provisions shall be made in the design of buildings in regions where local experience shows loss of life or extensive damage to buildings resulting from hurricanes, tornadoes, or floods in accordance with applicable building codes in §133.100(a) of this title (relating to Codes and Standards). Disaster planning shall be completed in accordance with NFPA 99, Annex I, Health Care Emergency Preparedness, which the Texas Department of Health (department) adopts by reference in §133. 100(b)(1)(M) of this title and the State of Texas Emergency Management Plan and applicable annexes and appendices which the department adopts by reference in §133.100(b)(3)(U) of this title. (Information regarding the State of Texas Emergency Management Plan is available from the city or county Emergency Management Coordinator).

(c) Hazardous conditions.

(1) General. New hospitals or additions to existing buildings shall not be constructed over underground liquid butane, propane, or gas transmission lines, over any underground high pressure lines, under high voltage electrical lines, or near hazardous or hazard producing plants.

(2) Flammables. New hospitals shall not be built within 300 feet of aboveground or underground liquid petroleum transmission lines or storage tanks containing flammable liquids used in connection with a bulk plant, marine terminal, aircraft refueling, or other bottling plant of a liquefied petroleum gas installation.

(d) Environmental control.

(1) General. Development of a hospital site and hospital construction shall be governed by state and local regulations and requirements with respect to the effect of noise and traffic on the community and the environmental impact on air and water.

(2) Undesirable locations. New hospitals shall not be located near nuisance producing industrial developments, feed lots, sanitary landfills, airports, manufacturing plants producing excessive noise or air pollution, or near a cemetery.

§133.99. Construction Requirements.

(a) Construction.

(1) General. All new construction, additions, alterations, and renovations to any building to be licensed by the Texas Department of Health (department) shall be done in accordance with this subchapter and other applicable standards referenced in §133.100(a) and (b) of this title (relating to Codes and Standards). NOTE: Where local codes in effect are in excess of these requirements, the more stringent shall apply.

(2) Design. Every building and every portion thereof shall be designed and constructed to sustain all dead and live loads in accordance with accepted engineering practices and standards including seismic forces, where applicable, and requirements which the department adopts by reference in §133.100(a) and (b) of this title.

(3) Foundations. Foundations shall rest on natural solid bearing if satisfactory bearing is available. Proper soil-bearing values shall be established in accordance with recognized requirements. If solid bearing is not encountered at practical depths, the structure shall be supported on driven piles or drilled piers designed to support the intended load without detrimental settlement, except that one-story buildings may rest on a fill designed by a soils engineer. When engineered fill is used, site preparation and placement of fill shall be done under the direct full-time supervision of the soils engineer. The soils engineer shall issue a final report on the compacted fill operation and certification of compliance with the job specifications. All footings shall extend to a depth not less than one foot below the estimated maximum frost line.

(4) Exceptions.

(A) Freestanding buildings (not for patient use). Separate freestanding buildings housing areas not for patient use such as the heating plant, boiler plant, laundry, repair workshops, or general storage may be of unprotected non-combustible construction, protected non-combustible construction, or fire-resistive construction and be designed in accordance with other occupancy classifications listed in National Fire Protection Association (NFPA) 101 regarding exit requirements. The department adopts by reference the various NFPA standards referenced in the section in §133.100(b)(1)(M) of this title.

(B) Freestanding buildings (for patient use other than sleeping). Buildings housing areas for patient use which do not contain patient sleeping areas and in which care or treatment is rendered to inpatients who are capable of judgment and appropriate physical action for self-preservation under emergency conditions, may be classified as business or ambulatory care occupancies as listed in NFPA 101 instead of hospital occupancy when the facilities are separated from the hospital by not less than two-hour fire protection rated construction.

(b) Fire-resistance.

(1) Enclosures.

(A) Hazardous areas. Hazardous areas shall be protected in accordance with NFPA 101 and local codes when applicable.

(B) Hot water heaters and steam generators. All hot water heaters and steam generators shall be located in the heating plant or in a room which meets NFPA 101 requirements for hazardous areas.

(C) Vertical enclosures. Enclosures for stairways, protected passageways, elevator shafts, chutes, and other vertical shafts shall meet the requirements of NFPA 101. Penetration of these enclosures by building services such as heating, ventilation, air-conditioning (HVAC) ducts is not permitted.

(2) Interior finishes. Interior finish materials shall comply with the flame spread limitations and the smoke production limitations shown in Table 2 in §133.101(a) of this title (relating to Tables and Figures). This does not apply to minor quantities of wood doors, cabinets, and wood trim (10% of combined floor-wall area), or to wall coverings less than 1 1/28 inches thick applied over a non-combustible base.

(3) Insulation materials. Building insulation materials, unless sealed on all sides and edges, shall have a flame spread rating of 25 or less and a smoke developed rating of 150 or less when tested in accordance with NFPA 255.

(c) Elevators.

(1) General. All hospitals having patient facilities (such as patient sleeping rooms, dining rooms, or recreation areas) or critical services (such as operating, delivery, diagnostic, or therapy) on floors not opening onto grade or other than the main entrance floor shall have electrical or electrical hydraulic elevators as part of the accessible route. Elevators shall also give access to all building levels normally used by the public. Installation and testing of new elevators shall comply with American Society of Mechanical Engineers (ASME) and American National Standards Institute (ANSI) A17.1 and A17.1a which the department adopts by reference in §133.100(b)(1) (D) of this title.

(A) Type and number required. When applicable, the number of hospital-type elevators for new facilities shall be:

(i) one elevator for the first 59 bed spaces;

(ii) two elevators for 60 to 200 bed spaces;

(iii) three elevators for 201 to 350 bed spaces; or

(iv) determined from a study of the hospital plan and the estimated vertical transportation requirements for facilities with more than 350 beds.

(B) Cars and doors. Cars of hospital-type elevators shall be at least five feet wide by seven feet six inches deep. The car door shall have a clear opening of not less than four feet.

(C) Leveling. All elevators shall be equipped with an automatic leveling device of the two-way automatic maintaining type with an accuracy of 1/2 inch.

(D) Operation. All elevators, except freight elevators, shall be equipped with a two-way service key-operated switch to permit cars to bypass all landing button calls and be dispatched directly to any floor.

(E) Accessibility of controls and alarms. Elevator controls, alarm buttons, and telephones shall be accessible to wheelchair occupants.

(F) Type of controls and alarms. Elevator call buttons, controls, and door safety stops shall be of a type that will not be activated by heat or smoke.

(2) Inspections and certification. In accordance with Health and Safety Code (HSC), Chapter 754, Subchapter B (relating to Inspection and Certification of Elevators, Escalators, and Related Equipment), all elevators shall comply with the following requirements.

(A) Inspection. All elevators, escalators, or related equipment shall be inspected and certified annually in accordance with the rules of the commissioner of licensing and regulation of the Texas Department of Licensing and Regulation (TDLR).

(B) Certification. A certificate of inspection evidencing that the elevators, escalators, and related equipment were inspected in accordance with the requirements in HSC Chapter 754, Subchapter B, and determined to be in compliance with the safety standards adopted under HSC, §754.014 shall be on record in each hospital.

(C) Submit certificate of inspection to TDLR. The hospital shall file with the commissioner of licensing and regulation of TDLR a copy of each certificate of inspection not later than 30 calendar days after the inspection date.

(D) Posting requirements. The hospital shall display the certificate of inspection:

(i) in the elevator mechanical room if the certificate relates to the elevator inspection;

(ii) in the escalator box if the certificate relates to the escalator inspection; or

(iii) in a place designated by the commissioner of licensing and regulation of TDLR if the certificate relates to the inspection of related equipment.

(d) Details and finishes.

(1) General.

(A) Details and finishes in new construction projects, including additions and alterations, shall be in compliance with NFPA 101 and local building codes when applicable.

(B) The fire safety evaluation system for health care occupancies, NFPA 101M, shall not be used in the design of new building construction or additions to existing facilities.

(2) Details. The following requirements shall be met.

(A) Fire safety features, including compartmentation, means of egress, fire alarms, automatic extinguishing systems, inspections, smoking regulations, and other details relating to fire prevention and fire protection shall comply with requirements listed in §133.71 of this title (relating to Fire Prevention and Protection) and NFPA 101 requirements for healthcare occupancies.

(i) The minimum corridor width in patient areas shall be eight feet in all new hospitals and constructed in accordance with requirements listed in NFPA 101.

(ii) Public corridors in outpatient suites, administrative, and service suites which would not be used by hospital patients being transported in beds or stretchers shall be not less than five feet in width.

(B) Items such as drinking fountains, telephone booths, vending machines, and portable equipment shall be located so that they do not project into and restrict exit corridor traffic or reduce the exit corridor width below the required minimum.

(C) Rooms containing bathtubs, showers, and water closets, subject to occupancy by patients, shall be equipped with doors and hardware which will permit access from the outside in any emergency. When such rooms have only one access, the doors shall be capable of opening outward.

(D) Suitable hardware shall be provided on doors to psychiatric patient toilet rooms so that access to these rooms can be controlled by staff. Hardware shall be utilized which is appropriate to prevent patient injury.

(E) Doors to patient rooms shall not be lockable from inside the room unless equipped for emergency unlocking from the corridor side by the use of a key or tool.

(F) Door dimensions shall be in accordance with the following criteria.

(i) Doors in the means of egress from hospital sleeping rooms and treatment areas shall be not less than 44 inches wide.

(ii) Exit access doors from pediatric and neonatal intensive care units or sleeping rooms shall be at least 36 inches wide and constructed in accordance with NFPA 101.

(iii) Openings providing access for the handicapped shall have a minimum clear opening of 32 inches with the door open 90 degrees, measured between the face of the door and the door frame stop. All doors along accessible routes and doors to toilet rooms for the handicapped shall be at least 36 inches wide.

(iv) No existing door from any occupied space shall be less than 28 inches wide.

(G) All doors in the means of egress shall comply with NFPA 101.

(H) No doors and rooms listed in subparagraph (C) of this paragraph equipped with the special hardware shall swing into the exit corridors in a manner that might obstruct traffic flow or reduce the required corridor width except those to spaces such as small closets which are not subject to occupancy. Walk-in type closets are considered as spaces subject to occupancy.

(I) Operable windows and outer doors which may be frequently left in an open position shall be provided with insect screens. All operable windows at the kitchen and dining areas shall have screens.

(J) Patient rooms intended for occupancy of 24 hours or more shall have an outside window or outside door arranged and located so that it can be opened from the inside to permit the venting of products of combustion and to permit any occupant to have direct access to fresh air in case of emergency. Windows may be fixed if the building is designed with an engineered smoke control system in accordance with NFPA 90A, is protected throughout with an automatic sprinkler system in accordance with NFPA 13, and meets applicable requirements in NFPA 101.

(K) Sidelights or borrowed lights at doors in exterior walls in which the glazing extends down to or below 18 inches of the floor (thereby creating possibility of accidental breakage by pedestrian traffic) shall be glazed with safety glass or plastic glazing material that will resist breaking and will not create dangerous cutting edges when broken. Similar materials shall be used in wall openings of recreation rooms and exercise rooms unless required otherwise for fire safety. Safety glass or plastic glazing materials shall be used for shower doors and bath enclosures. Openings in corridor walls shall be protected as required by NFPA 101.

(L) All fire doors shall be tested by an independent testing laboratory and shall meet the construction requirements for fire doors in NFPA 80. Reference to a labeled door shall be construed to include labeled frame and hardware.

(M) Elevator shaft openings shall have B labeled, 1 1/2-hour fire protection rated doors.

(N) Grab bars shall be provided at patient toilets, showers and tubs, and in other bathrooms. The bars shall be 1 1/2 inches in diameter, shall have 1 1/2 inches clearance to walls, and shall have sufficient strength and anchorage to sustain a concentrated load of 250 pounds.

(O) Break-away curtain rods shall be used in toilets, showers, and tubs in psychiatric units to prevent patient injury.

(P) Shower heads and water faucets of a type appropriate to prevent patient injury shall be used in showers and tubs in psychiatric units.

(Q) Recessed soap dishes shall be provided at showers and bathtubs.

(R) Location and arrangement of handwashing facilities shall permit their proper use and operation. Particular care shall be given to the clearances required for blade-type operating handles.

(S) Mirrors shall not be installed at handwashing fixtures in food preparation areas, nurseries, clean and sterile supply areas, scrub sinks, or other areas where asepsis control would be lessened by hair combing.

(T) Provisions for hand drying shall be included at all handwashing facilities. There shall be hot air dryers or individual paper or cloth units enclosed in such a way as to provide protection against dust or soil and ensure single unit dispensing.

(U) Lavatories and handwashing facilities shall be securely anchored to withstand an applied vertical load of not less than 250 pounds on the front of the fixture.

(V) The minimum ceiling height shall be eight feet with the following exceptions.

(i) Boiler rooms shall have ceiling clearances not less than two feet six inches above the main boiler header and connecting piping.

(ii) Rooms containing ceiling-mounted equipment shall have the ceiling height clearance increased to accommodate the equipment or fixtures. Radiographic, operating rooms, delivery rooms, trauma rooms, and central dietary kitchen (food processing areas) shall have ceiling heights not less than nine feet.

(iii) In corridors, ceilings heights not less than seven feet six inches may be acceptable with approval by the department.

(iv) Ceilings in storage rooms, toilet rooms, and other minor rooms shall be not less than seven feet six inches.

(v) Suspended tracks, rails, pipes, signs, lights, door closures, exit signs, and other fixtures that protrude into the path of normal traffic shall not be less than six feet eight inches above the finished floor.

(W) Recreation rooms, exercise rooms, and similar spaces where impact noises may be generated shall not be located directly over patient bed area unless special provisions are made to minimize noise.

(X) Rooms containing heat-producing equipment, heater rooms, and laundries shall be insulated and ventilated to prevent any occupied floor surface above from exceeding a temperature of 10 degrees Fahrenheit (60 degrees Centigrade) above the ambient room temperature.

(Y) Noise reduction criteria shown in Table 1 in §133.101(a) of this title shall apply to partitions, floor, and ceiling construction in patient areas.

(Z) Radiation protection requirements of X-ray and gamma ray installations shall conform with National Council on Radiation Protection (NCRP) Reports Number 33 and Number 49 which the department adopts by reference in §133.100(b)(1)(L) of this title. Radiation protection shall be designed by a qualified experienced individual in this field. The design and installation testing must be approved before use. All defects shall be corrected before acceptance will be granted.

(3) Finishes. The following requirements shall be met.

(A) Cubicle curtains and draperies shall be non-combustible and shall pass tests of NFPA 701. Copies of laboratory test reports for installed materials shall be provided.

(B) Flame spread and smoke developed limitations of finishes are covered in Table 2 in §133.101(a) of this title. The use of materials known to produce large amounts of noxious gases shall not be used in exit accesses or in patient areas Copies of laboratory test reports for installed materials shall be provided.

(C) Floor materials shall be easy to clean and have wear resistance appropriate for the location involved. Floors in areas used for food preparation or food assembly shall be water-resistant and grease-proof. Joints in tile and similar material shall be resistant to food acids. In all areas frequently subject to wet cleaning methods, floor materials shall not be physically affected by germicidal and cleaning solutions. Floors that are subject to traffic while wet (such as shower and bath areas, kitchens, and similar work areas) shall have a nonslip surface. Floors in areas and rooms in which flammable anesthetic agents are stored or administered shall comply with NFPA 99. Flooring used in operating rooms, delivery rooms, birthing rooms around bed area, nurseries, and emergency treatment rooms shall be of the seamless, monolithic or welded joint type (extending from wall to wall), scrubable, and impervious to water.

(D) Wall bases in kitchens, operating rooms, delivery rooms, nurseries, emergency treatment rooms, soiled workrooms, and other areas which are frequently subject to wet cleaning methods shall be made integral and coved with the floor, tightly sealed to the wall, constructed without voids that can harbor insects, and impervious to water.

(E) Wall finishes shall be washable, smooth, and moisture resistant in the immediate area of plumbing fixtures Finish, trim, flooring, and wall construction in dietary and food preparation areas shall be free from spaces that can harbor rodents and insects

(F) Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

(G) All exposed ceilings and ceiling structures in areas normally occupied by patients, staff, and visitors shall be finished so as to be cleanable with equipment used in daily housekeeping activities. Dietary and other areas where dust fallout would present a potential problem shall have finished ceilings that are made of washable smooth impervious materials, without open joints, that cover all conduits, piping, duct work, and open construction systems Ceilings and walls in operating and delivery rooms, isolation rooms, and sterile processing areas shall be monolithic from wall to wall without fissures, open joints, or crevices that may retain or permit passage of dirt particles. Acoustic and lay-in ceilings shall not be used where particulate matter may interfere with asepsis control.

(H) Noise reduction criteria shall apply to partitions, floors, and ceiling construction in patient areas as referenced in Table 1 in §133 101(a) of this title.

(I) Special conditions may require monolithic or bonded ceiling construction for security measures, such as in psychiatric units and storage of controlled substances.

(e) Mechanical.

(1) General.

(A) Design and cost. All mechanical systems shall be designed for overall efficiency and life cycle costing, including operational costs. In no case shall patient care or safety be sacrificed for conservation

(i) Mechanical systems including steam and hot and cold water systems, air-conditioning, heating, and ventilation systems, piping systems, and fire sprinkler systems may be shared by two separate hospitals sharing a building only when these systems comply with this section

(ii) All mechanical systems including steam and hot and cold water systems, air-conditioning, heating, and ventilating systems, piping systems, and fire sprinkler systems shall be provided separately for hospitals sharing a building with non-hospital occupancies and shall comply with this section.

(B) Performance and acceptance. Prior to completion and acceptance of the facility, all mechanical systems shall be tested, balanced, and operated to demonstrate to the design engineer or his representative that the installation and performance of these systems conform to the requirements of the plans and specifications.

(C) Material lists and instructions. Upon completion of the contract, the owner shall be furnished with a complete set of manufacturers' operating instructions, maintenance, and preventive maintenance instructions, parts lists, and procurement information with numbers and description for each piece of equipment. The owner shall also be provided with instructions in the operational use of systems and equipment as required.

(2) Air-conditioning, heating, and ventilating systems.

(A) Ventilation rates. The ventilation rates shown in Table 3 in §133. 101(a) of this title shall be used only as model requirements since they do not preclude the use of higher rates that may be appropriate.

(B) Ventilation system details. All rooms and areas in the hospital

shall have provision for positive ventilation. Fans serving exhaust systems shall be located at the discharge end and shall be conveniently accessible for service. Exhaust systems may be combined as necessary for efficient use of recovery devices required for energy conservation.

(i) To reduce utility costs, facility design shall utilize energy conserving procedures including recovery devices, variable air volume, load shedding, systems to shut down or reduce ventilation of certain areas when unoccupied, insofar as patient care is not jeopardized.

(ii) Mechanical ventilation shall be arranged to take advantage of outside air supply by using an economizer cycle when appropriate to reduce heating and cooling systems loads. Innovative design that provides for additional energy conservation while meeting the intent of this section for acceptable patient care will be considered.

(iii) Fresh air intakes shall be located at least 25 feet from exhaust outlets of ventilating systems, combustion equipment stacks, medical-surgical vacuum systems, plumbing vents, or areas which may collect vehicular exhaust or other noxious fumes. (Prevailing winds and proximity to other structures may require greater clearances). Plumbing and vacuum vents that terminate above the level of the top of the air intake may be located as close as ten feet. The bottom of outdoor air intakes serving central systems shall be located as high as practical but at least six feet above ground level, or if installed above the roof, three feet above the roof level. Exhaust outlets from areas that may be contaminated shall be above the roof level and arranged to minimize recirculation of exhaust air into the building.

(iv) The ventilation systems shall be designed and balanced to provide directional flow as shown in Table 3 in §133.101(a) of this title. For reductions and shut down of ventilation systems when a room is unoccupied, the provisions in note 8 of Table 3 may be followed. Fully ducted supply and return air for heating, ventilating, and air-conditioning (HVAC) systems shall be provided for all critical care areas, sensitive care areas, and all areas requiring a sterile regimen. Such areas include, but are not limited to, surgical facilities, delivery room, intensive care unit (ICU), cardiac care unit (CCU), bone marrow transplantation unit, neonatal care unit, special procedures room, nursery, birthing room, isolation room, sterile processing and sterile storage room(s).

(v) Air supply for the operating room and the delivery room shall be from ceiling outlets near the center of the work area to efficiently control air movement. Return air shall be from near the floor level. Each operating and delivery room shall have at least two return air inlets located as remotely from each other as practical. (Design should consider turbulence and other factors of air movement to minimize fall of particulates into a wound site). Where extraordinary procedures, such as organ transplants, may justify laminar air flow or other special designs, the installation shall be required to properly meet the performance needs. These special designs shall be reviewed on a case by case basis.

(vi) Air supply for nurseries, birthing rooms, special procedures rooms, and rooms used for invasive procedures shall be at or near the ceiling. Return air inlets shall be not less than three inches or higher than 12 inches from floor level

(vii) Each space routinely used for administering inhalation anesthesia shall be provided with a scavenging system to vent waste gases. If a vacuum system is used, the gas collecting system shall be arranged so that it does not interfere with the patient's respiratory system. Gases from the scavenging system shall be exhausted directly to the outside. The anesthesia evacuation system may be combined with the room exhaust system provided that the part used for anesthesia gas scavenging exhausts directly to the outside and is not part of the recirculation system. Separate scavenging systems are not required for areas where anesthetizing gases are used only occasionally such as the emergency treatment room, offices, or routine dental work. Acceptable levels of concentration of anesthetizing agents are unknown at this time. In the absence of specific figures, any scavenging system shall be designed to remove as much of the gases as possible from the room environment.

(viii) Ventilation for anesthetizing locations shall conform to the requirements of NFPA 99, Section 5.4.

(ix) The bottoms of ventilation openings shall be at least three inches above the floor.

(x) All central ventilation or air-conditioning systems shall be equipped with filters having efficiencies equal to, or greater than, those specified in Table 4 in §133.101(a) of this title. Where two filter beds are required, filter bed Number One shall be located upstream of the supply for air-conditioning equipment, and filter bed Number Two shall be downstream of any recirculating spray water system and water reservoir type humidifiers. Where only one filter bed is required, it shall be located upstream of the supply for air handlers unless an additional prefilter is employed. In this case, the prefilter shall be upstream of the air handler, and the main filter may be located further downstream. Filter efficiencies shall be average efficiencies tested in accordance with American Society of Heating, Refrigerating, and Air-conditioning Engineers (ASHRAE) Standard 52.1 which the department adopts by reference in §133.100(b)(1)(C) of this title except as noted otherwise. Filter frames shall be durable and dimensioned to provide an airtight fit with the enclosing ductwork. All joints between filter segments and the enclosing ductwork shall be gasketed or sealed to provide a positive seal against air leakage. A manometer or draft gauge shall be installed across each filter bed having a required efficiency of 75% or more including hoods requiring high efficiency particulate air (HEPA) filters.

(xi) Air handling duct systems shall meet the requirements of NFPA 90A and those contained in this section.

(xii) Ducts which penetrate construction intended for X-ray or other ray protection shall not impair the effectiveness of the protection.

(xiii) Fire and smoke dampers shall be constructed, located, and installed in accordance with the requirements of NFPA 101 and NFPA 90A. Fans and dampers shall be interconnected so that activation of dampers will not damage the ducts. Access for maintenance shall be provided at all dampers. Note: smoke dampers shall be activated by components of the fire alarm system, not by fan cut off alone. Controls for restarting fans may be installed for convenient fire department use to assist in evacuation of smoke after a fire is controlled, provided that provisions are made to avoid possible damage to the system because of closed dampers. Smoke dampers shall be equipped with remote control reset devices.

(xiv) If air supply requirements in Table 3 in §133.101(a) of this title do not provide sufficient air for use by hoods and safety cabinets, make-up air shall be provided to maintain the required air flow direction and to avoid depending upon infiltration from outdoor or from contaminated areas. The food preparation area may have air movement in during cooking and hood operation for odor control. Make-up systems for hoods shall be arranged to minimize short circuit of air movement and to avoid reduction in air velocity at the point of contaminant capture.

(xv) Laboratory hoods shall meet the following general requirements:

(I) have an average face velocity of at least 75 feet per minute;

(II) be connected to an exhaust system to the outside which is separate from the building exhaust system;

(III) have an exhaust fan located at the discharge end of the system; and

(IV) have an exhaust duct system of non-combustible corrosion-resistant material as needed to meet the planned usage of the hood.

(xvi) Laboratory hoods shall meet the following special requirements.

(I) Each hood which processes infectious or radioactive materials shall have a minimum face velocity of 100 feet per minute, be connected to an independent exhaust system, have filters with a 99.97% efficiency (based on the dioctylphthalate (DOP) test method) in the exhaust stream, and be designed and equipped to permit the safe removal, disposal, and replacement of contaminated filters. Filters shall be as close to the hood as practical to minimize duct contamination.

(II) Hoods which process radioactive materials shall meet requirements of the Nuclear Regulatory Commission (NRC). Note: Radioactive isotopes used for injections, without probability of airborne particulates or gases, may be processed in a clean work bench type hood if acceptable to the NRC.

(III) Ducts serving hoods for radioactive material shall be constructed of acid resistant stainless steel for their full length and shall have a minimum number of joints. Duct systems serving hoods in which strong oxidizing agents (e.g. perchloric acid) are used shall be constructed of acid resistant stainless steel for at least ten feet from the hood and shall be equipped with washdown operations.

(xvii) Exhaust hoods in food preparation centers shall comply with NFPA 96 requirements. All hoods over cooking ranges shall be equipped with grease filters, fire extinguishing systems, and heat-actuated fan controls. Clean-out openings shall be provided every 20 feet in horizontal exhaust duct systems serving these hoods.

(xviii) The ventilation system for anesthesia storage rooms shall conform to the requirements of NFPA 99, Health Care Facilities.

(xix) Where ethylene oxide is used for sterilization, provisions shall be made for complete exhaust of gases to the exterior. When the door is opened, arrangement shall ensure that gases are pulled away from the operator. Provisions shall be made for appropriate aeration of supplies. Aeration cabinets shall be vented to the outside. Where aeration cabinets are not used in ethylene oxide processing, an isolated area mechanically vented to the outside for aeration shall be provided. The hospital shall comply with appropriate provisions in 30 Texas Administrative Code (TAC), Chapter 116 (relating to Control of Air Pollution by Permits for New Construction or Modification) and the Health and Safety Code (HSC), Subtitle C, Chapter 381 (relating to Air Quality) administered by the Texas Natural Resources Conservation Commission (TNRCC).

(xx) Boiler rooms shall be provided with sufficient outdoor air to maintain equipment combustion rates and to limit work station temperatures to an Effective Temperature (ET) of not more than 90 degrees Fahrenheit as defined by the ASHRAE Handbook of Fundamentals which the department adopts by reference in §133.100(b)(1)(C) of this title. When ambient outside air temperature is higher, maximum temperature may be that of outside air up to a maximum of 97 degrees Fahrenheit

(xxi) Where appropriate and conditions permit, gravity exhaust may be used for nonpatient areas such as boiler rooms and central storage.

(3) Piping systems and plumbing fixtures.

(A) General. All piping systems and plumbing fixtures shall be designed and installed in accordance with the requirements of National Association of Plumbing-Heating-Cooling Contractors (PHCC) National Standard Plumbing Code which the department adopts by reference in §133.100(b)(1)(K) of this title, local codes, and this section.

(B) Plumbing fixtures. The materials used for plumbing fixtures shall be of nonabsorptive acid-resistant material.

(i) The water supply spout for lavatories and sinks required in patient care areas shall be mounted so that its discharge point is a minimum distance of five inches above the rim of the fixture. All fixtures used by medical and nursing staff and all lavatories used by patients and food handlers shall be trimmed with valves which can be operated without the use of hands.

(ii) Clinical sinks shall have an integral trap in which the upper portion of a visible trap seal provides a water surface.

(iii) Shower bases and tubs shall provide nonslip surfaces for standing patients.

(C) Water supply systems. Water service pipe to point of entrance to the building shall be brass pipe, copper tube (not less than type M when buried directly), copper pipe, cast iron water pipe, galvanized steel pipe, or approved plastic pipe. Water distribution system piping within buildings shall be brass pipe, copper pipe, copper tube, or galvanized steel pipe.

(i) Each water service main, branch main, riser, and branch to a group of fixtures shall be valved. Stop valves shall be provided at each fixture.

(ii) Backflow preventers (vacuum breakers) shall be installed on hose bibbs, laboratory sinks, janitor sinks, bedpan flushing attachments, autopsy tables, and on all other fixtures to which hoses or tubing can be attached.

(iii) Flush valves installed on plumbing fixtures shall be of a quiet operating type, equipped with silencers.

(iv) Bedpan flushing devices shall be provided in each patient toilet room except those in psychiatric units, chemical dependency units, and other ambulatory care facilities.

(v) Water distribution systems shall be arranged to provide hot water at each hot water outlet at all times. Hot water at patient bathing units shall not exceed 110 degrees Fahrenheit (measured at the outlet).

(vi) Emergency potable water storage facilities shall be provided. The storage tank capacity shall not be less than 500 gallons or 12 gallons per patient bed, whichever is greater. Hot water storage tanks may meet these requirements.

(D) Hot water heaters and tanks. The hot water heating equipment shall have sufficient capacity to supply water at the temperatures and amounts specified in Table 5 in §133.101(a) of this title.

(i) Water temperatures shall be taken at hot water point of use or at the inlet to processing equipment.

(ii) Storage tank(s) shall be fabricated of corrosion-resistant metal or lined with noncorrosive material.

(E) Drainage systems.

(i) Soil stacks, drains, vents, waste lines, and leaders installed above ground within buildings shall be drain-waste-vent (DWV) weight or heavier and shall be:

(I) copper pipe;

(II) copper tube;

(III) cast iron pipe; or

(IV) galvanized iron pipe.

(ii) All underground building drains shall be:

(I) cast iron soil pipe;

(II) hard temper copper tube, DWV or heavier;

(III) acrylonitrile-butodiene-styrene (ABS) plastic pipe, DWV Schedule 40 or heavier;

(IV) polyvinyl chloride (PVC) plastic pipe, DWV Schedule 40 or heavier; or

(V) extra strength vitrified clay pipe (VCP) with compression joints or couplings. Extra strength VCP shall have at least 12 inches of earth cover.

(iii) Separate drainage systems for chemical wastes (acids and other corrosive materials) shall be provided. Materials acceptable for chemical waste drainage systems shall include chemically resistant glass pipe, high silicone content cast iron pipe, vitrified clay pipe, plastic pipe, or plastic lined pipe.

(iv) Drainage and waste piping shall not be installed within the ceiling or installed in an exposed location in operating and delivery rooms, nurseries, food preparation centers, food serving facilities, food storage areas, and other critical areas unless special precautions are taken to protect these areas from possible leakage or condensation from necessary overhead piping systems.

(v) Floor drains shall not be installed in operating and delivery rooms. Flushing rim type floor drains may be installed in cystoscopic operating rooms.

(vi) Building sewers shall discharge into a community sewage system. Where such a system is not available, a facility providing sewage treatment shall conform to applicable state and local regulations.

(vii) In all buildings more than three stories high, a wet Class I standpipe system shall be provided in accordance with NFPA 14.

(viii) All piping including piping for heating, ventilating, air-conditioning (HVAC) shall be color coded or otherwise labeled for easy identification.

(ix) All fire sprinkler systems installed in hospitals shall meet the requirements of NFPA 13 and shall be maintained in accordance with NFPA 13A.

(I) Only special institutional sprinkler heads shall be installed in psychiatric units.

(II) Approval for occupancy of facilities requiring fire sprinkler system shall be granted only upon approval of fire sprinkler installation.

(F) Nonflammable medical gas and clinical vacuum systems. Nonflammable medical gas (including medical air) and clinical vacuum system installations shall be in accordance with the requirements of NFPA 99.

(i) Outlets. Nonflammable medical gas and clinical vacuum outlets shall be provided in accordance with Table 6 in §133.101(a) of this title.

(ii) Installer qualifications. All installations of the medical gas piping systems shall be done only by, or under the direct supervision of, a holder of a master plumber license or a journeyman plumber license with a medical gas piping installation endorsement issued by the Texas State Board of Plumbing Examiners.

(iii) Installer's inspection and test requirements. Installer inspections and tests of the medical gas piping system shall be performed on all new piped medical gas systems and existing system additions, renovations, or repaired portions. All systems that are breached and components that are added, renovated, or replaced shall be inspected and appropriately tested. The breached portions of the systems subject to inspection and testing shall be all of the new and existing components in the immediate zone or area located upstream of the point or area of intrusion and downstream to the end of the system or a properly installed isolation valve. Repair and maintenance work that does not breach the integrity of the system shall not be considered an installation.

(iv) Installer tests. Prior to closing of walls, the installer shall perform an initial pressure test, a blowdown test, a secondary pressure test, a cross-connection test, and a purge of the piping system as required by NFPA 99.

(v) Qualifications for conducting verification tests and inspections. Upon completion of the installer inspections and tests and after closing of walls, verification tests of the medical gas piping systems, the warning system, and the gas supply source shall be conducted by a party, other than the installer, that is technically competent and experienced in the field of medical gas pipeline testing as required by NFPA 99.

(vi) Verification tests. The verification tests shall include a cross-connection test, valve test, flow test, piping purge test, piping purity test, final tie-in test, operational pressure tests, and medical gas concentration test.

(vii) Verification test requirements. Verification tests of the medical gas piping systems shall be performed on all new piped medical gas systems, additions, renovations, or repaired portions of an existing system. All systems that are breached and components that are added, renovated, or replaced shall be inspected and appropriately tested. The breached portions of the systems subject to inspection and testing shall be all of the new and existing components in the immediate zone or area located upstream of the point or area of intrusion and downstream to the end of the system or a properly installed isolation valve.

(viii) Warning system verification tests. Verification tests of the warning system shall include tests of the source alarms and monitoring safeguards, master alarm systems, and the area alarm systems.

(ix) Source equipment verification tests. Source equipment verification tests shall include medical gas supply sources (bulk and manifold) and the compressed air source systems (compressors, dryers, filters, and regulators).

(x) Written certification. Upon successful completion of all verification tests, written certification for affected piped medical gas systems and piped medical vacuum systems including the supply sources and warning systems shall be provided by a party technically competent and experienced in the field of medical gas pipeline testing that the provisions of NFPA 99 have been adhered to and systems integrity has been achieved. The written certification shall be submitted directly to the hospital, the installer, and the Texas Department of Health.

(xi) Hospital responsibility. Before new piped medical gas systems, additions, renovations, or repaired portions of an existing system are put into use, the hospital shall be responsible for ensuring that the gas delivered at the outlet is the gas shown on the outlet label and that the proper connecting fittings are checked against their labels.

(xii) Documentation of medical gas and clinical vacuum outlets. Documentation shall be arranged tabularly by room numbers and room types, shall indicate the number of medical air, medical gas, and vacuum outlets installed in each room, and shall be submitted to the Texas Department of Health by the same party certifying the piped medical gas systems.

(4) Sprinkler system approval.

(A) Sprinkler shop drawings submitted. Sprinkler shop drawings shall be submitted for approval to one of the following agencies or a professional engineer:

(i) an insurance agency approved by the department; or

(ii) a professional engineer. The sprinkler shop drawings may be reviewed by a professional engineer licensed in Texas and experienced in hydraulic design and sprinkler system installation. The engineer shall not be employed by the sprinkler contractor or be connected in any way that would constitute a conflict of interest.

(B) Sprinkler shop drawings, certification letter, and approval.

(i) One set of approved shop drawings shall be forwarded to the department.

(ii) A certification letter from the agency or engineer attesting to review of the sprinkler system plans and stating that the sprinkler system design and plans comply with the requirements of NFPA 13 and that the system has been installed in accordance with the plans shall be forwarded to the department.

(iii) Shop drawings and certification letter shall be required before permission to occupy the area shall be granted by the department.

(5) Steam and hot water systems.

(A) Boilers. Boilers shall have the capacity, based upon the net ratings published by the Hydronics Institute, to supply the normal requirements of all systems and equipment. The number and arrangement of boilers shall be such that, when one boiler breaks down or routine maintenance requires that one boiler be temporarily taken out of service, the capacity of the remaining boiler(s) shall be sufficient to provide hot water service for clinical, dietary, and patient use, steam for sterilization and dietary purposes, and heating for operating, delivery, emergency, labor, recovery, intensive care, nursery, treatment, and general patient rooms. However, reserve capacity for space heating of noncritical care areas (e.g. general patient rooms and administrative areas) is not required in geographical areas where a design dry bulb temperature equals 25 degrees Fahrenheit or higher as based on the 99% design value shown in ASHRAE Handbook of Fundamentals.

(B) Boiler accessories. Boiler feed pumps, heating circulating pumps, condensate return pumps, and fuel oil pumps shall be connected and installed to provide normal and standby service.

(C) Valves. Supply and return mains and risers of cooling, heating, and process steam systems shall be valved to isolate the various sections of each system. Each piece of equipment shall be valved at the supply and return ends except that vacuum condensate returns need not be valved at each piece of equipment.

(D) Heating plants. Construction of heating plants shall meet the requirements of subsection (a)(4)(A) of this section.

(6) Thermal and acoustical insulation.

(A) Insulation. Insulation shall be provided within the building for the following:

(i) boilers, smoke breeching, and stacks;

(ii) steam supply and condensate return piping;

(iii) hot water piping above 120 degrees Fahrenheit and all hot water heaters, generators, and converters;

(iv) chilled water, refrigerant, other process piping, equipment operating with fluid temperatures below ambient dew point, and water supply and drainage piping on which condensation may occur. Insulation on cold surfaces shall include an exterior vapor barrier;

(v) air ducts and casings with outside surface temperature below ambient dew point or temperature above 80 degrees Fahrenheit; and

(vi) other piping, ducts, and equipment as necessary to maintain the efficiency of the system.

(B) Pipe insulation rating. Flame spread shall not exceed 25 and smoke development rating shall not exceed 150 for pipe insulation as determined by an independent testing laboratory in accordance with NFPA 255. Smoke development rating for pipe insulation located in environmental air areas shall not exceed 50.

(C) Exterior duct insulation. Insulation, including finishes and adhesives on the exterior surfaces of ducts and equipment, shall have a flame spread rating of 25 or less and a smoke developed rating of 50 as determined by an independent testing laboratory in accordance with NFPA 255 as required by NFPA 90A.

(D) Insulation in air plenums and ducts. Linings in air ducts and equipment shall meet the Erosion Test Method described in Underwriters' Laboratories, Inc., Standard Number 181 which the department adopts by reference in §133.100(b)(1)(N) of this title. These linings, including coatings and adhesives, and insulation on exterior surfaces of pipes and ducts in building spaces used as air supply or air return plenums, shall have a flame spread rating of 25 or less and a smoke developed rating of 50 or less as determined by an independent testing laboratory in accordance with NFPA 255.

(E) Duct linings. Duct linings exposed to air movement shall not be used in ducts, terminal boxes, or other air system components supplying operating rooms, delivery rooms, birthing rooms, labor rooms, recovery rooms, nurseries, trauma rooms, isolation rooms, and intensive care units unless terminal filters of at least 90% efficiency are installed downstream of linings. Internal duct linings shall not be used in supply and return ducts serving the food preparation area.

(F) Asbestos insulation. Asbestos insulation shall not be used in hospitals. Insulation of soft type (spray on) shall not be used where it is subject to air currents or mechanical erosion or where loose particles may create a maintenance problem (e.g. in elevator areas where particles may drift into electronic contacts).

(f) Electrical.

(1) General.

(A) Electrical installations. All material including equipment, conductors, controls, and signaling devices shall be installed in compliance with applicable sections of NFPA 70 and NFPA 99 and as necessary to provide a complete electrical system. All materials shall be listed as complying with approved established standards.

(i) Some electrical systems including electrical service, electrical switch gear, essential electrical systems, lighting and power distribution, and fire alarm systems may be shared by two separate hospitals sharing a building only when these systems comply with these rules.

(ii) Some electrical systems including electrical panels for lighting and power distribution and nurse call systems shall be provided separately for two hospitals sharing a building and shall comply with these rules.

(B) Installation testing. The electrical installations including all alarms, nurse call, and communication systems shall be tested to demonstrate that equipment installation and operation is appropriate for the intended use. Tests shall be conducted in accordance with applicable codes and standards in §133.100 of this title and shall include tests of conductive floors, isolated power, and alarm systems. Grounding continuity shall be tested as described in NFPA 99 for new or existing work.

(i) A written record of performance tests of special electrical systems and equipment shall be available for review.

(ii) All electrical systems including electrical service as permitted by the electrical utility, electrical switch gear, electrical panels for lighting and power distribution, fire alarm systems, and nurse call systems shall be provided separately for hospitals sharing a building with non-hospital occupancies and shall comply with this chapter.

(C) Installation certification. Certifications in affidavit form from a registered electrical engineer or electrical contractor shall be submitted to the department, upon request, attesting that the electrical service, electrical equipment, and electrical appliances have been installed in compliance with the applicable standards.

(2) Electrical details.

(A) Conduits. All conductors for controls, equipment, lighting and power operating at 100 volts or higher shall be installed in metal raceways.

(B) Receptacles (convenience outlets).

(i) Each operating room and delivery room shall have at least six hospital type receptacles at anesthetizing locations.

(ii) In locations where mobile X-ray is used, an additional receptacle distinctively marked for X-ray use shall be provided. NFPA 70, Article 517 receptacle requirements shall be met when capacitive discharge or battery operated mobile X-ray units are used.

(C) Patient rooms.

(i) Each patient room shall have duplex grounding receptacles as follows:

(I) one located on each side of the head of each bed;

(II) one for television, if used; and

(III) one on every other wall.

(ii) Receptacles may be omitted from exterior walls where construction would make installation impractical.

(iii) Nurseries shall have at least two duplex grounding receptacles for each bassinet.

(iv) Receptacles in pediatric and psychiatric units shall be of the tamper-proof type or protected by five milliampere ground fault interrupters (GFI) in accordance with NFPA 70.

(v) Critical care areas, as defined in NFPA 70, Article 517, including pediatric and neonatal intensive care, shall have at least six receptacles at the head of each bed, crib, or bassinet.

(vi) Emergency examination and treatment rooms shall have a minimum of six receptacles located convenient to the head of each bed.

(vii) Approximately 50% of receptacles located in critical and emergency patient care areas shall be connected to the critical branch of the emergency system power and be so labeled.

(D) Corridors. Duplex grounding receptacles for general use shall be installed approximately 50 feet apart in all corridors and within 25 feet of the ends of corridors. Receptacles in pediatric unit corridors shall be of the tamper-proof type or protected by five milliampere ground fault interrupters (GFI). Single polarized receptacles marked for use by X-ray equipment only shall be located in corridors of patient areas so that mobile equipment may be used in any location within a patient room without exceeding a cord length of 50 feet attached to the equipment. All receptacles for X-ray use shall be of a configuration that one plug will fit the receptacles in all locations. Where capacitive discharge or battery powered X-ray units are used, these polarized receptacles are not required.

(E) Emergency power receptacles. All receptacles, switches, and junction boxes served by the essential electrical system shall be colored red for easy identification. Devices, receptacles, and wiring shall comply with applicable sections of NFPA 70.

(F) X-ray illuminators. X-ray film illuminator unit or units to display at least two films simultaneously shall be installed in each operating room, trauma room, and X-ray viewing room of the radiology department. All illuminator units within one space or room shall have lighting of uniform intensity and color value.

(G) Ground fault interrupters. The electrical circuit(s) to equipment in wet areas shall be provided with five milliampere GFI. GFI circuits shall not be used in intensive care units, operating rooms, nurseries, and other sensitive areas.

(H) Special grounding system. In areas such as intensive care units, special nurseries, special procedures rooms where a patient may be treated with an internal probe or catheter connected to the heart, the ground system shall comply with Chapter 9, NFPA 99 and NFPA 70.

(3) Electrical switchgear and panels.

(A) Switchboards and power panels. These items shall comply with NFPA 70. The main switchboard shall be located in a separate room, separated from other occupancies and exposures by at least a one-hour fire protection rated enclosure, and accessible only to authorized persons. The switchboards shall be convenient for use, readily accessible for maintenance, clear of traffic lanes, and located in a dry, ventilated space free of corrosive or explosive fumes or gases. Overload protection devices shall operate properly in the ambient room temperatures.

(B) Panel boards. Panel boards serving normal lighting and appliance circuits shall be located on the same floor as the circuits they serve. Panel boards for emergency circuits shall be located on each floor which has major users (operating room, delivery room, intensive care unit). Panels for emergency circuits may also serve floors above and below for secondary users (general patient areas, administration, laboratory, X-ray).

(4) Essential electrical system.

(A) General. All hospitals shall have an approved standby electrical supply capable of supplying essential electrical service to selected lighting, receptacles, equipment, and motors as listed in NFPA 70 and NFPA 99. This standby electrical supply shall be a gas turbine or internal combustion engine-driven generator

set(s), designed to operate automatically by a drop in voltage in the primary electrical supply. When the generator set is located within the hospital, the unit shall be installed in a room which will afford a minimum of one-hour fire protection rated construction. Exterior located generator sets shall not be near patient rooms or other areas which would affect patient care. The generator set(s) including fuel tanks, exhaust lines and appurtenant parts shall be installed and maintained in accordance with NFPA 99 and NFPA 37. Stored fuel capacity shall be sufficient to permit continuous operation for at least 24 hours at full load. Generator sets located outside shall be designed and rated for exterior use.

(B) Transfer switches. The number of transfer switches to be used shall be based upon reliability, design, and load consideration

(i) One transfer switch shall be permitted to serve one or more branches or systems, provided that the connected load does not exceed 150 kilowatt amperes (KVA).

(ii) Requirements for small, medium, and large hospitals are illustrated in Figures 1, 2 and 3, respectively in §133.101(b) of this title.

(5) Fire alarm system.

(A) General. Fire alarm systems shall be installed in all areas of the hospital as required by NFPA 101 and NFPA 72

(B) Location. The fire alarm panel shall be located in a constantly attended location (such as PBX or nurses station) staffed by trained personnel who are qualified to take appropriate action in case of a fire emergency.

(C) Certification. Fire alarm system certification shall be provided by the licensed fire alarm installer when a fire alarm system is installed or modified.

(D) Malfunctioning equipment. Monitoring personnel shall also be able to identify malfunctioning equipment and report such equipment to the local fire authority. Equipment malfunctions shall be reported to the appropriate personnel for immediate repair

(6) Lighting.

(A) General illumination. All spaces within buildings which house people, machinery, and equipment and approaches to buildings and parking lots shall have fixtures for lighting.

(B) Patient rooms. Patient rooms shall have general lighting and night lighting. A reading light shall also be provided for each patient. Flexible light arms, if used, shall be mechanically controlled to prevent the bulb from coming in contact with bed linen. Switches for general illumination and night light fixtures shall be provided at the entrance to each patient room. All controls for lighting in patient areas shall be of the quiet operating type. Lighting for intensive care units (including neonatal and pediatric intensive care units) shall be of the type and arrangement that permit staff observation of patient but minimize glare.

(C) Operating and delivery rooms. Operating and delivery rooms shall have general lighting in addition to that provided by special lighting units at the surgical and obstetrical tables. Each fixed special lighting unit at the operating or delivery table shall be connected to an independent circuit. Portable units may share circuits.

(D) Corridors. All corridors shall have general illumination with provisions for reduction of light levels at night. Illumination of the means of egress and exit signs shall be in accordance with NFPA 99 and NFPA 101.

(E) Light intensity. Light intensity levels for staff and patient visual needs shall be as described in Lighting for Health Care Facilities and in the Lighting Handbook by the Illuminating Engineering Society of North America (IES) which the department adopts by reference in §133.100(b)(1)(J) of this title. An infinite number of procedures may be available to satisfy requirements, but the design shall consider light quality as well as quantity for effectiveness and efficiency.

(7) Nurse call system.

(A) General. A nurse call system shall be required in all hospitals and shall comply with the requirements in this paragraph.

(B) Patient areas. In general patient areas, each room shall be served by at least one calling station and each bed shall be provided with a call button. Two call buttons serving adjacent beds may be served by one calling station. Calls shall register both audible and visual signals with floor staff and shall actuate a visible signal in the corridor at the patient door, in the clean workroom, the soiled workroom, nurses lounge, and the nourishment station of the nursing unit. In multi-corridor nursing units, additional visible signals shall be installed at corridor intersections. In rooms containing two or more call stations, indicating lights shall be provided at each station. Nurse call systems which provide two-way voice communication shall be equipped with an indicating light at each call station which lights and remains lighted as long as the voice circuit is operating.

(C) Patient emergency. An emergency nurse call station shall be provided for patient use at each patient toilet, bath, sitz bath, and shower room. Such a station shall be usable by a collapsed patient lying on the floor (inclusion of a pull cable will satisfy this item).

(i) A signal activated at a patient's emergency nurse call station shall initiate distinct visible and audible signals which can be turned off only at the patient emergency nurse call station. The audible signal shall be repeated not less than every 15 seconds.

(ii) Calls shall register both audible and visual signals with floor staff and shall actuate a visible signal in the corridor at the patient door, in the clean workroom, the soiled workroom, nurses lounge, and the nourishment station of the nursing unit.

(D) Intensive care. In areas such as intensive care where patients are under constant surveillance, the nurse call system may be limited to a bedside station that will actuate a signal that can be readily seen and heard by the nurse. Neonatal and pediatric ICU's are exempt from this requirement.

(E) Nurse emergency (Code Blue). An emergency call station which may be used by nurses to summon assistance shall be provided in each operating room, delivery room, recovery room, emergency room, intensive care unit, neonatal and pediatric intensive care units, nursery, and supervised nursing unit for mental patients. The emergency nurse call system shall have voice communication capabilities so that the type of emergency or help required may be specified.

(F) Geropsychiatric. A hazard free call system shall be required on geropsychiatric unit(s). Desk or tap call bells shall not be acceptable. Pull cables shall not exceed 18 inches.

§133.100. Codes and Standards.

(a) General. In addition to compliance with this chapter, all other applicable building codes, ordinances, and regulations

under city, county, or other state agency's jurisdiction shall be observed. Compliance with local codes shall be prerequisite for licensing. In areas not subject to local building codes, any one of the following model building codes, which the department adopts by reference in this section, shall apply insofar as such codes are not in conflict with this chapter:

(1) Uniform Building Code, 1991, International Conference of Building Officials, 5360 Workman Mill Road, Whittier, California 90601-2298; and

(2) Standard Building Code, 1991, International, Inc., 900 Montclair Road, Birmingham, Alabama 35213-1206.

(b) Codes and standards.

(1) Referenced codes and standards. The following publications, which the department adopts by reference in this section, are a part of this chapter only when referenced in this chapter or when installations are provided in a new hospital or an addition to a hospital. Existing buildings or installations which do not comply with the publications referenced in this section may continue in service, unless replaced or renovated, and provided that lack of conformity with these standards does not present a serious hazard to the occupants:

(A) American Institute of Architects (AIA), Committee on Architecture for Health, Guidelines for Construction and Equipment of Hospital and Medical Facilities, 92/93 Edition (7.9D). Available through the American Institute of Architects, 1738 New York Avenue, N.W., Washington, D.C. 20006;

(B) American Association of Blood Banks (AABB), Standards for Blood Banks and Transfusion Services and Technical Manual, Fifteenth Edition 1993. Available through the American Association of Blood Banks, Committee on Standards, 8101 Glenbrook Road, Bethesda, MD 20814, (301) 215-6499;

(C) The following publications referenced are available through the American Society of Heating, Refrigerating, and Air-conditioning Engineers (ASHRAE), 1791 Tullie Circle, N.E., Atlanta, GA 30329:

(i) American Society of Heating, Refrigerating, and Air-conditioning Engineers (ASHRAE), Standard Number 90.1, 1989, Energy Efficiency Design of New Buildings;

(ii) ASHRAE, Standard Number 52.1, 1992, Methods of Testing Air Cleaning Devices Used in General Ventilation for Removing Particulate Matter;

(iii) ASHRAE, Standard Number 62.1, 1989, Ventilation for Acceptable Indoor Air Quality Including Requirements for Outside Air;

(iv) ASHRAE, Handbook of Applications, 1994; and

(v) ASHRAE, Handbook of Fundamentals, 1993;

(D) The following publications referenced are available through the American Society of Mechanical Engineers (ASME), 345 East 7th Street, New York, NY 10017:

(i) ASME and American National Standards Institute (ANSI), A17.1, 1990, Safety Code for Elevators and Escalators; and

(ii) ASME and American National Standards Institute (ANSI), A.17.3, 1990, Safety Code for Existing Elevators and Escalators;

(E) American National Standards Institute (ANSI), A.117.1, 1990, Safety Code for Elevators, Dumbwaiters, and Escalators - Requirements for Handicapped Individuals. Available through the American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036;

(F) The following publications referenced are available through the Compressed Gas Association, Inc. (CGA), 1235 Jefferson Davis Highway, Arlington, VA 22202:

(i) CGA Pamphlet G-8.1, 1979, Nitrous Oxide Systems at Consumer Sites;

(ii) CGA Pamphlet P-1, 1991, Safe Handling of Compressed Gases; and

(iii) CGA Pamphlet P-2, 1989, Characteristics of Safe Handling of Medical Gases;

(G) Food and Nutrition Board, National Research Council - National Academy of Sciences, Recommended Dietary Allowances, Tenth Edition, 1989. Available through the Food and Nutrition Board, Commission on Life Sciences, National Research Council, National Academy Press, 2101 Constitution Avenue, N.W., Washington, D.C. 20418;

(H) Gypsum Association's Fire Resistance Design Manual and Sound Control, 13th Edition, 1992. Available through the Gypsum Association, 810 First Street NE, Number 510, Washington, D.C. 20002;

(I) Hydronics Institute, Testing and Rating Standards for Cast-iron and Steel Heating Boilers, January 1977, 2nd Edition. Available through the Hydronics Institute, P.O. Box 218, Berkeley Heights, NJ 07922;

(J) Illuminating Engineering Society of North America (IES), Lighting Handbook, 1987, Volume 2, Applications and Lighting for Health Care Facilities, 1985. Available through the Illuminating Engineering Society of North America, 345 East 47th Street, New York , NY 10017;

(K) National Association of Plumbing-Heating-Cooling Contractors (PHCC), National Standard Plumbing Code, 1990. Available through the National Association of Plumbing-Heating-Cooling Contractors, P.O. Box 6808, Falls Church, VA 22040;

(L) The following publications referenced are available through the National Council on Radiation Protection (NCRP), 7910 Woodmont Avenue, Bethesda, MD 20814:

(i) NCRP, Report Number 33, 1968, Medical X-ray and Gamma Ray Protection for Energies Up to 10 MeV Equipment Design and Use; and

(ii) NCRP, Report Number 49, 1976, Medical X-ray and Gamma Ray Protection for Energies up to 10 MeV Structural Shielding Design and Evaluation;

(M) The following standards referenced are available through the National Fire Protection Association (NFPA), P.O. Box 91461, Batterymarch Park, Quincy, MA 02169:

(i) NFPA 10, 1990-"Standard for Portable Fire Extinguishers";

(ii) NFPA 11, 1988-"Standard for Low Expansion Foam and Combined Agent Systems";

(iii) NFPA 11A, 1988-"Standard for Medium and High Expansion Foam Systems";

(iv) NFPA 12, 1989-"Standard on Carbon Dioxide Extinguishing Systems";

(v) NFPA 12A, 1989-"Standard on Halon 1301 Fire Extinguishing Systems";

(vi) NFPA 12B, 1990-"Standard on Halon 1211 Fire Extinguishing Systems";

(vii) NFPA 13,

1989-"Standard for the Installation of Sprinkler Systems";

(viii) NFPA 13A, 1987-"Care and Maintenance of Sprinkler Systems";

(ix) NFPA 13D, 1989-"Standard for the Installation of Sprinkler Systems in One- and Two-family Dwellings and Mobile Homes";

(x) NFPA 14, 1990-"Standard for the Installation of Standpipes and Hose Systems";

(xi) NFPA 15, 1990-"Standard for Water Spray Fixed Systems for Fire Protection";

(xii) NFPA 16, 1991-"Standard for the Installation of Deluge Foam-water Sprinkler and Foam-water Spray Systems";

(xiii) NFPA 17, 1990-"Standard for Dry Chemical Extinguishing Systems";

(xiv) NFPA 20, 1990-"Standard for the Installation of Centrifugal Fire Pumps";

(xv) NFPA 22, 1987-"Water Tanks for Private Fire Protection";

(xvi) NFPA 30, 1990-"Flammable and Combustible Liquids Code";

(xvii) NFPA 31, 1987-"Standard for the Installation of Oil Burning Equipment";

(xviii) NFPA 37, 1988-"Standard for The Installation and Use of Stationary Combustion Engines and Gas Turbines";

(xix) NFPA 40, 1988-"Standard for the Storage and Handling of Cellulose Nitrate Motion Picture Film";

(xx) NFPA 50, 1990-"Standard for Bulk Oxygen Systems at Consumer Site";

(xxi) NFPA 54, 1988-"National Fuel Gas Code";

(xxii) NFPA 68, 1988-"Guide for Deflagrations";

(xxiii) NFPA 70, 1990-"National Electric Code";

(xxiv) NFPA 71, 1989-"Standard for the Installation, Maintenance and Use of Signaling Systems for Central Station Service";

(xxv) NFPA 72, 1990-"Standard for the Installation, Maintenance, and Use of Protective Signaling Systems";

(xxvi) NFPA 72E, 1990-"Standard on Automatic Fire Detectors";

(xxvii) NFPA 74, 1989-"Standard for the Installation, Maintenance and Use of Household Fire Warning Equipment";

(xxviii) NFPA 78, 1989-"Lightning Protection Code";

(xxix) NFPA 80, 1990-"Standards for Fire Doors and Windows";

(xxx) NFPA 80A, 1987-"Recommended Practices for Protection of Buildings from Exterior Fire Exposure";

(xxxi) NFPA 82, 1990-"Standards on Incinerators Waste and Linen Handling Systems and Equipment";

(xxxii) NFPA 88A, 1985-"Standards for Parking Structures";

(xxxiii) NFPA 90A, 1989-"Standard for the Installation of Air-conditioning and Ventilating Systems";

(xxxiv) NFPA 91, 1990-"Standard for the Installation of Blower and Exhaust Systems for Dust, Stock and Vapor Removal or Conveying";

(xxxv) NFPA 96, 1991-"Standard for the Installation of Equipment for the Removal of Smoke and Grease-laden Vapors from Commercial Cooking Equipment";

(xxxvi) NFPA 99, 1993-"Standard for Health Care Facilities";

(xxxvii) NFPA 99, Annex 1, 1993-"Standard for Health Care Emergency Preparedness";

(xxxviii) NFPA 101, 1991-"Code for Safety to Life from Fire in Buildings and Structures";

(xxxix) NFPA 101M, 1992-"Alternative Approaches to Life Safety";

(xl) NFPA 204M, 1991-"Guide for Smoke and Heat Venting";

(xli) NFPA 206M, 1976-"Guide on Building Areas and Heights";

(xlii) NFPA 220, 1985-"Standard for Types of Building Construction";

(xliii) NFPA 251, 1990-"Standard Methods of Fire Tests of Building Construction and Materials";

(xliv) NFPA 252, 1990-"Standard Methods of Fire Tests of Door Assemblies";

(xlv) NFPA 253, 1990-"Standard Methods of Tests for Critical Radiant Flux of Floor Covering Systems Using Radiant Heat Energy Source";

(xlvi) NFPA 255, 1990-"Method of Test of Surface Burning Characteristics of Building Materials";

(xlvii) NFPA 256, 1987-"Standard Methods of Fire Tests of Roof Coverings";

(xlviii) NFPA 258, 1989-"Standard Test Method for Measuring the Smoke Generated by Solid Materials";

(xlix) NFPA 325M, 1991-"Fire Hazard Properties of Flammable Liquids, Gases, and Volatile Solids";

(l) NFPA 418, 1990-"Standard on Roof-top Heliport Construction and Protection"; and

(li) NFPA 701, 1989-"Standard Methods of Fire Test for Flame-resistant Textiles and Films"; and

(N) Underwriters' Laboratories, Inc. (UL), Standard Number 181, 1974, Factory Made Air Duct Material and Air Duct Connectors. Available through Underwriter's Laboratories, Inc., 333 Pfingsten Road, Northbrook, IL 60062-2096.

(2) Referenced federal laws, regulations, and standards. The following federal laws, regulations, and standards, either all or in part, are a part of this chapter only when referenced in this chapter. The Federal Register, CFR, and all other publications listed in this paragraph are available through the Superintendent of Documents, United States Government Printing Office (GPO), Washington, D.C. 20402-9325, (202) 512-1800. All facilities operating under this chapter shall comply with the following federal laws, regulations, and standards as applicable:

(A) Title 42 USC, §1395i-4 (relating to Hospitals Providing Rural Health Care Services as a Designated Essential Access Community Hospital or as a Rural Primary Care Hospital), as amended Nov. 5, 1990.

(B) Title 42 USC, §1395cc (relating to Agreements with Hospitals for Referral and Admission of Patients Requiring Inpatient Services or Diagnostic or Other Specialized Services Which are Not Available at the Special Hospital), as amended Aug. 6, 1991;

(C) Title 42 USC, §1395ww(d)(2)(D) (relating to the Definition of a Rural Area), as amended Aug. 10, 1993;

(D) Title 42 USC, §1395ww(d)(5)(C) (relating to the Definition of a Rural Referral Center), as amended August 10, 1993;

(E) Title 42 USC, §1395x(aa) (relating to Federal Requirements for Rural Primary Care), as amended Aug 10, 1993,

(F) Title 42 USC, §1395x(e) (relating to Staffing Requirements Applicable to Rural Hospitals), as amended Aug 10, 1993,

(G) Title 42 USC, §1395x(gg) (relating to the Definitions of Professional Personnel Required to be Available to Furnish Patient Care Services in Rural Hospitals), as amended Aug 10, 1993;

(H) Title 42 USC, §12101, The Americans with Disabilities Act (ADA) of 1990, (pub. L 101-336, §2, July 26, 1990, 104 Stat 328) and Appendix to 1191- ADA Accessibility Guidelines to Buildings and Facilities, Federal Register, Volume 56, Number 144, July 26, 1991, Rules and Regulations, pages 35455-35542,

(I) The Rehabilitation Act of 1973, §504 and 45 CFR, §84.22 and §84 23 (relating to Program and Facility Accessibility for the Handicapped) 42 FR 22677, May 4, 1977, as amended at 55 FR 52138, 52142, Dec 19, 1990,

(J) United States Department of Agriculture (USDA), Nutrition and Your Health. Dietary Guidelines for Americans, Third Edition, 1990, USDA Pamphlet HG-232 Multiple copies available through the GPO. Single copies available through the Superintendent of Documents, Consumer Information Center-4C, P.O Box 100, Pueblo, CO 81002,

(K) USDA, Human Nutrition Information Service, Home and Garden Bulletin Number 252, Food Guide Pyramid, 1993-Dietary Guidelines. Multiple copies available through the GPO. Single copies available through the Superintendent of Documents, Consumer Information Center-4C, P O. Box 100, Pueblo, CO 81002;

(L) United States Environmental Protection Agency (EPA), List of Chemical Germicides and Sterilants, Jan 1994. Available through the Disinfectants Branch, Registration Division, Office of Pesticides, EPA, 401 M Street, S.W., Washington, D.C. 20460;

(M) United States Department of Health and Human Services (DHHS), Public Health Service, Food and Drug Administration (FDA), Food Services Sanitation Manual, DHHS Publication Number (FDA) 78-2081, 1976 Edition;

(N) DHHS, Health Care Financing Administration (HCFA), Pub. L. 100- 578, Oct 31, 1988, 102 Stat. 2903, Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988) and 42 CFR, §§493 1-493 2001, 57 FR 9576, Mar. 14, 1990, 57 FR 7139, Feb 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993,

(O) DHHS, HCFA, Medicare Conditions of Participation for Hospitals, 42 CFR, §§482.2-482.66, 51 FR 22042, June 17, 1986, as amended at 53 FR 6648, Mar. 2, 1988; as amended at 59 FR 46514, Sept. 8, 1994

(P) DHHS, HCFA, 42 CFR, §482(b)(1)(i) (relating to Fire Safety Requirements for Hospitals Which Have Been Vacated or Used for an Occupancy Other Than a Hospital, 51 FR 22042, June 17, 1986, as amended at 59 FR 46514, Sept 8, 1994,

(Q) DHHS, HCFA, 42 CFR, Part 400, §412.96 (relating to Special Treatment. Referral Centers) as amended, 59 FR 45398, Sept. 1, 1994;

(R) DHHS, Centers for Disease Control and Prevention (CDC), Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Facilities, Morbidity and Mortality Weekly Report (MMWR), October 28, 1994, Volume 40, Number RR- 13. These guidelines are also available from the U.S. GPO in the Federal Register, Volume 59, Number 208, October 28, 1994; and

(S) United States Department of Justice, Drug Enforcement Administration, Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 USC §853, as amended Oct. 27, 1986, and §881, as amended Nov 2, 1992.

(3) Referenced state acts and rules. These sections implement the following state acts and rules, either all or in part, when referenced in this chapter. These laws are available at public libraries and county law libraries or may be purchased through West Publishing Company, 610 Opperman Drive, St. Paul, MN 55164, 1-800-328-9352·

(A) Health and Safety Code (HSC) 161. 132 (relating to Posting and Reporting Requirements for Abuse and Neglect and Illegal, Unprofessional, or Unethical Conduct), as amended and effective Sept 1, 1993;

(B) HSC, Chapter 61, §§61.030-61.032 and §§61 057-61 059 (relating to Mandated Providers, Indigent Health Care and Treatment Act) as amended and effective Sept 1, 1993,

(C) HSC, Chapter 85, Subchapter I, §85.203(a) (relating to Prevention of Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV) by Infected Health Care Workers), as amended and effective Sept. 1, 1993;

(D) HSC, Chapter 311, §311 0025 (relating to Audits of Billing), as amended and effective Sept 1, 1993,

(E) HSC, Chapter 313 (relating to Cooperative Agreements and Certificates of Public Advantage), effective Sept. 1, 1993;

(F) HSC, Subtitle C, Chapter 382 (relating to Clean Air), as amended and effective Sept. 1, 1993,

(G) HSC, Chapter 502 and §§295.1-295.9 of this title (relating to Hazard Communications), as amended and effective Sept. 1, 1993;

(H) HSC, Chapter 506 and §295.182 of this title (relating to Public Employer Community Right To-Know), as amended and effective Sept. 1, 1993;

(I) HSC, Chapter 507 and §295.183 of this title (relating to Nonmanufacturing Facilities Community Right-To-Know), as amended and effective Sept. 1, 1993;

(J) HSC, Chapter 161, Subchapter I (relating to Illegal Remuneration), effective Sept 1, 1993;

(K) HSC, Chapter 671 (relating to Determination of Death and Autopsy Reports), as amended and effective Sept. 1, 1991;

(L) HSC, Chapter 692, Texas Anatomical Gift Act, as amended and effective Aug. 30, 1993;

(M) HSC, Chapter 711, as amended and effective Sept. 1, 1993, and Chapter 191 of this title (relating to Vital Statistics), as amended and effective Sept. 1, 1993;

(N) HSC, Chapter 754, Subchapter B (relating to Inspection and Certification of Elevators, Escalators, and Related Equipment), as amended and effective Sept 1, 1993;

(O) Human Resources Code, Chapter 48 (relating to Posting and Reporting Requirements for Abuse and Neglect and Illegal, Unprofessional, or Unethical Conduct), as amended and effective Aug. 30, 1993;

(P) Nursing Practice Act, Texas Civil Statutes (TCS), Articles 4513-4528c, as amended and effective Sept. 1, 1993 Available through the Board of Nurse Examiners for the State of Texas, P.O. Box 140466, Austin, TX 78714;

(Q) Vocational Nurse Act, TCS, Article 4528c, as amended and effective Sept. 1, 1993 Available through the Board of Vocation Nurse Examiners for the State of Texas, 9101 Burnet Road, Number 105, Austin, TX 78758;

(R) Medical Practice Act of Texas, TCS, Article 4495b, as amended and effective Sept. 1, 1993. Available through the Board of Medical Examiners, 1812 Centre Creek Drive, Austin, TX 78754;

(S) Architectural Barriers Act, TCS Article 9102, as amended and effective Sept. 1, 1993;

(T) Texas Accessibility Standards (TAS) of the Architectural Barriers Act, April 1, 1994 Edition, 19 TexReg 167. TAS is available through the Office of the Secretary of State, Texas Register Division, P.O. Box 13824, Austin, TX 78711-3824, (512) 463-5561;

(U) Texas Boiler Law, HSC Chapter 755, as amended and effective Sept. 1, 1993, and TCS, Article 9100 (relating to Boiler Rules), as amended and effective Sept. 1, 1993;

(V) Texas Controlled Substances Act, HSC Chapter 481, as amended and effective Sept. 1, 1993;

(W) Texas Dangerous Drug Act, HSC, Chapter 483, as amended and effective Sept. 1, 1993;

(X) Texas Emergency Management Plan, issued in accordance with the provisions of the Texas Disaster Act of 1975, TCS, Government Code Title 4, Chapter 418, as amended and effective Sept. 1, 1987. (Texas Emergency Management Plan and applicable annexes and appendices are available from the city or county emergency management coordinator;

(Y) Texas Pharmacy Act, TCS, Article 4542a-1, as amended and effective Sept. 1, 1993, and 22 TAC, Chapter 281 (relating to Texas Board of Pharmacy Rules of Procedure), as amended and effective June 1, 1994,

(Z) §§97.1-97.13 of this title (relating to the Control and Reporting of Notifiable Conditions), as amended and effective Oct. 1994, and §§97.131-97.134 of this title (relating to Reporting Sexually Transmitted Diseases), as amended and effective Mar. 14, 1994;

(AA) HSC Chapter 431, as amended and effective Sept. 1, 1993, and §§229.161-229.171 of this title (relating to Food Service Sanitation), as amended and effective Nov. 30, 1977;

(BB) §§1.131-1.137 of this title (relating to Definition, Treatment and Disposition of Special Waste from Health Care-related Facilities), as amended and effective Dec. 21, 1993;

(CC) HSC Chapter 401, as amended and effective Sept. 1, 1993, and Chapter 289 of this title (relating to Radiation Control), as amended and effective Mar. 1, 1994;

(DD) HSC, Title 7, Subtitle C, Texas Mental Health Code, as amended and effective Sept. 1, 1993, and Chapter 401, Subchapter J of this title (relating to Standards of Care and Treatment in Psychiatric Hospitals), as amended and effective Feb. 10, 1994;

(EE) HSC, Title 7, Subtitle C, Texas Mental Health Code, as amended and effective Sept. 1, 1993, and Chapter 404, Subchapter E of this title (relating to Rights of Persons Receiving Mental Health Services), as amended and effective Dec. 10, 1993;

(FF) HSC, Title 7, Subtitle C, Texas Mental Health Code, as amended and effective Sept. 1, 1993, and Chapter 405, Subchapter E of this title (relating to Electroconvulsive Therapy), as amended and effective Dec. 10, 1993;

(GG) HSC, Title 7, Subtitle C, Texas Mental Health Code, as amended and effective Sept. 1, 1993, and Chapter 405, Subchapter FF of this title (relating to Consent to Treatment with Psychoactive Medication), as amended and effective June 2, 1994; (HH) HSC, Title 7, Subtitle C, Texas Mental Health Code, as amended and effective Sept. 1, 1993, and Chapter 405, Subchapter F of this title (relating to Restraint and Seclusion in Mental Health Facilities), as amended and effective Aug. 20, 1984;

(II) 30 TAC, §101.1 (relating to Definitions), defines incinerators, as amended and effective Jan. 27, 1995;

(JJ) HSC, Chapter 382, as amended and effective Sept. 1, 1993, and 30 TAC, Chapter 116 (relating to Control of Air Pollution by Permits for New Construction or Modification), includes Regulation VI and Standard Exemption Number 89, as amended and effective Dec. 8, 1994;

(KK) HSC, Chapter 382, as amended and effective Sept. 1, 1993, and 30 TAC, Chapter 111 (relating to Control of Air Pollution From Visible Emissions and Particulate Matter), as amended and effective July 23, 1993;

(LL) HSC, Chapter 361, as amended and effective Sept. 1, 1993, and 30 TAC, Chapter 330 (relating to Municipal Solid Waste), as amended and effective Feb. 9, 1995;

(MM) Texas Water Code, §5.103 and §5.105, as amended and effective Sept. 1, 1993, and 30 TAC, Chapter 335 (relating to Industrial Solid Waste and Municipal Hazardous Waste), as amended and effective Jan. 2, 1995;

(NN) HSC, Chapter 366, as amended and effective Sept. 1, 1993, and 30 TAC, Chapter 285 (relating to Construction Standards for On-site Sewerage Facilities), as amended and effective Jan. 23, 1993; and

(OO) HSC, Title 6, Subtitle B, Chapter 464, as amended and effective Sept. 1, 1993, and 40 TAC, Chapter 148 (relating to Licensure Rules for Chemical Dependency Treatment Facilities), as amended and effective Jan. 1, 1995.

(4) Agency addresses.

(A) Board of Nurse Examiners for the State of Texas, P.O. Box 140466, Austin, Texas 78714, (512) 835-8662.

(B) Board of Vocational Nurse Examiners for the State of Texas, 9101 Burnet Road, Number 105, Austin, Texas 78758, (512) 835-2071.

(C) Board of Medical Examiners, 1812 Centre Creek Drive, Austin, Texas 78454, P.O. Box 13562, Austin, Texas 78711-3562, switchboard (512) 834-7728, incquiries (512) 834-7860.

(D) Office of the Secretary of State, Texas Register Division, P.O. Box 13824, Austin, Texas 78711-3824; 1019 Brazos, Room 245, Austin, Texas 78701, (512) 463-5561, FAX (512) 463-5569.

(E) Texas Department of Health, Hazard Communication Branch, Division of Occupational Safety and Health, 1100 West 49th Street, Austin, Texas 78756, (512) 834-6600.

(F) Texas Department of Health, Bureau of Radiation Control, 1100 West 49th Street, Austin, Texas 78756, (512) 834-6688.

(G) Texas Department of Health, Food and Drugs Division, 1100 West 49th Street Austin, Texas 78756, (512) 719-0200.

(H) Texas Department of Health, Bureau of Environmental Health, 1100 West 49th Street, Austin, Texas 78756, (512) 834-6640.

(I) Texas Department of Health, Health Facility Licensure and Certification Division, 1100 West 49th Street, Austin, Texas 78756, (512) 834-6650.

(J) Texas Department of Health, Bureau of HIV/STD Prevention, 1100 West 49th Street, Austin, Texas 78756, (512) 458-7328.

(K) Texas Department of Health, Bureau of Communicable Disease Control, 1100 West 49th Street, Austin, Texas 78756, (512) 458-7455.

(L) Texas Department of Licensing and Regulation, Licensure and Certification Division, Attention: Boiler Division, Elimination of Architectural Barriers Section, or Elevator Section, P.O. Box 12157, Capitol Station, Austin, Texas 78711, (512) 463-5522.

(M) Texas Natural Resources Conservation Commission, Municipal Solid Waste, P.O. Box 13087, Austin, Texas 78711-3087, (512) 239-6695

(N) Texas State Board of Pharmacy, 8505 Cross Park Drive, Suite 110, Austin, Texas 78754-4594, (512) 832-0661.

(O) Texas State Board of Plumbing Examiners, 929 East 41st Street, Austin, Texas 78751, (512) 458-2145.

(P) Texas Commission on Alcohol and Drug Abuse, 720 Brazos, Suite 403, Austin, Texas 78701-2506, (512) 867-8700.

(Q) Texas Department of Mental Health and Mental Retardation, P.O. Box 12668, Austin, Texas 78711, (512) 203-4670.

(R) Texas Department of Protective and Regulatory Services, Adult and Child Protective Services, 701 West 51st Street, Austin, Texas 78714-9030, (512) 450-3011. Mail code E-561 for adult services. Mail code E-550 for child services (licensing component).

§133.101. Tables and Figures.

(a) Tables.

(1) Table 1.
FIGURE 1: 25 TAC §133.101(a)(1)

(2) Table 2.
FIGURE 2: 25 TAC §133.101(a)(2)

(3) Table 3.
FIGURE 3: 25 TAC §133.101(a)(3)

(4) Table 4.
FIGURE 4: 25 TAC §133.101(a)(4)

(5) Table 5.
FIGURE 5: 25 TAC §133.101(a)(5)

(6) Table 6
FIGURE 6: 25 TAC §133.101(a)(6)

(b) Figures.

(1) Figure 1.
FIGURE 7: 25 TAC §133.101(b)(1)

(2) Figure 2.
FIGURE 8. 25 TAC §133.101(b)(2)

(3) Figure 3.
FIGURE 9. 25 TAC §133.101(b)(3)

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 15, 1995.

TRD-9503186

Susan K. Steeg
General Counsel
Texas Department of Health

Earliest possible date of adoption. April 21, 1995

For further information, please call: (512) 458-7236

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Subchapter F. Patient Transfers

• 25 TAC §133.101, §133.102

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the offices of the Texas Department of Health or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities, Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health, Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals, Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements, Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed action.

§133.101. Hospital Patient Transfer Policies.

§133.102. Hospital Patient Transfer Agreements.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 15, 1995

TRD-9503196 Susan K Steeg
General Counsel
Texas Department of Health

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Subchapter G. Enforcement

• 25 TAC §§133.111-133.113

(Editor's note: The text of the following sections proposed for repeal will not be published. The sections may be examined in the offices of the Texas Department of Health or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeals are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health, Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services, and §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act, 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed action.

§133.111. Inspections and Investigation Procedures.

§133.112. Audits of Billing.

§133.113. Disciplinary Action and Emergency Orders.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

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TRD-9503197 Susan K Steeg
General Counsel
Texas Department of Health

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For further information, please call: (512) 458-7236

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Subchapter I. Patient Transfers

• 25 TAC §133.111, §133.112

The new sections are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health, Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family

Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102, Government Code Title 4, Chapter 418, Texas Water Code, §5 103 and §5.105, 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note, 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act, 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881, and The Rehabilitation Act of 1973, §504 are affected by this proposed new action

§133.111. Hospital Patient Transfer.

(a) General.

(1) Policy The governing body of each hospital shall adopt, implement, and enforce a policy relating to patient transfers that is consistent with this section and contains each of the requirements in subsection (b) of this section. The hospital administration is the person who has the authority to represent a hospital during the transfer from or receipt of patients into the hospital.

(2) Adoption. The transfer policy shall be adopted by the governing body of the hospital after consultation with the medical staff

(3) Transfers not covered by a transfer agreement. The policy shall govern transfers not covered by a transfer agreement.

(4) Stable patient. The movement of a stable patient from a hospital to another hospital is not considered to be a transfer under this section if it is the understanding and intent of both hospitals that the patient is going to the second hospital only for tests, the patient will not remain overnight at the second hospital, and the patient will return to the first hospital. This paragraph applies only when a patient remains stable during transport to and from hospitals and during testing.

(5) Transportation. The hospital's transfer policy shall include a written operational plan to provide for patient transfer transportation services if the hospital does not provide its own patient transfer transportation services.

(6) Transfer agreements. If possible, each governing body, after consultation with the medical staff, shall implement its transfer policy by adopting transfer agreements with other hospitals in accordance with §133. 112 of this title (relating to Hospital Patient Transfer Agreements).

(7) Acceptance of transfer. A public hospital or a hospital district shall accept the transfer of its eligible residents if the public hospital or hospital district has appropriate facilities, services, and staff available for providing care to the patient.

(b) Requirements for transfer of patients between hospitals.

(1) Discrimination. Except as is specifically provided in paragraphs (6) (E) and (F) and (7)(A) and (B) of this subsection, relating, respectively, to mandated providers and designated providers, the transfer of a patient shall not be predicated upon arbitrary, capricious, or unreasonable discrimination based upon race, religion, national origin, age, sex, physical condition, or economic status.

(2) Disclosure. The hospital shall recognize the right of an individual to request transfer into the care of a physician and a hospital of his own choosing; however, if a patient is transferred for economic reasons and the patient's choice is predicated upon or influenced by representations made by the transferring physician or hospital administration regarding the availability of medical care and hospital services at a reduced cost or no cost to the patient, the physician or hospital administration shall fully disclose to the patient the eligibility requirements established by the patient's chosen physician or hospital.

(3) Patient.

(A) Immediate or continuing care. A patient is an individual seeking medical treatment who may or may not be under the immediate supervision of a personal attending physician, has one or more undiagnosed or diagnosed medical conditions, and who, within reasonable medical probability, requires immediate or continuing hospital services and medical care.

(B) Admitted. A patient is an individual admitted to the hospital as a patient.

(4) Patient evaluation. The hospital shall provide the following for each patient who arrives at the hospital.

(A) Physician evaluation. Each patient shall be evaluated by a physician who is present in the hospital at the time the patient presents or is presented or evaluated by a physician on call who:

(i) is physically able to reach the patient within 30 minutes after being informed that a patient is present at the hospital who requires immediate medical attention; or

(ii) is available by direct telephone or radio communication within 30 minutes with authorized nursing staff at the hospital under orders to assess and report the patient's condition to the physician.

(B) Physician examination. Each patient shall be personally examined and evaluated by the physician before an attempt to transfer is made; however:

(i) after receiving a report on the patient's condition from the hospital's nursing staff by telephone or radio, if the physician on call determines that an immediate transfer of the patient is medically appropriate and that the time required to conduct a personal examination and evaluation of a patient will unnecessarily delay the transfer to the detriment of the patient, the physician on call may order the transfer by telephone or radio; and

(ii) physician orders for the transfer of a patient which are issued by telephone or radio shall be reduced to writing in the patient's medical record, signed by the hospital staff member receiving the order, and countersigned by the physician authorizing the transfer as soon as possible. The patient transfers resulting from physician orders issued by telephone or radio shall be subject to automatic review by the medical staff pursuant to paragraph (9) of this subsection.

(5) Hospital personnel, written protocols, standing delegation orders, eligibility and payment information. The transferring and receiving hospital shall provide that licensed nurses and other qualified personnel are available and on duty to assist with patient transfers and to provide accurate information regarding eligibility and payment practices. The hospital shall provide that written protocols or standing delegation orders are in place to guide hospital personnel when a patient requires transfer to another hospital.

(6) Transfer of patients who have emergency medical conditions.

(A) Patient not stabilized. If a patient at a hospital has an emergency medical condition which has not been stabilized or when stabilization of the patient's vital signs is not possible because the hospital or emergency department does not have the appropriate equipment or personnel to correct the underlying process (e.g. children's hospitals, thoracic surgeon on staff, or cardiopulmonary bypass capability), evaluation and treatment shall be performed and transfer shall be carried out as quickly as possible.

(B) Transfer-not stabilized. The hospital shall not transfer a patient with an emergency medical condition which has not been stabilized unless:

(i) the patient or a legally responsible person acting on the patient's behalf, after being informed of the hospital's obligations under this section and of

the risks and benefits of transfer, requests transfer to another hospital in writing;

(ii) a licensed physician has signed a certification, which includes a summary of the risks and benefits, that, based on the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another hospital outweigh the increased risks to the patient and, in the case of labor, to the unborn child from effecting the transfer; or

(iii) if the licensed physician who made the determination to transfer a patient with an emergency condition is not physically present in the emergency department at the time of transfer, a qualified medical person may sign a certification described in clause (ii) of this subparagraph after consultation with the licensed physician. The licensed physician shall countersign the physician certification within a reasonable period of time.

(C) Medical reasons. Except as provided by subparagraphs (E) and (F) of this paragraph and paragraph (7)(A) and (B) of this subsection, the transfer of patients who have emergency medical conditions, as determined by a physician, shall be undertaken for medical reasons only.

(D) Receiving hospital. Except as expressly permitted in clauses (i) and (ii) of this subparagraph, a hospital shall provide for the receipt of patients who have an emergency medical condition from other hospitals so that upon notification from a transferring physician or a transferring hospital prior to transfer, the receiving hospital shall respond to the transferring hospital and transferring physician with the status of the transfer request within 30 minutes and either accept or refuse the transfer. The time period begins to run at the time a member of the staff of the receiving hospital receives the call initiating the request to transfer.

(i) The receiving hospital may permit response to the transferring hospital and transferring physician within a period of time in excess of 30 minutes but no longer than one hour if there are extenuating circumstances for the delay. If the transfer is accepted, the reason for the delay shall be documented on the memorandum of transfer.

(ii) The response time may be extended before the expiration of the initial 30 minutes period by agreement among the transferring hospital and transferring physician and the receiving hospital and receiving physician. If the transfer is accepted, the agreed extension shall be documented in the memorandum of transfer.

(E) Compliance. The hospital shall recognize and comply with the requirements of the Indigent Health Care and Treatment Act, Health and Safety Code, §§61.030-61.032 and §§61.057-61.059 (relating to Mandated Providers) since those requirements may apply to a patient.

(F) Contractual obligations The hospital shall acknowledge contractual obligations and comply with statutory or regulatory obligations which may exist concerning a patient and a designated provider.

(G) Informed refusal. The hospital shall require that all reasonable steps are taken to secure the informed refusal of a patient refusing a transfer or a related examination and treatment or of a person acting on a patient's behalf refusing a transfer or a related examination and treatment. Reasonable steps include:

(i) a factual explanation of the increased medical risks to the patient reasonably expected from not being transferred, examined, or treated at the transferring hospital;

(ii) a factual explanation of any increased risks to the patient from not effecting the transfer;

(iii) a factual explanation of the medical benefits reasonably expected from the provision of appropriate treatment at another hospital; and

(iv) the informed refusal of a patient, or of a person acting on a patient's behalf, to examination or evaluation related to subsection (a)(4) and (6) of this section or treatment related to subsection (a)(6) of this section and paragraph (8) of this subsection and documents reflecting such refusals, signed if possible by the patient or by a person acting on the patient's behalf, dated and witnessed by the attending physician or hospital employee, and placed in the patient's medical record.

(H) Optimal care. Transfer of patients may occur routinely or as part of a regionalized plan for obtaining optimal care for patients at a more appropriate or specialized facility.

(7) Nonemergency. Transfer of patients who do not have emergency medical conditions.

(A) Compliance. The hospital shall recognize and comply with the requirements of the Indigent Health Care and Treatment Act, Health and Safety Code, §§61.030-61.032 and §§61.057-61.059 (relating to Mandated Providers) since those requirements may apply to a patient.

(B) Contractual obligations. The hospital shall acknowledge contractual obligations and comply with statutory or regulatory obligations which may exist concerning a patient and a designated provider

(C) Informed refusal The hospital shall require that all reasonable steps are taken to secure the informed refusal of a patient refusing a transfer or a related examination and treatment or of a person acting on a patient's behalf refusing a transfer or a related examination and treatment. Reasonable steps include·

(i) a factual explanation of the increased medical risks to the patient reasonably expected from not being transferred, examined, or treated at the transferring hospital;

(ii) a factual explanation of any increased risks to the patient from not effecting the transfer,

(iii) a factual explanation of the medical benefits reasonably expected from the provision of appropriate treatment at another hospital; and

(iv) the informed refusal of a patient, or of a person acting on a patient's behalf, to examination or evaluation related to subsection (a)(4) and (6) of this section or treatment related to subsection (a)(6) of this section and paragraph (8) of this subsection and documents reflecting such refusals, signed if possible by the patient or by a person acting on the patient's behalf, dated and witnessed by the attending physician or hospital employee, and placed in the patient's medical record

(D) Optimal care. Transfer of patients may occur routinely or as part of a regionalized plan for obtaining optimal care for patients at a more appropriate or specialized facility.

(E) Patient rights. The hospital shall recognize the right of an individual to request a transfer into the care of a physician and a hospital of the individual's own choosing.

(8) Physician's duties and standard of care.

(A) Life support. The transferring physician shall determine and order life support measures which are medically appropriate to stabilize the patient prior to transfer and to sustain the patient during transfer.

(B) Personnel and equipment. The transferring physician shall determine and order the utilization of appropriate personnel and equipment for the transfer.

(C) Reasonable and prudent care. In determining the use of medically appropriate life support measures, personnel, and equipment, the transferring physician shall exercise that degree of care which a reasonable and prudent physician exercising ordinary care in the same or similar locality would use for the transfer.

(D) Patient examination and evaluation. Except as allowed under paragraph (4)(B) of this subsection, prior to each patient transfer, the physician who authorizes the transfer shall personally examine and evaluate the patient to determine the patient's medical needs and to ensure that the proper transfer procedures are used.

(E) Receiving physician. Prior to transfer, the transferring physician shall secure a receiving physician and a receiving hospital that are appropriate to the medical needs of the patient and that will accept responsibility for the patient's medical treatment and hospital care.

(9) Record review for standard of care. The hospital shall provide that the hospital's medical staff review appropriate records of patients transferred from the hospital to determine that the appropriate standard of care has been met.

(10) Medical record

(A) Forwarded with transfer. The hospital shall provide that a copy of those portions of the patient's medical record which are available and relevant to the transfer and to the continuing care of the patient be forwarded to the receiving physician and receiving hospital with the patient. If all necessary medical records for the continued care of the patient are not available at the time the patient is transferred, the records shall be forwarded to the receiving physician and hospital as soon as possible.

(B) Contents. The medical record shall contain at a minimum:

(i) a brief description of the patient's medical history and physical examination;

(ii) a working diagnosis and recorded observations of physical assessment of the patient's condition at the time of transfer;

(iii) the reason for the transfer;

(iv) the results of all diagnostic tests, such as laboratory tests;

(v) pertinent X-ray films and reports; and

(vi) any other pertinent information.

(11) Memorandum of transfer.

(A) Requirements. The hospital shall ensure that a memorandum of transfer be completed for every patient who is transferred.

(B) Contents. The memorandum shall contain the following information:

(i) the patient's full name, if known;

(ii) the patient's race, religion, national origin, age, sex, physical handicap, if known;

(iii) the patient's address and next of kin, address, and phone number if known;

(iv) the names, telephone numbers and addresses of the transferring and receiving physicians;

(v) the names, addresses, and telephone numbers of the transferring and receiving hospitals;

(vi) the time and date on which the patient first presented or was presented to the transferring physician and transferring hospital;

(vii) the time and date on which the transferring physician secured a receiving physician;

(viii) the name, date, and time hospital administration was contacted in the receiving hospital;

(ix) signature, time, and title of the transferring hospital administration who contacted the receiving hospital;

(x) the certification required by paragraph (6)(B)(ii) of this subsection, if applicable (the certification may be part of the memorandum of transfer form or may be on a separate form attached to the memorandum of transfer form);

(xi) the time and date on which the receiving physician assumed responsibility for the patient;

(xii) the time and date on which the patient arrived at the receiving hospital;

(xiii) signature and date of receiving hospital administration;

(xiv) type of vehicle and company used;

(xv) type of equipment and personnel needed in transfers;

(xvi) name and city of hospital to which patient was transported;

(xvii) diagnosis by transferring physician; and

(xviii) attachments by transferring hospital.

(C) Receipt. The receipt of the memorandum of transfer shall be acknowledged in writing by the receiving hospital administration and receiving physician.

(D) Retention. A copy of the memorandum of transfer shall be retained by the transferring and receiving hospitals. The memorandum shall be filed separately from the patient's medical record and in a manner which will facilitate its inspection by the department.

(c) Violations. A hospital violates the Act and this subchapter if:

(1) the hospital fails to comply with the requirements of this subchapter; or

(2) the governing body fails or refuses to:

(A) adopt a transfer policy which is consistent with this section and contains each of the requirements in subsection (b) of this section;

(B) adopt a memorandum of transfer form which meets the minimum requirements for content contained in this section; or

(C) enforce its transfer policy and the use of the memorandum of transfer.

§133.112. Hospital Patient Transfer Agreements.

(a) General provisions.

(1) Voluntary. Transfer agreements between hospitals are voluntary.

(2) Governed by the agreement. If transfer agreements are executed between hospitals that are consistent with the requirements of subsection (b) of this section, any patient transfers between the hospitals shall be governed by the agreement. The memorandum of transfer described in §133.111(b)(11) of this title (relating to Hospital Patient Transfer) shall not be required between hospitals governed by an agreement.

(3) Review. The transfer agreement shall be submitted to the department for review to determine if the agreement meets the requirements of subsection (b) of this section.

(4) Multiple agreements. Multiple transfer agreements may be entered into by a hospital based upon the type or level of medical services available at other hospitals.

(b) Rules for hospital patient transfer agreements.

(1) Discrimination. A patient transfer agreement shall provide the following.

(A) Basis. Except as specifically provided in paragraph (4) of this subsection, relating to mandated providers, the transfer of a patient shall not be predicated upon arbitrary, capricious, or unreasonable discrimination based upon race, religion, national origin, age, sex, physical condition, or economic status.

(B) Ability to pay. The transfer or receipt of patients in need of emergency care shall not be based upon the individual's inability to pay for the services rendered by the transferring or receiving hospital.

(2) Standards of care. The hospital patient transfer agreement shall require that patient transfers between the hospitals be accomplished in a medically appropriate manner from physician to physician and from hospital to hospital.

(A) Life support. The use of medically appropriate life support measures which a reasonable and prudent physician in the same or similar locality exercising ordinary care would use to stabilize the patient prior to transfer and to sustain the patient during the transfer shall be provided.

(B) Personnel and equipment. The provision of appropriate personnel and equipment which a reasonable and prudent physician in the same or similar locality exercising ordinary care would use for the transfer shall be provided.

(C) Records. The transfer of all necessary records for continuing the care for the patient shall be provided.

(D) Availability of facilities, services, staff. The consideration of the availability of appropriate facilities, services, and staff for providing care to the patient shall be provided.

(3) Freedom of choice. The hospitals shall recognize the right of an individual to request transfer into the care of a physician and hospital of the individual's own choosing.

(4) Mandated providers. The hospitals shall recognize and comply with the requirements of the Indigent Health Care and Treatment Act, Health and Safety Code, Chapter 61 (relating to the Transfer of Patients to Mandated Providers).

(5) Emergency medical conditions. The hospital patient transfer agreement shall provide that the hospital shall not transfer a patient with an emergency medical condition which has not been stabilized unless the following occurs.

(A) Written transfer request. The patient, or a legally responsible person acting on the patient's behalf, after being informed of the hospital's obligations under this section and of the risk of transfer, has requested transfer to another hospital in writing.

(B) Physician certification. A licensed physician has signed a certification, which includes a summary of the risks and benefits, that, based on the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another hospital outweigh the increased risks to the patient and, in the case of labor, to the unborn child from effecting the transfer.

(C) Nonphysician certification. If a licensed physician is not physically present in the emergency department at the time a patient is transferred, a qualified medical person has signed a certification described in subparagraph (B) of this paragraph after consultation with a licensed physician who has made the determination described in subparagraph (B) of this paragraph and who will subsequently countersign the certification within a reasonable period of time.

(c) Review of transfer agreements and approval or rejection.

(1) Submission procedure. Each party to a transfer agreement may obtain the Texas Department of Health's (department) review of a transfer agreement by jointly submitting to the department:

(A) a copy of the current or proposed agreement between the parties; and

(B) the signature of the chairman and secretary of each party's governing body attesting to:

(i) the date of the adoption of the agreement; and

(ii) the effective date of the agreement.

(2) Alternate submission procedure. The governing body may submit a document, executed by both the chairman and secretary, delegating to the administrator of the hospital or other designee the authority to negotiate and adopt transfer agreements.

(A) Representation. If such a delegation is made, in the joint submission of the transfer agreement, the administrator or other designee shall act on behalf of the governing body from which the authority was obtained.

(B) Signed agreement. The submission of a transfer agreement adopted by designees shall include a copy of the current or proposed agreement between the parties which has been signed by each administrator or other designee of each party's governing body and attestation to:

(i) the date of the adoption of the agreement; and

(ii) the effective date of the agreement.

(3) Exception to submission requirements.

(A) Waived documents. The department may waive the submittal of the documents required under paragraphs (1) or (2) of this subsection to avoid the repetitious submission of required documentation and approved agreements.

(B) Later agreement. If a governing body or a governing body's designee executes a transfer agreement and the entire text of that agreement consists of the entire text of an agreement that has been previously approved by the department, the governing body or the governing body's designee shall not be required to submit the later agreement for review. On the date the later agreement is fully executed and before the later agreement is implemented, the governing body or the governing body's designee shall give adequate notice to the department that the later agreement has been executed.

(C) Notice. Adequate notice of a later agreement consists of the following:

(i) specific reference to the quoted agreement;

(ii) identification of the hospitals that are party to the later agreement; and

(iii) if a party hospital has not previously submitted any agreement for approval, the documentation for that party hospital, required in paragraphs (1) or (2) of this subsection, relating respectively to the documentation that must be submitted to verify the action taken by the hospital's governing body or to verify the governing body's delegation of authority to the hospital administrator or other designee.

(4) Review. The department shall review the agreement within 30 calendar days after the department's receipt of the agreement to determine if the agreement is consistent with the requirements of this section.

(5) Approval. After the department's review of the agreement, if the department determines that the agreement is consistent with the requirements contained in this section, the department shall notify the hospital administration that the agreement has been approved.

(6) Rejection. If the department has reason to believe that the agreement is not consistent with the requirements contained in this section, the dep tment shall give notice to the hospital administration that the agreement is deficient

(7) Deficiency notice.

(A) Deficiencies. The deficiency notice shall contain a complete statement of the deficiencies.

(B) Recommendations The deficiency notice shall contain recommendations for correction or an offer of consultation.

(C) Cautions. The deficiency notice shall contain a statement of caution to the submitting hospitals that a rejection by the department has the effect of continuing each hospital's respective hospital patient transfer policy.

(d) Appeals.

(1) Reconsideration. If the department rejects a patient transfer agreement, the hospitals that are parties to the agreement may jointly request an internal reconsideration of the department's decision.

(2) Appeal. A hospital that is party to a rejected agreement shall appeal the rejection jointly with an appeal by other appealing parties or waive that hospital's opportunity to appeal.

(3) Notification. To initiate the appeal process, the party hospitals shall notify the department, in writing, that each party hospital requests a hearing on the decision.

(4) Hearing request. The request must be received by the department within 20 calendar days from the receipt of the department's rejection notice by the hospital that submitted the proposed agreement for review and approval.

(5) Rejection. Failure of the party hospitals to provide a written request for appeal shall be deemed a waiver of the opportunity for an internal reconsideration by the department, and the rejection shall become final.

(6) Rejection review. An internal review of a rejection shall consist of a review of the actions taken to-date concerning the rejection of the agreement.

(7) Review panel. The review shall be conducted by a three member panel. The members shall be appointed by the commissioner of health (commissioner). The panel members shall not have participated in the department's decision.

(A) Meeting. The panel shall meet as necessary.

(B) Review. The panel shall review all agreement submissions for which an appeal has been requested.

(C) Documentation. The review shall be based primarily on the documentation provided with the request for an appeal, but the party (parties) requesting the appeal may appear before the panel, if desired.

(D) Decision The panel's decision is binding on the department and the hospital(s)

(e) Amendments to an agreement.

(1) Proposed amendments. The governing body of a hospital or governing body's designee may adopt proposed amendments to a transfer agreement which has been approved by the department. Before the amendments are implemented, the governing body or the governing body's designee shall submit the proposed amendments to the department for review in the same manner as the agreement to be amended was submitted.

(2) Review, approve, reject. The department shall review the amendments and shall approve or reject them in the same manner as provided for the review of the agreement to be amended.

(f) Complaints. Complaints alleging a violation of a transfer agreement shall be treated in the same manner as complaints alleging violations of the Act or this chapter.

(g) Enforcement.

(1) Notification. After investigation of the complaint, if it is determined that the violation alleged in the complaint is not a violation of a rule required by subsection (b) of this section, the department shall notify the complainant that the complaint is not within the jurisdiction of the department and that the complainant may proceed by undertaking private resolution.

(2) Proceeding. After investigation of the complaint, if the department determines that a hospital has violated a rule required by subsection (b) of this section, the department may proceed against the violating hospital in the same manner as provided for enforcement of the Act and this chapter.

(3) Exception. The department may not enforce provisions of a hospital patient transfer agreement that are not required by subsection (b) of this section

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 15, 1995

TRD-9503187 Susan K. Steeg
General Counsel
Texas Department of Health

Earliest possible date of adoption April 21, 1995

For further information, please call: (512) 458-7236

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Subchapter H. Hospital Investigation

• 25 TAC §133.121

(Editor's note: The text of the following section proposed for repeal will not be published. The section may be examined in the offices of the Texas Board of Health or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeal is proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals, Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family

Code, Chapter 34, Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102, Government Code Title 4. Chapter 418, Texas Water Code, §5 103 and §5 105, 42 United States Code (USC), Chapter 126, 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act, 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30), 21 USC, §853 and §881, and The Rehabilitation Act of 1973, §504 are affected by this proposed action

§133.121 Complaints Against the Department

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt

Issued in Austin, Texas, on March 15, 1995

TRD-9503198 Susan K Steeg
General Counsel
Texas Department of Health

Earliest possible date of adoption April 21, 1995

For further information, please call (512) 458-7236

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Subchapter J. Enforcement

• 25 TAC §§133.121-133.124

The new sections are proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities, Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices, Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation, Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health, Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements, Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and §12 001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health

Health and Safety Code (HSC), Chapters 61, 81 172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773, HSC, Title 7 Subtitle C, Texas Mental Health Code, Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102, Government Code Title 4, Chapter 418; Texas Water Code, §5 103 and §5 105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note, 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed new action.

§133 121 Inspection and Investigation Procedures.

(a) Inspection or investigation. The Texas Department of Health (department) shall make any inspection or investigation that it considers necessary. A representative of the department shall enter the premises of a hospital at any reasonable time to make an inspection or an investigation to ensure compliance with or prevent a violation of the Texas Hospital Licensing Act (Act) or this chapter, an order or special order of the commissioner of health (commissioner), a special license provision, a court order granting injunctive relief, or other enforcement procedures.

(b) Access The department or a representative of the department is entitled to access to all books, records, or other documents maintained by or on behalf of the hospital to the extent necessary to enforce the Act, this chapter, an order or special order of the commissioner, a special license provision, a court order granting injunctive relief, or other enforcement procedures The department shall maintain the confidentiality of hospital records as applicable under federal or state law.

(c) Consent. By applying for or holding a hospital license, the hospital consents to entry and inspection or investigation of the hospital by the department or a representative of the department in accordance with the Act and this chapter.

(d) Health inspection. A hospital is not subject to additional health licensing inspections before the department issues the hospital a renewal license while the hospital maintains

(1) certification under Title XVIII of the Social Security Act, 42 United States Code (USC), §§1395 et seq, or

(2) accreditation by the Joint Commission on Accreditation of Healthcare Organizations or by the American Osteopathic Association.

(e) Authority of the department.

(1) Reinspect. The department has the authority to reinspect a hospital if a hospital applies for the reissuance of its license after the suspension or revocation of the hospital's license, the assessment of administrative or civil penalties, or the issuance of an injunction against the hospital for violations of the Act, this chapter, a special license condition, or an order of the commissioner.

(2) Complaint investigation. The department has the authority to investigate a complaint against a hospital and, if appropriate, enforce the provisions of the Act on a finding by the department that reasonable cause exists to believe that the hospital has violated provisions of the Act, this chapter, special license conditions, or orders of the commissioner, provided that the department shall coordinate with the federal Health Care Financing Administration and its agents responsible for the inspection of hospitals to determine compliance with the conditions of participation under Title XVIII of the Social Security Act, (42 USC, §§1395 et seq), so as to avoid duplicate investigations.

(f) Reporting alleged violations. If an individual wishes to report an alleged violation of the Act or this chapter, the individual shall notify the department by telephone at 1-800-228-1570, by writing the department at 1100 West 49th Street, Austin, Texas 78756-3199, or by personal visit. The department shall inform, in writing, a complainant who identifies himself by name and address of the following.

(1) Receipt. The complainant shall be informed of the receipt of the complaint

(2) Violation. The complainant shall be informed if the complainant's allegations are potential violations of the Act or this chapter warranting an investigation.

(3) Investigation. The complainant shall be informed whether the complaint will be investigated by the department.

(4) Referral. The complainant shall be informed whether and to whom the complaint will be referred.

(5) Findings. The complainant shall be informed of the findings of the complaint investigation.

(g) Entrance conference. The department's representative shall hold a conference with the hospital administrator or designee before beginning the on-site inspection or investigation to explain the nature, scope, and estimated time schedule of the inspection or investigation.

(h) Preliminary findings. The department shall fully inform the hospital administrator or designee of the preliminary findings of the inspection or investigation and shall give the person a reasonable opportunity to submit additional facts or other information to the department's authorized representative in response to those findings. The response shall be made a part of the record of the inspection or investigation for all purposes and must be received by the

department within ten working days of the hospital's receipt of the preliminary findings.

(i) Exit conference After an inspection or investigation of a hospital by the department, the department's representative shall hold an exit conference with the hospital administrator or designee and other invited staff and provide the following to the hospital administrator or designee.

(1) Investigation The specific nature of the inspection or investigation shall be provided

(2) Allegations. Any alleged violations of a specific statute or rule shall be provided

(3) Findings The specific nature of any finding regarding an alleged violation or deficiency shall be provided.

(4) Deficiency found. If the deficiency is alleged, the severity of the deficiency shall be provided.

(5) No deficiency found. If there are no deficiencies found, a statement indicating this fact shall be provided.

(6) Department representatives. If requested by the hospital, information on the identity, including the signature, of each department representative conducting, reviewing or approving the results of the inspection or investigation and the date on which the department representative acted on the matter shall be provided.

(7) Inspection documents. If requested by the hospital, copies of all documents relating to the inspection or investigation maintained by the department or provided by the department to any other federal or state agency that are not confidential under state law shall be provided.

(8) Duplicated records. Identity of any records that were duplicated shall be provided

(j) Surveyor responsibilities.

(1) Statement of deficiencies The surveyor shall prepare a statement of deficiencies, if any

(2) Plan of correction For deficiencies, the surveyor shall obtain a plan of correction which is provided by the hospital and indicates the date(s) by which correction(s) will be made.

(3) Signature. The surveyor shall obtain the signature of the hospital administrator or designee acknowledging the receipt of the statement of deficiencies and plan of correction form.

(4) Comments. The surveyor shall obtain within ten working days of the inspection or investigation, written comments, if any, by the hospital administrator or designee concerning the inspection or investigation Additional facts, written comments, or other information provided by the hospital in response to the findings shall be made a part of the record of the inspection or investigation for all purposes.

(5) Administrative review. The surveyor shall inform the administrator or designee of the hospital's right to an informal administrative review when there is disagreement with the surveyor's findings and recommendations or when additional information bearing on the findings is available

(k) Additional plan of correction. If deficiencies are cited and the plan of correction is not acceptable, the department shall notify the hospital in writing and request that the plan of correction be resubmitted within ten calendar days of the hospital's receipt of the department's written notice. Upon resubmission of an acceptable plan of correction, written notice shall be sent by the department to the hospital acknowledging same.

(l) Compliance. The hospital shall come into compliance by the completion date provided on the statement of deficiencies and plan of correction form or come into compliance at least 30 calendar days prior to the expiration date of the temporary initial license or annual license, whichever comes first.

(m) Verification of correction. The department shall verify the correction of deficiencies by mail or by an on-site inspection or investigation

(n) Disciplinary action. The department may initiate disciplinary action even if a plan of correction is accepted and completed

§133.122. Audits of Billing.

(a) Purpose The purpose of this section is to implement Health and Safety Code, §311.0025 (relating to Audits of Billing) This section applies to all hospitals.

(b) Treatment not provided. A hospital shall not submit to patients or third party payors a bill for treatments which are improper, unreasonable or medically or clinically unnecessary or for treatments which were not provided.

(c) Billing complaint. A complaint relating to billing shall specify the patient for whom the bill was submitted.

(d) Internal investigation. Upon receiving a complaint warranting an investigation, the department shall send the complaint to the hospital requesting the hospital to conduct an internal investigation. Within 30 calendar days of the hospital's receipt of the complaint, the hospital shall submit the following to the department.

(1) Report. A report outlining the hospital's investigative process shall be submitted.

(2) Resolution or conclusion. The resolution or conclusion reached by the hospital with the patient, third party payor, or complainant shall be submitted

(3) Corrections. Corrections, if any, in the hospital's policies or protocols which were made as a result of its investigative findings shall be submitted.

(e) Department investigation. In addition to the hospital's internal investigation, the department may also conduct an investigation to audit any billing and patient records of the hospital.

(f) Complainant notification. The department shall inform, in writing, a complainant who identifies himself by name and address of the following.

(1) Receipt. The complainant shall be informed of the receipt of the complaint.

(2) Violations. The complainant shall be informed if the complainant's allegations are potential violations of the Act or this chapter warranting an investigation.

(3) Investigation by the department. The complainant shall be informed whether the complaint will be investigated by the department.

(4) Internal investigation. The complainant shall be informed if the complaint was referred to the hospital for internal investigation.

(5) Referral. The complainant shall be informed whether and to whom the complaint will be referred.

(6) Results. The complainant shall be informed of the results of the hospital's investigation and the hospital's resolution with the complainant.

(7) Findings. The complainant shall be informed of the department's findings if an on-site audit investigation was conducted.

(g) Licensing agency. The department shall refer investigative reports of billing by health care professionals who have provided improper, unreasonable, or medically or clinically unnecessary treatments, or billed for treatments which were not provided to the appropriate licensing agency.

§133.123. Disciplinary Action and Emergency Order.

(a) Disciplinary action. The Texas Department of Health (department) may deny, suspend, or revoke a hospital's license if the department finds that the hospital:

(1) has failed to comply with:

(A) a provision of the Act;

(B) a requirement in this

chapter;

(C) a special license condition;

(D) an order or emergency order by the commissioner of health (commissioner); or

(E) another enforcement procedure permitted under this chapter;

(2) has a history of noncompliance with this chapter relating to patient health, safety, and rights which reflects more than nominal noncompliance;

(3) has aided, abetted, or permitted the commission of an illegal act; or

(4) has committed fraud, misrepresentation, or concealment of a material fact on any documents required to be submitted to the department or required to be maintained by the hospital pursuant to the provisions of this chapter

(b) Denial of a license. The department may deny a license if the applicant or licensee:

(1) fails to provide the required application or renewal information;

(2) fails to pay administrative penalties in accordance with the Act; or

(3) discloses any of the following actions against or by the applicant or the licensee, or against or by affiliates or managers of the applicant or the licensee, within the two-year period preceding the application:

(A) operation of a hospital that has been decertified or had its contract cancelled under the Medicare or Medicaid program in any state,

(B) federal Medicare or state Medicaid sanctions or penalties;

(C) federal or state criminal convictions which imposed incarceration;

(D) federal or state tax liens;

(E) unsatisfied final judgments,

(F) eviction involving any property or space used as a hospital in any state;

(G) unresolved federal Medicare or state Medicaid audit exceptions;

(H) denial, suspension, or revocation of a hospital license, a private psychiatric hospital license, or a license for any health care facility in any state; or

(I) a court injunction prohibiting ownership or operation of a hospital.

(c) Types of licenses covered by a denial Denial of a license includes denial of a temporary initial license, first annual license, or a renewal license.

(d) Conviction of felony or misdemeanor The department may suspend or revoke an existing valid license or disqualify a person from receiving a license because of a person's conviction of a felony or misdemeanor if the crime directly relates to the duties and responsibilities of the ownership or operation of a hospital.

(1) Fitness determination. In determining the present fitness of a person who has been convicted of a crime, the department shall consider the provisions of Texas Civil Statutes, Article 6252-13c.

(2) Criminal offenses. The following felonies and misdemeanors directly relate because these criminal offenses indicate an ability or a tendency for the person to be unable to own or operate a hospital:

(A) a violation of the Act;

(B) an offense involving moral turpitude;

(C) an offense relating to deceptive business practice;

(D) an offense of practicing any health-related profession without a required license;

(E) an offense under any federal or state law relating to drugs, dangerous drugs, or controlled substances;

(F) an offense under Title 5 of the Texas Penal Code involving a patient or client of a health care facility or agency;

(G) an offense under various titles of the Texas Penal Code:

(i) Title 5 concerning offenses against the person;

(ii) Title 7 concerning offenses against property;

(iii) Title 9 concerning offenses against public order and decency;

(iv) Title 10 concerning offenses against public health, safety, and morals; or

(v) Title 4 concerning offenses of attempting or conspiring to commit any of the offenses in this subsection; or

(H) other misdemeanors or felonies which indicate an inability or tendency for the person to be unable to own or operate a hospital if action by the department will promote the intent of the Act, this chapter, or Texas Civil Statutes, Article 6252-13c.

(3) Revocation of license. Upon a licensee's felony conviction, felony probation revocation, revocation of parole, or revocation of mandatory supervision, the license shall be revoked

(e) Notification and opportunity for hearing. If the department proposes to deny, suspend, or revoke a license, the department shall notify the applicant or the hospital by certified mail, return receipt requested, of the reasons for the proposed action and offer the applicant or hospital an opportunity for a hearing. The applicant or hospital shall request a hearing within 30 calendar days of receipt of the notice. The request shall be in writing and submitted to the Hospital Licensing Director, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199 A hearing shall be conducted pursuant to the Administrative Procedure Act, Government Code, Chapter 2001, and the department's formal hearing procedures in Chapter 1 of this title (relating to Texas Board of Health). If the applicant or hospital does not request a hearing, in writing, within 30 calendar days of receipt of the notice or does not appear at a scheduled hearing, the applicant or hospital is deemed to have waived the opportunity for a hearing, and the proposed action shall be taken. Receipt of the notice is presumed to occur on the 10th day after the notice is mailed to the last address known to the department unless another date is reflected on a United States Postal Service return receipt.

(f) Application for reissuance of license. A hospital whose license is suspended or revoked may apply to the department for the reissuance of a license. A hospital shall apply for reissuance according to §133.11 of this title (relating to Application and Issuance of Temporary Initial License for First-time Applicants). The department may reissue the license if the department determines that the hospital has corrected the conditions that led to the suspension or revocation of the hospital's license.

(g) Emergency order. Following notice to the hospital and opportunity for hearing, the commissioner or a person designated by the commissioner may issue an emergency order, either mandatory or prohibitory in nature, in relation to the opera-

tion of a hospital if the commissioner or the commissioner's designee determines that the hospital is violating or threatening to violate the Act, this chapter, a special licensing provision, injunctive relief, an order of the commissioner or the commissioner's designee, or another enforcement procedure permitted under the Act and the provision, rule, license provision, injunctive relief, order, or enforcement procedure relates to the health or safety of the hospital's patients.

(1) Hearing notice. The department shall send a written, certified notice of the hearing and shall include within the notice the time and place of the hearing. The hearing shall be held within ten calendar days after the date of the hospital's receipt of the notice.

(2) Hearing procedure. The hearing shall not be governed by the contested case provisions of the Administrative Procedure Act, Government Code, Chapter 2001 and its subsequent amendments but, instead, shall be held in accordance with the board's informal hearing procedures in Chapter 1 of this title (relating to Texas Board of Health).

(3) Effective date. The order shall be effective on delivery to the hospital or at a later date specified in the order.

§133.124. Administrative Penalty.

(a) A penalty may be assessed against hospitals for violations of licensing regulations that occur on services other than comprehensive medical rehabilitation services, mental health services, or chemical dependency services.

(1) Authority. The director may assess an administrative penalty against a hospital that violates this chapter, a rule adopted pursuant to this chapter, a special license provision, an order or emergency order issued by the commissioner of health (commissioner) or the commissioner's designee, or another enforcement procedure permitted under this chapter.

(2) Penalty limits. The penalty against hospitals for violations that occur on services other than comprehensive medical rehabilitation services, mental health services, or chemical dependency services:

(A) shall not exceed $1,000 for each violation; and

(B) may consider each day a violation continues or occurs as a separate violation.

(3) Amount of penalty. In determining the amount of the penalty, the department shall consider:

(A) the hospital's previous violations;

(B) the seriousness of the violation;

(C) any threat to the health, safety, or rights of the hospital's patients;

(D) the demonstrated good faith of the hospital; and

(E) such other matters as justice may require.

(4) Penalty process.

(A) When it is determined that a violation has occurred, the director shall issue a report that states the facts on which the determination is based and the director's recommendation on the imposition of a penalty, including a recommendation on the amount of the penalty.

(B) Within 14 calendar days after the date the report is issued, the director shall give written notice of the report to the person, delivered by certified mail. The notice shall:

(i) include a brief summary of the alleged violation;

(ii) include a statement of the amount of the recommended penalty; and

(iii) inform the person of the right to a hearing on the occurrence of the violation, the amount of the penalty, or both.

(C) Within 20 calendar days after the date the person receives the notice, the person in writing may:

(i) accept the determination and recommended penalty of the director; or

(ii) make a written request for a hearing on the occurrence of the violation, the amount of the penalty, or both.

(D) If the person accepts the determination and recommended penalty of the director, the commissioner by order shall impose the recommended penalty.

(E) If the person requests a hearing or fails to respond timely to the notice, the Texas Department of Health (department) shall set a hearing, give notice of the hearing to the person, and proceed as follows.

(i) The hearing shall be held by the department.

(ii) The person conducting the hearing shall make findings of fact and conclusions of law and promptly issue to the commissioner a proposal for a decision about the occurrence of the violation and the amount of the penalty.

(iii) Based on the findings of fact, conclusions of law, and proposal for a decision, the commissioner by order shall:

(I) find that a violation has occurred and impose a penalty; or

(II) find that no violation occurred.

(iv) The notice of the commissioner's order given to the person under the Administrative Procedure Act, Government Code, Chapter 2001, and its subsequent amendments shall include a statement of the right of the person to judicial review of the order.

(F) Within 30 calendar days after the date the commissioner's order is final as provided by §16(c), Administrative Procedure Act, Government Code, Chapter 2001, and its subsequent amendments, the person shall:

(i) pay the amount of the penalty;

(ii) pay the amount of the penalty and file a petition for judicial review contesting the occurrence of the violation, the amount of the penalty, or both; or

(iii) without paying the amount of the penalty, file a petition for judicial review contesting the occurrence of the violation, the amount of the penalty, or both.

(G) Within the 30 calendar day period, a person, who acts under subparagraph (F)(iii) of this paragraph, may:

(i) stay enforcement of the penalty by:

(I) paying the amount of the penalty to the court for placement in an escrow account; or

(II) giving to the court a supersedeas bond that is approved by the court for the amount of the penalty and that is effective until all judicial review of the commissioner's order is final; or

(ii) request the court to stay enforcement of the penalty by:

(I) filing with the court a sworn affidavit of the person stating that the person is financially unable to pay the amount of the penalty and is financially unable to give the supersedeas bond, and

(II) sending a copy of the affidavit to the commissioner by certified mail

(H) Within five calendar days after receipt of a copy of an affidavit, the commissioner may contest the affidavit by filing with the court.

(i) The court shall hold a hearing on the facts alleged in the affidavit as soon as practicable and shall stay the enforcement of the penalty on finding that the alleged facts are true.

(ii) The person who files an affidavit has the burden of proving that the person is financially unable to pay the amount of the penalty and to give a supersedeas bond

(I) If the person does not pay the amount of the penalty and the enforcement of the penalty is not stayed, the commissioner may refer the matter to the attorney general for collection of the amount of the penalty.

(J) If a monetary penalty is assessed and is not paid, the hospital license shall not be renewed.

(5) Judicial review.

(A) Judicial review of the order of the commissioner is:

(i) instituted by filing a petition as provided by §19, Administrative Procedure Act, Government Code, Chapter 2001, and its subsequent amendments; and

(ii) under the substantial evidence rule

(B) If the court sustains the occurrence of the violation, the court may uphold or reduce the amount of the penalty and order the person to pay the full or reduced amount of the penalty.

(C) If the court does not sustain the occurrence of the violation, the court shall order that no penalty is owed.

(D) When the judgment of the court becomes final, the court shall proceed as follows.

(i) If the person paid the amount of the penalty and if that amount is reduced or is not upheld by the court, the court shall order that the appropriate amount plus accrued interest be remitted to the person within 30 calendar days after the judgment of the court becomes final.

(I) The rate of the interest is the rate charged on loans to depository institutions by the New York Federal Reserve Bank

(II) The interest shall be paid for the period beginning on the date the penalty was paid and ending on the date the penalty is remitted.

(ii) If the person gave a supersedeas bond and if the amount of the penalty is not upheld by the court, the court shall order the release of the bond.

(iii) If the person gave a supersedeas bond and if the amount of the penalty is reduced, the court shall order the release of the bond after the person pays the amount.

(E) A penalty collected under these rules shall be remitted to the comptroller for deposit in the general revenue fund.

(b) A penalty may be assessed against hospitals providing mental health services, chemical dependency services, or comprehensive medical rehabilitation services when a violation occurs on one or more of these services.

(1) Authority. The director may impose an administrative penalty against a person licensed or regulated under this chapter who violates this chapter or a rule or order adopted under this chapter relating to the provision of mental health, chemical dependency, or comprehensive medical rehabilitation services.

(2) Penalty limits. The penalty for hospitals providing mental health, chemical dependency, or comprehensive medical rehabilitation services, when the violation occurs on one or more of these services, shall:

(A) not exceed $25,000 for each violation; and

(B) consider each day a violation continues or occurs as a separate violation.

(3) Amount of penalty. The amount of the penalty shall be based on:

(A) the seriousness of the violation, including the nature, circumstances, extent, and gravity of any prohibited acts, and the hazard or potential hazard created to the health, safety, or economic welfare of the public;

(B) enforcement costs relating to the violation;

(C) the history of previous violations;

(D) the amount necessary to deter future violations;

(E) efforts to correct the violation; and

(F) any other matter that justice may require.

(4) Penalty process.

(A) If the director determines that a violation has occurred, the director shall issue a report that states the facts on which the determination is based and the director's recommendation on the imposition of a penalty, including a recommendation on the amount of the penalty.

(B) Within 14 calendar days after the date the report is issued, the director shall give written notice of the report to the person delivered by certified mail. The notice shall:

(i) include a brief summary of the alleged violation;

(ii) include a statement of the amount of the recommended penalty; and

(iii) inform the person of the right to a hearing on the occurrence of the violation, the amount of the penalty, or both

(C) Within 20 calendar days after the date the person receives the notice, the person in writing may:

(i) accept the determination and recommended penalty of the director; or

(ii) make a written request for a hearing on the occurrence of the violation, the amount of the penalty, or both.

(D) If the person accepts the determination and recommended penalty of the director, the commissioner by order shall approve the determination and impose the recommended penalty.

(E) If the person requests a hearing or fails to respond timely to the notice, the department shall set a hearing

and give notice of the hearing to the person.

(i) The administrative law judge shall make findings of fact and conclusions of law and promptly issue to the commissioner a proposal for a decision about the occurrence of the violation and the amount of a proposed penalty.

(ii) Based on the findings of fact, conclusions of law, and proposal for a decision, the commissioner by order shall:

(I) find that a violation has occurred and impose a penalty; or

(II) find that no violation has occurred.

(iii) The notice of the commissioner's order given to the person under the Administrative Procedure Act, Government Code, Chapter 2001, shall include a statement of the right of the person to judicial review of the order.

(F) Within 30 calendar days after the date the commissioner's order is final as provided by §16(c), Administrative Procedure Act, Government Code, Chapter 2001, the person shall:

(i) pay the amount of the penalty;

(ii) pay the amount of the penalty and file a petition for judicial review contesting the occurrence of the violation, the amount of the penalty, or both; or

(iii) without paying the amount of the penalty, file a petition for judicial review contesting the occurrence of the violation, the amount of the penalty, or both.

(G) Within the 30 day period, a person, who acts under subparagraph (F) (iii) of this paragraph, may:

(i) stay enforcement of the penalty by:

(I) paying the amount of the penalty to the court for placement in an escrow account; or

(II) giving to the court a supersedeas bond that is approved by the court for the amount of the penalty and that is effective until all judicial review of the commissioner's order is final; or

(ii) request the court to stay enforcement of the penalty by:

(I) filing with the court a sworn affidavit of the person stating that the person is financially unable to pay the amount of the penalty and is financially unable to give the supersedeas bond; and

(II) sending a copy of the affidavit to the commissioner by certified mail.

(H) Within five calendar days after the receipt of a copy of an affidavit, the commissioner may contest the affidavit by filing with the court.

(i) The court shall hold a hearing on the facts alleged in the affidavit as soon as practicable and shall stay the enforcement of the penalty on findings that the alleged facts are true.

(ii) The person who files an affidavit has the burden of proving that the person is financially unable to pay the amount of the penalty and to give a supersedeas bond.

(I) If the person does not pay the amount of the penalty and the enforcement of the penalty is not stayed, the commissioner may refer the matter to the attorney general for collection of the amount of the penalty.

(J) If a monetary penalty is assessed and not paid, the hospital license shall not be renewed.

(5) Judicial review.

(A) Judicial review of the order of the commissioner is:

(i) instituted by filing a petition as provided by §19, Administrative Procedure Act, Government Code, Chapter 2001; and

(ii) under the substantial evidence rule.

(B) If the court sustains the occurrence of the violation, the court may uphold or reduce the amount of the penalty and order the person to pay the full or reduced amount of the penalty.

(C) If the court does not sustain the occurrence of the violation, the court shall order that no penalty is owed.

(D) When the judgment of the court becomes final, the court shall proceed as follows.

(i) If the person paid the amount of the penalty and if that amount is reduced or is not upheld by the court, the court shall order that the appropriate amount plus accrued interest be remitted to the person.

(I) The rate of the interest is the rate charged on loans to depository institutions by the New York Federal Reserve Bank.

(II) The interest shall be paid for the period beginning on the date the penalty was paid and ending on the date the penalty is remitted.

(ii) If the person gave a supersedeas bond and if the amount of the penalty is not upheld by the court, the court shall order the release of the bond.

(iii) If the person gave a supersedeas bond and if the amount of the penalty is reduced, the court shall order the release of the bond after the person pays the amount.

(E) A penalty collected under this section shall be remitted to the comptroller for deposit in the general revenue fund.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 15, 1995.

TRD-9503188 Susan K Steeg
General Counsel
Texas Department of Health

Earliest possible date of adoption: April 21, 1995

For further information, please call: (512) 458-7236

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Subchapter I. Cooperative Agreements

• 25 TAC §133.131

(Editor's note: The text of the following section proposed for repeal will not be published. The section may be examined in the offices of the Texas Department of Health or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeal is proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313,

which provides the board with the authority to adopt rules concerning cooperative agreements, Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services, and §12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health

Health and Safety Code (HSC), Chapters 61, 81 172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code, Human Resources Code, Chapter 48; Family Code, Chapter 34, Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102, Government Code Title 4, Chapter 418, Texas Water Code, §§5 103 and 5 105, 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note, 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act, 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30), 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed action

§133 131 Cooperative Agreements and Certificates of Public Advantage.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt

Issued in Austin, Texas, on March 15, 1995

TRD-9503199 Susan K Steeg
General Counsel
Texas Department of Health

Earliest possible date of adoption April 21, 1995

For further information, please call: (512) 458-7236

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Subchapter K. Internal Investigation

• 25 TAC §133.131

The new section is proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices; Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection, and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health, Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals, Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements, Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services, and Section 12 001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health

Health and Safety Code (HSC), Chapters 61, 81 172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773, HSC, Title 7 Subtitle C, Texas Mental Health Code, Human Resources Code, Chapter 48, Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102, Government Code Title 4, Chapter 418, Texas Water Code, §5.103 and §5 105; 42 United States Code (USC), Chapter 126, 42 USC, §§201, 201 note, 263a, and 263a note, 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30), 21 USC, §853 and §881, and The Rehabilitation Act of 1973, §504 are affected by this proposed new action

§133 131 Complaints Against the Department

(a) A hospital may register with the Health Facility Licensure and Certification Division a complaint against a division surveyor who conducts an inspection or investigation

(b) A complaint against a surveyor shall be registered with and shall be submitted in writing to the Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199, telephone 1-800-228-1570

(1) When a complaint against a surveyor is received by telephone, it shall be referred within two working days to the appropriate supervisor The caller shall be requested to submit the complaint in writing to the department

(2) When a complaint is received in writing, it shall be forwarded to the appropriate supervisor within two working days. Within ten calendar days of receipt of the written complaint, the division shall inform the complainant in writing that the complaint has been forwarded to the appropriate supervisor.

(3) Within ten calendar days of the supervisor's receipt of the complaint, the supervisor shall notify the complainant in writing that an investigation will be done

(4) The supervisor shall review the documentation in the survey packet and interview the surveyor identified in the complaint to obtain facts and assess the objectivity of the surveyor in the surveyor's application of this chapter during the hospital's inspection or investigation.

(5) The supervisor shall review the applicable rules, personnel policies, and review the training and qualifications of the surveyor as it relates to the inspection or investigation

(6) The supervisor shall document the investigation. A report of the investigation shall be placed in the hospital's file if the complaint and investigation affected the inspection process. A counseling form shall be used and placed in the surveyor's personnel file if the complaint relates to personnel performance

(7) The supervisor shall offer to meet with the complainant to resolve the issue. The surveyor identified in the complaint shall participate in the discussion The resolution meeting may be conducted at the division's office or during an on-site follow-up visit to the hospital.

(8) Changes and deletions shall be made to the inspection report, if necessary

(9) The supervisor shall notify the complainant in writing of the status of the investigation within 30 calendar days of the date the supervisor received the complaint

(10) The supervisor shall forward all final documentation to the director and notify the complainant of the results

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt

Issued in Austin, Texas, on March 15, 1995

TRD-9503189 Susan K Steeg
General Counsel
Texas Department of Health

Earliest possible date of adoption: April 21, 1995

For further information, please call: (512) 458-7236

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Subchapter L. Cooperative Agreements

• 25 TAC §133.141

The new section is proposed under the Health and Safety Code, Chapter 161, which provides the Texas Board of Health (board) with the authority to adopt rules concerning abuse, neglect, and unprofessional or unethical conduct in health care facilities; Chapter 164, which provides the board with the authority to adopt rules concerning treatment facilities' marketing and admission practices, Chapter 222, which provides the board with the authority to adopt rules concerning health care facility surveys, construction, inspection,

and regulation; Chapter 241, which provides the board with the authority to adopt rules concerning general and special hospitals to be licensed by the Texas Department of Health; Chapter 311, which provides the board with the authority to adopt rules concerning powers and duties of hospitals; Chapter 313, which provides the board with the authority to adopt rules concerning cooperative agreements; Chapter 321, which provides the board with the authority to adopt rules concerning provision of mental health, chemical dependency, and rehabilitation services; and Section 12.001 which provides the board with the authority to adopt rules for the performance of every duty imposed by law upon the board, the department, and the commissioner of health.

Health and Safety Code (HSC), Chapters 61, 81.172, 85, 181, 191-195, 361, 366, 381, 382, 401, 431, 464, 481, 483, 502, 506, 507, 611, 671, 692, 711, 754, 755, 773; HSC, Title 7 Subtitle C, Texas Mental Health Code; Human Resources Code, Chapter 48; Family Code, Chapter 34; Texas Civil Statutes, Articles 4513-4528c, 4542a-1, 4495b, 9100, and 9102; Government Code Title 4, Chapter 418; Texas Water Code, §5.103 and §5.105; 42 United States Code (USC), Chapter 126; 42 USC, §§201, 201 note, 263a, and 263a note; 42 USC, §§1102, 1136, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; 42 USC, §§1302, 1320bb, 1338, 1395f(a)(6), 1395x(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396(a), and 1396(a)(30); 21 USC, §853 and §881; and The Rehabilitation Act of 1973, §504 are affected by this proposed new action.

§133.141. Cooperative Agreements and Certificates of Public Advantage.

(a) Purpose. The purpose of this section is to establish procedures to implement the Health and Safety Code (HSC), Chapter 313, as added by Chapter 638, 73rd Legislature, Regular Session, 1993 (House Bill 1884), by which hospitals may enter into cooperative agreements with other hospitals in the state.

(b) Review of cooperative agreements.

(1) Hospitals which are parties to a cooperative agreement shall file an application with the department for a certificate of public advantage governing the cooperative agreement.

(A) Only persons licensed as a hospital under the HSC, Chapter 241 or 577, may be parties to the cooperative agreement.

(B) The cooperative agreement shall be filed at least 120 calendar days prior to the effective date of the agreement.

(C) The cooperative agreement shall be executed by all parties.

(D) The application shall be filed jointly by all parties to the cooperative agreement; however, the parties shall designate one person to be the contact person with the department.

(2) The application shall include:

(A) a table of contents;

(B) a written copy of the cooperative agreement;

(C) the exact name of each party and the address of the principal business office of each party;

(D) the name of the registered agent and address of the registered office for each party which is a corporation;

(E) the name, address, and telephone number of one contact person authorized to receive notices and communications with respect to the application;

(F) a notarized statement by a responsible officer or partner, as appropriate, of each party attesting to the accuracy and completeness of the enclosed information;

(G) a brief summary of the nature and scope of the cooperative agreement;

(H) a description of any consideration passing to any party;

(I) a statement of the likely benefits resulting from the cooperative agreement addressing one or more of the benefits of the cooperative agreement listed in the HSC, §313.002(e) and any other benefits;

(J) a statement of the disadvantages attributable to a reduction in competition that might result from the cooperative agreement addressing each appropriate factor listed in the HSC, §313.002 (f) and any other factors which should be considered;

(K) a statement of how and why the likely benefits resulting from the cooperative agreement outweigh the disadvantages attributable to a reduction in competition that might result from the cooperative agreement;

(L) a description of the geographic territory to be served by the health care equipment, facilities, personnel, or services which are the subject of the cooperative agreement;

(M) if the geographic territory described in subparagraph (L) of this paragraph is different from the territory in which the parties have provided similar health care equipment, facilities, personnel, or services over the last five years, a description of how and why the geographic territory differs;

(N) identification of whether and how any services, personnel, facilities, or health care equipment similar to those covered by the cooperative agreement are currently being offered to or utilized by other health care providers, facilities, or patients in the geographic territory described in subparagraph (L) of this paragraph;

(O) identification of the steps necessary under current market and regulatory conditions for other parties to enter the territory described in subparagraph (L) of this paragraph and compete with the parties to the cooperative agreement in the delivery of health care services which are the subject of the cooperative agreement;

(P) a description of the previous history of business transactions involving the delivery of health care services which are the subject of the cooperative agreement between the parties to the cooperative agreement;

(Q) a detailed explanation of the projected effects, including expected volume, change in price, and increased revenue, of the proposed cooperative agreement on each party;

(R) the present share of the health care services which are the subject of the cooperative agreement of each party to the cooperative agreement and of other health care providers or facilities affected by the cooperative agreement and projected shares of that health care market after implementation of the cooperative agreement;

(S) a statement of why the projected levels of cost, access, or quality could not be achieved in the existing market without the cooperative agreement;

(T) an explanation of how the cooperative agreement relates to any likely adverse impact or reduction in com-

petition effecting negotiation of optimal payment and service arrangements or the furnishing of goods or services including quality, availability, and price;

(U) an explanation of the availability of arrangements that are less restrictive to competition and achieve similar benefits;

(V) a detailed explanation of how the cooperative agreement will affect cost, access, and quality of services provided by each party;

(W) a non-refundable application fee in the amount of $10,000;

(X) the proposed effective date of the agreement; and

(Y) if the parties to the application desire a public hearing, a written request for a public hearing.

(3) A copy of the application and copies of all additional related materials shall be submitted to the Office of the Attorney General, Antitrust Division, Austin, Texas and to the Texas Department of Health (department) at the same time.

(4) The department shall determine whether the application is complete within 30 calendar days of receipt of an application. If the department determines that an application is unclear, incomplete, or provides an insufficient basis on which to base a decision, the department shall return the application and specify the additional information required. The applicant shall complete or revise the application and resubmit it.

(5) The application shall not be considered to be filed until a complete application is received by the department, including additional information requested under paragraph (4) of this subsection.

(6) Any person may request a public hearing within 30 calendar days of the filing of an application.

(A) The department shall inform the applicants in writing and publish in the Texas Register the date, time, and location of the public hearing.

(B) The purpose of the hearing shall be to receive public comments on the application.

(C) The comments shall be considered by the department and the attorney general in the determination on the request for a certificate of public advantage.

(7) Any person may request a copy of the application with the supporting documentation at the person's expense.

(8) The department shall consult with the attorney general on every application.

(9) The department shall grant or deny the application within 120 calendar days of the date of filing of the application

(10) The department shall issue a certificate of public advantage for a cooperative agreement if it determines that the applicants have demonstrated by clear and convincing evidence that the likely benefits resulting from the agreement outweigh any disadvantages attributable to a reduction in competition that may result from the agreement.

(A) The certificate of public advantage shall include the terms by which the application was approved and shall contain any conditions by which the department and the attorney general shall monitor the benefits and disadvantages resulting from the approved agreement.

(B) The certificate of public advantage shall be signed by the commissioner of health.

(c) Denial of an application. If the department determines that there is not clear and convincing evidence that the likely benefits resulting from the agreement outweigh any disadvantages attributable to a reduction in competition that may result from the cooperative agreement, the department shall deny the application. The department's informal hearing procedures in Chapter 1 of this title (relating to Texas Board of Health) shall apply.

(d) Periodic submission of measurable data. A decision approving an application shall require the periodic submission of specific data relating to cost, access, and quality and, to the extent feasible, identify objective standards of cost, access, and quality by which the success of the arrangement will be measured. If the department determines that the scope of a particular proposed arrangement is such that the arrangement is certain to have neither a positive nor negative impact on one or two of the criteria, the department's decision need not require the submission of data or establish an objective standard relating to those criteria.

(e) Monitoring of cooperative agreements. The department shall appropriately supervise, monitor, and regulate approved arrangements.

(1) The department shall require the parties to an approved cooperative agreement to submit information and supporting data on an annual basis regarding the current status of the agreement, including information relative to the continued benefits and any disadvantages of the agreement.

(2) The information and supporting data that must be submitted to the department by hospitals under paragraph (1) of this subsection shall include:

(A) any proposed change in the cooperative agreement;

(B) any change in the name or address of the principal business office of each party;

(C) any change in the address of the registered agent or the address of the registered office of each party which is a corporation;

(D) a statement concerning how and why the benefits resulting from the cooperative agreement outweigh any disadvantages attributable to a reduction in competition resulting from the agreement;

(E) any change in the geographic territory that is served by the health care equipment, facilities, personnel, or services which are subject of the cooperative agreement;

(F) a detailed explanation of the actual effects of the agreement on each party, including any change in volume, market share, prices, and revenues;

(G) an explanation of how the cooperative agreement has impacted the ability of health care payors to negotiate optimal payment and service arrangements with health care providers; and

(H) a detailed explanation of how the cooperative agreement has affected the cost, access, and quality of services provided by each party.

(3) If, at any time following the approval of a cooperative agreement, the department determines that there may have been a change in the facts or circumstances under which the agreement was approved, the department may require the parties to the agreement to submit information required by paragraph (2) of this subsection and any other information needed by the department to determine whether the benefits of the approved agreement continue to outweigh any disadvantages attributable to a reduction in competition resulting from the agreement If requested, the department shall hold a public hearing to solicit addi-

tional information concerning the effects of the cooperative agreement.

(4) Following its review of any information submitted or received under paragraph (2) or (3) of this subsection, the department shall notify the parties to the cooperative agreement whether they are in compliance with the approved certificate of public advantage. If the parties are not in compliance with the requirements of the certificate, the department shall identify the manner in which the parties are out of compliance and shall provide an opportunity for the parties to bring the agreement into compliance.

(5) Hospitals receiving notification that an arrangement is not in compliance with the certificate of public advantage have 30 calendar days from receipt of the notice in which to respond with additional data or rationale concerning the validity of the cooperative agreement. This response shall include a proposal and a time schedule by which the hospitals will bring the arrangement into compliance with a certificate of public advantage. If the arrangement is not in compliance and the department and the hospitals cannot agree to the terms of bringing the arrangement into compliance, the matter shall be set for a contested case hearing.

(6) If the department determines that as a result of changed circumstances, the benefits from an approved agreement no longer outweigh any disadvantages attributable to a reduction in competition resulting from the agreement, the department may initiate proceedings to terminate the certificate of public advantage.

(f) Termination. The department may terminate a certificate of public advantage in accordance with the Health and Safety Code, §313.004 and the department's informal hearing procedures in Chapter 1 of this title (relating to Board of Health) if:

(1) the arrangement is not in substantial compliance with the terms of the application;

(2) the arrangement is not in substantial compliance with the conditions of approval;

(3) the arrangement has not and is not likely to substantially achieve the improvements in cost, access, or quality identified in the approval order as the basis for the department's approval of the arrangement; or

(4) the conditions in the marketplace have changed to such an extent that competition would promote reductions in cost and improvements in access and quality better than does the arrangement at issue. In order to terminate on the basis that conditions in the marketplace have changed, the department's order shall identify specific changes in the marketplace and articulate why those changes warrant termination

(g) Notice. The department shall begin a proceeding to terminate approval by providing written notice to the applicant describing in detail the basis for the proposed termination.

(h) Procedure. A proceeding to terminate an approval shall be conducted as a contested case proceeding upon the written request of the applicant. Decisions of the department in a proceeding to terminate approval are subject to judicial review.

(i) Alternatives to termination. In deciding whether to terminate an approval, the department shall take into account the hardship that the termination may impose on the applicant and any potential disruption of the market as a whole The department shall not terminate an approval if the arrangement can be modified, restructured, or regulated so as to remedy the problem upon which the termination proceeding is based. The applicant may submit proposals for alternatives to termination. An approved modified or restructured arrangement is subject to appropriate supervision.

(j) Impact of termination. The applicant cannot be held liable under federal or state antitrust laws for acts that occurred while the approval was in effect, except to the extent that the applicant failed to substantially comply with the terms of its application or failed to substantially comply with the terms of the approval. The applicant is fully subject to federal and state antitrust laws after the termination becomes effective and shall be held liable for acts that occur after the termination.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 15, 1995.

TRD-9503190 Susan K Steeg
General Counsel
Texas Department of Health

Earliest possible date of adoption: April 21, 1995

For further information, please call: (512) 458-7236

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TITLE 28. INSURANCE

Part II. Texas Workers' Compensation Commission

Chapter 126. General Provisions Applicable to All Benefits

• 28 TAC §126.10

The Texas Workers' Compensation Commission proposes new §126.10, concerning the designated doctor list The commission simultaneously proposes an amendment to existing §130.6, concerning general provisions regarding designated doctors The amendment is published elsewhere in this issue of the *Texas Register* New §126 10 is proposed in order to establish a list of doctors approved by the commission and afforded the privilege to perform medical evaluations to resolve disputes regarding certification of maximum medical improvement and/or assignment of impairment rating The proposed new rule requires designated doctors to be active on the Approved Doctor List as well as have commission-approved training in the assignment of impairment ratings, and requires all doctors to apply to the commission for possible addition to the Designated Doctor List The proposed new rule also establishes specific criteria for approval, suspension and removal of doctors from the Designated Doctor List, as well as requiring that designated doctors comply with all the requirements as set forth in §130.6 of this title (relating to Designated Doctor General Provisions) The proposed new rule also establishes a process for suspending or removing doctors from the Designated Doctor List

Janet Chamness, Chief of Budget, has determined that for the first five-year period the rule is in effect there will be no fiscal implications for state or local governments as a result of enforcing or administering the rule

Ms Chamness also has determined that for each year of the first five years the rule is in effect the public benefits anticipated as a result of enforcing the rule will be establishment of standard requirements for doctors to serve in the capacity as a designated doctor, better medical evaluation of an injured employee because only doctors who have completed commission-approved training will be allowed to serve as a designated doctor for determination of maximum medical improvement and/or assignment of an impairment rating, and establishment of a qualified, objective, and available pool of doctors to serve as designated doctors with presumptive or conclusive weight given to their medical opinions

There will be minimal anticipated economic costs to persons required to comply with the new rule. The doctors approved to serve as designated doctors will incur a minimal additional cost as the result of the proposed requirement that they attend commission-approved training in the proper use of the AMA Guides prior to or within six months after the effective date of this amended rule and successfully complete commission-

approved training at least every two years from the date of the last training In addition, the health care providers who perform testing and psychological testing for the designated doctor will also incur a minimal additional cost as the result of the proposed requirement that they attend commission-approved training in the application of the AMA Guides

The rule may result in savings to insurance carriers and health care providers, caused by a potential decrease in the number of dispute resolution proceedings to resolve the issues of certification of maximum medical improvement and assessment of impairment

There will be no difference in the costs of compliance with the proposed rule as amended for small businesses and large businesses

Comments on the proposal will be accepted for at least 30 days after publication of this document in the *Texas Register* and may be submitted to Elaine Crease, Office of the General Counsel, Mailstop #4-D, Texas Workers' Compensation Commission, Southfield Building, 4000 South IH-35, Austin, Texas 78704-7491

The new rule is proposed under the Texas Labor Code, §402 061, which authorizes the commission to adopt rules necessary to administer the Act, and the Texas Labor Code, §408.121, which describes when an employee becomes entitled to impairment income benefits, and when the benefits end, as well as when the insurance carrier begins to pay impairment income benefits, states that the benefits shall be paid for a period based on the impairment rating, unless that rating is disputed, and, if disputed, that the carrier shall pay the employee impairment income benefits for a period based on the carrier's reasonable assessment of the correct rating; §408.122, which describes the criteria for deciding an employee's eligibility for impairment income benefits and, in a dispute, gives the commission the authority to choose a designated doctor to examine the employee, and to direct the employee to be examined by the designated doctor, whose opinion has presumptive weight, §408.123, which states the procedural requirements for certification of maximum medical improvement and evaluation of the impairment rating; §408.124, which states that an award of impairment income benefits shall be based on the standards in *Guides to the Evaluation of Permanent Impairment*, third edition, second printing, dated February 1989, published by the American Medical Association, §408.125, which describes the procedural requirements of the dispute resolution process when there is a dispute as to an impairment rating, and states that the presumptive opinion of a designated doctor mutually agreed upon by both parties to the dispute will control, and that the designated doctor chosen by the commission has presumptive weight, unless the other medical evidence is to the contrary, in which case the commission shall adopt the impairment rating of one of the other doctors; §413.002, which gives the commission authority to monitor health care providers, insurance carriers, and workers' compensation claimants who receive medical services to ensure the compliance of those persons with rules adopted by the commission relating to health care, and gives the commission the authority to implement Chapter 413 under the policies and rules adopted by the commission, §413.011, which requires the commission by rule to establish medical policies and guidelines relating to fees charged or paid for medical services for employees who suffer compensable injuries, use of medical services by employees, and fees charged, as well as requiring the commission to design medical policies to ensure the quality of medical care and to achieve effective cost control, and §413 053, which requires the commission by rule to establish standards of reporting and billing governing both form and content The proposed new rule also contains provisions included to comply with pending amendments to the Texas Labor Code, §§408 122, 408.125, and 413 002, and the addition of §413 044 These revisions to the Texas Labor Code are contained in House Bill 1089 filed and currently pending before the 74th Legislature In the event it is adopted by the 74th Legislature, House Bill 1089 will provide additional statutory authority for this proposed new rule

This proposed new rule affects the following statutes Texas Labor Code, §402 061, §§408 121-408 125, 413 002, 413 011(a), (b), (d), and §413 053

§126.10 Commission Approved List of Designated Doctors.

(a) The following words and terms, when used in this section, will have the following meanings, unless the context clearly indicates otherwise.

(1) Designated Doctor List-A list of doctors approved by the commission and afforded the privilege to perform medical evaluations to resolve disputes regarding certification of maximum medical improvement and/or assignment of impairment rating.

(2) AMA Guides-Guides to the Evaluation of Permanent Impairment, third edition, second printing, dated February 1989, published by the American Medical Association.

(3) Division-The Medical Review Division of the Texas Workers' Compensation Commission.

(b) Doctors included in the Designated Doctor List shall:

(1) be currently active on the list of approved doctors as set forth in the Texas Labor Code, §408.023 (relating to List of Approved Doctors);

(2) have successfully completed commission-approved training in the proper use of the AMA Guides prior to or within six months after the effective date of this section and successfully complete commission-approved training at least every two years from the date of the last training,

(3) schedule appointments to examine employees for a date as set forth in §130.4 and §130.5 of this title (relating to Presumption that Maximum Medical Improvement has been Reached and Resolution when MMI has not been Certified; and Impairment Rating Disputes, respectively);

(4) reschedule the examination for a date as set forth in §130.4 and §130.5 of this title (relating to Presumption that Maximum Medical Improvement has been Reached and Resolution when MMI has not been Certified; and Impairment Rating Disputes, respectively) when notified by the injured employee of a scheduling conflict;

(5) submit copies of all contracts described in subsection (c) of this section and all new, renewed or modified contracts within 30 days of entering into, renewal or modification; and

(6) comply with all the provisions for designated doctor as specified in §130 6 of this title (relating to Designated Doctor. General Provisions).

(c) Doctors may request to be on the Designated Doctor List by filing form TWCC-72, Designated Doctor List Application, with the division. The doctor shall attach to the application, a copy of all current contracts for professional services between the doctor and insurance carriers, employers, or adjusting firms. The division will notify the doctor of the approval or denial of the application.

(d) The division shall, in addition to the documentation submitted with the doctor's request, consider the following in determining whether to add, suspend or remove a doctor from the Designated Doctor List:

(1) any impairment ratings previously assessed and compared to like injuries;

(2) accuracy of previously assessed impairment ratings and certification of maximum medical improvement;

(3) any extensions of maximum medical improvement when self-referral is involved;

(4) previous billing or treatment practices;

(5) substantiated patient complaints against the doctor;

(6) any violation of the Texas Workers' Compensation Act or commission rules; and

(7) any licensing body or regulatory agency disciplinary action.

(e) When deemed necessary, the commission may waive any of the requirements as specified in this section for an out-of-state doctor to perform as a designated doctor.

(f) Doctors may be suspended or removed from the Designated Doctor List for noncompliance with requirements of this section or actions which include, but are not limited to, any of the following.

(1) two refusals within a 90 day period, or two consecutive refusals to perform within the required time frames, a commission requested appointment for which the doctor is qualified;

(2) two untimely submissions within a 90 day period of medical evaluation reports in accordance with §130.1 of this title (relating to Reports of Medical Evaluation, Maximum Medical Improvement and Permanent Impairment);

(3) failure to amend patterns of practice after being advised by the commission of performance requiring correction;

(4) misrepresenting or omitting information in the designated doctor application process;

(5) misrepresenting or omitting pertinent facts in medical evaluation and narrative reports;

(6) unnecessary referrals not required for the assignment of impairment rating or determination of maximum medical improvement (MMI);

(7) failure to examine and analyze a referred/supervised health care provider's testing results to ensure appropriate application of the AMA Guides;

(8) failure to timely respond to request for clarification from the commission regarding an examination; or

(9) overturned assignments of maximum medical improvement and/or impairment ratings.

(g) The division will notify a doctor in writing by certified mail, return receipt requested, or by personal delivery with receipt acknowledged, of suspension from the Designated Doctor List. The notification will include the reasons for suspension as well as details regarding how and when the doctor may be reinstated to the Designated Doctor List.

(1) The suspension will be effective from the date of receipt of the notice by the doctor.

(2) Within 14 days after receiving the suspension notice, a doctor may submit a written rebuttal relating to the suspension. The rebuttal should be sent by certified mail, return receipt requested, or by personal delivery with receipt acknowledged, to the division.

(3) The division will review the rebuttal and determine the appropriate action: reinstatement; suspension with a specified timeframe; or removal from the Designated Doctor List. The division will notify a doctor in writing of the relevant action.

(4) A doctor who has been suspended from the Designated Doctor List for the time period specified in the notification, may submit a letter to the division requesting reinstatement to the Designated Doctor List. The letter shall include a statement affirming the doctor's commitment to meet the requirements of the designated doctor rules and provide corrective measures undertaken to resolve the suspension issue. The division will evaluate the request for reinstatement and make a determination of the doctor's status on the Designated Doctor List and notify the doctor as specified in paragraph (3) of this subsection.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 14, 1995.

TRD-9503216 Susan Cory
General Counsel
Texas Workers' Compensation Commission

Earliest possible date of adoption: April 21, 1995

For further information, please call: (512) 440-3508

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Chapter 130. Impairment and Supplemental Income Benefits

Subchapter A. Impairment Income Benefits

• 28 TAC §130.6

The Texas Workers' Compensation Commission proposes an amendment to §130.6, concerning general provisions regarding designated doctors. The commission simultaneously proposes a new §126.10, concerning the designated doctor list, which is also published in this issue of the *Texas Register*. The amendment to §130.6 is proposed in order to clarify the commission requirements for doctors who serve in the capacity as designated doctors and to clarify the process for assigning designated doctors. If a dispute relating to either assignment of impairment rating or determination of maximum medical improvement exists, the proposed amendment provides for a designated doctor, either agreed to by the insurance carriers and injured employee or appointed by the commission to examine the employee. The proposed amendment requires all designated doctors to meet the conditions set forth by §126.10 of this title (relating to Commission Approved List of Designated Doctors). If a doctor is not on the Designated Doctor List, the proposed amendment clarifies that he or she may not serve as a designated doctor for the commission. The proposed amendment provides that to serve in a particular case, a designated doctor must be on the Approved Doctor List, not have previously treated or examined the injured employee, and not be economically associated with the employer or insurance carrier providing workers' compensation insurance for the injured employee. The proposed amendment also: includes the requirement for commission staff to notify the employee at several stages throughout the dispute process of the commission's requirement to adopt the impairment rating made by a mutually agreed upon designated doctor and to explain when a designated doctor's opinion has presumptive weight; requires the treating doctor to forward medical records to the designated doctor; limits the designated doctor's communication with parties before and after the examination; requires the designated doctor to perform a physical examination of the employee, holds the designated doctor responsible for the integrity of testing performed by a referral health care provider; requires submission of the medical evaluation report in accordance with §130. 1 of this title (relating to Reports of Medical Evaluation: Maximum Medical Improvement); requires the designated doctor to maintain certain records relating to the examination and referrals; addresses the time frame within which a carrier must begin payment of income benefits after a designated doctor's report; and establishes billing procedures and reimbursement amounts for designated doctor services until such time as the Medical Fee Guideline specifically addresses this issue.

Janet Chamness, Chief of Budget, has determined that for the first five-year period the rule is in effect there will be no fiscal implications for state or local governments as a result of enforcing or administering the rule.

Ms. Chamness also has determined that for each year of the first five years the rule is in effect the public benefits anticipated as a result of enforcing the rule will be possible lower costs for the health care provided because the rule establishes standard reimbursement for the designated doctor services as well as indicates all the services which are included in the service which heretofore may have been billed for separately. With the increased requirements placed on designated doctors for their expertise in application of the AMA Guides, the number of designated doctor determinations overturned in the Appeals Panel process should be greatly reduced.

There will be minimal anticipated economic costs to persons who are required to comply with the rule as amended. The doctors approved to serve as designated doctors will incur an additional cost as the result of the proposed requirement that they attend commission-approved training in the proper use of the AMA Guides prior to or within six months after the effective date of this amended rule and successfully complete commission-approved training at least every two years from the date of the last training. In addition, the health care providers who perform testing and psychological testing for the designated doctor will also incur a minimal additional cost as the result of the proposed requirement that they attend commission-approved training in the application of the AMA Guides. The fees set by this amended

rule may be a reduction for some doctors who are currently serving as designated doctors, although the latest data available to the commission do not reflect that this will be the case in the majority of instances

The rule as amended may result in savings to insurance carriers and health care providers, caused by a potential decrease in the number of dispute resolution proceedings to resolve the issues of certification of maximum medical improvement and assessment of impairment

There will be no difference in the costs of compliance with the proposed rule as amended, for small businesses and large businesses

Comments on the proposal will be accepted for at least 30 days after publication of this document in the *Texas Register* and may be submitted to Elaine Crease, Office of the General Counsel, Mailstop #4-D, Texas Workers' Compensation Commission, Southfield Building, 4000 South IH-35, Austin, Texas 78704-7491

The amendment is proposed under the Texas Labor Code, §402 061, which authorizes the commission to adopt rules necessary to administer the Act, and the Texas Labor Code, §408 121, which describes when an employee becomes entitled to impairment income benefits, and when the benefits end, as well as when the insurance carrier begins to pay impairment income benefits, states that the benefits shall be paid for a period based on the impairment rating, unless that rating is disputed, and, if disputed, that the carrier shall pay the employee impairment income benefits for a period based on the carrier's reasonable assessment of the correct rating, §408 122, which describes the criteria for deciding an employee's eligibility for impairment income benefits and, in a dispute, gives the commission the authority to choose a designated doctor to examine the employee, and to direct the employee to be examined by the designated doctor, whose opinion has presumptive weight, §408 123, which states the procedural requirements for certification of maximum medical improvement and evaluation of the impairment rating, §408 124, which states that an award of impairment income benefits shall be based on the standards in *Guides to the Evaluation of Permanent Impairment*, third edition, second printing, dated February 1989, published by the American Medical Association, §408.125, which describes the procedural requirements of the dispute resolution process when there is a dispute as to an impairment rating, and states that the presumptive opinion of a designated doctor mutually agreed upon by both parties to the dispute will control, and that the designated doctor chosen by the commission has presumptive weight, unless the other medical evidence is to the contrary, in which case the commission shall adopt the impairment rating of one of the other doctors, §413 002, which gives the commission authority to monitor health care providers, insurance carriers, and workers' compensation claimants who receive medical services to ensure the compliance of those persons with rules adopted by the commission relating to health care, and gives the commission the authority to implement Chapter 413 under the policies and rules adopted by the commission; §413.011, which requires the commission by rule to establish medical policies and guidelines relating to: fees charged or paid for medical services for employees who suffer compensable injuries, use of medical services by employees, and fees charged, as well as requiring the commission to design medical policies to ensure the quality of medical care and to achieve effective cost control; and §413.053, which requires the commission by rule to establish standards of reporting and billing governing both form and content. The proposed amendment also contains provisions included to comply with pending amendments to the Texas Labor Code, §§408.122, 408.125, and 413.002, and the addition of §413.044. These revisions to the Texas Labor Code are contained in House Bill 1089 filed and currently pending before the 74th Legislature. In the event it is adopted by the 74th Legislature, House Bill 1089 will provide additional statutory authority for this proposed rule as amended.

This proposed amendment affects the following statutes: Texas Labor Code, §402 061, §§408.122-408.125, 413.002, 413.011(a), (b), and (d), and §413. 053.

§130.6. Designated Doctor: General Provisions.

(a) If the commission receives a notice from the employee or the insurance carrier that disputes [either] maximum medical improvement **and/or** an assigned impairment rating, the commission shall notify the employee and the insurance carrier that a designated doctor, **agreed upon by the parties or chosen by the commission,** will be directed to examine the employee. **The commission's notification shall:**

(1) state that the Texas Labor Code, §408.125 requires the commission to adopt the impairment rating made by a mutually agreed upon designated doctor; and

(2) explain when the designated doctor's report has presumptive weight with respect to maximum medical improvement and/or impairment ratings as specified in the Texas Labor Code, §408.122 and §408.125.

(b) In order to be a designated doctor for a dispute, the doctor shall:

(1) be on the Designated Doctor List as described in §126.10 of this title (relating to Commission Approved List of Designated Doctors);

(2) not have previously treated or examined the employee with regard to the same injury; and

(3) not be economically associated with or share office space with the employer or insurance carrier that provides the workers' compensation insurance for the disputed claim.

(c)[(b)] After notifying the employee and the insurance carrier as specified in subsection (a) of this section, the commission shall allow the employee and insurance carrier five [ten] days to agree on a designated doctor. **An unrepresented employee shall be notified that commission staff** [The commission shall inform an unrepresented employee that an OMBUDSMAN is] **are** available to explain the contents of the agreement for a designated doctor **and the possible effects of such an agreement on future benefits. If at the end of the fifth day, a designated doctor is not agreed upon, the commission will presume that an agreement is not possible.**

(d) If the commission is notified at any time during the five day period that an agreement on a designated doctor is not possible or if the commission is not notified by the end of the fifth day, the commission shall issue an order directing the employee to be examined by a designated doctor selected by the commission. The commission shall schedule the examination for a date as set forth in §130.4 and §130.5 of this title (relating to Presumption that Maximum Medical Improvement has been Reached and Resolution when MMI has not been Certified; and Impairment Rating Disputes, respectively). The order shall specify the name, business address, and telephone number of the designated doctor, as well as the date and time of the examination.

(e)[(c)] If the employee and the insurance carrier agree on a designated doctor, the insurance carrier shall **schedule an appointment for the designated doctor to examine the employee for a date as set forth in §130.4 and §130.5 of this title (relating to Presumption that Maximum Medical Improvement has been Reached and Resolution when MMI has not been Certified; and Impairment Rating Disputes, respectively). [,within] Within three** [ten] days **after reaching agreement, the insurance carrier shall** send a confirmation letter to the employee, with a copy to the commission **and designated doctor.** The letter shall include:

(1) the **commission's file number** [workers' compensation number assigned to the claim by the commission];

(2) the employee's name, address, and social security number;

(3) the date of the injury; [and]

(4) the designated doctor's name, business address, and telephone number, and the time and date of the examination; **and**

(5) the language prescribed by the commission relating to the Texas Labor Code, §408.122 and §408.125 as

specified in subsection (a).

(f) [(d)] Upon receipt of the notification from the insurance carrier that the parties have agreed on a designated doctor, the [The] commission shall contact the employee [worker] to confirm the agreement. Upon confirmation by the employee, the commission shall send all parties an order confirming the agreement and directing the employee to be examined by the agreed-upon doctor. The order shall remind the parties of the requirements in the Texas Labor Code, §408.122 and §408.125 as specified in subsection (a) of this section. [If the commission is not notified by the end of the tenth day that an agreement has been reached, the commission shall issue an order directing the employee to be examined by a designated doctor chosen by the commission. The examination shall be held within a reasonable time after the order is made. The order shall specify the name, business address, and telephone number of the designated doctor, and the date and time of the examination.]

(g)[(e)] If a scheduling conflict exists, the employee shall contact the doctor at least 24 hours prior to the scheduled examination to reschedule [the examination to a time within ten days before or after the scheduled examination]. The 24 hour requirement will be waived in an emergency situation. The rescheduled examination shall be set for a date as set forth in §130.4 and §130.5 of this title (relating to Presumption that Maximum Medical Improvement has been Reached and Resolution when MMI has not been Certified); and established by §130.5 of this title (relating to Impairment Rating Disputes). The employee shall notify the commission of the time and date of the rescheduled examination.

(h) The treating doctor is responsible for forwarding copies of the employee's medical records including reports, radiographic films, and test results to the designated doctor. If the designated doctor has not received the medical records at least three days prior to the examination, the designated doctor's office shall notify the commission at the appropriate field office. The appropriate commission staff will send an order to the treating doctor for the delivery of medical records.

(i) To avoid undue influence on a person selected as a designated doctor under the Texas Labor Code, §408.125, only the employee or an appropriate member of the staff of the commission may communicate with the designated doctor about the case regarding the employee's medical condition or history before the examination of the employee by the designated doctor. After that examination is completed, communication with the designated doctor regarding the employee's medical condition or history may be made only through appropriate commission staff members. The designated doctor may initiate communication with any doctor who has previously treated or examined the employee for the work-related injury. Noncompliance with this section by an insurance carrier or health care provider shall constitute administrative violations under the Texas Labor Code, §406.010 and Chapter 415 respectively.

(j) An evaluation or certification under the AMA Guides shall include a physical examination and evaluation by the designated doctor. Although the AMA Guides provides that any knowledgeable physician or any other knowledgeable person may compare the clinical findings on a particular patient with the criteria in the AMA Guides, the designated doctor shall conduct a physical evaluation and is responsible for the integrity of the evaluation process. This means the designated doctor must evaluate the complete clinical and non-clinical history of the medical condition(s), perform an examination of the employee, analyze the medical history with the clinical and laboratory findings and assess and certify an impairment rating according to the AMA Guides.

(k) When performing impairment rating testing, the AMA Guides specifies that additional testing be performed if consistency requirements are not met. If additional testing remains inconsistent after six measurements, the designated doctor shall consider the test invalid and shall reschedule testing within seven days of the first testing.

(l) Range of motion, sensory, and strength testing should be performed by the designated doctor, when applicable. If this testing or psychological testing is not performed by the designated doctor, the health care provider performing the testing must have successfully completed commission-approved training in the proper use of the AMA Guides.

(m) For testing other than that listed in subsection (l) of this section, the designated doctor may authorize additional testing or refer employees to another health care provider when deemed necessary to determine whether maximum medical improvement has been reached and/or to assess an impairment rating. Any additional testing is subject to preauthorization requirements in accordance with the Texas Labor Code, §413.014 (relating to Preauthorization).

(n)[(f)] The designated doctor shall complete and file the medical evaluation report in accordance with §130.1 of this title (relating to Reports of Medical Evaluation: Maximum Medical Improvement and Permanent Impairment). **If testing must be rescheduled or the employee is referred to another health care provider as specified in subsections (k)-(m) of this section, the medical evaluation report shall be completed and filed within seven days of the rescheduled testing or referral appointment date.**

(o) The designated doctor shall maintain accurate records to reflect:

(1) the date and time of any designated doctor appointments scheduled with employees;

(2) the circumstances regarding a cancellation, no-show or other situation where the examination did not occur as scheduled;

(3) the date of the examination;

(4) the date medical records were received from the treating doctor or any other party;

(5) the date the medical evaluation report was submitted to all parties in accordance with §130.1 of this title (relating to Reports of Medical Evaluation: Maximum Medical Improvement and Permanent Impairment); and

(6) the name of all referral health care providers, date of appointments and reason for referral.

(p) The commission may:

(1) issue an order requiring timely submission of medical evaluation reports or narrative reports;

(2) issue administrative violations;

(3) issue an order for refund to the insurance carrier of the examination payment if an improper or incomplete examination or report is performed;

(4) take action to remove a doctor from the Designated Doctor List as described in accordance with §126.10 of this title (relating to Commission Approved List of Designated Doctors); and/or

(5) take action to remove a doctor from the Approved Doctor List in accordance with §126.8 of this title (relating to Commission Approved Doctor List).

(q)[(g)] The insurance carrier shall pay any accrued income benefits, and shall begin or continue to pay weekly income benefits, in accordance with the designated doctor's report, no later than five [ten] days after receipt of the report or upon receipt of an order by the commission, whichever is earlier.

(r) The designated doctor billing and reimbursement will be as established in this subsection until the designated doctor reimbursement is specifically addressed by the Medical Fee Guideline. At such time, the Medical Fee Guideline will supersede this subsection.

(1) The insurance carrier is responsible for paying the reasonable cost of a designated doctor examination.

(2) The reimbursement for determination of maximum medical improvement and/or impairment ratings shall be inclusive of:

(A) the examination;

(B) consultation with the employee;

(C) review of records and films;

(D) the preparation and submission of reports and calculation tables (worksheets);

(E) range of motion, strength, and sensory testing and measurements; and

(F) other tests used to validate the impairment rating.

(3) The reimbursement shall be the lesser of the health care provider's charged amount or the reimbursement for the applicable service specified as follows.

(A) Level I examinations are those cases where less than six months have elapsed from the date of injury and may be reimbursed up to $350.

(B) Level II examinations are those cases where more than six months but less than one year has elapsed from the date of injury and may be reimbursed up to $500.

(C) Level III examinations are those cases where more than one year has elapsed from the date of injury and may be reimbursed up to $850.

(D) Reconsideration of earlier decisions upon request of the commission based upon information not available at the initial time of examination may be reimbursed up to $150. This does not include commission requests for clarification of a previously submitted report.

(E) If the employee fails to attend the examination or cancels the commission ordered examination within 24 hours of the appointment, payment of up to $100 may be made.

(4) Regardless of the maximum allowable reimbursement specified in this subsection, the designated doctor's charge for services should correlate with the actual time and level of service involved with each patient.

(5) If testing is performed by a health care provider other than the designated doctor as specified in subsection (l) of this section, the total reimbursement of both providers shall not exceed 100% of the appropriate reimbursement listed in paragraph (3)(A)-(C) of this subsection. Each health care provider must bill for their respective services using CPT code 99199 and include the appropriate modifier: -26 for professional component (doctor examination, records review, etc.); -27 for the technical component (testing only); or -WP for the whole procedure. The total reimbursement value may be apportioned between the providers by agreement based on which party performed the required services and in accordance with medical ethics.

(6) Additional testing or referrals specified in subsection (m) of this section will be reimbursed in addition to the fees specified in paragraph (3)(A)-(C) of this subsection if the additional testing was required to perform the assignment of impairment rating and/or determination of maximum medical improvement. These services should be billed using the appropriate CPT code as specified in the Medical Fee Guideline.

(7) No payment will be made to the designated doctor until a complete medical evaluation report with required attachments has been received by the insurance carrier.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 14, 1995.

TRD-9503217 Susan Cory
General Counsel
Texas Workers' Compensation Commission

Earliest possible date of adoption: April 21, 1995

For further information, please call: (512) 440-3700

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TITLE 30. ENVIRONMENTAL QUALITY

Part I. Texas Natural Resource Conservation Commission

Chapter 321. Control of Certain Activities by Rule

Subchapter B. Commercial Livestock and Poultry Production Operations

The Texas Natural Resource Conservation Commission (Commission or TNRCC) proposes the repeal of §321.34 and new §321.34 (Subchapter B) and §§321.181-321.198 (Subchapter K), concerning concentrated animal feeding operations (CAFOs) The purpose of the proposed rules is to streamline and consolidate the existing authorization procedures under the Texas Water Code, Chapter 26 and the Texas Clean Air Act, while still maintaining air and water quality. Such streamlining shall be accomplished by: making consistent state and federal requirements; avoiding the duplication of actions of the commission and the State Soil and Water Conservation Board; shortening the application review period and making more explicit performance standards and best management practices to be utilized and/or to be met; expanding the range of operations which may be authorized by rule; providing for both air and water quality issues to be addressed in a simultaneous and comprehensive manner; and focusing the agency's limited resources on those areas of the state being designated under these proposed rules as Dairy Outreach Program Areas.

In accordance with the Texas Water Code, §26.028(e), the proposed amendment to §321.34, Procedure for Making Application for an Amendment, provides that an application to renew a permit for a confined animal feeding operation which was issued between July 1, 1974, and December 31, 1977, may be renewed by the commission at a regular meeting without holding a public hearing if the applicant does not seek to discharge into or adjacent to waters in the state and does not seek to change materially the pattern or place of disposal. Additionally, existing provisions of §321.34 are proposed to be subdivided into subsections to make the provisions more readable and understandable.

New Subchapter K, §321.181-321.198, is being proposed, in part, to make state requirements for new facilities consistent with existing, federal requirements contained in 40 CFR Part 122 relating to concentrated animal feeding operations. Subchapter K shall not, however, apply to existing facilities which were authorized under Subchapter B of this title. In addition to providing more consistency with federal requirements, Subchapter K would consolidate air and water quality requirements under a single authorization and provide that CAFOs throughout most areas in the state with a greater minimum head numbers than provided by Subchapter B be required to submit an application for an

individual permit, rather than be authorized by rule

Proposed new Subchapter K would allow a CAFO to obtain an air quality standard permit This standard permit would satisfy the Texas Clean Air Act permitting requirements so that a separate air quality permit would not be required If an applicant could not meet the air quality criteria of this Subchapter, or if the CAFO were a major source or major modification as defined in Chapter 116 of this title, then a separate air quality permit would have to be obtained

Proposed new §321 181, Waste and Wastewater Discharge and Air Emission Limitations, provides that wastewater may be discharged whenever rainfall events result in the overflow from retention facilities designed, constructed, and operated to contain wastewater and runoff from a 25-year, 24-hour rainfall event. This is consistent with existing state and federal rules The proposed rule also provides that facilities must be operated in a manner as to prevent a public health nuisance or a condition of air pollution as provided by Texas Health and Safety Code, Chapters 341 and 382

Proposed new §321.182, Definitions, contains the definitions and meanings of key words and phrases found throughout the subchapter.

Proposed new §321 183, Applicability, provides that all new concentrated animal feeding operations are subject to Subchapter K. It also provides that CAFOs which would ordinarily be authorized by rule under Subchapter K may be required to file an application to obtain an individual permit if it is necessary to protect water quality, the facility is not in compliance with the rules, or it is an existing facility seeking to expand its operations so that it may stable or confine and feed or maintain for a total of 45 days or more in any 12-month period a number of animals equal to or greater than that requiring an individual permit CAFOs in the Dairy Outreach Program Areas having greater than or equal to 300 animal units but less than 1000 animal units are required to either file an application for a permit under this subchapter or meet the education and audit requirements of §321.194, Other Requirements Any CAFOs which are not required to file an application for a permit under the provisions of this subchapter shall comply with all the requirements under §§321.191-321 195 of this subchapter, relating to Proper CAFO Operation and Maintenance, Pollution Prevention Plans, Best Management Practices, Other Requirements, and Monitoring and Reporting Requirements

This provision also prohibits new facilities on the Edward's Aquifer recharge zone consistent with existing provisions contained in Subchapter B

The proposed rule would also allow certain CAFO's to obtain an air quality standard permit authorization by meeting air quality criteria contained in Subchapter K. Qualification for the air quality standard permit authorization would be determined in the consolidated review and authorization process provided by Subchapter K. However, certain CAFO's are prohibited from using the standard permit authorization and must obtain a separate air quality permit Any CAFO which cannot meet the air quality criteria in Subchapter K must obtain air quality authorization under Chapter 116 of this title. Any CAFO which is a new major source or major modification as defined in Chapter 116 of this title must obtain an air quality permit under Chapter 116 of this title Additionally, animal feeding operations that are not required to obtain a CAFO permit under Subchapter K, may be required to obtain air quality authorization under Chapter 116 of this title (certain operations may qualify for an exemption from air quality permitting requirements)

Regardless of any authorization granted pursuant to Subchapter K, CAFO's must comply with any applicable federal air quality regulations including, but not limited to, National Emission Standards for Hazardous Air Pollutants ("NESHAPs") or New Source Performance Standards ("NSPS") Additionally, any CAFO that constitutes a major source as defined in Chapter 122 of this title must obtain a federal operating permit under that Chapter.

The rule would also exempt from Subchapter K any existing CAFO, as defined and authorized under Subchapter B of this title, which is operating under a certified water quality management plan or any facility which qualifies and obtains such a plan from the Texas State Soil and Water Conservation Board, unless the CAFO or facility is referred by the Board to the commission for non-compliance pursuant to the Texas Agriculture Code, §201 026

Finally, the proposed rule would provide that upon written request of the owner/operator a facility currently authorized by Subchapter B may be authorized under Subchapter K

Proposed new §321 184, Application Requirements, provides application content requirements and associated fees It also provides that permits issued under Subchapter K shall not exceed a term of five years, unless extended by order of the commission Finally, it provides that permitted livestock and poultry operations must provide, at the time of the initial application a minimum air quality buffer of one-quarter mile from any occupied residence or business structure, school, church, or public park unless the owner of such affected property provides written consent, in order to qualify for the air quality standard permit

Proposed new §321 185, Applications Review, provides that applications must be reviewed by the executive director for administrative and technical completeness within 15 working days of receipt of the application If the application is not complete, the executive director must notify the applicant within this review period and allow the applicant a maximum 30-day period to provide the necessary information If the applicant does not timely submit such information, the application shall be returned The proposed combination of the administrative and technical review period to 15 working days will cut in half the maximum period currently provided in Chapter 281 of this title for existing procedures relating to the review of applications

Proposed new §321.182, Notice of Application, provides notice content requirements, a 30-day published notice in a local newspaper, and mailed notice to affected persons including adjoining landowners and river authorities in the Dairy Outreach Program Areas These provisions are consistent with those applicable to other types of applications provided by Chapter 305 of this title.

Proposed new §321.187, Public Comment, provides that public comments and a request for a hearing on the application must contain certain, minimum information and must be timely submitted within 30 days of notice in order to be considered by the executive director. If the executive director receives no comments or does not receive comments demonstrating that the application does not meet the technical requirements specified in Subchapter K, request for hearing shall be denied and the permit shall be issued. The executive director shall provide copies and a response to public comments to the applicant, all commenters, and the public interest counsel If the executive director determines that the comment raises a question of technical sufficiency of the application, the executive director shall notify the applicant, all commenters, and the public interest counsel In response to such notification, the applicant shall either: withdraw the application; remedy the application if it would not constitute a major amendment to the application, request an alternative dispute resolution proceeding, or request commission review of the executive director's determination. If such action(s) are not taken by the applicant within 30 days of receipt of notice, the application shall be dismissed without prejudice If these actions other than a request for an evidentiary hearing do not address all outstanding technical merit issues to the satisfaction of the executive director, then the matter shall be referred to the Office of Hearings Examiners for an evidentiary hearing

Proposed new §321.188, Permit Issuance, provides minimum permit conditions including term, name and address of permittee, location and size of facility, operating, maintenance, monitoring, and reporting requirements as well as references to other standard permit conditions provided by Chapter 305 of this title.

Proposed new §321.189, Permit Amendment, provides that changes to the conditions of a permit require the prior approval of the commission or executive director, as applicable. It also provides that a permit shall remain effective pending a determination on the application for an amendment. These provisions are consistent with those now contained in Chapter 305 of this title.

Proposed new §321.190, Permit Renewal, provides that an application for permit renewal must be filed not later than the 180th day prior to the date the permit is to expire. It also provides required content requirements and associated fees. Finally, an application for permit renewal may be granted without a public hearing if no change to the facility is being proposed and no formal major enforcement action has been brought against the facility during the previous 36-month period. In addition to the previous provisions, any

application for renewal within a Dairy Outreach Program Area, an annual compliance inspection will have to have been completed within 12 months of the date the executive director processes the application for renewal.

Proposed new §321.191, Operation and Maintenance, requires the owner/operator of any CAFO authorized by Subchapter K to implement and document all best management practices provided by new §321.193 as well as other necessary measures contained in the facility's pollution prevention plan as provided by proposed new §321.192 or a Natural Resources Conservation Service (NRCS) plan, as applicable Copies of such records and plans shall be provided to the executive director upon request

Proposed new §321.192, Pollution Prevention Plans, requires each facility, whether authorized by permit or rule, to develop and implement a Pollution Prevention Plan (PPP) providing pollution prevention and abatement measures as specified in the rule. Provisions contained in a NRCS plan may be substituted or referenced for those in the PPP.

Proposed new §321.193, Best Management Practices, provides a list of best management practices that must be utilized by all CAFOs authorized under Subchapter K, as reasonable and appropriate, and based upon existing physical conditions. Where provisions in a NRCS plan are equivalent or more protective than those provided by this section, such provisions may be used in lieu of corresponding BMPs in this section.

In accordance with the Texas Water Code, §26.048, a CAFO authorized to discharge agricultural waste into a playa or to use a playa as a wastewater retention facility for agricultural waste before the adoption of these rules may continue such discharge provided water samples from wells at the site are tested for chlorides and nitrates. If the test results indicate a significant increase in the levels of these contaminants, the commission shall investigate the cause and require necessary corrective action.

Proposed new §321.194, Other Requirements, provides additional conditions to any authorization granted under Subchapter K including those relating to education and training, inspections and recordkeeping, internal reporting procedures, audits and visual and site inspections. Any owners/operators of CAFOs with greater than or equal to 300 animal units in the Dairy Outreach Program Areas and covered by the provisions of this subchapter are required to either obtain a permit under this subchapter or do the following: within 12 months of coming under the provisions of this subchapter, complete an eight hour course in animal waste management; complete an additional eight hours of continuing animal waste management education within each 24 month period of the initial course; and have conducted, by an independent third party, an audit at least once every five years of all aspects of the CAFO facility. The proposed rules identify the procedures and timeframes for completing the audit in a timely manner. Any facility, for which an audit has been conducted and a detailed workplan approved by the executive director, shall not be liable to the state for violations identified in subsequent inspections if the circumstances which form the basis of the violation are identified as problems in the audit and are the subject of an on-going workplan to correct the problem.

Proposed new §321.195, Monitoring and Reporting Requirements, requires an owner or operator of any facility authorized under Subchapter K to report to the executive director any discharge from the CAFO to waters into or adjacent to waters in the state. Such report must be done orally within 24 hours and in writing within five working days of the discharge. These provisions are consistent with those contained in Chapter 305 of this title.

Proposed new §321.196, Registration, requires all new CAFOs which plan or propose to confine 300 animal units under Subchapter K to register with the executive director. No fees will be imposed as the result of this registration. Any facilities which have no potential to discharge into waters in the state are not required to register.

Proposed new §321.197, Dairy Outreach Program Areas delineates certain counties in the state which are involved in the Dairy Outreach Program as of the effective date of these rules. The areas include all of the following counties: Erath, Bosque, Hamilton, Comanche, Johnson, Hopkins, Wood and Rains. Such areas must be delineated by rule. This section of the rules shall be reviewed by the commission on at least a triennial basis to determine whether counties should be added or deleted from designation.

Proposed new §321.198, Effect of Conflict or Invalidity of Rule, contains a standard severability clause providing that the invalidity of any one provision shall not affect the validity of any of the remaining provisions. Additionally, to the extent of any irreconcilable conflict between the provisions of Subchapter K and those outside the subchapter, the former shall control.

Mr. Stephen Minick, Strategic Planning and Appropriations Division, has determined that for the first five years these sections as proposed are in effect, there will be fiscal implications as a result of enforcement and administration of the sections. The effects on state government will be an estimated decrease in revenue of approximately $1,500 for each facility eligible for a consolidated permit under these rules. Adoption of the rule will result in additional costs to the state associated with the requirement to inspect the affected facilities. Exact costs of the inspections cannot be determined at this time, but the costs are anticipated to range between $60, 000 and $120,000 annually, depending on teh number of facilities which will require inspection. There are no affects anticipated for local governments.

The rule as proposed will increase costs of engineering and certification of waste management facilities at affected livestock and poultry operations. Most of these costs are also required for compliance with the federal EPA general permit for concentrated animal feeding operations and are not completely attributed to the rule as proposed here. These costs will vary on a case-by-case basis with the size, location and type of affected facility, but are anticipated to average approximately $2,000 for most operations. Because the permit that is proposed is a consolidated permit, affected operators will also realize a cost savings due to the elimination of requirements associated with application for separate water quality and air quality permits. These cost savings for cannot be determined exactly, but are anticipated to substantially mitigate the potential cost increases attributed to additional engineering and certification requirements. For all affected facilities collectively the total costs are estimated to approach or equal the total savings, however the net affect on any individual operator cannot be determined exactly. Affected operators may be defined as small businesses and the fiscal implications identified will vary for these businesses on a case- by-case basis.

Mr. Minick also has determined that for each of the first five years these sections as proposed are in effect, the public benefit anticipated as a result of enforcement of and compliance with the sections will be: simplification and more cost-effective administration of the permitting program for concentrated animal feeding operations, increased focus of water quality protection efforts on more critical areas of potential degradation, more comprehensive management of both air and water quality issues, and enhanced coordination of state and federal water quality control programs. There are no fiscal effects anticipated for any person required to comply with the sections as proposed except as previously identified.

Comments on the proposal may be submitted to Lutrecia Oshoko, Office of Policy and Regulatory Development, Texas Natural Resource Conservation Commission, P.O. Box 13087, Austin, Texas 78711-3087, not later than 5:00 p.m., April 21, 1995. For more information contact, James Kowis, Agriculture and Rural Assistance Division, at (512) 239-4709 or Mark McFarland at (521) 239-4797.

A public hearing will be held on the proposed rules on Friday, April 21, 1995, from 10:00 a.m. to 2:00 p.m. at the TNRCC Park 35 Office Complex, Building E, Room 201 S, located at 12015 North IH-35, Austin, Texas.

• 30 TAC §321.34

(Editor's note: The text of the following section proposed for repeal will not be published. The section may be examined in the offices of the Texas Natural Resources Conservation Commission or in the Texas Register office, Room 245, James Earl Rudder Building, 1019 Brazos Street, Austin.)

The repeal is proposed under the Texas Water Code, §§5.103, 5.105, 5. 120, 26.028 (c) and §26.040, which provides the commission with the authority to promulgate rules as necessary to carry out its powers and duties under the Texas Water Code and other laws of the state, and to establish and approve all general policies of the commission.

The repeal affects the Texas Health and Safety Code, §382.017, which provides the commission with the authority to adopt rules

consistent with the policy and purposes of the Texas Clean Air Act, and the Texas Water Code, §§5.103, 5.105, 5.120, 26.028 (c) and §26.040, which provides the commission with the authority to promulgate rules as necessary to carry out its powers and duties under the Texas Water Code and other laws of the state, and to establish and approve all general policies of the commission

§321.34. Procedure for Making Application for a Permit

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 15, 1995

TRD-9503208 Lydia Gonzalez Gromatzky
Acting Director, Legal Division
Texas Natural Resource Conservation Commission

Earliest possible date of adoption: April 21, 1995

For further information, please call: (512) 239-4640

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The new section is proposed under the Texas Water Code, §§5.103, 5.105, 5.120, 26.028 (c) and §26.040, which provides the commission with the authority to promulgate rules as necessary to carry out its powers and duties under the Texas Water Code and other laws of the state, and to establish and approve all general policies of the commission

The new sections affect the Texas Health and Safety Code, §382.017, which provides the Commission with the authority to adopt rules consistent with the policy and purposes of the Texas Clean Air Act

§321.34. Procedures for Making Application for a Permit.

(a) Any person whose feedlot operation does not conform to the criteria for regulation by rule set forth under §321.33 of this title (relating to Applicability) shall apply for a permit. Application for a permit shall be made on forms provided by the executive director. The applicant shall provide such additional information in support of the application as may be necessary for an adequate technical review of the application. At a minimum, the application shall demonstrate compliance with the technical requirements set forth in §321.35 of this title (relating to Surface Water Protection), §321.36 of this title (relating to Ground Water Protection), §321.37 of this title (relating to Feedlot Waste Utilization or Disposal by Land Spreading), §321.38 of this title (relating to Other Waste Disposal Methods) and §321.39 of this title (relating to Pesticide Use), or other equivalent technical requirements. Applicants shall comply with §§305.41-305.45 of this title (relating to Applicability; Application Required; Who Applies; Signatories to Applications, Contents of Application for Permit). Each applicant shall pay an application fee as required by §305.53 of this title (relating to Application Fees). An annual waste treatment inspection fee is also required of each permittee as required by §305.503 of this title (relating to Fee Assessments). Except as provided in subsections (b)-(e) of this section, each permittee shall comply with §305.61-305.68 of this title (relating to Applicability, Amendment, Renewal, Transfer of Permits, Corrections of Permits; Permit Denial, Suspension and Revocation; Revocation and Suspension Upon Request or Consent; and Action and Notice on Petition for Revocation or Suspension). Each permittee shall comply with §305.125 of this title (relating to Standard Permit Conditions). Permits authorized under this subchapter may be effective for the life of the project as determined by §305.127(1)(C) of this title (relating to Conditions to be Determined for Individuals Permits)

(b) Permit Renewal.

(1) An application to renew a permit for a confined animal feeding operation which was issued between July 1, 1974, and December 31, 1977, may be renewed by the commission at a regular meeting without holding a public hearing if the applicant does not seek to discharge into or adjacent to waters in the state and does not seek to change materially the pattern or place of disposal

(2) Except as provided by §305.63(3) of this title (relating to Consolidated Permits-Renewals), an application for a permit renewal which does not propose any other change to the permit and where there has been no related formal major enforcement action against the permitted facility during the last 36 months of the term of the permit may be granted by the executive director without a public hearing. As used in this subchapter, the term "major enforcement action" shall apply to those enforcement actions in which the executive director or the commission has determined that an unauthorized discharge has occurred; such discharge was within the reasonable control of the permittee; and such discharge could have been reasonably foreseen by the permittee. In addition to the provisions listed in this section, for any application for renewal of a permit within an area designated under §321.197 of this title (relating to Dairy Outreach Program Areas), an annual compliance inspection shall have been completed within the 12 months prior to the executive director processing the application.

(c) A fee of $315 to be applied toward processing of the application.

(d) A permittee submitting an application for renewal satisfying the criteria in subsection (b)(2) of this section will automatically be issued a notice of renewal for the existing permit by the executive director.

(e) If the application for renewal cannot meet all of the criteria in subsection (b) of this section, then an application for renewal shall be filed in accordance with subsection (a) of this section

(f) Any permittee with an issued and effective permit shall submit an application for renewal at least 180 days before the expiration date of the effective permit, unless permission for a later date has been granted by the executive director. The executive director shall provide the permittee notice of deadline for the application for renewal at least 240 days before the permit expiration date. The executive director shall not grant permission for applications to be submitted later than the expiration date of the existing permit.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 15, 1995.

TRD-9503209 Lydia Gonzalez Gromatzky
Acting Director, Legal Division
Texas Natural Resource Conservation Commission

Earliest possible date of adoption: April 21, 1995

For further information, please call: (512) 239-4640

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Subchapter K. Concentrated Animal Feeding Operations

• 30 TAC §§321.181-321.198

The new sections are proposed under the Texas Water Code, §§5.103, 5.105, 5.120, 26.028(c), and §26.040, which provides the commission with the authority to promulgate rules as necessary to carry out its powers and duties under the Codes and other laws of the state, and to establish and approve all general policies of the commission.

The new sections affect the Texas Health and Safety Code, §382.017, which provides the commission with the authority to adopt rules consistent with the policy and purposes of the Texas Clean Air Act.

§321.181. Waste and Wastewater Discharge and Air Emission Limitations.

(a) It is the policy of the Texas Natural Resource Conservation Commission that there shall be no discharge or disposal of waste and/or wastewater from animal feeding operations into or adjacent to waters

in the state, except in accordance with subsection (b) of this section, subchapter B of this title (relating to Commercial Livestock and Poultry Production Operations) or §305.1 of this title (relating to Scope and Applicability). Waste and/or wastewater generated by a concentrated animal feeding operation under this subchapter shall be retained and utilized or disposed of in an appropriate and beneficial manner as provided by commission rules, orders, authorizations or permits.

(b) Wastewater pollutants in the overflow may be discharged to waters in the state whenever rainfall events, either chronic or catastrophic, cause an overflow of process wastewater from a facility designed, constructed and operated to contain process generated wastewaters plus the runoff (storm water) from a 25-year, 24-hour rainfall event for the location of the point source (facility authorized under this subchapter). There shall be no effluent limitations on discharges from retention structures constructed and maintained to contain the 25-year, 24-hour storm event if the discharge is the result of a rainfall event which exceeds the design capacity and the retention structure has been properly maintained. Retention structures shall contain process wastewaters plus the 25-year, 24-hour storm event.

(c) Facilities shall be operated in such a manner as to prevent the creation of a nuisance or a condition of air pollution as mandated by Chapters 341 and 382 of the Texas Health and Safety Code.

§321.182. Definitions. The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

Affected person–Any person who establishes, by a demonstration of technical merit, that the proposed issuance of a permit will have an adverse effect on a personal, justiciable interest.

Agronomic rates–The land application of animal wastes and/or wastewater at rates of application which provide the crop or forage growth with needed nutrients for optimum health and growth.

Air contaminant–Particulate matter, radioactive material, dust, fumes, gas, mist, smoke, vapor, or odor or any combination thereof produced by processes other than natural. Water vapor is not an air contaminant.

Animal feeding operation–A lot or facility (other than an aquatic animal production facility) where animals have been, are, or will be stabled or confined and fed or maintained for a total of 45 days or more in any 12-month period, and the animal confinement areas do not sustain crops, vegetation, forage growth, or post harvest residues in the normal growing season. Two or more animal feeding operations under common ownership are a single animal feeding operation if they adjoin each other, or if they use a common area or system for the disposal of wastes.

Animal unit–A unit of measurement for any animal feeding operation calculated by adding the following numbers: the number of slaughter and feeder cattle and dairy heifers multiplied by 1.0, plus the number of mature dairy cattle multiplied by 1.4, plus the number of swine weighing over 55 pounds multiplied by 0.4, plus the number of sheep multiplied by 0.1, plus the number of horses/mules multiplied by 2.0.

Aquifer–A saturated permeable geologic unit that can transmit, store and yield to a well, the quality and quantities of ground water sufficient to provide for a beneficial use. An aquifer can be composed of unconsolidated sands and gravels, permeable sedimentary rocks such as sandstones and limestones, and/or heavily fractured volcanic and crystalline rocks. Ground water within an aquifer can be confined, unconfined or perched.

Auction market–Any person engaged in the business of buying or selling livestock on a commission basis; or furnishing stockyard services for livestock producers, feeders, market agencies, and buyers. Stockyard services include pens or other enclosures and their appurtenances, in which live cattle, sheep, goats, swine, horses/mules are received, held, or kept for sale or shipment. For the purposes of this subchapter, the term auction market is synonymous with the terms sale ring, auction barn, livestock commission companies and livestock sale barn, as these terms are commonly used in the agriculture industry.

Best Management Practices ("BMPs")–The schedules of activities, prohibitions of practices, maintenance procedures , and other management practices to prevent or reduce the pollution of waters in the state. Best Management Practices also include treatment requirements, operating procedures, and practices to control site runoff, spillage or leaks, sludge or waste disposal, or drainage from raw material storage.

Chronic or catastrophic rainfall event–For the purposes of these rules, these terms shall mean a series of rainfall events which would not provide opportunity for dewatering and which would be equivalent to or greater than the 25-year, 24-hour storm event or any single event which would be equivalent to or greater than the 25-year, 24-hour storm event. Catastrophic conditions could include tornados, hurricanes, or other catastrophic conditions which could cause overflow due to the high winds or mechanical damage.

Commission–The Texas Natural Resources Conservation Commission.

Concentrated animal feeding operation "CAFO"–Any animal feeding operation which the executive director designates as a significant contributor of pollution or any animal feeding operation defined as follows:

(A) Any new and existing operations which stable and confine and feed or maintain for a total of 45 days or more in any 12-month period more than the numbers of animals specified in any of the following categories:

(i) 1,000 slaughter or feeder cattle;

(ii) 700 mature dairy cattle (whether milkers or dry cows);

(iii) 2,500 swine weighing over 55 pounds;

(iv) 500 horses;

(v) 10,000 sheep;

(vi) 55,000 turkeys;

(vii) 100,000 laying hens or broilers when the facility has unlimited continuous flow watering systems;

(viii) 30,000 laying hens or broilers when facility has a liquid waste handling system;

(ix) 5,000 ducks; or

(x) 1,000 animal units from a combination of slaughter steers and heifers, mature dairy cattle, swine over 55 pounds and sheep.

(B) Any new and existing operations covered under this subchapter which discharge pollutants into waters in the state either through a man-made ditch, flushing system, or other similar man-made device, or directly into the waters in the state, and which stable or confine and feed or maintain for a total of 45 days or more in any 12-month period more than the numbers or types of animals in the following categories:

(i) 300 slaughter or feeder cattle;

(ii) 200 mature dairy cattle (whether milkers or dry cows);

(iii) 750 swine weighing over 55 pounds;

(iv) 150 horses;

(v) 3,000 sheep;

(vi) 16,000 turkeys;

(vii) 30,000 laying hens or broilers when the facility has unlimited continuous flow watering systems;

(viii) 9,000 laying hens or broilers when facility has a liquid waste

handling system;

(ix) 1,500 ducks; or

(x) 300 animal units from a combination of slaughter steers and heifers, mature dairy cattle, swine over 55 pounds and sheep

(C) Provided, however, that no animal feeding operation is a concentrated animal feeding operation as defined above if such animal feeding operation discharges only in the event of a 25-year, 24-hour storm event. Poultry facilities that have no discharge to waters in the state normally are not considered a concentrated animal feeding operation. However, poultry facilities that use a liquid waste handling system or stockpile litter near watercourses or dispose of litter on land such that stormwater runoff or flooding can wash it into surface water or ground water may be considered a concentrated animal feeding operation. For the purposes of this subchapter, the term CAFO includes any associated feed handling and/or feed milling operations located on the same site as the CAFO.

Control facility-Any system used for the retention of wastes on the premises until their ultimate disposal. This includes the collection and retention of manure, liquid waste, process wastewater and runoff from the feedlot area.

Dairy Outreach Program Areas-The areas of the state involved in the commission's Dairy Outreach Program as of the effective date of these rules. The areas include all of the following counties: Erath, Bosque, Hamilton, Comanche, Johnson, Hopkins, Wood and Rains.

Edwards Aquifer-That portion of an arcuate belt of porous, waterbearing limestones composed of the Comanche Peak, Edwards,and Georgetown formations trending from west to east to northeast through Kinney, Uvalde, Medina, Bexar, Comal, Hays, Travis and Williamson Counties. (See Chapter 313 of this title relating to Edwards Aquifer)

Edwards Aquifer recharge zone-Generally, that area where the Edwards and associated limestones crop out in Kinney, Uvalde, Medina, Bexar, Comal, Hays, Travis and Williamson Counties and the outcrops of other formations in proximity to the Edwards limestone, where faulting and fracturing may allow recharge of the surface waters to the Edwards Aquifer, and the area in Uvalde County within 500 feet of the Nueces, Dry Frio, Frio, and Sabinal Rivers downstream from the northern Uvalde County line to the recharge zone as otherwise defined. The recharge zone is specifically that geological area delineated on official maps located in the offices of the commission and the Edwards Underground Water District. (See Chapter 313 of this title relating to Edwards Aquifer.)

Executive Director-The executive director of the commission or an employee of the commission acting in the behalf of and under the direction of the executive director.

Flushwater waste handling system-A system in which fresh water or wastewater is recycled or used in transporting waste.

Ground water-Subsurface water that occurs below the water table in soils and geologic formations that are saturated, and is other than underflow of a stream or an underground stream.

Houses or housed lot-Totally roofed buildings with open or enclosed sides wherein livestock or poultry are housed on solid concrete or dirt floors, slotted (partially open) floors over pits or waste collection areas in pens, stalls or cages, with or without bedding materials and mechanical ventilation. For the purposes of this subchapter, the term housed lot is synonymous with the terms slotted floor building, barn, stable, or house, for livestock or poultry.

Hydrologic connection-The interflow and exchange between control facilities, surface runoff or surface impoundments and waters in the state through an aboveground or underground corridor or connection.

Lagoon-An earthen structure for the biological treatment of liquid organic wastes. Lagoons can be aerobic, anaerobic, or facultative depending on their design and can be used in series to produce a higher quality effluent.

Land application-The removal of wastewater and waste solids from a control facility and distribution to, or incorporation into the soil mantle primarily for beneficial reuse purposes.

Liner-Any barrier in the form of a layer, membrane or blanket, naturally existing, constructed or installed to prevent a significant hydrologic connection between liquids contained in retention structures and waters in the state.

Natural Resources Conservation Service "NRCS"-An agency of the U. S. Department of Agriculture which includes the agency formerly known as the Soil Conservation Service "SCS".

New concentrated animal feeding operation-A new concentrated animal feeding operation which is not authorized under subchapter B of this title (relating to Commercial Livestock and Poultry Production Operations) as of the effective date of these rules.

No discharge-The absence of flow of waste, process generated wastewater, contaminated rainfall runoff or other wastewater from the premises of the animal feeding operation, except for overflows which result from chronic or catastrophic rainfall.

Nuisance-Any discharge of air contaminant(s), including but not limited to odors, of sufficient concentration and duration that are or may tend to be injurious to or which adversely affects human health or welfare, animal life, vegetation, or property, or which interferes with the normal use and enjoyment of animal life, vegetation, or property.

Open lot-Pens or similar confinement areas with soil, concrete, or other paved or hard surfaces wherein animals or poultry are substantially or entirely exposed to the outside environment except for small portions of the total confinement area affording protection by windbreaks or small shed-type shade areas. For the purposes of this subchapter, the term open lot is synonymous with the terms dirt lot or dry lot, for livestock or poultry, as these terms are commonly used in the agricultural industry.

Operator-The owner or one who is responsible for the management of a concentrated animal feeding operation or animal feeding operation subject to the provisions of this subchapter.

Permanent Odor Sources-Those odor sources which may emit odors 24 hours per day. For the purposes of this subchapter, permanent odor sources include but are not limited to pens, confinement buildings, lagoons, retention facilities, manure stockpile areas and solid separators. For the purposes of this subchapter, permanent odor sources shall not include any feed handling facilities, land application equipment or land application areas.

Permit-A permit issued by the commission or the executive director under this chapter.

Permittee-Any person issued a permit under this subchapter or whose concentrated animal feeding operation is subject to the requirements of this subchapter.

Pesticide-A substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, or any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant.

Process wastewater-Any process generated wastewater directly or indirectly used in the operation of a CAFO (such as spillage or overflow from animal or poultry watering systems which comes in contact with waste); washing, cleaning or flushing pens, barns, manure pits, direct contact swimming, washing, or spray cooling of animals; and dust control), and precipitation which comes into contact with any manure or litter, bedding, or any other raw material or intermediate or final material or product used in or resulting from the production of animals or poultry or direct products (e.g. milk, meat or eggs).

Recharge zone/feature-Those natural features either on or beneath the ground surface, in any location specific to the site under evaluation where, due to surface and/or geologic features, a significant hydrologic connection exists between the ground surface and the underlying ground

water within an aquifer. Examples include, but are not limited to: a permeable and porous soil material that directly overlies a weakly cemented or fractured limestone, sandstone, or similar type aquifer; and fractured or karstified limestone or similar type formation that crops out on the surface, especially near a water course.

Retention facility or retention structure-All collection ditches, conduits and swales for the collection of runoff and wastewater, and all basins, ponds, pits, tanks and lagoons used to store wastes, wastewaters and manures.

Technical merit-For the purpose of this subchapter, "technical merit" means evidence demonstrating that the application on its face does not meet all technical requirements of this subchapter and therefore issuance of the permit may result in detrimental impacts to ground water underlying the related CAFO, detrimental impacts to surface water quality within one mile of the CAFO, or evidence demonstrating that history of compliance by the applicant has resulted in detrimental impacts to such ground water or surface water quality within these geographic limits.

25-Year, 24-Hour rainfall event/25-Year rainfall event-The maximum rainfall event with a probable recurrence interval of once in 25-years, with a duration of 24 hours, as defined by the National Weather Service in Technical Paper Number 40, "Rainfall Frequency Atlas of the United States", May 1961, and subsequent amendments, or equivalent regional or state rainfall information developed therefrom.

Waste-Manure (feces and urine), litter, bedding, or feedwaste from animal feeding operations.

Wastewater-Water containing waste or contaminated by waste contact, including process-generated and contaminated rainfall runoff.

Waters in the state-Ground water, percolating or otherwise, lakes, bays, ponds, impounding reservoirs, springs, rivers, streams, creeks, estuaries, marshes, inlets, canals, the Gulf of Mexico inside the territorial limits of the state, and all other bodies of surface water, natural or artificial, inland or coastal, fresh or salt, navigable or nonnavigable, and including the beds and banks of all watercourses and bodies of surface water, that are wholly or partially inside or bordering the state or inside the jurisdiction of the state.

Qualified ground water scientist-A scientist or engineer who has received a baccalaureate or post-graduate degree in natural sciences or engineering and has sufficient training and experience in ground water hydrology and related fields as may be demonstrated by state registration, professional certification, or completion of accredited university programs that enable that individual to make sound professional judgements regarding ground water monitoring, contamination fate and transport, and corrective action.

§321.183. Applicability.

(a) Any existing feedlot/concentrated animal feeding operation as defined and authorized under subchapter B of this title (relating to Commercial Livestock and Poultry Production Operations) on the effective date of these rules shall continue to be regulated in accordance with subchapter B of this title and subject to the terms and conditions of any permit issued under subchapter B of this title. Any CAFO which has submitted an administratively complete permit application under subchapter B of this title on the effective date of these rules shall be subject to the terms and conditions of subchapter B of this title in the processing and/or issuance of any such permit and shall continue to be regulated under subchapter B of this title following issuance of the permit. Any application for permit renewal, amendment or transfer for any permit issued under subchapter B of this title shall be reviewed and/or issued under the provisions of subchapter B of this title

(b) In accordance with the Texas Water Code, §26.040, any new concentrated animal feeding operation may be regulated by rule, rather than by individual permit, subject to subsections (b)-(l) of this section, provided such operations comply with §§321.191-321.197 of this title (relating to Proper CAFO Operation and Maintenance; Pollution Prevention Plans; Best Management Practices; Other Requirements; Monitoring and Reporting Requirements, Registration; and Dairy Outreach Program Areas). The provisions of this subsection are applicable to all new concentrated animal feeding operations, either housed or open lots, including beef cattle, dairy cattle or milk production areas; swine; sheep; goats; horses; chickens, including broilers, layers and/or breeders; turkeys, including breeders and/or feeders; any other animal species not specifically listed; and auction markets for which a permit is required on or after the effective date of these rules.

(c) The executive director may require any animal feeding operation to comply with the requirements of this subchapter in order to achieve the policy and purposes enumerated in the Texas Water Code, §5.120 and §26.003; the Health and Safety Code, Chapters 341, 361 and 382; and §321.181 of this title (relating to Waste and Wastewater Discharge and Air Emission Limitations). The executive director may require the operator of any new concentrated animal feeding operation to apply for and obtain a permit under this subchapter. Cases for which a permit may be required include, but are not limited to, situations where:

(1) the operation is located near surface and/or ground water resources;

(2) compliance with standards in addition to those listed in this subchapter is necessary in order to protect fresh water from pollution; or

(3) the operation is not in compliance with the standards of this subchapter. A CAFO operator shall submit a complete permit application within 90 days of notification from the executive director that a permit is required.

(d) Any new or expanding concentrated animal feeding operation not authorized pursuant to subsection (a) of this section and which is designed to stable or confine and feed or maintain for a total of 45 days or more in any 12-month period more than the numbers of animals specified in the definition of CAFO in §321.182(A) of this title (relating to Definitions) shall apply for and obtain a permit under this subchapter.

(e) Notwithstanding the provisions of subsection (d) of this section, any new or expanding CAFO located in areas designated under §321.197 of this title (relating to Dairy Outreach Program Areas), and that is designed to stable or confine and feed or maintain for a total of 45 days or more in any 12-month period more than the number of animals specified the definition of CAFO in §321.182(B) of this title (relating to Definitions) shall either apply for and obtain a permit under this subchapter or comply with the provisions of §321.194(a)(1), (g) and (h) of this title (relating to Other Requirements).

(f) New concentrated animal feeding operations are prohibited on the Edwards Aquifer recharge zone.

(g) Operators of an animal feeding operation not required to obtain a permit under this section must locate, construct and manage waste control facilities and air control facilities (where applicable) to protect the air, surface water and ground water in accordance with the requirements of this subchapter.

(h) Any new or expanding concentrated animal feeding operation, which is required to obtain a permit in accordance with this subchapter may not commence physical construction and/or operation of any waste management facilities or any facility that has the potential to emit air contaminants without first receiving a final effective permit or other commission authorization.

(i) Any CAFO which has existing authority under the Texas Clean Air Act does not have to meet the air quality criteria of this subchapter. Pursuant to the Texas Clean Air Act (TCAA) , §382.051, any new CAFO which meets all of the requirements

of this subchapter is hereby entitled to an air quality standard permit authorization under this subchapter in lieu of the requirement to obtain an air quality permit under Chapter 116 of this title (relating to Control of Air Pollution by Permits for New Construction or Modification). Those CAFO's which would otherwise be required to obtain an air quality permit under Chapter 116 of this title, which cannot satisfy all of the requirements of this subchapter shall apply for and obtain an air quality permit pursuant to Chapter 116 of this title in addition to any permit required under this subchapter. Those animal feeding operations which are not required to obtain a permit under this subchapter may be subject to requirements under Chapter 116 of this title. Any change in conditions such that a person is no longer eligible for authorization under this section requires authorization under Chapter 116 of this title. No person may concurrently hold an air quality permit issued under Chapter 116 of this title and a permit with air quality provisions under this subchapter for the same site.

(j) Any animal feeding operation authorized under this subchapter which is a new major source, or major modification as defined in Chapter 116 of this title (relating to Control of Air Pollution by Permits for New Construction or Modification) shall obtain a permit under Chapter 116 of this title.

(k) Any facility operating under a certified water quality management plan from the Texas State Soil and Water Conservation Board or any facility which qualifies for and obtains such a plan, is not a CAFO for purposes of this subchapter and is not covered by the provisions of this subchapter, unless referred to the commission in accordance with the Texas Agriculture Code, §201.026.

(l) Upon written request to the executive director by the owner/operator, any facility authorized under subchapter B of this title (relating to Commercial Livestock and Poultry Production Operations) shall be authorized under this subchapter without notice and hearing. Such new authorization under this subchapter shall not impose any additional conditions or other requirements unless there is substantial modification to the facility constituting a major amendment as defined by §305.62 of this title (relating to Amendment) or to address compliance problems with the facility or its operations in accordance with a commission order or permit amendment. Any owner/operator of a CAFO having less than 1000 but more than or equal to 300 animal units, located in any area designated under §321.197 of this title (relating to Dairy Outreach Program Areas) and requesting coverage under this subsection are subject to provisions of subsection (e) of this section.

§321.184. Application Requirements.

(a) Any person whose concentrated animal feeding operation is required to file an application for a permit under this subchapter, or who requests an amendment, modification or renewal of a permit issued under this subchapter shall complete, sign and submit an application to the executive director, according to the provisions of this section.

(b) Applicants shall comply with the applicable provisions of §§305.43, 305.44, 305.46, and 305.47 of this title (relating to Who Applies; Signatories to Applications; Designation of Material as Confidential; and Retention of Application Data).

(c) Application for a permit under this subchapter shall be made on forms prescribed by the executive director. The applicant shall submit an original completed application with attachments and three copies to the executive director at the headquarters in Austin, Texas, and one additional copy of the application with attachments to the appropriate regional office. The completed application shall be submitted to the executive director signed and notarized and with the following information:

(1) The verified legal status of the applicant.

(2) The payment of applicable fees.

(3) The signature of the applicant, in accordance with agency requirements.

(4) The maximum number of animals for which the facilities have been designed.

(5) A final site plan for the facility showing the boundaries of land owned, operated or controlled by the applicant and to be used as a part of a concentrated animal feeding operation, the locations of all pens, lots, ponds, disposal areas and any other types of control or retention facilities, and all adjacent landowners within 500 feet of the property line of all tracts containing facilities and all on-site or off-site waste disposal areas, including their name, address and telephone number. As used in this subchapter, the term "disposal area" does not apply to any lands not owned, operated or controlled by the concentrated animal feeding operation operator for the purpose of off-site land application of manure, wherein the manure is given or sold to others for beneficial use.

(6) A County General Highway Map (with graphic scale clearly shown) to identify the relative location of the concentrated animal feeding operation and at least a one mile area surrounding the facility.

(7) One original (remainder in copies) U.S. Geological Survey 7 1/2 minute quadrangle topographic map or an equivalent high quality copy showing the boundaries of land owned, operated or controlled by the applicant and to be used as a part of a concentrated animal feeding operation, and the location of all private water wells (abandoned or in use) within 150 feet and public wells within 500 feet of the outer boundary of retention facilities and all springs, lakes or ponds downstream of the facility within one mile of the outer boundary of the retention facilities.

(8) A copy of the pollution prevention plan for the concentrated animal feeding operation for which the application is filed.

(9) A copy of a recorded deed or tax records showing ownership, or a copy of a contract or lease agreement between the applicant and the owner of any lands to be utilized under the proposed concentrated animal feeding operation. This requirement does not apply to any lands not owned, operated or controlled by the applicant for the purpose of off-site land application of manure wherein the manure is given or sold to others for beneficial use.

(10) A certification by a NRCS engineer, registered professional engineer or qualified ground water scientist that no recharge features exist on any tracts owned, operated or controlled by the applicant and utilized under the application.

(11) Where the applicant can not document the absence of recharge features on the tracts for which an application is being filed, the final site plan shall also indicate the specific location of any and all recharge features on any property owned, operated or controlled by the applicant under the application as certified by a NRCS engineer, registered professional engineer or qualified ground water scientist. The applicant shall also submit a plan, developed and certified by a NRCS engineer, registered professional engineer or qualified ground water scientist, to prevent impacts on the recharge zone/feature and associated ground water formation which may include the following.

(A) Installation of the necessary and appropriate protective measures such as impervious cover, berms or other equivalent protective measures covering all affected facilities and disposal areas; or

(B) Submission of a detailed ground water monitoring plan covering all affected facilities and disposal areas. At a minimum, the ground-water monitoring plan shall specify procedures to annually collect a ground-water sample from representative wells, have each sample analyzed

for chlorides, nitrates and total suspended solids and compare those values with background values for each well; or

(C) Any other similar method or approach demonstrated by the applicant to be protective of any associated recharge zone/feature.

(12) Area land use map (Air quality only). This map should identify the property line, the permanent odor sources and the distance and direction to any residences, animal feeding operations, businesses or occupied structures within a one mile radius of the permanent odor sources. The map shall include the north arrow and scale of map.

(d) Each applicant shall pay an application fee as required by §305.53 of this title (relating to Application Fees). An annual waste treatment inspection fee is also required of each permittee as required by §305.503 of this title (relating to Fee Assessment). No fees under Chapter 116 (relating to Control of Air Pollution by Permits for New Construction or Modification) shall be required of an applicant for a permit issued under this subchapter.

(e) Each permittee shall comply with §§305.61 and 305.64-305.68 of this title (relating to Applicability, Transfer of Permits, Corrections of Permits, Revocation and Suspension, Revocation and Suspension Upon Request or Consent, Action and Notice on Petition for Revocation or Suspension).

(f) Permits issued under this subchapter shall be effective for a term not to exceed five years, unless extended by order of the commission.

(g) Air quality buffer distance requirements for new concentrated animal feeding operations. At the time of initial application, any CAFO designed to confine livestock in numbers greater than 1000 animals or 1000 animal units, whichever is greater, or confine poultry at numbers greater than 30,000 with a liquid waste handling system shall not locate any permanent odor sources within 0.25 miles of any occupied residence or business structure, school, church, or public park without written consent and approval from the landowner. For the purposes of this subchapter, any measurement of a buffer distance shall be from the nearest edge of the permanent odor source to the nearest edge of an occupied structure or designated recreational area listed under this subsection.

§321.185. Application Review.

(a) Initial review. Applications for permits or major amendments under this subchapter shall be reviewed by the executive director for administrative and technical completeness within 15 working days of receipt of the application by the executive director. Upon determination that the application contains the information and attachments required under this subchapter, the executive director shall declare that the application is administratively and technically complete.

(b) Within five working days of declaration of administrative completeness, the executive director shall assign the application a number for identification purposes, and prepare a statement of the receipt of the application and declaration of administrative and technical completeness which is suitable for publishing or mailing, under the requirements of §321.186(b) of this title (relating to Notice of Application) , and shall forward that statement to the applicant.

§321.186. Notice of Application.

(a) The notice of application and administrative/technical completeness shall contain the following information:

(1) the identifying number given the application by the commission;

(2) the type of permit sought under the application;

(3) the name and address of the applicant;

(4) the date on which the application was submitted;

(5) a brief summary of the information included in the application, including but not limited to the general location of facilities and disposal areas associated with the application;

(6) the format for submission of a comment in accordance with this subchapter to the executive director regarding the application; and

(7) the date, time and place where all comments are to be received by the executive director in relation to the numbered application, such comment period shall not be less than 30 days or more than 35 days from the actual date of publication.

(b) Publication.

(1) The applicant shall cause the notice of application and administrative/technical completeness approved by the executive director to be published once in a newspaper regularly published, and generally circulated within the county and area wherein the proposed facility is to be located, and within an adjoining county wherein any potential affected person may reside.

(2) The date of publication for notice of application and administrative/technical completeness shall not be later than the date set by the executive director

(3) The applicant is responsible for the cost of publication. The applicant shall notify the executive director verbally or by facsimile within 24 hours of the first available working day after the publication of the notice, and shall provide the executive director a certified copy of the publication, within 20 calendar days of the date established by the executive director for publication. If the applicant does not provide the executive director with the appropriate publisher's affidavit within 20 days of the date established by the executive director, the executive director shall cease processing and return the application.

(c) Application returned. If an application is received which is not administratively/technically complete, the executive director shall notify the applicant of the deficiencies prior to expiration of the review period (15 working days) by certified mail return receipt requested. If the additional requested information is received within 30 days of receipt of the deficiency notice, the executive Director will evaluate the information within eight working days and, where applicable, shall prepare a statement of receipt of the application and declaration of administrative/technical completeness in accordance with subsection (a) of this section. If the requested information is not submitted by the applicant within 30 days of the date of receipt of the deficiency notice, the executive director shall return the incomplete application to the applicant.

(d) Notice by mail.

(1) The executive director will transmit the notice of application and administrative/technical completeness by first-class mail to persons listed in paragraph (2) of this subsection and to other persons who, in the judgment of the executive director, may be affected. The applicant is responsible for the cost of required notice. A record on file with the staff of the executive director which includes the list of persons to whom notice was mailed and the date of mailing, signed by a person with personal knowledge that the mailout occurred, shall create a presumption that notice was mailed in accordance with this section.

(2) the notice shall be mailed by the executive director to the following:

(A) the potentially affected landowners named on the final site plan submitted with the application;

(B) the mayor and health officials of the city or town in which the facility is or will be located or in which waste is or will be disposed of;

(C) the county judge and health authorities of the county in which the facility is located or in which waste is or will be disposed of;

(D) the Texas Department of Health;

(E) the Texas Parks and Wildlife Department;

(F) the applicant;

(G) persons who request to be put on the mailing list, including participants in past commission permit proceedings for the facility who have submitted a written request to be put on the mailing list;

(H) state and federal agencies for which notice is required in 40 CFR 124.10(c); and

(I) for applications regarding operations located in an area designated under §321.197 of this subchapter (relating to Dairy Outreach Program Areas), notice shall be mailed to the river authority whose jurisdictional watershed includes that location; and

(3) the date of mailing for a notice of application and administrative/technical completeness shall be established by the executive director.

(4) The notice shall include instructions regarding the requirements contained in §321.187 of this title (relating to Public Comments) providing the manner and timeframe for the submission of comments to the proposed application.

§321.187. Public Comments.

(a) For comments to the application to be considered by the executive director, such comments must:

(1) be sworn and in writing;

(2) be received by the executive director not later than 30 days from the date of publication or actual receipt of the notice;

(3) describe in detail how the application, if approved, would affect a personal, property, or other legally justiciable interest of the commentor;

(4) describe in detail how the application lacks technical merit, i.e., fails to meet the applicable requirements set forth in this subchapter and therefore issuance of the permit may result in detrimental impacts to ground water underlying the related CAFO, detrimental impacts to surface water quality within one mile of the facility or evidence demonstrating that the history of compliance by the applicant has resulted in detrimental impacts to such ground or surface water quality within these geographic limits; and

(5) the specific action, e.g., special conditions, denial of application, etc., the commentor wishes the commission to take in response to the application.

(b) Response to comments. The executive director shall prepare and make available to all commentors, the applicant and the public interest counsel a copy of and response to all comments to the proposed application which were timely filed with the executive director in accordance with the notice of application and administrative completeness, and determined by the executive director to not have demonstrated technical merit.

(c) If the executive director receives no comments having technical merit from any person owning land within the one-mile area described in the definition of "technical merit" found in §321.182 of this title (relating to Definitions) or any river authority receiving notice under §321.186(d)(2)(I) of this subchapter (relating to Notice of Application), then the executive director shall issue a permit in accordance with this subchapter within 14 days. The issuance of a permit under this subsection can only occur if the executive director determines that all technical merit issues, have been resolved and there has been no substantial modification(s) to the concentrated animal feeding operation or application and final site plan as originally submitted such that other persons could be reasonably affected by the modifications.

(d) In the event a properly filed comment is determined by the executive director to have technical merit, the executive director shall, within 21 days from the deadline for receipt of comments, notify the persons commenting, the public interest counsel and the applicant of the basis of such determination in writing.

(e) Not later than 20 days following the date of the letter under subsection (d) of this section notifying the applicant of the executive director's determination of technical merit regarding the application under consideration, the applicant shall request the executive director to do one of the following:

(1) withdraw the application from consideration without prejudice and without reimbursement of fees; or

(2) set up an alternative dispute resolution session in accordance with Chapter 264 of this title (relating to Alternative Dispute Resolution) between the applicant, executive director and the person offering the comments which were determined to have technical merit; or

(3) send the application to the commission for the commission's review of the executive director's determination of technical merit.

(f) If the commission's review of the executive director's determination of technical merit, as provided at subsection (e)(3) of this section, affirms the executive director's determination, the applicant may request either that the commission initiate a contested case proceeding in accordance with the commission rules or remand the application to the executive director. In the event the applicant elects to have the commission remand the application to the executive director, the applicant, not later than 10 days following the date of remand, shall submit additional information to the technical merit issue. If the executive director determines the issue of technical merit still exists, the executive director shall either forward the application to the office of hearings examiners for a contested hearing in accordance with applicable rules or proceed as provided at subsection (e)(2) of this section. In the event the technical merit issue remains unresolved, the executive director shall than forward the application for contested hearing.

(g) If technical merit could be satisfied by the submission of additional information or other change to the application which would not constitute a major amendment to the application as provided by §281.23 of this title (relating to Application Amendment), as an alternative to the provisions of subsection (e) of this section the applicant may, not later than 20 days following the date of the letter notifying the applicant of the executive director's determination of technical merit regarding the application under consideration, request the suspension of action on the application until the application defect is remedied. Such suspension shall be for a period not greater than 30 days.

(h) In the event the applicant does not provide written response to the executive director in accordance with subsection (e) of this section, then the executive director may notify the applicant and person(s) commenting in writing that the application is denied or returned, or take other appropriate action as authorized by Chapter 305 of this title (relating to Consolidated Permits) and the provisions of this subchapter.

§321.188. Permit Issuance.

(a) A permit issued under this subchapter by the executive director shall contain the following:

(1) name and address of the permittee;

(2) the maximum number and type of animals authorized for confinement at the facility;

(3) the applicable water quality and/or air quality provisions of §§321.191-321 195 of this title (relating to Proper CAFO Operation and Maintenance, Pollution Prevention Plans, Best Management Practices, Other Requirements, and Monitoring and Reporting Requirements); and

(4) the applicable provisions of §305 125 of this title (relating to Standard Permit Conditions) .

(b) A permit issued by the commission after contested case hearing as provided by §321 187 of this title (relating to Public Comments) shall contain the elements listed under subsection (a) of this section and any additional conditions or provisions the commission has determined appropriate in accordance with its findings of fact and conclusions of law.

§321.189. Amendments.

(a) Any request for a change in term, condition or provision of a permit issued under this subchapter or a modification of the final site plan will require the permittee to file an application in accordance with §321 184 of this title (relating to Application Requirements).

(b) The existing permit will remain effective and will not expire until action on the application for amendment is final. The commission or executive director, in accordance with this subchapter, may extend the term of a permit when taking action on an application for amendment.

(c) For applications filed in accordance with this subchapter, an application for an amendment to a permit may also be considered as an application for renewal of the permit if so requested by the applicant.

§321.190. Renewal. The permittee shall file an application for renewal of a permit issued under this subchapter. Any permittee with an issued and effective permit shall submit an application for renewal at least 180 days before the expiration date of the effective permit, unless permission for a later date has been granted by the executive director. The executive director shall provide the permittee notice of deadline for application for renewal at least 240 days before the permit expiration date. The executive director shall not grant permission for applications to be submitted later than the expiration date of the existing permit.

(1) An application for a renewal of a permit which does not propose any other change to the authorization and where there has been no related formal major enforcement action against the authorized facility during the last 36 months of the term of the permit may be granted by the executive director without a public hearing. As used in this subchapter, the term "major enforcement action" shall apply to those enforcement actions in which the executive director or the commission has determined that an unauthorized discharge has occurred; such discharge was within the reasonable control of the permittee; and such discharge could have been reasonably foreseen by the permittee. In addition to the above provisions, for any application for renewal of a permit within an area designated under §321.197 of this subchapter (relating to Dairy Outreach Program Areas), an annual compliance inspection shall have been completed within the 12 months prior to the executive director processing the application.

(2) A fee of $315 to be applied toward processing of the application.

(3) Upon receipt of the application, the executive director shall determine whether the application for renewal satisfies the criteria in paragraph (1) of this section within 15 working days. A permittee submitting an application for renewal satisfying the criteria in subsection (a) of this section will automatically be issued a notice of renewal by the executive director in accordance with §321.188(a) of this title (relating to Permit Issuance).

(4) If the application for renewal cannot meet all of the criteria in paragraph (1) of this section, then an application for renewal shall be filed in accordance with §321.184 of this title (relating to Application Requirements).

(5) If an application for renewal requests a major modification of the existing permit, an application shall be filed in accordance with §321.184 of this title (relating to Application Requirements).

(6) If renewal procedures have been initiated before the permit expiration date, the existing issued permit will remain in full force and effect and will not expire until action on the application for renewal is final.

(7) The executive director may deny an application for renewal for the grounds set forth in §305.66 of this title (relating to Revocation and Suspension).

§321.191. Proper CAFO Operation and Maintenance. The facilities covered under this subchapter are required to document all Best Management Practices (BMPs) used to comply with all applicable waste and wastewater discharge and air emission limitations in this subchapter. Such documentation shall be included in the Pollution Prevention Plan (PPP) outlined in this subchapter and shall be made available to the executive director upon request. Where applicable, equivalent and applicable measures contained in a site specific animal waste management plan prepared by the Natural Resources Conservation Service (NRCS), may be substituted for the BMPs and PPP requirements in this subchapter. Where provisions in the NRCS plan are substituted for applicable BMPs or portions of the PPP, the PPP must refer to the appropriate section of the NRCS plan. If the PPP contains reference to the NRCS Plan, a copy of the NRCS plan must be kept on site.

§321.192. Pollution Prevention Plans.

(a) A pollution prevention plan shall be developed for each facility covered under this subchapter. Pollution prevention plans shall be prepared in accordance with good engineering practices and should include measures necessary to limit pollutants to waters in the state and nuisance and odor conditions. The plan shall describe and ensure the implementation of practices which are to be used to assure compliance with the limitations and conditions of this subchapter. The plan shall identify a specific individual(s) at the facility who is responsible for developing, implementation, maintenance, and revision of the pollution prevention plan. The activities and responsibilities of the pollution prevention personnel should address all aspects of the facility's pollution prevention plan.

(b) Where a NRCS plan has been prepared for the facility, the pollution prevention plan may refer to the NRCS plan when the NRCS plan documentation contains equivalent requirements for the facility. When the permittee uses a NRCS plan as partial completion of the pollution plan, the NRCS plan must be kept on site. Design and construction criteria developed by the NRCS can be substituted for the documentation of design capacity and construction requirements (see subsection (f) of this section) of the pollution prevention plan provided the required inspection logs and water level logs in §321.192(f)(3) and (11) of this title (relating to Pollution Prevention Plans) are kept with the NRCS Plan. Waste management plans developed by the NRCS can be substituted for the documentation of application rate calculations in subsection (f) (19) and (24) of this section. NRCS Waste Management Plans which have been prepared since January 1, 1989 are considered by the Natural Resources Conservation Service to contain adequate management practices. To insure the protection of water quality, the Natural Resources Conservation Service has determined that NRCS plans prepared prior to 1989 must be submitted for renewal with the Natural Resources Conservation Service or waste management

professional before December 1995. NRCS has determined that all plans should be reviewed every five years to insure proper management of wastes.

(c) The plan shall be signed by the owner or other signatory authority in accordance with §305.44 of this title (relating to Signatories to Applications), and be retained on site in accordance with §305.39(d) of this title (relating to Monitoring and Reporting Requirements). The plan shall be updated as appropriate.

(d) Upon completion of a plan review, the executive director may notify the permittee at any time that the plan does not meet one or more of the minimum requirements of this subchapter. After such notification from the executive director, the permittee shall make changes to the plan within 90 days after such notification unless otherwise provided by the executive director.

(e) The permittee shall amend the plan prior to any change in design, construction, operation, or maintenance, which has a significant effect on the potential for the discharge of pollutants to waters in the state or if the pollution prevention plan proves to be ineffective in achieving the general objectives of controlling pollutants in discharges or creating a nuisance condition from concentrated animal feeding operations.

(f) The plan shall include, at a minimum, the following items:

(1) Each plan shall provide a description of potential sources which may reasonably be expected to add pollutants to waters in the state or create a nuisance condition from the facility. Each plan shall identify activities and materials which may potentially be pollutant sources or create a nuisance. Each plan shall include:

(A) A site plan/map, or topographic map indicating, an outline of the drainage area of the concentrated animal feeding area; each existing structural control measure to reduce pollutants in wastewater and precipitation runoff; and surface water bodies.

(B) The plan shall identify the specific location of any recharge zones/features located on any tracts of land planned to be utilized under the provisions of this subchapter. In addition, the plan should also locate and describe the function of all measures installed to prevent impacts to identified recharge zones/features.

(C) A list of significant materials that are used, stored or disposed of at the concentrated animal feeding operation (such as pesticides, cleaning agents, fuels etc.). And a list of any significant spills of these materials at the facility after the effective date of these rules, or for new facilities, since date of operation.

(D) All existing sampling data.

(2) The pollution prevention plan for each facility shall include a description of management controls appropriate for the facility, and the permittee must implement such controls. The appropriateness and priorities of any controls shall reflect the identified sources of pollutants or nuisance at the facility.

(3) The plan shall include the location and a description of existing structural and nonstructural controls. Structural controls shall be inspected at least four times per year for structural integrity and maintenance. The plan shall include dates for inspection of the retention facility, and a log of the findings of such inspections.

(4) The plan must include documentation of the assumptions and calculations used in determining the appropriate volume capacity of the retention facilities. In addition to the 25-year, 24-hour rainfall, the volume capacity of the retention facility shall be designed to meet the demands of a hydrologic needs analysis (water balance) which demonstrates the irrigation water requirements for the cropping system maintained on the wastewater application site(s). Precipitation inputs to the hydrologic needs analysis (water balance) shall be the average monthly precipitation taken from an official source such as the "Climatic Atlas of Texas", LP-192, published by the Texas Department of Water Resources, dated December, 1983, or the most recent edition, or successor publication. The consumptive use requirements of the cropping system shall be developed on a monthly basis, and shall be calculated as a part of the hydrologic needs analysis (water balance). The following volumes shall be considered in determining the analysis:

(A) the runoff volume from all open lot surfaces;

(B) the runoff volume from all areas between open lot surfaces that is directed into the retention facilities;

(C) the rainfall multiplied by the area of the retention and waste basin;

(D) the volume of rainfall from any roofed area that is directed into the retention facilities;

(E) all waste and process generated wastewater produced during a 21 day, or greater, period;

(F) the estimated storage volume for a minimum one year of sludge accumulation;

(G) the storage volume required to contain all wastewater and runoff during periods of low crop demand;

(H) the evaporation volume from retention facility surfaces;

(I) the volume applied to crops in response to crop demand;

(J) the minimum treatment volume required for waste treatment, if treatment lagoon; and/or

(K) any additional storage volume required as a safety measure as determined by the system designer.

(5) The maximum required storage value calculated by the hydrologic analysis requirements should not encroach on the storage volume required for the 25-year, 24-hour rainfall event. Wastewater application rates utilized in the hydrologic needs analysis (water balance) should not induce runoff or create tailwater.

(6) In addition, the design capacity should include a top freeboard of two feet and in no case less than one foot.

(7) A lagoon in a single lagoon system and a primary lagoon in a multistage lagoon system shall be designed to maintain the necessary treatment volume or surface area as calculated using the manure production data (mean plus one standard deviation) published by American Society of Agricultural Engineers (ASAE) standards D384.1, dated June, 1988, and applicable updates to comply with anaerobic lagoon design criteria as established by ASAE standards EP-403.2, dated December, 1992, and applicable updates, or other site-specific data documented in the PPP.

(8) Evaporation systems shall be designed to withstand a ten-year (consecutive) period of maximum recorded monthly rainfall (other than catastrophic), as determined by a hydrologic needs analysis (water balance), and sufficient freeboard (not less than one foot) shall be maintained to dispose of rainfall and rainfall runoff from the 25-year, 24- hour rainfall event without overflow. In the hydrologic needs analysis determination, any month in which a catastrophic event occurs the analysis shall replace such an event with not less than the long term average rainfall for that month.

(9) Where appropriate, site specific information should be used to determine retention capacity and land application rates. All site specific information used must be documented in the pollution prevention plan.

(10) The plan shall include a description of the design standards for the retention facility embankments. The following minimum design standards are required for construction and/or modification of a retention facility:

(A) Soils used in the embankment shall be free of foreign material such as trash, brush, and fallen trees;

(B) The embankment shall be constructed in lifts or layers no more than six inches thick and compacted at optimum moisture content;

(C) Site specific variation in embankment construction must be accompanied by compaction testing, certification by a professional engineer, or certified to be in accordance with NRCS design standards. Compaction tests must be certified by a professional engineer; and

(D) All embankment walls shall be stabilized to prevent erosion or deterioration.

(11) The plan must include a schedule for liquid waste removal. A date log indicating weekly inspection of wastewater level in the retention facility, including specific measurement of wastewater level will be kept with the plan. Retention facilities shall be equipped with either irrigation or evaporation or liquid removal systems capable of dewatering the retention facilities. Operators using pits, ponds, tanks or lagoons for storage and treatment of storm water, manure and process generated wastewater, including flush water waste handling systems, shall maintain in their wastewater retention facility sufficient freeboard to contain rainfall and rainfall runoff from a 25-year, 24-hour rainfall event. The operator shall restore freeboard for a 25-year, 24-hour rainfall event after any rainfall event or accumulation of wastes or process generated wastewater which reduces such freeboard, weather permitting. Equipment capable of dewatering the wastewater retention structures of waste and/or wastewater shall be available whenever needed to restore the freeboard required to accommodate the rainfall and runoff resulting from the 25-year, 24-hour rainfall event.

(12) A permanent marker (measuring device) shall be maintained in the wastewater retention facilities to show the following: the volume required for a 25-year, 24-hour rainfall event; and the predetermined minimum treatment volume within any treatment pond. The marker shall be visible from the top of the levee. At no time shall a lagoon at a CAFO that is operated under an air quality permit be dewatered to a level below the predetermined treatment volume, except for cleanout periods or periods where the net effect of evaporation and rainfall render it impractical to maintain the treatment volume without pumping fresh ground water from an aquifer.

(13) The primary lagoon in a multi-stage lagoon system shall be designed and operated so that the lagoon maintains a constant level at all times unless prohibited by climatic conditions. Where practical, any contaminated runoff should be routed around the primary lagoon into the secondary lagoon.

(14) A rain gauge shall be kept on site and properly maintained. A log of all measurable rainfall events shall be kept with the pollution prevention plan.

(15) Concentrated animal feeding operations constructing a new or modifying an existing wastewater retention facility shall insure that all construction and design is in accordance with good engineering practices. Where site specific variations are warranted, the permittee must document these variations and their appropriateness to the plan. Existing facilities which have been properly maintained and show no signs of structural breakage or leakage will be considered to be properly constructed. Structures built in accordance with site specific Natural Resources Conservation Service plans and specifications will be considered to be in compliance with the design and capacity requirements of this subchapter if the site specific conditions are the same as those used by the NRCS to develop the plan (numbers of animals, runoff area, wastes generated, etc.) All retention structure design and construction shall, at a minimum, be in accordance with the technical standards developed by the NRCS. The permittee must use those standards that are current at the time of construction.

(16) The permittee shall include in the plan, site specific documentation that no significant hydrologic connection exists between the contained wastewater and waters in the state. Where the permittee cannot document that no significant hydrologic connection exists, the ponds, lagoons and basins of the retention facilities must have a liner which will prevent the potential contamination of surface waters and ground waters.

(A) The permittee can document lack of hydrologic connection by either: documenting that there will be no significant leakage from the retention structure; or documenting that any leakage from the retention structure would not migrate to waters in the state. This documentation should be certified by a NRCS engineer, professional engineer or qualified groundwater scientist and must include information on the hydraulic conductivity and thickness of the natural materials underlying and forming the walls of the containment structure up to the wetted perimeter.

(B) For documentation of no significant leakage, in-situ materials must, at a minimum, meet the minimum criteria for hydraulic conductivity and thickness described below. Documentation that leakage will not migrate to waters in the state must include maps showing ground water flow paths, or that the leakage enters a confined environment. A written determination by a NRCS engineer, a professional engineer, or qualified groundwater scientist that a liner is not needed to prevent leakage of significant amounts of pollutants into waters in the state will be considered documentation that no significant hydrologic connection exists.

(17) Site-specific conditions shall be considered in the design and construction of liners. NRCS liner requirements or liners constructed and maintained in accordance with NRCS design specifications in Technical Note 716 (or its current equivalent) shall be considered to prevent hydrologic connections which could result in the contamination of waters in the state. Liners for retention structures should be constructed in accordance with good engineering practices. Where no site specific assessment has been done by a NRCS engineer, professional engineer, or qualified groundwater scientist the liner shall be constructed to have hydraulic conductivities no greater than 1 X 10-7 cm/sec, with a thickness of 1.5 feet or greater or its equivalency in other materials.

(18) Where a liner is installed to prevent hydrologic connection the permittee must maintain the liner to inhibit infiltration of wastewaters. Liners shall be protected from animals by fences or other protective devices. No trees shall be allowed to grow within the potential distance of the root zone. Any mechanical or structural damage to the liner will be evaluated by a NRCS engineer, professional engineer, or qualified groundwater scientist within 30 days of the damage. Documentation of liner maintenance shall be kept with the pollution prevention plan. The permittee shall have a NRCS engineer, professional engineer, or qualified groundwater scientist review the documentation and do a site evaluation every five years. If notified by the executive director that significant potential exists for the contamination of waters in the state or drinking water, the permittee shall install a

leak detection system or monitoring well(s) in accordance with that notice. Documentation of compliance with the notification must be kept with the pollution prevention plan, as well as all sampling data. In the event monitoring well(s) are required, the permittee must sample each monitor well annually for nitrate as nitrogen, chloride, and total dissolved solids using the methods outlined in the PPP, and compare the analytical results to the baseline data. If a ten percent deviation in concentration of any of the sampled constituents is found, the permittee must notify the executive director within 30 days of receiving the analytical results. Data from any monitoring wells must be kept on site for three years with the pollution prevention plan. The first year's sampling shall be considered the baseline data and must be retained on site for the life of the facility.

(19) Retention facilities shall be equipped with either irrigation or evaporation systems capable of dewatering the retention facilities, or a regular schedule of wastewater removal by contract hauler. The pollution prevention plan must include all calculations, as well as, all factors used in determining land application rates, acreage, and crops. Land application rates must take into account the nutrient contribution of any land applied manures. If land application is utilized for disposal of wastewater, the following requirements shall apply:

(A) The discharge or drainage of irrigated wastewater is prohibited where it will result in a discharge to waters in the state.

(B) When irrigation disposal of wastewater is used, application rates shall not exceed the nutrient uptake of the crop coverage or planned crop planting with any land application of wastewater and/or manure. Land application rates of wastewaters should be based on the available nitrogen content, however, where local water quality is threatened by phosphorus, the permittee shall limit the application rate to the recommended rates of available phosphorus for needed crop uptake and provide controls for runoff and erosion as appropriate for site conditions.

(C) Wastewater shall not be irrigated when the ground is frozen or saturated or during rainfall events (unless used to filter wastewaters from retention structures which are going to overflow directly to waters in the state).

(D) Irrigation practices shall be managed so as to reduce or minimize ponding or puddling of wastewater on the site, contamination of waters in the state, and the occurrence of nuisance conditions.

(E) It shall be considered "Proper Operation and Maintenance" for a facility which has been properly operated, and that is in danger of imminent overflow due to chronic or catastrophic rainfall, to discharge wastewaters to land application sites for filtering prior to discharging to waters in the state.

(F) Facilities including ponds, pipes, ditches, pumps, diversion and irrigation equipment shall be maintained to insure ability to fully comply with the terms of this subchapter and the pollution prevention plan.

(G) Adequate equipment or land application area shall be available for removal of such waste and wastewater as required to maintain the retention capacity of the facility for compliance with this subchapter.

(H) Where land application sites are isolated from surface waters and ground waters and no potential exists for runoff to reach any waters in the state, application rates may exceed nutrient crop uptake rates only upon written approval of the executive director. No land application under this subsection shall cause or contribute to a violation of water quality standards or create a nuisance.

(20) Solids shall be removed in accordance with a pre- determined schedule for cleanout of all treatment lagoons to prevent the accumulation of solids from exceeding 50 percent of the original treatment volume. Removal of solids shall be conducted during favorable wind conditions that carry odors away from nearby receptors and the operator shall notify the regional office of the commission as soon as the lagoon cleaning is scheduled, but not less than 10 days prior to cleaning, and verification shall be reported to the same regional office within 5 days after the cleaning has been completed. At no time shall emissions from any activity create a nuisance. Any increase in odors associated with a properly managed cleanout under this subsection will be taken into consideration by the executive director when determining compliance with the provisions of this subchapter.

(21) Manure and Pond Solids Handling and Land Application. Storage and land application of manure shall not cause a discharge of significant pollutants to waters in the state, cause a water quality violation in waters in the state or cause a nuisance condition. At all times, sufficient volume shall be maintained within the control facility to accommodate manure, other solids, wastewaters and rain waters (runoff) from the concentrated animal feeding areas.

(22) Where the permittee decides to land apply manures and pond solids the plan shall include: a description of waste handling procedures and equipment availability; the calculations and assumptions used for determining land application rates; and any nutrient analysis data. Land application rates of wastes should be based on the available nitrogen content of the solid waste. However, where local water quality is threatened by phosphorus, the application rate shall be limited to the recommended rates of available phosphorus for needed crop uptake and provide controls for runoff and erosion as appropriate for site conditions.

(23) If the waste (manure) is sold or given to other persons for disposal, the permittee must maintain a log of: date of removal from the CAFO; name of hauler; and amount, in wet tons, dry tons or cubic yards, of waste removed from the CAFO. (Incidental amounts, given away by the pick-up truck load, need not be recorded.) Where the wastes are to be land applied by the hauler, the permittee must make available to the hauler any nutrient sample analysis from that year.

(24) The procedures documented in the pollution prevention plan must ensure that the handling and disposal of wastes as defined in §321.182 of this title (relating to Definitions) comply with the following requirements:

(A) Adequate manure storage capacity based upon manure and waste production and land availability shall be provided. Storage and/or surface disposal of manure in the 100- year flood plain, near water courses or recharge zone/feature is prohibited unless protected by adequate berms or other structures. The land application of wastes at agricultural rates shall not be considered surface disposal in this case and is not prohibited.

(B) When manure is stockpiled, it shall be stored in a well drained area with no ponding of water, and the top and sides of stockpiles shall be adequately sloped to ensure proper drainage. Runoff from manure storage piles must be retained on site.

(C) Waste shall not be applied to land when the ground is frozen or saturated or during rainfall events.

(D) Waste manure shall be applied to suitable land at appropriate times and rates. Discharge (run-off) of waste from the application site is prohibited. Timing and rate of applications shall be in response to crop needs, assuming usual nutrient

losses, expected precipitation and soil conditions.

(E) All necessary practices to minimize waste manure transport to waters in the state shall be utilized and documented to the plan.

(F) Edge-of-field, grassed strips shall be used to separate water courses from runoff carrying eroded soil and manure particles. Land subject to excessive erosion shall be avoided.

(G) Where land application sites are isolated from surface waters and no potential exists for runoff to reach waters in the state, application rates may exceed nutrient crop uptake rates only upon written approval by the executive director. No land application under this subchapter shall cause or contribute to a violation of surface water quality standards, contaminate ground water or create an nuisance condition.

(H) Nighttime application of liquid and/or solid waste shall only be allowed in areas with no occupied residence(s) within 0.25 mile from the outer boundary of the actual area receiving waste application, unless the current occupants of such residences have in writing agreed to such nighttime applications. Application in other areas shall only be allowed from one hour after sunrise until one hour before sunset to minimize the occurrence of nuisance odors.

(I) Accumulations of solids on concrete cow lanes at dairies and concrete swine pens, without slotted floors, shall be scraped or flushed at least once per week or in accordance with proper design and maintenance of the facility. Farrowing pens at swine facilities which are not scraped or flushed once per week shall be scraped/flushed after each group of sows have been removed from the facility.

(J) Buildings designed with mechanical flush/scrape systems shall be flushed/scraped at least once per week or as often as necessary to maintain the design efficiency. This provision would include, but would not be limited to swine and caged poultry operations.

(K) Earthen pens shall be designed and maintained to ensure good drainage and to prevent ponding.

(L) Facilities that utilize a solid settling basin(s) shall remove solids from the basin as often as necessary to maintain the design efficiency.

(25) The plan shall include an appropriate schedule for preventative maintenance. Operators will provide routine maintenance to their control facilities in accordance with a schedule and plan of operation to ensure compliance with this subchapter. The permittee shall keep a maintenance log documenting that preventative maintenance was done. A preventive maintenance program shall involve inspection and maintenance of all runoff management devices (mechanical separators, catch basins) as well as inspecting and testing facility equipment and containment structures to uncover conditions that could cause breakdowns or failures resulting in discharge of pollutants to waters in the state or the creation of a nuisance condition

(26) The plan shall identify areas which, due to topography, activities, or other factors, have a high potential for significant soil erosion. Where these areas have the potential to contribute pollutants to waters in the state the pollution prevention plan shall identify measures used to limit erosion and pollutant runoff.

(27) The permittee shall document to the pollution prevention plan as soon as possible, any planned physical alterations or additions to the permitted facility. The permittee must insure that any change or facility expansion will not result in a discharge in violation of the provisions of this subchapter or will require an amendment to an existing permit in force at the time of modification.

(28) Prior to commencing wastewater irrigation and/or waste application on land owned or operated by the permittee, and annually thereafter, the permittee shall collect and analyze representative soil samples of the wastewater and waste application sites according to the following procedures:

(A) Sampling procedures shall employ accepted techniques of soil science for obtaining representative and analytical results.

(B) Samples should be taken within the same 45 day time-frame each year.

(C) Obtain one composite sample for each soil depth zone per land management unit and per uniform (soils with the same characteristics and texture) soil type within the land management unit. For the purposes of this subchapter, a land management unit shall be considered to be an area associated with a single center pivot system or a tract of land on which similar soil characteristics exist and management practices are being used.

(D) Composite samples shall be comprised of 10-15 randomly sampled cores obtained from each of the following soil depth zones:

(i) Zone 1: 0-6 inches

(ii) Zone 2: 6-24 inches

(E) Soil samples shall be submitted to a soil testing laboratory along with a previous crop history of the site, intended crop use and yield goal. Soil reports should include nutrient recommendations for the crop yield goal.

(F) Chemical/nutrient parameters and analytical procedures for laboratory analysis of soil samples from wastewater and waste application sites shall include the following:

(i) Nitrate reported as nitrogen in parts per million (ppm)

(ii) Phosphorus (extractable, ppm)-Texas Agricultural Extension Service Soil Testing Laboratory-TAMU extractant, P1 Weak Bray, or Mehlich III extraction

(iii) Potassium (extractable, ppm)

(iv) Sodium (extractable, ppm)

(v) Magnesium (extractable, ppm)

(vi) Calcium (extractable, ppm)

(vii) Soluble salts/electrical conductivity (dS/m)-determined from extract of 2:1 (v/v) water/soil mixture

(viii) Soil water pH

(G) When results of the annual soil analysis for extractable phosphorus in subparagraph (F) of this paragraph indicates a level greater than 200 ppm of extractable phosphorus (reported as P) in the 0-6 inch depth (Zone 1) for a particular waste and/or wastewater disposal field, then the permittee shall limit waste and/or wastewater application on that site to the recommended P rates based on crop uptake. Waste and/or wastewater application shall remain limited to recommended P rates until soil analysis indicates extractable phosphorus levels have been reduced below 200 ppm P.

(29) The permittee shall annually analyze at least one representative sample of irrigation wastewater and one representative sample of solid waste for total nitrogen, total phosphorus and total potassium.

(30) Results of initial and annual soils, wastewater and solid waste analyses shall be maintained on-site as part of the pollution prevention plan.

(31) Permittees submitting applications for renewal or expansion of existing facilities authorized under this subchapter to utilize a playa lake as a wastewater retention structure shall within 90 days of the effective date of the renewal, submit a ground water monitoring plan to the Agriculture Permitting and Enforcement Section, Agriculture and Rural Assistance Division of the Texas Natural Resource Conservation Commission. At a minimum, the ground water monitoring plan shall specify procedures to annually collect a ground water sample from each well providing water for the facility, have each sample analyzed for chlorides and nitrates and compare those values to background values for each well.

§321.193. Best Management Practices. The following Best Management Practices (BMPs) shall be utilized by concentrated animal feeding operations owners/operators, as appropriate, based upon existing physical and economic conditions, opportunities and constraints. Where the provisions in a NRCS plan are equivalent or more protective the permittee may refer to the NRCS plan as documentation of compliance with the BMPs required by this subchapter.

(1) Control facilities must be designed, constructed, and operated to contain all process generated wastewaters and the contaminated runoff from a 25-year, 24-hour rainfall event for the location of the point source. Calculations may also include allowances for surface retention, infiltration, and other site specific factors. Waste control facilities must be constructed, maintained and managed so as to retain all contaminated rainfall runoff from open lots and associated areas, process generated wastewater, and all other wastes which will enter or be stored in the retention structure

(2) Facilities shall not expand operations, either in size or numbers of animals, prior to amending or enlarging the waste handling procedures and structures to accommodate any additional wastes that will be generated by the expanded operations.

(3) Open lots and associated wastes shall be isolated from outside surface drainage by ditches, dikes, berms, terraces or other such structures designed to carry peak flows expected at times when the 25-year, 24-hr. rainfall event occurs.

(4) New or expanding facilities shall not be built in any stream, river, lake, wetland, or playa lake (except as defined by and in accordance with the Texas Water Code, §26.048).

(5) No waters in the state shall come into direct contact with the animals confined on the concentrated animal feeding operation. Fences and other methods may be used to restrict such access.

(6) Wastewater retention facilities or holding pens may not be located in the 100-year flood plain unless the facility is protected from inundation and damage that may occur during that flood event.

(7) There shall be no water quality impairment to public and neighboring private drinking water wells due to waste handling at the permitted facility. Facility wastewater retention facilities, holding pens or waste/wastewater disposal sites shall not be located closer than 500 feet of a public water supply well or 150 of a private water wells, except in accordance Chapter 338 of this title (relating to Water Well Drillers).

(8) Waste handling, treatment, and management shall not create a nuisance condition or an environmental or a public health hazard; shall not result in the contamination of drinking water, shall conform with State guidelines and/or regulations for the protection of surface and ground water quality.

(9) Solids, sludges, manure, or other pollutants removed in the course of treatment or control of wastewaters shall be disposed of in a manner such as to prevent significant pollutants from being discharged into waters in the state or create a nuisance condition.

(10) The operator shall prevent the discharge of pesticide contaminated waters into waters in the state. All wastes from dipping vats, pest and parasite control units, and other facilities utilized for the application of potentially hazardous or toxic chemicals shall be handled and disposed of in a manner such as to prevent any significant pollutants from entering the waters in the state or create a nuisance condition.

(11) Dead animals shall be properly disposed of within three days unless otherwise provided for by the executive director. Animals shall be disposed of in a manner to prevent contamination of waters in the state or create a nuisance or public health hazard.

(12) Collection, storage, and disposal of liquid and solid waste should be managed in accordance with recognized practices of good agricultural management. The economic benefits derived from agricultural operations carried out at the land disposal site shall be secondary to the proper disposal of waste and wastewater.

(13) Appropriate measures necessary to prevent spills and to clean up spills of any toxic pollutant shall be taken. Where potential spills can occur materials, handling procedures and storage shall be specified Procedures for cleaning up spills shall be identified and the necessary equipment to implement a clean up shall be available to personnel.

§321.194 Other Requirements.

(a) Education and Training.

(1) Any CAFO owner/operator with greater than or equal to 300 animal units but less than 1,000 animal units and located within an area designated under §321.197 of this title (relating to Dairy Outreach Program Areas) shall either file an application and obtain a permit under this subchapter or, within 12 months of coming under the provisions of §321.183(b) or (l) of this title (relating to Applicability), the owner/operator or his designee with operational responsibilities shall complete an eight hour course or its equivalent on animal waste management. In addition, that owner/operator shall also complete at least eight additional hours of continuing animal waste management education for each two year period after the first twelve months. The minimum criteria for the initial eight hours and the subsequent eight hours of continuing animal waste management education shall be developed by the executive director and the Texas Agricultural Extension Service.

(2) Where the employees are responsible for work activities which relate to compliance with provisions of this subchapter, those employees must be regularly trained or informed of any information pertinent to the proper operation and maintenance of the facility and waste disposal. Employee training shall inform personnel at all levels of responsibility of the general components and goals of the pollution prevention plan. Training shall include topics as appropriate such as land application of wastes, proper operation and maintenance of the facility, good housekeeping and material management practices, necessary recordkeeping requirements, and spill response and clean up. The permittee is responsible for determining the appropriate training frequency for different levels of personnel and the pollution prevention plan shall identify periodic dates for such training.

(b) Inspections and Recordkeeping. The operator or the person named in the pollution prevention plan as the individual responsible for drafting and implementing the plan shall be responsible for inspections and recordkeeping.

(c) Recordkeeping and Internal Reporting Procedures. Incidents such as spills, other discharges or nuisance conditions, along with other information describing the pollution potential and quality of the dis-

charge shall be included in the records. Inspections and maintenance activities shall be documented and recorded. These records must be kept on site for a minimum of three years.

(d) Visual Inspections. The authorized person shall inspect designated equipment and facility areas. Material handling areas shall be inspected for evidence of, or the potential for, pollutants entering the drainage system or the creation of a nuisance. A follow-up procedure shall be used to ensure that appropriate action has been taken in response to the inspection.

(e) Site Inspection. A complete inspection of the facility shall be done and a report made documenting the findings of the inspection made at least once/year. The inspection shall be conducted by the authorized person named in the pollution prevention plan, to verify that the description of potential pollutant sources is accurate; the drainage map has been updated or otherwise modified to reflect current conditions; and the controls outlined in the pollution prevention plan to reduce pollutants and avoid nuisance conditions are being implemented and are adequate. Records documenting significant observations made during the site inspection shall be retained as part of the pollution prevention plan. Records of inspections shall be maintained for a period of three years.

(f) Additional Requirements. No condition of this authorization shall release the permittee from any responsibility or requirements under other statutes or regulations, Federal, State or Local.

(g) Audits Any CAFO owner/operator with greater than or equal 300 animal units but less than 1,000 animal units and located within an area designated under §321.197 of this title (relating to Dairy Outreach Program Areas) shall either file an application and obtain a permit under this subchapter or have an independent third party conduct a detailed audit of the owner's/operator's facility at least once every five years beginning with the date the facility initially came under the provisions of this subchapter. The minimum criteria of the audit shall be developed by the executive director and the Texas Agricultural Extension Service. Any CAFO owner/operator having an audit conducted in accordance with this section shall notify the executive director of the initial date of an audit inspection. Such notification shall be made to the executive director not less than five calendar days after the date of initial inspection. The final audit inspection shall be completed within ten days of the initial date, unless an extension is agreed to in writing by the executive director

(h) Protection from Liability to the State. Any CAFO owner/operator who conducts the audit identified in subsection (g) of this section, in accordance with the following requirements, shall not be liable to the state for violations identified during a subsequent inspection by the state, if the management circumstances which form the basis for the violation are identified as problems in the audit and are the subject of an on-going workplan, agreed to by the executive director, to correct the problem. An audit report and detailed workplan must be provided to the executive director for agreement within ninety days of the final day of the audit inspection and shall provide the following information:

(1) Identify all problems which could contribute to a detrimental impact on air, surface or ground water quality,

(2) Provide a workplan which specifically lists action to be taken to assure that the problems identified are solved so that these circumstances can no longer contribute to detrimental impacts on air, surface or ground water quality; and

(3) Provide a detailed schedule showing the initiation and completion date for each item on the list of actions to be taken. Within thirty days of actual receipt of an audit report and workplan, the executive director shall inform the owner/operator submitting the audit report and workplan that the executive director agrees that the workplan submitted solves the problems identified in the audit report within a reasonable period of time or the executive director shall inform the owner/operator that it does not If the executive director does not agree that the workplan will solve the problems identified within a reasonable period of time, the executive director shall inform the owner/operator specifically what changes must be made to the workplan in order to obtain such agreement. The executive director shall presume agreement with the owner/operator on the needed changes unless the owner/operator notifies the executive director in writing. Unless agreement can be reached between the executive director and the owner/operator within thirty days of the date the executive director notifies the owner/operator of disagreement, then protection pursuant to this subsection shall not apply. Upon agreement between the executive director and the owner/operator on the workplan, the owner/operator shall have a protection from liability from the state for any violation identified in an inspection by the state subsequent to the initial audit inspection date to the completion date of the items in the workplan which specifically address the cause of the violations.

§321.195. Monitoring and Reporting Requirements.

(a) If, for any reason, there is a discharge to waters in the state, the permittee is required to notify the executive director orally within 24 hours and in writing within 5 working days of the discharge from the retention facility or any component of the waste handling or disposal system. In addition, the permittee shall document the following information to the pollution prevention plan within 14 days of becoming aware of such discharge:

(1) A description and cause of the discharge, including a description of the flow path to the receiving water body. Also, an estimation of the flow and volume discharged.

(2) The period of discharge, including exact dates and times, and, if not corrected the anticipated time the discharge is expected to continue, and steps being taken to reduce, eliminate and prevent recurrence of the discharge.

(3) If caused by a precipitation event(s), information from the on site rain gauge concerning the size of the precipitation event.

(4) Unless otherwise directed by the executive director, facilities authorized under this subchapter shall sample and analyze all discharges from retention facilities. Sample analysis shall be documented to the pollution prevention plan.

(5) Samples shall consist of grab samples taken from the over-flow or discharges from the retention structure. A minimum of one sample shall be taken from the initial discharge (within 30 minutes). The sample shall be taken and analyzed in accordance with EPA approved methods for water analysis listed in 40 CFR 136. Measurements taken for the purpose of monitoring shall be representative of the monitored discharge

(6) Sample analysis of the discharge must, at a minimum, include the following: Fecal Coliform bacteria; 5-day Biochemical Oxygen Demand (BOD5); Total Suspended Solids (TSS); ammonia nitrogen; and any pesticide which the operator has reason to believe could be in the discharge.

(7) In lieu of discharge sampling data, the permittee must document description of why discharge samples could not be collected when the discharger is unable to collect samples due to climatic conditions which prohibit the collection of samples including weather conditions that create dangerous conditions for personnel (such as local flooding, high winds, hurricane, tornadoes, electrical storms, etc.). Once dangerous conditions have passed, the permittee shall collect a sample from the retention structure pond or lagoon. The sample shall be analyzed in accordance with paragraph (6) of this subsection.

(b) All discharge information and data will be made available to the executive

director upon request. Signed copies of monitoring reports shall be submitted to the executive director if requested at the address specified in the request.

(c) Any person who knowingly makes any false statement, representation, or certification in any record or other document submitted or required to be maintained under the provisions of this subchapter, including reports of compliance or noncompliance shall be subject to administrative penalties not to exceed $10,000 per violation. Such person(s) may also be subject to civil and criminal penalties pursuant to the Texas Water Code, §26.122 and §26.213.

(d) The permittee shall retain copies of all records required by this subchapter for a period of at least three years from the date reported. This period may be extended by request of the executive director at any time.

(e) The permittee shall furnish to the executive director, within a reasonable time, any information which the executive director may request to determine compliance with the provisions of this subchapter. The permittee shall also furnish to the executive director, upon request, copies of records required to be kept by the provisions of this subchapter.

(f) When the permittee becomes aware that they failed to submit any relevant facts or submitted incorrect information in any report to the executive director, they shall promptly submit such facts or information.

(g) All reports or information submitted to the Director shall be signed and certified in accordance with §305.44 of this title (relating to Signatories to Applications).

(h) The permittee shall maintain ownership, operation or control over the retention facilities, disposal areas and control facilities identified in the final site plan submitted with the application under §321.184 of this title (relating to Application Requirements). In the event permittee loses ownership, operation or control of any of these areas, the permittee shall notify the executive director prior to such loss of control and immediately request and file an application to amend the existing permit, an application for a new permit under this subchapter or present the executive director with a plan to cease all concentrated animal feeding operations at that site.

(i) Any permittee required to obtain a permit under §321.183 of this title (relating to Applicability) shall locate and maintain all facilities in accordance with the final site plan submitted with the application as required under §321.184 of this title (relating to Application Requirements). In the event the permittee does not properly locate and maintain such facilities in accordance with the final site plan they shall be deemed in noncompliance with the provisions of this subchapter.

§321.196. Registration. All new animal feeding operations which confine 300 animal units or more and/or any animal feeding operation which confines 300 head or more of a species or combination of species not specifically listed under the definition of CAFO as stated in §321.182 of this title (relating to Definitions) and have a potential to discharge into the waters in the state shall notify the executive director of their business name, physical location including a map or hand drawn sketch, mailing address and number of head in confinement. Such notification shall be in writing and signed by the owner/operator and shall be submitted not later than 180 days of the effective date of these rules or commencement of operation, whichever is later. Additionally, should an animal feeding operation covered by this section change ownership or substantially change the number of head in confinement, that operator shall submit an amended notification. No fees are associated with registration of animal feeding operations under this section.

§321.197. Dairy Outreach Program Areas for the purposes of this subchapter involve all of the following counties: Erath, Bosque, Comanche, Hamilton, Johnson, Hopkins, Wood and Rains. The commission shall review the areas designated under this section on at least a triennial basis to determine whether counties should be deleted or other areas should be added. Areas under this section shall be added or deleted in accordance with the rulemaking process.

§321.198. Effect of Conflict or Invalidity of Rule.

(a) If any provision of this subchapter or its application to any person or circumstances is held invalid, the invalidity does not affect other provisions or applications of the provisions contained in this subchapter which can be given effect without the invalid provision or application, and to this end the provisions of this subchapter are severable

(b) To the extent of any irreconcilable conflict between provisions of this subchapter and other rules of the commission, the provisions of this subchapter shall supersede.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued in Austin, Texas, on March 15, 1995

TRD-9503210

Lydia Gonzalez Gromatzky
Acting Director, Legal Division
Texas Natural Resource Conservation Commission

Earliest possible date of adoption: April 21, 1995

For further information, please call: (512) 239-4640

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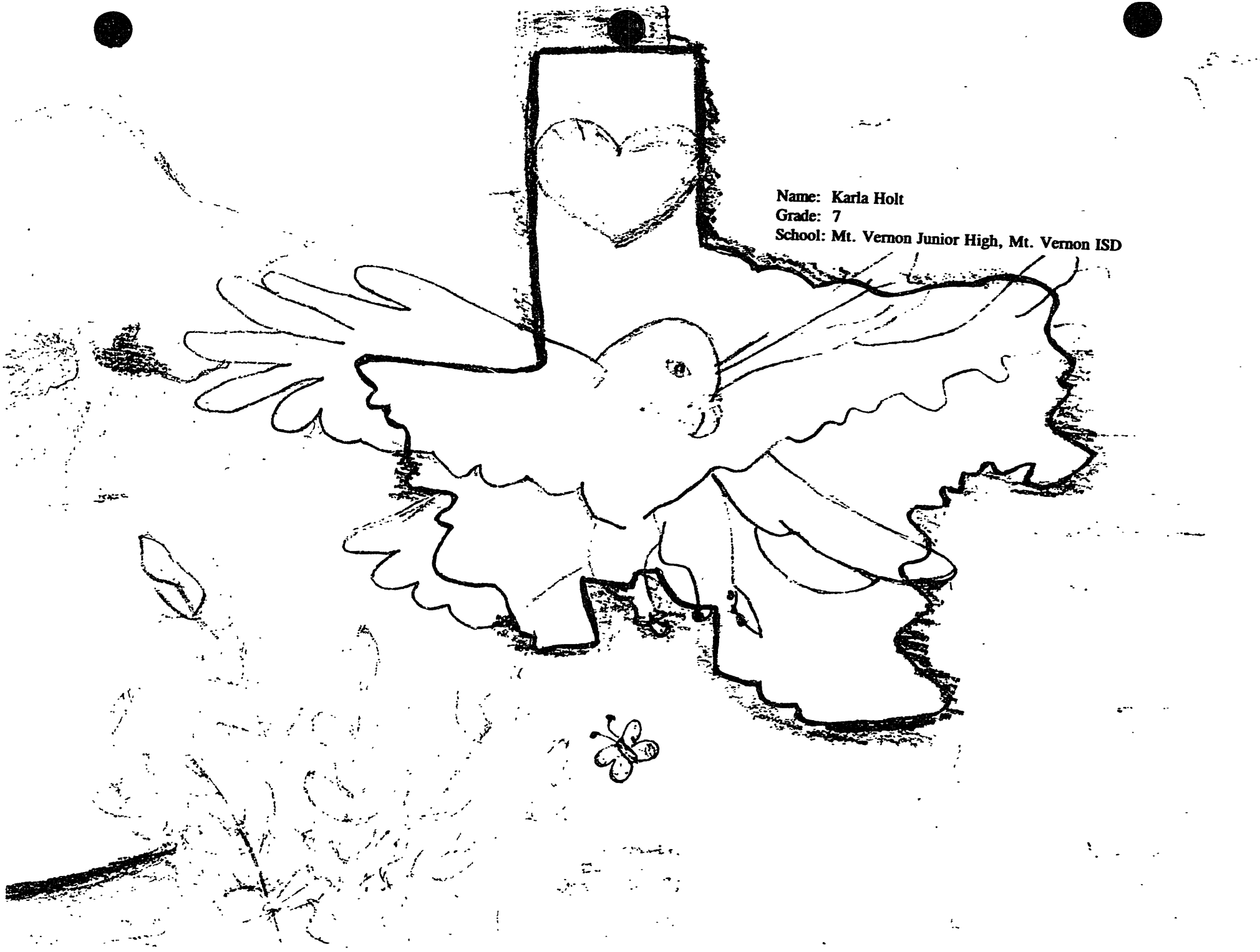

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WITHDRAWN RULES

An agency may withdraw a proposed action or the remaining effectiveness of an emergency action by filing a notice of withdrawal with the ***Texas Register***. The notice is effective immediately upon filling or 20 days after filing as specified by the agency withdrawing the action. If a proposal is not adopted or withdrawn within six months of the date of publication in the ***Texas Register***, it will automatically be withdrawn by the office of the Texas Register and a notice of the withdrawal will appear in the ***Texas Register***.

TITLE 30. ENVIRONMENTAL QUALITY

Part I. Texas Natural Resource Conservation Commission

Chapter 321. Control of Certain Activities by Rule

Subchapter B. Commercial Livestock and Poultry Production Operations

• 30 TAC §321.34

The Texas Natural Resource Commission has withdrawn from consideration for permanent adoption a proposed repealed §321.34, which appeared in the December 27, 1994, issue of the *Texas Register* (19 TexReg 10315). The effective date of this withdrawal is March 15, 1995.

Issued in Austin, Texas, on March 15, 1995.

TRD-9503206 Lydia Gonzalez Gromatzky
Acting Director, Legal Division
Texas Natural Resource Conservation Commission

Effective date: March 15, 1995

For further information, please call: (817) 239-4640

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• 30 TAC §321.34

The Texas Natural Resource Conservation Commission has withdrawn from consideration for permanent adoption a proposed new §321.34, which appeared in the December 27, 1994, issue of the *Texas Register* (19 TexReg 10316). The effective date of this withdrawal is March 15, 1995.

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For further information, please call: (817) 239-4640

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Subchapter K. Concentrated Animal Feeding Operation

• 30 TAC §§321.181-321.198

The Texas Natural Resource Conservation Commission has withdrawn from consideration for permanent adoption a proposed new §§321.181-321.198, which appeared in the December 27, 1994, issue of the *Texas Register* (19 TexReg 10318). The effective date of this withdrawal is March 15, 1995.

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Texas Natural Resource Conservation Commission

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1995 Publication Schedule for the *Texas Register*

Listed below are the deadline dates for the January-December 1995 issues of the *Texas Register*. Because of printing schedules, material received after the deadline for an issue cannot be published until the next issue. Generally, deadlines for a Tuesday edition of the *Texas Register* are Wednesday and Thursday of the week preceding publication, and deadlines for a Friday edition are Monday and Tuesday of the week of publication. No issues will be published on July 7, November 10, November 28, and December 29. An asterisk beside a publication date indicates that the deadlines have been moved because of state holidays.

FOR ISSUE PUBLISHED ON	ALL COPY EXCEPT NOTICES OF OPEN MEETINGS BY 10 A.M.	ALL NOTICES OF OPEN MEETINGS BY 10 A.M.
1 Tuesday, January 3	Wednesday, December 28	Thursday, December 29
2 Friday, January 6	Monday, January 2	Tuesday, January 3
3 Tuesday, January 10	Wednesday, January 4	Thursday, January 5
4 Friday, January 13	Monday, January 9	Tuesday, January 10
5 Tuesday, January 17	Wednesday, January 11	Thursday, January 12
Friday, January 20	1993 ANNUAL INDEX	
6 Tuesday, January 24	Wednesday, January 18	Thursday, January 19
7 Friday, January 27	Monday, January 23	Tuesday, January 24
8 Tuesday, January 31	Wednesday, January 25	Thursday, January 26
9 Friday, February 3	Monday, January 30	Tuesday, January 31
10 Tuesday, February 7	Wednesday, February 1	Thursday, February 2
11 Friday, February 10	Monday, February 6	Tuesday, February 7
12 Tuesday, February 14	Wednesday, February 8	Thursday, February 9
13 Friday, February 17	Monday, February 13	Tuesday, February 14
14 Tuesday, February 21	Wednesday, February 15	Thursday, February 16
15 Friday, February 24	*Friday, February 17	Tuesday, February 21
16 Tuesday, February 28	Wednesday, February 22	Thursday, February 23
17 Friday, March 3	Monday, February 27	Tuesday, February 28
18 Tuesday, March 7	Wednesday, March 1	Thursday, March 2
19Friday, March 10	Monday, March 6	Tuesday, March 7
20 Tuesday, March 14	Wednesday, March 8	Thursday, March 9
21 Friday, March 17	Monday, March 13	Tuesday, March 14
22 Tuesday, March 21	Wednesday, March 15	Thursday, March 16
23 Friday, March 24	Monday, March 20	Tuesday, March 21
24 Tuesday, March 28	Wednesday, March 22	Thursday, March 23
25 Friday, March 31	Monday, March 27	Tuesday, March 28
26 Tuesday, April 4	Wednesday, March 29	Thursday, March 30
27 Friday, April 7	Monday, April 3	Tuesday, April 4
28 Tuesday, April 11	Wednesday, April 5	Thursday, April 6
Friday, April 14	FIRST QUARTERLY INDEX	
29 Tuesday, April 18	Wednesday, April 12	Thursday, April 13
30 Friday, April 21	Monday, April 17	Tuesday, April 18
31 Tuesday, April 25	Wednesday, April 19	Thursday, April 20