TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 135. AMBULATORY SURGICAL CENTERS

SUBCHAPTER A. OPERATING REQUIREMENTS FOR AMBULATORY SURGICAL CENTERS

25 TAC §135.2, §135.26

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) adopts on an emergency basis in Title 25 Texas Administrative Code, Chapter 135, Ambulatory Surgical Centers (ASCs), amendments to §135.2 and §135.26, in order to expand ASCs' treatment capabilities and modify current reporting requirements to mitigate issues caused by patient surge due to COVID-19. As authorized by Government Code §2001.034, HHSC may adopt an emergency rule without prior notice or hearing upon a finding that an imminent peril to the public health, safety, or welfare requires adoption on fewer than 30 days' notice. Emergency rules adopted under Government Code §2001.034 may be effective for not longer than 120 days and may be renewed for not longer than 60 days.

BACKGROUND AND PURPOSE

The purpose of the emergency rulemaking is to support the governor's March 13, 2020, proclamation certifying that the COVID-19 virus poses an imminent threat of disaster in the state and declaring a state of disaster for all counties in Texas. In this proclamation, the Governor authorized the use of all available resources of state government and of political subdivisions that are reasonably necessary to cope with this disaster and directed that government entities and businesses would continue providing essential services. HHSC accordingly finds that an imminent peril to the public health, safety, and welfare of the state exists and requires immediate adoption of these amendments to mitigate issues caused by patient surge due to COVID-19.

To protect current and future patients in health care facilities and the public health, safety, and welfare of the state during the COVID-19 pandemic, HHSC is adopting emergency amendments to allow a currently licensed ASC to (1) expand its treatment options to include other health care services, not surgical services alone; (2) allow for patient stays longer than 23 hours; and (3) remove current reporting requirements related to longer patient stays and hospital transfers. The emergency amendment also requires an ASC to report the number of functioning ventilators and other respiratory support equipment it has, and any other information as required, to the Department of State Health Services.

STATUTORY AUTHORITY

The emergency rulemaking is adopted under Government Code §2001.034 and §531.0055 and Health and Safety Code §241.026. Government Code §2001.034 authorizes the adoption of emergency rules without prior notice and hearing, if an agency finds that an imminent peril to the

public health, safety, or welfare requires adoption of a rule on fewer than 30 days' notice. Government Code §531.0055 authorizes the Executive Commissioner of HHSC to adopt rules and policies necessary for the operation and provision of health and human services by the health and human services system. Health and Safety Code §241.026 requires HHSC to develop, establish, and enforce standards for the construction, maintenance, and operation of licensed ASCs.

§135.2.Definitions.

The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--Texas Ambulatory Surgical Center Licensing Act, Health and Safety Code, Chapter 243.

(2) Action plan--A written document that includes specific measures to correct identified problems or areas of concern; identifies strategies for implementing system improvements; and includes outcome measures to indicate the effectiveness of system improvements in reducing, controlling or eliminating identified problem areas.

(3) Administrator--A person who is a physician, is a registered nurse, has a baccalaureate or postgraduate degree in administration or a health-related field, or has one year of administrative experience in a health care setting.

(4) Advanced practice registered nurse (APRN)--A registered nurse approved by the Texas Board of Nursing to practice as an advanced practice registered nurse in Texas. The term includes a nurse practitioner, nurse midwife, nurse anesthetist, and clinical nurse specialist. The term is synonymous with "advanced nurse practitioner."

(5) Ambulatory Surgical Center (ASC)--A facility that primarily provides surgical services <u>but</u> <u>may provide other health care services</u> to patients [who do not require overnight hospitalization or extensive recovery, convalescent time or observation. The planned total length of stay for an ASC patient shall not exceed 23 hours. Patient stays of greater than 23 hours shall be the result of an unanticipated medical condition and shall occur infrequently. The 23-hour period begins with the induction of anesthesia</u>].

(6) Autologous blood units--Units of blood or blood products derived from the recipient.

(7) Available--Able to be physically present in the facility to assume responsibility for the delivery of patient care services within five minutes.

(8) Certified registered nurse anesthetist (CRNA)--A registered nurse who has current certification from the Council on Certification of Nurse Anesthetists and who is currently authorized to practice as an advanced practice registered nurse by the Texas Board of Nursing.

(9) Change of ownership--

(A) a sole proprietor who transfers all or part of the ASC's ownership to another person or persons;

(B) the removal, addition, or substitution of a person or persons as a general, managing, or controlling partner in an ASC owned by a partnership and the tax identification number of that ownership changes; or

(C) a corporation that transfers all or part of the corporate stock which represents the ASC's ownership to another person or persons and the tax identification number of that ownership changes.

(10) Dentist--A person who is currently licensed under the laws of this state to practice dentistry.

(11) Department--The Department of State Health Services.

(12) Disposal--The discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste (whether containerized or uncontainerized) into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharge into any waters, including ground waters.

(13) Extended observation--The period of time that a patient remains in the facility following recovery from anesthesia and discharge from the postanesthesia care unit, during which additional comfort measures or observation may be provided.

(14) Health care practitioners (qualified medical personnel)--Individuals currently licensed under the laws of this state who are authorized to provide services in an ASC.

(15) Licensed vocational nurse (LVN)--A person who is currently licensed by the Texas Board of Nursing as a licensed vocational nurse.

(16) Medicare-approved reference laboratory--A facility that has been certified and found eligible for Medicare reimbursement, and includes hospital laboratories which may be Joint Commission or American Osteopathic Association accredited or nonaccredited Medicare approved hospitals, and Medicare certified independent laboratories.

(17) Person--Any individual, firm, partnership, corporation, or association.

(18) Physician--An individual licensed by the Texas Medical Board and authorized to practice medicine in the State of Texas.

(19) Premises--A building where patients receive outpatient surgical services.

(20) Registered nurse (RN)--A person who is currently licensed by the Texas Board of Nursing as a registered nurse.

(21) Surgical technologist--A person who practices surgical technology as defined in Health and Safety Code, Chapter 259.

(22) Title XVIII--Title XVIII of the United States Social Security Act, 42 United States Code (USC), §§1395 et seq.

§135.26.Reporting Requirements.

(a) The ambulatory surgical center (ASC) shall make a report of the following incidents to the <u>Health and Human Services Commission (HHSC) Complaint and Incident Intake unit. An online</u> report prescribed by <u>HHSC or a [department. A]</u> written letter of explanation with supporting documents shall be <u>submitted [mailed]</u> to <u>HHSC [the department]</u> within 10 business days of the incident. [The mailing address is Department of State Health Services, Facility Licensing Group, Post Office Box 149347, Austin, Texas 78714-9347.]

(1) The death of a patient while under the care of the ASC; and

[(2) The transfer of a patient to a hospital;]

(2) [(3)] Patient development of complications within 24 hours of discharge from the ASC resulting in admission to a hospital. [; and]

[(4) A patient stay exceeding 23 hours.]

(b) On an annual basis, the ASC shall report the types and numbers of procedures performed and the average length of stay during the previous 12-month period. The report shall be made using a form to be prescribed by <u>HHSC</u> [the department].

(c) Any theft of drugs and/or diversion of controlled drugs shall be reported to the local police agency, the Texas State Board of Pharmacy, the Texas Department of Public Safety, and/or the Drug Enforcement Administration, and the Department of State Health Services.

(d) An ASC that performs abortions shall comply with the reporting requirements specified in the Texas Health and Safety Code, Chapters 171 and 245, and Chapter 139 of this title.

(e) The ASC shall submit reports to the department in accordance with the reporting requirements in Texas Health and Safety Code, §98.103 and §98.1045 (relating to Reportable Infections and Reporting of Preventable Adverse Events).

(f) Occurrences of fire in the ASC shall be reported as specified under §135.41(a)(2) of this title (relating to Fire Prevention and Protection) and §135.43(b)(6) of this title (relating to Handling and Storage of Gases, Anesthetics, and Flammable Liquids).

(g) An ASC that donates human fetal tissue under Texas Health and Safety Code, Chapter 173, shall submit an annual report to the Health and Human Services Commission that includes for each donation the specific type of fetal tissue donated and the accredited public or private

institution of higher learning that received the donation. The ASC shall submit the annual report no later than January 31st of the subsequent year.

(h) The ASC shall submit to the Department of State Health Services (DSHS) the number of functioning ventilators and other respiratory support equipment at the ASC and any additional information required by DSHS, in the manner prescribed by DSHS.

The agency certifies that legal counsel has reviewed the emergency adoption and found it to be within the state agency's legal authority to adopt.

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