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Regulation of **Health Care Facilities in Texas**

Outcome objectives



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- Review the requirements concerning the operation of a licensed and certified ambulatory surgical center in Texas;
- Review statement(s) that define “ambulatory surgical center (ASC)”;
- Identify current Conditions for Coverage (Federal requirements), and
- Identify current minimum standards for a licensed ASC (State rules).

Current definitions

1. FEDERAL [42 CFR 416.2]: "... Any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part ..."

1. STATE [25 TAC 135.2]: "... A facility that operates primarily to provide surgical services to patients who do not require overnight hospital care



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Licensing and Regulation

1. To protect the health and safety of patients receiving their services, nearly all Texas health care facilities are required by law to have a state-issued license before they can open and operate.
2. The Regulatory Services Division at the Texas Health and Human Services Commission (HHSC) licenses and regulates facilities providing acute (as opposed to long-term) health care services. These facility types are:



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General and special hospitals	End stage renal disease (dialysis) clinics
Psychiatric hospitals	Free-standing emergency medical centers
Birthing centers	Substance Abuse Treatment Facilities
Ambulatory surgical centers	Narcotic Treatment Clinics
Special care facilities	Abortion facilities

Regulations



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All facility regulations are based on what the Texas Legislature enacts into statute. Some examples are:

- Chapter 241 of the Texas Health and Safety Code is the enabling act for hospital licensing. From the chapter is derived:
 - 25 Texas Administrative Code (TAC) 133.41 and following – licensing rules for general and special hospitals
- Chapter 577 of the Texas Health and Safety Code is the enabling act for licensing of free-standing psychiatric hospitals and crisis stabilization units:
 - 25 TAC 134.41 and following – licensing rules for psychiatric hospitals (As of June 1, 2019 this regulation set has changed to Title 26)
- Chapter 243- 25 TAC 135- Ambulatory surgery centers
- Chapter 244- 25 TAC 137- Birthing centers
- Chapter 245- 25 TAC 131- Free-standing emergency medical centers

Regulations - Continued



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- In addition to state licensure, facilities can seek federal certification through the Centers for Medicare & Medicaid Services (CMS). These separate, federal regulations, known as Conditions of Participation or Conditions for Coverage, must be met for facilities to participate in the Medicare and Medicaid programs and receive funding through them.
- These federal conditions are based on the U.S. Social Security Act, which created Medicare and Medicaid in 1965. The rules governing these programs can be found in Title 42 of the Code of Federal Regulations (CFR).
- Some regulated facility types only maintain a CMS Certification because there is no state licensure required.

Accreditation



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- In addition to licensing and certification, specific types of facilities can also pursue voluntary accreditation through a CMS-approved national accreditation organization.
- Accreditation gives facilities “deemed status,” which allows them to receive Medicare certification and exempts them from routine surveys by HHSC to determine their compliance with the Medicare conditions of participation.
- A facility must pay to be accredited and must be surveyed by the accrediting organization’s staff to determine it is providing services based on the minimum standards as set forth by CMS.

Differences: Licensing, Certification, Accreditation



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- State licensure regulations outline the *minimum standards* a health care facility must follow to operate and serve patients. This is established by the state agency.
- The CMS Conditions of Participation/Coverage are more of a combination of minimum standards and best practices as decided by the federal government. In many areas, state licensure regulations mirror the federal regulations. However, some standards are more stringent.
- Accreditation guidelines are required to reflect the minimum standards of federal COPs, but are allowed to require “best practices” as part of their oversight.



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The Survey

- When the ASC refuses access – Court decisions, both Federal and State hold that the acceptance of the Medicare or State licensure is implied consent by the ASC to permit authorized officials to make unannounced visits. Refusal of access to the ASC can be a basis for termination of participation in Medicare. (See 42 CFR 489.53)
- The State may apply same as standard of operation for termination of licensure.

Documentation:



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- CMS Form 378 (Federal) is a surveyor's tool in which the applicable regulations to the ASC are contained
- A corresponding State worksheet which contains all state rules is also used



The Survey Process

- Unannounced survey for all providers and suppliers
- Surveyor escorts during a survey:
 - PROs: May answer surveyor's questions or concerns; may facilitate survey process
 - CONs: May hinder the survey process
 - Escorting surveyor is at surveyor's discretion



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Governing Body

- Governing Body and Management (42 CFR 416.41)
- The ASC has a governing body (GB).

ASC Operation
(Governance ^{25 TAC}
135.4)

- The governing body (GB) determines the mission, goals, and objectives of the ASC.
- GB sets policy and assumes full legal responsibility for ASC's total operation



Surgical Services

- Surgical Services (42 CFR 416.42)
 - Surgical procedures are performed in a safe manner by qualified physicians who have been granted privileges by the GB ...
 - Standard: Anesthetic risk and evaluation -
 - Standard: Administration of anesthesia -
 - Standard: Discharge -
 - Standard: State exemption
- ✓ Anesthesia & Surgical Services (25TAC135.11)
 - Anesthesia services provided are limited to those approved by the ASC's GB.
 - Surgical services are limited to those approved by the GB.



Quality

- Evaluation of Quality (42 CFR 416.43)
 - The ASC, with active participation of medical staff, conducts an ongoing self-assessment of the quality of care it provides, including medical necessity of procedures performed and appropriateness of care.
 - It uses its findings in revision of center policies and consideration of clinical privileges.

Quality of Care (25 TAC 135.7)

All health care practitioners have necessary & appropriate training and skills to deliver ASC services.

Health care practitioners practice in accordance with applicable state law and conform to the standards and ethics of their professions.

Patient care responsibilities are delineated in accordance with recognized standards.

There are qualified medical personnel available for emergency treatment when a patient who received services is in the ASC.

When necessary, patients and information are transferred appropriately and timely.



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Environment of Care

- Environment (42 CFR 416.44)
 - A safe and sanitary environment must be maintained.
 - Standard: Physical environment -
 - Standard: Safety from fire -
 - Standard: Emergency equipment -
 - Standard: Emergency personnel -
- ✓ Facilities and Environment (25TAC135.10)
 - Facilities are clean and properly maintained.
 - The ASC has the necessary personnel, equipment, and procedures to handle medical emergencies.
 - There is a system that provides for the protection of patients, staff, and the environment.



Nursing Services

- Nursing Services (42 CFR 416.46)

- Nursing service is directed and staffed to assure nursing needs of patients are met.
- Standard:
Organization and staffing -

- ✓ Facility Staffing & Training (25 TAC 135.15)

- (a) Nursing Services.

- There is an organized nursing service under the direction of a qualified registered nurse (RN).
- There is a written plan of administrative authority for all nursing services. The scope of nursing services encompasses preop-, intra-op- and postoperative care rendered.
- There must be an adequate number of RNs on duty to meet minimum staff requirements: director of the department, supervisory and staff personnel for each service area.



Medical Records

- Medical Records (42 CFR 416.47)
 - The ASC maintains complete, comprehensive and accurate medical records to ensure adequate patient care.
 - Standard: Organization -
 - Standard: Form and content of record –

Quality Assurance (QA) (25 TAC 135.8)

- QA activities encompass, and are not limited to, clinical performance of health care practitioners; **medical records**; quality controls for use of radiology, pathology, and medical laboratory services; professional and technical services; and studies of patient satisfaction.

Pharmaceutical Services



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- Pharmaceutical Services (42 CFR 416.48)
 - The ASC provides drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under direction of one designated responsible for pharmaceutical services.
 - Standard: Administration of drugs –
- Quality Assurance



Laboratory & Radiology

- **Laboratory and Radiologic Services**
(42CFR416.49)

- If the ASC performs lab services [directly], it must meet requirements of part 493 of this chapter.
- If it does not provide its own lab services it must have procedures for obtaining routine and emergency laboratory services from a certified lab.
- The ASC must have procedures for obtaining radiologic services from a Medicare approved facility.

- **Pathology & Medical Laboratory Services**
(25 TAC 135.13)

- Quality control of the lab must be monitored through the QA Committee. ■



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Health Care Quality



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- This unit is housed within HHSC under the Regulatory Services Division.
- Its composition is Facility Licensing, Architectural Review Group, Health Facility Compliance, Enforcement, Professional Licensing Group, and Policy/Rules/Training.
- Each group composes a piece of health care facility regulation.

Facility Licensing Group



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- Licensing activities are executed by the Health Care Quality- Facility Licensing Group.
- The Facility Licensing Group is responsible for developing rules that establish minimum standards for acute care facility licensing procedures and fees.
- Facility Licensing is also responsible for collaborating on operational requirements; inspection and investigation procedures; construction; fire prevention and safety requirements; waivers; license denial, probation, suspension and revocation.

Architectural Review Unit



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- This unit is responsible for the oversight of architectural requirements for health care facilities.
- An architectural review is one of the processes that is necessary in order to receive license approval from HHSC and must be completed for hospitals, ambulatory surgical centers (ASCs), dialysis facilities (ESRDs), free standing emergency medical care facilities (FEMCs), and special care facilities (SCF).
- This group works with facilities onsite and in the office reviewing facility plans.

Enforcement Unit

- This group is responsible for providing oversight over enforcement actions imposed on licensed healthcare facilities based on non-compliance with state licensing rules.
- Decisions on enforcement actions can come from Facility Licensing, Health Facility Compliance, and Architecture.
- This unit is required to collaborate with the above teams in determining enforcement actions due to non-compliance.



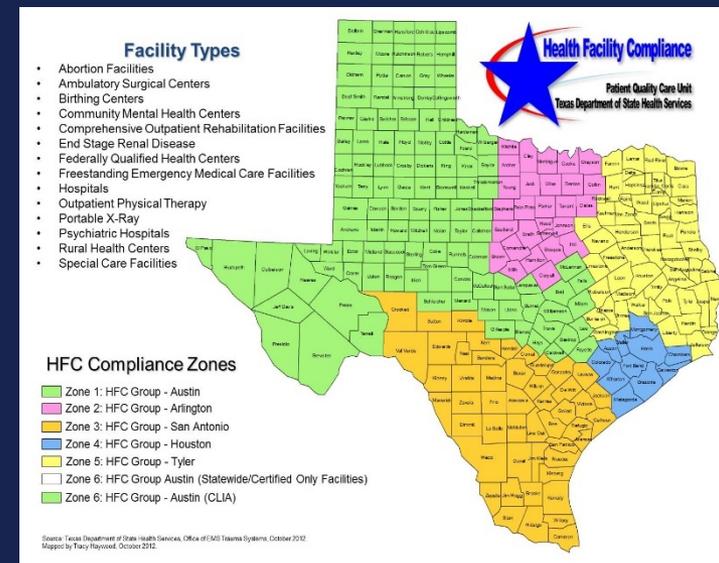
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Health Facility Compliance



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- This group is responsible for the onsite review of compliance of regulated acute care facilities.
- These facilities (licensed and certified) are grouped by county and assigned a “Zone office”.
- Texas is broken into 6 regulatory zones: Austin (Zone 1 & 6), Arlington (Zone 2), San Antonio (Zone 3), Houston (Zone 4), Tyler (Zone 5).
- Each zone is responsible for their assigned counties, and any of the facilities within those counties.
- There are approximately 96 staff members in total, and roughly 85 work exclusively in the field.



Licensed and Certified Facilities in Texas



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- Hospitals: 642
- Psychiatric hospitals: 57
- Ambulatory surgical centers: 523
- End stage renal disease (dialysis) clinics: 750
(Note: Texas has one-tenth of all dialysis facilities in the United States.)

Licensed-only Facilities



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- Free-standing emergency medical centers: 212
- Birthing centers: 91
- Abortion facilities: 13
- Special care facilities: 11
- Crisis stabilization units: 3
- Substance abuse treatment facilities: 754
- Narcotic treatment programs: 96
- Faith-based facilities: 169

Certified-only Facilities



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- Rural health clinics: 227
- Federally Qualified Health Centers: 173
- Outpatient Physical Therapy/Speech Therapy: 137
- Comprehensive Outpatient Rehabilitation Facilities: 39
- Community Mental Health Centers: 12
- Portable X-rays: 36

Substance Abuse Compliance Group- subgroup of HFC



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- Substance Abuse Treatment Facility- a licensed facility that offers chemical dependency treatment.
- Narcotic Treatment Program- licensed programs that treat patients addicted to heroin or other opiates.
- SACG team is central to Austin and travels throughout the state. There is no division of workload.

Clinical Laboratory Improvement Amendments (CLIA) – subgroup of HFC



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CLIA certification: Before laboratories can accept human samples for diagnostic testing, they must be certified by CMS.

CLIA-certified labs in TX: 25,034

- CLIA recognizes 4 types of laboratories: Waived, Provider-performed Microscopy, Compliance, and Accredited.
- Determination of laboratory type is based on the level of complexity of tests performed.

Complaints



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- Complaints for all provider types (acute and long-term care) are received and triaged by Complaint & Incident Intake.
 - A unit under Regulatory Services Division.
- Complaints are reviewed and assigned a triage priority based on the scope of allegations.
- Allegations of abuse, neglect, or exploitation usually receive the most urgent priorities, and therefore a faster turnaround with an investigation.
- All complaints, regardless of allegations, are analyzed for non-compliance with state and federal rules. If this state agency believes they do not have jurisdiction, then we attempt to refer it to another regulatory authority.

What determines and onsite visit?



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- Based on statute and federal rules, facilities can be visited at any reasonable time.
- Most often, facilities are visited for an investigation based on a complaint where the allegations were determined to possibly violate state and/or federal requirements.
- However, each facility has re-licensure/recertification requirements to maintain status within the state/federal programs. Onsite visits can be conducted for routine inspections looking for compliance with the rules.

Re-licensure & Recertification

- Intervals vary for onsite inspections/surveys depending on the provider type.
- **Hospitals**- required to be recertified around every 4 years, but the state laws do not mandate a re-licensure inspection interval.
 - Re-licensure inspection would only be “required” if the hospital was not CMS certified.
- **Rural Health Clinics**- recertification at least every seven years.
- **CLIA**- recertification at least every two years.
- **Ambulatory Surgical Center**- at least once every three years for certification and the state may inspect for re-licensure every three years.
- Many of the state licensure requirements do not mandate an onsite visit to renew the license.
- Due to more stringent CMS requirements for recertification, the state agency conducts concurrent surveys of federal and state standards.



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Inspection/Survey vs. Investigation



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- **Inspection/Survey:** The examination and/or review of a licensed facility's physical location. This includes of a review of the facility's physical environment, personnel records, patient records, policy and procedures, quality assurance, and all other clinical requirements as outlined by state and federal rules.
- **Investigation (complaint)-**The gathering and examination of specific information to possibly establish a preponderance of evidence related to specific allegations of noncompliance of state and federal rules.
 - **Note:** It is possible that there is no evidence/the activities did not occur and therefore allegations are unsubstantiated.
- **Complaints** are a more focused survey on a few rules/regulations. Full inspections are looking at all of the rules/regulations.
- The activities of the survey staff are essentially the same in both cases. They will look at policies, procedures, logs, patient records, etc. They will interview specific staff or patients based on the need.



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Questions?

Contacts



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- Facility Licensing Group- Pamela Adams, Manager
 - (512) 834-6648
- Architectural Review Group- Rebecca Read, Manager
 - (512) 834-6649
- Enforcement Unit- Anthony Luna, Manager
 - 512-834-6651
- Health Facility Compliance-
 - <https://www.dshs.texas.gov/facilities/compliance-contact.aspx>
 - 512-834-6650
- Substance Abuse Compliance- Cherri Schmidt, Manager
 - 512-834-6650
- Complaint Hotline:
 - 888-973-0022
 - Hfc.complaints@hhsc.state.tx.us
 - ciicomplaints@hhsc.state.tx.us



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Thank You

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