



# Presentation to House Committee on State Affairs

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# DSHS Regulatory Functions: Overview

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DSHS is statutorily charged with public health regulation of:

- Certain healthcare professionals
- Environmental health
- Radiation control
- Food and drug safety
- Healthcare facilities
  - Hospitals
  - Ambulatory surgical centers
  - Abortion facilities
  - Others



# DSHS Regulatory Functions: Overview

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- Annual processing of licenses, certifications and permits in fiscal year 2015 for:
  - Over 100,000 healthcare professionals and
  - More than 70,000 businesses, facilities, and equipment
- Total number of licensees over 350,000 for FY15
  - Over 200,000 of which are healthcare professionals
  - A 52 percent increase in the number of licenses between 2002 and 2015

# DSHS Regulatory Functions for Facilities: Overview

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- DSHS regulatory authority is specific to DSHS-licensed entities and the scope of authority includes, but is not limited to:
  - Patient safety
  - Patient rights
  - Infection control
- Consistent practices for all regulated facilities
  - Inspections and investigations
  - Corrective action plans
  - Escalated enforcement
  - Emergency/immediate suspension
  - Due process



# DSHS Statutory Authority: Abortion

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- Health and Safety Code, Chapters 170 and 171
  - Specific to the abortion procedure, including required notifications and informed consent
- Family Code, Chapter 33
  - Abortion requirements for unemancipated minors
- Health and Safety Code, Chapters 241, 243, and 245
  - DSHS regulatory authority over hospitals, ambulatory surgical centers, and abortion facilities

## DSHS Role Related to Tissue

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- DSHS role related to tissue is limited to specific actions that occur within the facility:
  - *Appropriate storage and handling*
  - *Infection control*
- DSHS authority does not extend outside of the facility:
  - *Transport*
  - *Sale*
  - *Donation*



# Range of Regulatory Authority in Facilities

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- Minimum standards for construction, maintenance, and operations of the physical facility
- Documentation of appropriate staffing and training
- Policies for and adherence to standards of infection control
- Facility standards and policies that ensure appropriate patient care
- Procedures that protect patient rights

# Annual Abortion Facility Inspections

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- Inspections are unannounced, regardless of facility type
  - This is reflected in long-standing DSHS rules
- Predictability of inspections has been a historical challenge
  - Before 2013, inspections occurred near the date of annual renewal
- In 2013, the Legislature required that abortion facility inspections also be random
  - DSHS changed the survey interval from every 12 months to every 10 to 14 months
- Due to insufficient randomness, DSHS amended its inspection scheduling process in 2015
  - The inspection schedule requires management review and approval

# Facility Inspection Process

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- The inspection process uses the following general process:
  - Unannounced facility inspection
  - Review of facility policies and procedures
  - Review of medical records
  - Facility staff interviews
  - Observation of surgical procedure with patient and physician consent
- Medical records review is based on surveyor selection of patient name or procedure type
- 11 licensure and re-licensure inspections and 3 complaint-based investigations of abortion facilities in 2015

- Focus on bringing facilities into compliance
  - Correction plans to address deficiencies within set timeframes
- More stringent action for serious deficiencies
  - Administrative penalties
  - Emergency/ immediate suspension or license revocation
  - Civil and criminal penalties in certain circumstances
- Due Process
  - Informal conference
  - State Office of Administrative Hearings

- Completion of a management-initiated review by internal audit
  - Purpose was to identify improvements for scheduling of annual abortion facility surveys
- Development of a computerized randomization tool to ensure annual abortion facility surveys are as random as possible
- Implementation of a policy requiring senior management approval for the annual survey schedule

- Retraining of DSHS surveyors to reinforce the importance of the unannounced inspection requirement
- Implementation of a formal unannounced inspection policy to reinforce long-standing practice
- Development of additional protocols for surveys