

Regulatory Services Division (RSD)

Kathy Perkins, Assistant Commissioner

FTEs: 755.5

The RSD provides oversight, monitoring, and strategic direction for implementing programs to regulate emergency medical services (EMS), trauma services, food and drug safety, environmental health, radiation use, healthcare professionals, and healthcare facilities. RSD has included detailed information about regulatory services provided to each of these licensing categories in a separate Section VII description.

Organizationally, the division has two sections and one unit reporting to the Assistant Commissioner.

- Health Care Quality Section establishes and administers rules and standards to maintain the health and safety of Texans by performing licensing, surveying, and inspection activities for healthcare providers, allied health professionals, and related programs and services.
- Environmental and Consumer Safety Section establishes regulatory standards and policies consistent with federal requirements and conducts compliance activities to protect public health related to foods (including meat), drugs, uses of radiation, and environmental hazards.
- The Enforcement Unit ensures compliance with all DSHS regulations and processes enforcement cases.

VII. GUIDE TO AGENCY PROGRAMS - CONTINUED

A. Provide the following information at the beginning of each program description.

Name of Strategy	Emergency Medical Services (EMS) and Trauma
Location/Division	8407 Wall Street, Austin - Regulatory Services Division (RSD)
Contact Name	Kathryn C. Perkins, Assistant Commissioner, RSD
Actual Expenditures, FY 2012	\$68,903,514
Number of Actual FTEs as of June 1, 2013	20.9
Statutory Citation for Program	Chapter 773, Texas Health and Safety Code

B. What is the objective of this program or function? Describe the major activities performed under this program.

EMS and Trauma has as its primary objective to develop and enhance regionalized emergency healthcare systems. Major activities include the following.

Trauma Facility Designation

Trauma Facility Designation ensures that the citizens and visitors of Texas receive quality trauma-care services provided by qualified designated trauma facilities that meet essential criteria. Staff conducts site surveys and/or reviews site survey reports of approximately 80 hospitals annually and monitors compliance with Trauma Facility Designation rules that require expeditious, appropriate, quality care for major and severe trauma patients.

Stroke Facility Designation

Stroke Facility Designation ensures that the citizens and visitors of Texas receive quality stroke-care services provided by qualified designated stroke facilities that meet essential criteria. Staff conducts site surveys and/or reviews site survey reports of approximately 50 hospitals annually; and monitors compliance with stroke facility designation rules that require expeditious, appropriate, quality care for stroke patients.

Regional EMS/Trauma Systems Designation

Regional EMS/Trauma Systems Designation encourages the growth of regional EMS/trauma systems by providing technical assistance to each Regional Advisory Council (RAC) to develop DSHS-approved regional trauma plans. The plans include the following components: injury prevention, access to the regional system, communications, medical oversight, pre-hospital triage criteria, diversion policies, bypass protocols, regional medical control, inter-hospital transfers, planning for designation of trauma facilities, and a system process improvement program. Regional EMS/Trauma Systems Designation facilitates and encourages RACs to

establish and monitor public health trends in traumatic death or disability, address community-injury health problems through prevention education, and implement system process improvement activities based upon data collection and monitoring.

EMS/Trauma Systems Grants

EMS/Trauma Systems Grants staff manages funding programs to assure that emergency first responders and EMS providers are available around the state to provide emergency care and transport. Additionally, funding programs assure that RACs build local regional trauma care systems that deliver major and severe trauma patients to the appropriate trauma facilities. Funding programs provide for the reimbursement of a portion of the uncompensated trauma care provided by eligible hospitals. The grants fund equipment and staff educational programs, as well as provide emergency grant monies for extraordinary situations when there is a potentially serious degradation of EMS services to a community. The grants also help fund communication and medical equipment needed to facilitate access to the regional EMS/trauma system. Whenever possible, staff determines awards through funding based on local need.

Stakeholder Information

Stakeholder Information provides technical assistance and education to the public about “Out of Hospital-Do Not Resuscitate” processes. Through injury prevention materials and media releases, staff educates the public about the role of EMS and the ways in which EMS can save lives. Staff also provides continuing education through the Texas EMS Conference, which draws more than 3,000 attendees from around the state, to ensure that medical continuing education courses for EMS personnel and emergency/trauma nurses are available at an affordable price. Each issue of *Texas EMS Magazine* contains a continuing education article and stakeholders have access to information through the website at:

<http://www.dshs.state.tx.us/emstraumasystems/default.shtm>.

RACs and over 54,000 EMS personnel in Texas also have access to articles in *Texas EMS Magazine* and press releases that assist them in teaching injury prevention techniques and strategies in communities across the state.

C. What evidence can you provide that shows the effectiveness and efficiency of this program or function? Provide a summary of key statistics and performance measures that best convey the effectiveness and efficiency of this function or program.

EMS and Trauma measures the effectiveness and efficiency of its functions by the ongoing monitoring and continued development of designated trauma and stroke facilities. In fiscal year 2012, DSHS provided EMS/Trauma Systems funding to 2,523 providers.

	Texas Regional EMS/Trauma Systems	Texas Designated Trauma Facilities	Texas Designated Stroke Facilities	Texas Trauma Mortality Rates per 100,000
1989		0*		60.00*
1998		108**		
2000		183**		52.61****
2006	22***	242***		56.50****
2008	22***	244***		55.18****
2009	22***	246***		56.08****
2010	22***	256***	57 Level II Primary Stroke Facilities*	54.63****
2011	22***	262***	83 Level II; 1 Level III	
2012	22***	276***	94 Level II; 3 Level III	
2013	22***	268*****	2 Level I; Level II 108; 4 Level III	

* *Texas Trauma System: Interim Report on the EMS/Trauma System Fund*, September 1998. Texas Department of Health (TDH), Bureau of Emergency Management.

** *EMS and Trauma Care Systems Account: Final Report to the 77th Legislature*, February 2001. TDH, Bureau of Emergency Management.

*** DSHS Office of EMS/Trauma Systems.

**** *Centers for Disease Control WISQARS Injury Mortality Report*, age adjusted 2000 standard year (last statistics available in 2010).

***** The decrease in the number of facilities with trauma designations from 2012 to 2013 is due to 13 facilities that underwent a change of ownership, which rendered them undesignated in 2013. These same facilities immediately re-entered the program “in active pursuit of designation,” meaning the facility is required to acquire trauma facility designation within two years from the date of entering such status.

D. Describe any important history regarding this program not included in the general agency history section, including how the services or functions have changed from the original intent.

1989 – The Omnibus Rural Health Care Rescue Act directs the Bureau of Emergency Management of TDH to develop and implement a statewide EMS and Trauma Care System, designate trauma facilities, create the Trauma Technical Advisory Committee, and develop a trauma registry to monitor the system and provide statewide cost and epidemiological statistics. The act does not provide funding for the endeavor at that time; however, in 1997, the Legislature establishes funding for this activity.

1992 – The Texas Board of Health adopts rules for implementation of the trauma system. These rules divide the state into 22 regions called trauma service areas (TSAs), provide for the formation of a RAC in each region to develop and implement a regional trauma system plan,

delineate the trauma facility designation process, and provide the development of a state trauma registry.

1995 – All TSAs establish RACs and all RACs have regional system plans approved by TDH, now DSHS. The Texas EMS/Trauma System continues to develop RACs and implement regional EMS/trauma systems, active quality performance improvement programs, and effective intra-regional communication systems that allow almost immediate contact with their membership. Many expand their roles to include other projects, such as participation in hospital, disaster, and bioterrorism preparedness planning and development of acute care coordination in the form of stroke and cardiac care protocols.

1998 – The Board of Health adopts rules to require EMS and hospital participation in the development of regional trauma systems and regional system plans, and submission of data to the state registry. TDH disburses funds to EMS providers and RACs to promote system development and to hospitals for uncompensated hospital trauma care.

2003 – The Legislature adds Section 12.0111, Texas Health and Safety Code, which requires DSHS to charge a fee sufficient to cover the cost of administering and enforcing the stroke designation program.

2005 – Senate Bill 330 amends Sections 773.204 and 773.205, Texas Health and Safety Code, and requires DSHS, with the assistance of the Governor’s EMS and Trauma Advisory Council and its Stroke Committee, and in collaboration with the Texas Council on Cardiovascular Disease and Stroke, to develop stroke facility criteria and a statewide stroke emergency transport plan.

2013 – House Bill 15 amends Chapter 241, Texas Health and Safety Code. The new Subchapter H requires HHSC and DSHS, with the assistance of a newly created Perinatal Advisory Council, to develop and implement a statewide Perinatal and Maternal Care System, to divide the state into neonatal/maternal care regions, and to designate neonatal and maternal levels of care facilities.

E. Describe who or what this program or function affects. List any qualifications or eligibility requirements for persons or entities affected. Provide a statistical breakdown of persons or entities affected.

The EMS and Trauma System affects all citizens and visitors to Texas. Approximately 39 Texans die every day from injuries, at a rate of almost 13,750 a year. Since trauma is the leading cause of death in persons ages 1-44, the years of potential life lost are staggering – approximately 347,000 in 2010. Using a per-capita income of \$25,548, this represents \$8.86 billion in lifetime income lost and a reduction to the state in lifetime tax revenues of \$1.07 billion for that one year of trauma mortality alone.

Every 45 seconds, someone in America has a stroke. About 700,000 Americans will have a stroke this year. Stroke is the nation's number three killer and a leading cause of severe, long-term disability.

House Bill 15, 83rd Legislature, Regular Session, 2013, directs DSHS to designate neonatal and maternal levels of care. In order to receive Medicaid reimbursement, DSHS must designate a facility separately as either maternal or neonatal services. DSHS anticipates that the 253 facilities currently providing these services will seek designation for either or both services. If all 253 receive designation, this will exceed the number of facilities currently in the trauma and stroke designation programs combined.

F. Describe how your program or function is administered. Include flowcharts, timelines, or other illustrations as necessary to describe agency policies and procedures. Indicate how field/regional services are used, if applicable.

RSD, Office of EMS/Trauma Systems Coordination administers EMS and Trauma. Sections 773.119 and 773.122, Texas Health and Safety Code, charge the Office of EMS/Trauma Systems with establishing a program to award grants that initiate, expand, maintain, and improve EMS and to support medical systems and facilities that provide trauma care. The program staff manages the distribution of the EMS/Trauma Care System Account; EMS, Trauma Facilities, and Trauma Care System Fund; Permanent Fund for EMS and Trauma Care (Tobacco Endowment Fund); and the Designated Trauma Facility and EMS Account. Funding programs include local project grants to EMS providers, first responder organizations, EMS education organizations, and pre-hospital injury prevention organizations; RAC development grants; extraordinary emergency fund grants to EMS providers, first responder organizations, and trauma facilities; emergency care attendant training grants to EMS providers and first responder organizations; and uncompensated trauma care grants to EMS providers, RACs, and trauma facilities.

Section 773.113, Texas Health and Safety Code, charges the Office of EMS/Trauma Systems with developing and maintaining statewide EMS and trauma care systems, and a method for trauma reporting and analysis system. Section 773.115, Texas Health and Safety Code, mandates designating trauma facilities that are part of an EMS trauma care system at four levels:

- Level I: comprehensive trauma facility,
- Level II: major trauma facility,
- Level III: advanced trauma facility, and
- Level IV: basic trauma facility.

DSHS designates Level I and Level II trauma facilities in accordance with American College of Surgeons (ACS) guidelines and additional rules adopted by DSHS. DSHS designates Level III trauma facilities in accordance with rules adopted by DSHS and ACS guidelines or those of another DSHS-approved organization. DSHS designates Level IV trauma facilities in accordance with rules adopted by DSHS. To ensure concordance, DSHS staff secondarily reviews

conclusions about a hospital’s trauma-care performance standards documented by the ACS surveyors in their trauma facility site survey reports. Facilities that contract directly with ACS bear the survey costs.

The Office of EMS/Trauma Systems also assists in the development of stroke facility criteria and a statewide stroke emergency transport plan, in accordance with Sections 773.204 and 773.205, Texas Health and Safety Code. DSHS designates stroke facilities that are part of the regionalized emergency healthcare systems at three levels:

- Level I: comprehensive stroke facility,
- Level II: primary stroke facility, and
- Level III: support stroke facility.

DSHS designates Level I and Level II stroke facilities in accordance with The Joint Commission (TJC) Comprehensive Stroke and Primary Stroke Certification Program. DSHS designates Level III stroke facilities in accordance with DSHS support stroke criteria, the DSHS-approved survey organization for trauma and stroke, and additional DSHS rules. To ensure concordance, DSHS staff secondarily reviews conclusions about a hospital’s stroke-care performance standards documented by TJC surveyors’ site survey reports. Facilities that contract directly with TJC bear the survey costs.

The program has organizational charts and descriptions of units for review located at: <http://www.dshs.state.tx.us/orgchart/regulatory.shtm>.

G. Identify all funding sources and amounts for the program or function, including federal grants and pass-through monies. Describe any funding formulas or funding conventions. For state funding sources, please specify (e.g., general revenue, appropriations rider, budget strategy, fees/dues).

Funding Source	Amount
Federal	\$0
General Revenue	\$22,963
General Revenue-Dedicated	\$68,880,551
Other	\$0

There are no funding appropriations for stroke facilities and neonatal maternal facilities at this time.

H. Identify any programs, internal or external to your agency, that provide identical or similar services or functions to the target population. Describe the similarities and differences.

Internal Programs

Name	Similarities	Differences
DSHS Healthcare Facility Licensing	DSHS uses patient-centered rules establishing minimum standards for general hospital licensing procedures, and trauma-facility designation essential criteria. The rules include such things as fees, operational requirements, inspection and investigation procedures, license/designation denial, suspension, and revocation.	Hospitals operating in Texas most follow DSHS rules establishing minimum standards. DSHS allows voluntary adherence to rules for establishing minimum trauma facility designation standards, although significant funding opportunities associated with adherence exist.

External Programs

Name	Similarities	Differences
ACS Trauma Verification Program	ACS verifies a hospital's trauma care capability and performance by an on-site review of the hospital to evaluate compliance with ACS Level I and II essential criteria. The review team consists of experienced trauma surgeons, an emergency physician, and trauma nurses.	DSHS designation is a formal recognition of a hospital's trauma care capabilities and commitment verified by ACS for Level I and II designation or by an on-site review to evaluate compliance with DSHS Level III and IV essential criteria. The review team consists of experienced trauma surgeons and nurses.
TJC	Through an on-site survey review process, TJC verifies compliance with TJC standards and issues findings in the form of facility accreditation of certification for disease specific programs. TJC provides stroke center certification that indicates a hospital meets TJC performance standards.	TJC accreditation and stroke certification is a nationwide seal of approval for all hospital departments. DSHS designation is a state-specific process that recognizes the performance standards of those areas of the hospital that affect stroke patients. Designation also indicates that the facility participates in the regional stroke system of its TSA.

I. Discuss how the program or function is coordinating its activities to avoid duplication or conflict with the other programs listed in Question H and with the agency's customers. If applicable, briefly discuss any memorandums of understanding (MOUs), interagency agreements, or interagency contracts.

A Level I or Level II DSHS-designated trauma facility must meet, among other things, the current ACS essential criteria for verification, as required by Title 25, Texas Administrative Code, Section 157.125, Requirements for Trauma Facility Designation. While there are no memorandums of understanding, ACS staff performs and documents hospital survey reports which, by rule, serve as an acceptable part of the trauma facility designation process. Additionally EMS and Trauma Program staff consults the ACS Committee on Trauma’s *Resources for Optimal Care of the Injured Patient* during trauma facility designation rules reviews in order to ensure that state standards are similar to national standards of trauma care.

Level I or II DSHS-designated stroke facilities must meet, among other things, TJC essential criteria for certification, as required by Title 25, Texas Administrative Code, Section 157.133, Requirements for Stroke Facility Designation. While there are no memorandums of understanding with TJC, TJC staff performs and documents hospital survey reports which, by rule, serve as an acceptable part of the stroke facility designation process. Additionally, during rule review and to ensure standards are similar to national standards, DSHS relies on recommendations from the Stroke Committee of the Governor’s EMS and Trauma Advisory Council, in collaboration with the Texas Council on Cardiovascular Disease and Stroke, which refers to the Brain Attack Coalition’s essential criteria for Level I and II stroke centers.

Neonatal and maternal levels of care designations have not been developed in rule; however, DSHS is not aware of any national, regional, or state organization that is currently providing accreditation, verification, or certification at any level for either neonatal or maternal levels of care.

J. If the program or function works with local, regional, or federal units of government include a brief description of these entities and their relationship to the agency.

Local Units of Government

Name	Description	Relationship to DSHS
Hospital districts	Hospital districts provide medical assistance, including hospitalization when required, to indigent persons residing within their geographic boundaries.	No direct relationship exists; however, DSHS has designated as trauma facilities many hospitals funded by hospital districts as safety net hospitals for indigent persons.
Academic health science centers	Academic health science centers train health professionals, conduct research that advances health, and provide care especially to the most ill and poorest populations.	No direct relationship exists; however, DSHS has designated as trauma facilities most academic health science centers that serve as safety net hospitals for indigent persons.

K. If contracted expenditures are made through this program please provide:

- a short summary of the general purpose of those contracts overall;
- the amount of those expenditures in fiscal year 2012;
- the number of contracts accounting for those expenditures;
- top five contracts by dollar amount, including contractor and purpose;
- the methods used to ensure accountability for funding and performance; and
- a short description of any current contracting problems.

DSHS established contracts in this program for the following:

- EMS attendance certification training;
- emergency funding for hospitals and EMS providers with disruption of services;
- equipment, supplies, and operational expenses for EMS providers;
- trauma systems development for EMS providers and RACs;
- ambulances during disasters;
- partnership to train nurses and physicians in emergency and trauma care;
- funding to create a Medicaid “Trauma Add-on” to maximize funding to hospitals for uncompensated trauma care; and
- disbursement to hospitals for a portion of uncompensated trauma care.

Amount of contracted expenditures in fiscal year 2012: \$8,479,490

Number of program contracts: 446 (includes contracts with no expenditures)

The top five contracts for the program are as follows.

Amount Expended FY 12	Contractor	Purpose
\$310,983	North Central Texas Trauma RAC	Trauma systems development for EMS
\$292,418	Southwest Texas RAC	Trauma systems development for EMS
\$286,387	North Texas Central Trauma RAC	Trauma systems development for RACs
\$286,057	Texas J RAC	Trauma systems development for EMS
\$261,359	Southeast Texas RAC	Trauma systems development for EMS

Regional emergency medical services and trauma systems funding is tied to performance, which is measured by contractual benchmarks. Each of the 22 RACs operates as a 501(c)(3) nonprofit organization. DSHS staff monitors performance through quarterly and annual financial and programmatic reporting. Biannually, each RAC completes a self-assessment followed by programmatic desk audit.

To ensure accountability, the assigned contract manager monitors contract performance and takes action to resolve performance and compliance issues as needed. Additionally, staff in the Chief Financial Office audits each invoice to confirm accuracy. The accounting system includes edits to match invoices with purchase orders and verification of receipt of goods and services. Staff in the Chief Operating Office performs target financial compliance reviews and provides consultative services and technical assistance on financial management of contracts. DSHS uses an automated contract management system, SOURCE.Net, to document contractor information, contract management activities, and monitoring reports. The program has no known contracting problems.

L. Provide information on any grants awarded by the program.

DSHS awards local project grants in this program for EMS. In fiscal year 2012, DSHS made 108 awards (\$1,171,935) for EMS-related equipment, supplies, education, training, and emergency response vehicles for EMS providers, first responders, and EMS education providers. The program awards grants through competitive solicitations.

M. What statutory changes could be made to assist this program in performing its functions? Explain.

The program does not have any statutory changes to suggest.

N. Provide any additional information needed to gain a preliminary understanding of the program or function.

The preceding discussion is sufficient to gain a preliminary understanding of the program.

- O. Regulatory programs relate to the licensing, registration, certification, or permitting of a person, business, or other entity. For each regulatory program, if applicable, describe:**
- why the regulation is needed;
 - the scope of, and procedures for, inspections or audits of regulated entities;
 - follow-up activities conducted when non-compliance is identified;
 - sanctions available to the agency to ensure compliance; and
 - procedures for handling consumer/public complaints against regulated entities.

Not applicable.

P. For each regulatory program, if applicable, provide the following complaint information. The chart headings may be changed if needed to better reflect your agency's practices.

Not applicable.

VII. GUIDE TO AGENCY PROGRAMS – CONTINUED

A. Provide the following information at the beginning of each program description.

Name of Strategy	Food and Drug Safety
Location/Division	8407 Wall Street, Austin - Regulatory Services Division (RSD)
Contact Name	Kathryn C. Perkins, Assistant Commissioner, RSD
Actual Expenditures, FY 2012	\$23,396,766
Number of Actual FTEs as of June 1, 2013	335.5
Statutory Citation for Program	Chapters 145, 146, 431, 432, and 486, Texas Health and Safety Code

B. What is the objective of this program or function? Describe the major activities performed under this program.

The primary objective of Food and Drug Safety is to design and implement regulatory programs to ensure the safety of food, drugs, and medical devices. Major activities include the following.

Foods Manufacturing Program

The Foods Manufacturing Program inspects food processors, wholesalers, certificates of free sale, warehouse operators, and food salvage establishments; establishes standards and ensures compliance through voluntary means and formal enforcement; and tests and issues certificates of competency to operators of bottled and vended water establishments.

Foods Establishment Program

The Foods Establishment Program inspects retail food establishments in Texas that local jurisdictions do not inspect; establishes standards and ensures compliance through voluntary means and formal enforcement; and tests and issues certifications for the certified food manager and food service worker programs. The Foods Establishment Program also accredits food handler education or training programs, conducts school cafeteria inspections, and trains local inspectors.

Drugs and Medical Devices Program

The Drugs and Medical Devices Program inspects drug and medical device manufacturers and wholesale distributors, such as tattoo, tanning, and body piercing facilities, and retailers of pseudo-ephedrine containing products. The group establishes standards and ensures compliance through voluntary means and formal enforcement procedures.

Meat Safety Assurance (MSA) Program

The MSA Program ensures that retailers produce goods bearing the *Texas Mark of Inspection* come from healthy livestock animals that are humanely slaughtered and are prepared in a sanitary manner, contain no harmful ingredients, and are truthfully labeled. The MSA Program conducts inspections of 100 percent of livestock animals presented for humane slaughter and performs daily inspections of livestock slaughter and meat and poultry processing facilities engaged in intrastate sales. The program establishes standards and ensures compliance by both voluntary means and formal enforcement procedures to maintain the meat inspection program “at least equal to” the U.S. Department of Agriculture (USDA) federal standards in accordance with state law.

Milk and Dairy Products Program

The Milk and Dairy Products Program inspects milk processing plants, cheese manufacturers, dairy farms, manufacturers of frozen desserts, and milk transportation operations. The Milk and Dairy Products Program establishes standards and ensures compliance by both voluntary means and formal enforcement procedures.

Seafood Program

The Seafood Program inspects molluscan shellfish and crabmeat harvesters and processors and monitors fish from public waterways and shellfish growing and harvesting areas for chemical and microbiological contaminants. The Seafood Program establishes standards and ensures compliance through voluntary means and formal enforcement.

C. What evidence can you provide that shows the effectiveness and efficiency of this program or function? Provide a summary of key statistics and performance measures that best convey the effectiveness and efficiency of this function or program.

The functional alignment of activities as described in Question E streamlined the process of Food and Drug Safety inspections, eliminated overlap, and provided for more uniformity by using common resources including personnel and equipment. In addition, functional reorganization has enabled RSD to establish uniform policies and procedures and unified enforcement activities. Reorganization has aided the program in completing many of the previous Sunset Commission Review recommendations noted below.

Following the passage of House Bill 2085, 76th Legislature, Regular Session, 1999, as a follow-up to Sunset Commission Review of the agency, DSHS regulatory programs implemented numerous changes to improve effectiveness and efficiency. These changes include a wide array of topics, including the following:

- cross-utilization of staff when appropriate;
- standard processes for review of completed inspection reports to ensure uniformity;
- direct line authority by the Austin office over the field staff in most programs;
- implementation of Enforcement Review Committees for formal enforcement for all programs;

- standardized enforcement policy;
- additional enforcement authorities for several programs (amendments to laws);
- institution of an “informal settlement” procedure;
- publication of final enforcement actions and trends;
- expanded programmatic and licensing information on program websites;
- participation in the Texas e-Government portal for licensing; and
- solicitation of more stakeholder input into the rulemaking process.

During fiscal year 2012, regulatory programs obtained thousands of documented voluntary corrections of unsanitary conditions during inspections of regulated industries, thereby averting numerous potential illnesses, injuries, and/or deaths from conditions that might have adulterated and/or contaminated foods, drugs, and medical devices destined for public distribution. Food and Drug Safety staff calculates the cost of correcting these conditions as \$7 million.

During fiscal year 2012, Food and Drug Safety Program staff witnessed the voluntary destruction of the following foods, drugs, and medical devices found to be adulterated, contaminated, or misbranded:

- 32,618 pounds of meat in retail stores valued at \$113,510;
- 427 units of drugs and devices valued at \$3,165;
- 94,883 pounds of meat at meat plants valued at \$475,000, not including the pounds of product condemned voluntarily by establishments; and
- 4,543,401 pounds of milk valued at \$734,213.

These were products intended for sale to consumers in Texas and elsewhere. By discovering and removing these products, Food and Drug Safety prevented public exposure to these items and the threats to public health and safety.

Federal agencies conduct formal audits of certain areas within Food and Drug Safety to ensure that they are operating in a manner consistent with federal counterparts as far as grants, contracts, and funding. These areas are the Medical Devices, U.S. Food and Drug Administration (FDA) contract inspection program; the Manufactured Foods, FDA contract inspection program; the Foods Country of Origin Labeling, USDA contract inspection program; and the Meat Safety, USDA inspection program. For example, the MSA Unit, which is 50 percent funded by USDA, receives significant attention from USDA’s Food Safety and Inspection Service (FSIS) similar to the other 26 states that have state meat-inspection programs. The MSA Unit must maintain its “equal to” status to receive federal funding. To meet the USDA federal requirements, the MSA Unit must inspect 100 percent of livestock animals presented for humane slaughter and must conduct daily inspections at meat and poultry processing establishments that wholesale their products for intrastate commerce. The MSA Unit submits yearly self-assessments to USDA/FSIS, and USDA/FSIS conducted on-site evaluations of the Meat Safety Program in 2006, 2009, and 2012. The MSA Unit has continually met all federal standards and requirements.

Food and Drug Safety has procedures to ensure that inspectors maintain a required number of inspections. The Manufactured Foods FDA contract inspection program requires state inspectors to pass yearly inspection audits conducted by FDA personnel. Additionally, Food and Drug Safety conducts audit desk reviews of completed reports to ensure the laws and rules are properly enforced, the reporting of violations, and the completeness and thoroughness of reports and evidence to document violations. The staff receives explicit training in these areas.

D. Describe any important history regarding this program not included in the general agency history section, including how the services or functions have changed from the original intent.

1990s – Food and Drug Safety implements a risk assessment to ensure that the program uses limited resources are for the greatest impact on public health. Each area evaluates the risks posed by the regulated products and establishments, so that the products and facilities presenting the greatest risk to public health receive the greatest attention.

2001 – The legislatively mandated Business Practices Evaluation Report finds that the legacy Texas Department of Health (TDH) needs a complete reordering of the administrative and organizational infrastructure in order to function efficiently. In response to findings, Food and Drug Safety undergoes staff reorganizations that centralize inspection teams within programs and combine certain programs according to functionality.

2003 – Senate Bill 1152 requires Food and Drug Safety to provide regulated entities the option of renewing licenses via Texas Online, the official e-government website. The Legislature also mandates two-year terms for each license issued by state agencies. This requirement applies to licenses, permits, registrations, and certificates issued or renewed on or after January 1, 2005, and to all activities within Food and Drug Safety, except meat safety grants of inspection that do not expire.

As a result of legislation that passes in 2003, Food and Drug Safety realigns into functional units. TDH combines policies, standards, and quality assurance for all programs, as well as all inspection activities, licensing, and enforcement. Prior to this reorganization, Food and Drug Safety had seven separate divisions, with each division operating each aspect (policies, procedures and standards; compliance; and enforcement) independently, with the exception of licensing that DSHS combined at the bureau level. The reorganization also leads to locating all central office Food and Drug Safety staff within a single building, which improves communications and leads to improved efficiency in operations.

2005 – The RSD enters into a contract for the creation of a Regulatory Automation System (RAS). RAS integrates licensing, inspection, investigation, enforcement, and compliance activities. This combined database eliminates the need and cost to maintain separate systems for licensure, inspections, and other database documentation.

2006 – DSHS amends rules concerning the regulation of retail food establishments to reflect current science and knowledge regarding best practices, emerging pathogens, and new retail food technologies. The new rules are consistent with the current FDA model Food Code.

2007 – Senate Bill 943 establishes inspection requirements and exemptions under the Prescription Drug Monitoring Act, federal law and regulations regarding state licensing of wholesale drug distributors and accompanying operation requirements.

2009 – Senate Bill 1645 establishes additional pedigree exemptions for secondary wholesale drug distributors, which are firms that receive their drugs from other wholesale drug distributors. The Legislature requires these firms to pass pedigrees, a paper trail from the sale of the drug from the manufacturer through all subsequent sales. This bill exempts government-run, nonprofit wholesalers that provide drugs to mental health hospitals from the pedigree requirement.

2009 – Senate Bill 1271 amends Chapter 605, Texas Occupations Code, to require licensure for an orthotist or a prosthetist as a device manufacturer, if fabricating or assembling without an order from certain healthcare professionals.

2009 – House Bill 1310 requires DSHS to initiate rulemaking efforts to conduct inspections where appropriate to ensure compliance with the new provisions for tanning salons.

2009 – Food and Drug Safety elects to participate in a grant program to develop a rapid response team (RRT). The scope of the RRT is to provide preparedness, prevention, and an immediate response to a food/feed-related disaster affecting the citizens of Texas. This includes a large-scale investigation involving food and/or feed and large scale recalls of food and/or feed. The intended scope of the RRT does not include natural disasters (e.g., hurricanes or forest fires); however, there are outcomes from natural disasters that are within the scope of the RRT, such as flooding, windstorms, tornadoes, power outages, and fires, if the food chain is threatened and the outbreak is not part of a statewide emergency response activation.

2010 – Food and Drug Safety includes the Manufactured Food Regulatory Program Standards as part of a contract with the FDA for conducting inspections of food manufacturers. The program standards establish a uniform foundation for the design and management of state programs responsible for the regulation of food plants. Additionally, the program standards establish requirements for staff training, inspection, quality assurance, food defense preparedness and response, foodborne illness and incident investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment.

2010 – House Bill 2729 requires DSHS to develop rules to allow donation of unused, unopened, non-dispensed medications. The rules limit donations to pharmacies, physicians, wholesalers, and manufacturers that want to donate drugs that are in stock and not dispensed to patients.

2011 – The Legislature adds requirements for cottage food production operations to Chapter 437, Texas Health and Safety Code. DSHS adopts rules to require a cottage food production operation to label foods sold to consumers in accordance with the statute in order make the public aware that food produced by a cottage food operation is not inspected by DSHS or a local health department (LHD). Additionally, the Legislature amends Chapter 437, Texas Health and Safety Code, which addresses farmers’ markets. DSHS or a LHD may issue a temporary food establishment permit to a person who sells food at a farmers’ market without limiting the number of days for which the permit is effective, with the maximum period of the permit being no more than one year.

2013 – House Bill 1395 requires DSHS to initiate rulemaking efforts relating to the exemption of registered dental laboratories from certain distributing and manufacturing licensing requirements. Senate Bill 329 requires DSHS to implement changes to the tanning facility rules to prohibit a person younger than 18 years of age from using a tanning device in a tanning facility.

E. Describe who or what this program or function affects. List any qualifications or eligibility requirements for persons or entities affected. Provide a statistical breakdown of persons or entities affected.

As everyone consumes food, nearly everyone takes drugs, and many utilize medical devices, Food and Drug Safety impacts all citizens of Texas. In addition, licensure, inspections of regulated facilities and/or products, and enforcement of standards affect all persons who engage in any of the regulated activities.

Food and Drug Safety imposes restrictions on the eligibility for persons regulated under certain programs. These include certain felony convictions related to specific licenses by statute. For instance, a manufacturer or distributor of drugs may not employ or use in any capacity an individual with a conviction of a drug-related offense. DSHS must license regulated facilities to operate in Texas. For successful licensure, the facility must complete a multi-page license application properly and pay the required licensing fee. Additionally, in some programs, an applicant must undergo a pre-licensing inspection and pass a criminal background check prior to the issuing of a license. A license is valid for two years. For a facility to retain its license, the results of any inspections, along with follow-up visits, must show the facility to be in substantial compliance with the currently applicable state laws and rules.

Number of Firms and Certifications Fiscal Year 2012	
Food Manufacturers	14,535
Food Wholesalers	1,627
Food Warehouse Operators	563
Food Wholesale Registrants	810

Number of Firms and Certifications Fiscal Year 2012	
Multiple Products (Food, Drug, Device)*	2,055
Drug Distributors (Prescription and Non-prescription)	1,871
Drug Manufacturer (Prescription and Non-prescription)	381
Device Manufacturers	322
Device Distributor	1,321
Food, Drug, and Device Salvage	326
Bottled and Vended Water (Machines)	5,770
Bottled and Vended Water (Operators)	574
Pseudo-Ephedrine Retailers Distributors	23
Tanning	1,720
Tattoo	1,539
Body Piercing	886
Retail Establishments (Including Mobile Food Units)	12,023
Producer Dairies	603
Milk Tankers	821
Pasteurization (Includes Out of State)	43
Frozen Desserts (Includes Out of State)	74
Milk Transfer/Receiving Station	28
Retail Raw	65
Non-Grade A	82
Seafood (Shellfish and Crab)	68
Meat Safety (Meat Establishments Facilities, Haulers, Renderers)	353
Meat Group Rendering Establishments	86
Meat Group Transfer Stations	12
Meat Group Related Stations	1
Meat Group Renderable Raw Material, Dead Animal, and	143
Meat Group Decals	1,356
Meat Group Construction Permit	5
Certified Food Managers (Certified at Test Sites)	2,536
Certified Food Manager Programs and Test Sites	15
Accredited Food Handler Programs	23
School Cafeteria Inspection Fee Applications Processed	1,052

* Due to changes in reporting from the database, Food and Drug Safety cannot list the number of multiple product licenses by the specific types of products.

F. Describe how your program or function is administered. Include flowcharts, timelines, or other illustrations as necessary to describe agency policies and procedures. Indicate how field/regional services are used, if applicable.

RSD administers the Food and Drug Safety programs. RSD administers all activities from the Austin office and operates functionally with respect to policies and standards, compliance and enforcement, and licensure. Food and Drug Safety makes assignments to the field inspection staff according to risk. Field inspection staff returns completed inspection reports to the Austin office for review and determination of the need for any additional voluntary or formal regulatory action to protect public health. All field staff members located in DSHS health service regions (HSRs) are home-based or have duty stations in meat processing plants. Food and Drug Safety distributes field staff throughout the state, according to workload, under the direct supervision of the Austin office supervisors. The exception is sanitarians working for the Food Establishment Group; these staff members are supervised by the respective HSR directors.

Except for meat safety inspections, field staff forwards completed inspection reports to the Environmental and Consumer Safety Section, Policy, Standards, and Quality Assurance (PSQA) Unit; the PSQA Unit enters the reports into a central database. The PSQA Unit reviews the reports and recommends re-inspection or forwarding to the Enforcement Unit. The PSQA Unit also maintains and revises procedure handbooks to ensure compliance with state and federal mandates. The Environmental and Consumer Safety Section, MSA Unit conducts meat inspections and enters reports into the USDA Performance Based Inspection System.

Food and Drug Safety has a risk-based matrix to ensure that the establishments posing the highest risk receive the most attention through inspections and follow-up visits. Examples of criteria used to categorize the risk of an establishment include the inherent risk of the food being processed, the type of processing the food undergoes, the compliance history of the firm, the number of people served, and the kinds of individuals served (for example, the very young or the elderly, as opposed to all individuals). An example of a high-risk establishment is one that produces low acid canned foods; if the food is underprocessed, it could be contaminated with botulinum toxin. Establishments such as low risk food warehouses, manufacturers of low risk foods, and manufacturers and distributors of low risk medical devices and over-the-counter drugs no longer receive routine inspections, except for times when field staff is in an area and has the opportunity to conduct inspections.

Food and Drug Safety uses various authorities granted by law to gain compliance, including the detention and destruction of adulterated foods, drugs, and medical devices. The program may issue warning letters in an attempt to gain voluntary compliance following inspections where staff observes significant violations. When Food and Drug Safety is unable to obtain voluntary compliance, staff may proceed with formal enforcement actions. Food and Drug Safety uses enforcement review committees, composed of program representatives. These representatives review each case and the evidence documenting the continued violations to determine the type of formal action needed to obtain correction.

Both field and Austin office staff receive complaints against regulated industries and enter them into a central database, where staff assigns the complaints unique identification numbers. The program investigates complaints according to a risk matrix, based upon the risk to public health associated with the nature of the complaint, especially if illness or injury is imminent or has occurred.

Food and Drug Safety staff works closely with epidemiologists in the DSHS Disease Control and Prevention (DCP) Services Division, Infectious Disease Prevention Section, Infectious Disease Control Unit during investigations of food-borne illness outbreaks.

The program has organizational charts and descriptions of units for review located at: <http://www.dshs.state.tx.us/orgchart/regulatory.shtm>

G. Identify all funding sources and amounts for the program or function, including federal grants and pass-through monies. Describe any funding formulas or funding conventions. For state funding sources, please specify (e.g., general revenue, appropriations rider, budget strategy, fees/dues).

Funding Source	Amount
Federal	\$6,883,172
General Revenue	\$11,202,752
General Revenue-Dedicated	\$5,307,454
Other	\$3,388

H. Identify any programs, internal or external to your agency, that provide identical or similar services or functions to the target population. Describe the similarities and differences.

Internal Programs

Name	Similarities	Differences
DCP Services Division, Zoonosis Control Unit	The Zoonosis Control Unit has authority over zoonotic diseases that are transmissible to man.	Food and Drug Safety reports zoonotic diseases identified during pre-slaughter and/or post-slaughter examination of food animals both to Zoonosis Control and to the Texas Animal Health Commission (TAHC).

External Programs

Name	Similarities	Differences
FDA	FDA conducts inspections of many of the same industries regulated by DSHS and uses	FDA issues no licenses and only inspects businesses engaged in interstate commerce. FDA has only

Name	Similarities	Differences
	similar laws and regulations.	enough staff to inspect 2-3 percent of the regulated industries. FDA oversees but rarely inspects dairies or shellfish producers, as state programs conduct these inspections following federal standards.
USDA, FSIS	FSIS conducts on-site continuous inspections of meat and poultry processing facilities using federal laws and regulations.	DSHS MSA Unit inspects meat and poultry from federally amenable livestock species for intrastate commerce, while FSIS inspects products destined for interstate commerce. MSA also inspects meat and poultry from non-federally amenable livestock species for interstate commerce.
Local health jurisdictions	Local health jurisdictions inspect and permit retail food service establishments using ordinances that, in many respects, are identical to state regulations.	Home rule cities may adopt rules that are different or more stringent than state law and rules. DSHS only inspects retail facilities in areas of the state that are not under local inspection and permitting (188 counties).
Texas Commission on Environmental Quality (TCEQ)	TCEQ laws and regulations cover certain types of environmental problems that may relate to facilities inspected by Food and Drug Safety, such as public water supplies and fish contaminants.	TCEQ has no inspection authority over food, drug, or medical device facilities or products.
Texas Department of Agriculture (TDA)	TDA regulates shell eggs.	By amendment to the Texas Agriculture Code in 1999, TDA has authority over the quality of shell eggs, while DSHS has authority over the safety of shell eggs. TDA grades eggs, while DSHS checks the storage and temperature of the eggs for safety.
TAHC	TAHC oversees animal health in Texas, including the protection of livestock, wildlife, and pets from disease; and tests for the presence of bovine spongiform	The MSA Unit has joint responsibility with TAHC for the health of food animals and wildlife defined by law as “amenable” (acceptable for sale for human

Name	Similarities	Differences
	encephalopathy (BSE) – joint jurisdiction with the DSHS MSA Unit. TAHC ensures disposal of inedible materials from the slaughter and processing of livestock, while the MSA Unit has inspectional jurisdiction over similar materials sent to rendering facilities. TAHC protects human health from animal diseases that are transmissible to people. TAHC performs similar functions to the MSA Unit in areas and facilities not under DSHS jurisdiction.	consumption). MSA’s jurisdiction begins at slaughter and ends at consumption, while TAHC’s authority ends when the animal is brought to slaughter, as TAHC does not have jurisdiction in the slaughter plants other than periodically collecting blood samples. Both share responsibilities with respect to BSE.
Texas Parks and Wildlife Department (TPWD)	TPWD regulates hunting, fishing, and recreational activities in Texas. The DSHS Seafood Program collects information used by DSHS to establish safe harvest areas. TPWD enforces bans made by DSHS. TPWD has jurisdiction over indigenous game animals, such as white tail deer, for which the hunter must obtain a hunting license from TPWD.	The DSHS Seafood Program samples shellfish and finfish harvest areas. When DSHS declares seafood harvest areas prohibited, TPWD game wardens enforce the closure areas.
Office of the Texas State Chemist (OTSC)	OTSC regulates pet food products. The DSHS MSA Unit regulates renderable, raw materials, which includes unprocessed or partially processed inedible material of animal or plant origin that manufacturers may render into pet food.	The DSHS MSA Unit regulates inedible, renderable raw materials until manufacturers render the products. If, and when, the manufacturers render the inedible products into pet food, OTSC has jurisdiction of the product.

I. Discuss how the program or function is coordinating its activities to avoid duplication or conflict with the other programs listed in Question H and with the agency’s customers. If applicable, briefly discuss any memorandums of understanding (MOUs), interagency agreements, or interagency contracts.

Food and Drug Safety patterns all food, drug, and medical device safety, labeling, and efficacy requirements after federal law. Texas has adopted the majority of its rules by reference to federal requirements or adopted standards using federal regulations as models.

Food and Drug Safety coordinates inspections with the FDA to minimize duplication of inspections. Electronic access to each other's lists of establishments subject to inspection allows each agency to check for inspection assignments or pending regulatory actions. DSHS contracts with FDA to conduct inspections for FDA of establishments that FDA will not inspect. DSHS and FDA establish partnership agreements, whereby DSHS conducts inspections for FDA in exchange for other equipment, services, or training. These partnerships include inspections of food and drug imports, medical gases, over-the-counter drug manufacturers, and certain medical devices. A memorandum of understanding between FDA and DSHS outlines use of information and resource sharing to eliminate duplication and enhance consumer protection.

The USDA pays up to 50 percent of the costs of the state meat and poultry inspection program for inspections provided in establishments that slaughter federally amenable livestock species and/or process meat and poultry products from federally amenable livestock species to be sold in intrastate commerce. USDA also pays the State of Texas up to 50 percent of the costs (100 percent of the costs for reimbursable services) for DSHS inspections of "Talmadge-Aiken" (facilities that may legally ship in interstate commerce) meat and poultry processing facilities that USDA is unable to staff. Consequently, there is no duplication of services. Texas is recognized by USDA as an "equal to" state based upon complete annual (self-assessment) and tri-annual (self-assessment and on-site) programmatic audits by USDA.

The TAHC has jurisdiction over livestock before slaughter in a plant regulated by the DSHS MSA Unit; however, MSA staff contacts TAHC if MSA staff suspect that livestock brought into a slaughtering facility might have a zoonotic, communicable, or foreign animal disease. TAHC assists the MSA Unit veterinarians in sampling for diseases, quarantining animals, tracking an animal's history, and providing guidance on appropriate disposal of carcasses and parts of suspect animals. There is no duplication of services, but rather cooperation in areas of joint jurisdiction.

Chapter 437, Texas Health and Safety Code, limits DSHS inspections of retail food establishments to those establishments that are not under inspection and permit approval by local health jurisdictions. Local jurisdictions concentrate on the good sanitation practices, as outlined in the rules for Texas Food Establishments (Title 25, Texas Administrative Code, Chapter 229, Subchapter K).

The TCEQ contracts with the DSHS Seafood Safety Group to conduct sampling of fish from public waterways for heavy metals and other chemical adulterants. The Seafood Safety Group then analyzes the results of the samples and completes a risk characterization. Further, various laws and rules enforced by DSHS contain references to water source surveys conducted by TCEQ, rather than requiring the DSHS regulatory programs to duplicate these activities.

Amendments to the Texas Agriculture Code, following the TDA Sunset Review in 1997, eliminated any duplication that might otherwise occur between DSHS and TDA with food safety programs. In part, these stipulated that TDA have authority over shell egg quality (grading of the eggs) only, while DSHS has authority over the safety of shell eggs (temperature monitoring and inspection at wholesale and retail). In addition, TDA only promotes companies that have appropriate DSHS licensure under the “Go Texan” program. DSHS coordinates activities with TDA.

There is no duplication between DSHS and TPWD, but rather a cooperative effort, whereby DSHS issues fish advisories and sets limits on where the industry can harvest molluscan shellfish. TPWD establishes and enforces harvesting limits by the industry. TPWD has jurisdiction over indigenous game animals, such as white tail deer, for which the hunter must obtain a hunting license from TPWD.

There is no duplication between DSHS and OTSC, as OTSC jurisdiction begins where DSHS jurisdiction ends (i.e., when the previously inedible material of animal or plant origin has been rendered into the finished pet food product). DSHS coordinates with OTSC, as necessary, when either entity receives complaints concerning pet food products.

J. If the program or function works with local, regional, or federal units of government include a brief description of these entities and their relationship to the agency.

Local Units of Government

Name	Description	Relationship to DSHS
Rural school districts	Another DSHS program, Environmental Health, inspects schools, including school cafeterias, not located within the confines of a local public health jurisdiction; however, Environmental Health sends the inspection reports to the Food Establishments Group in Food and Drug Safety for review.	DSHS inspects the schools, including the cafeterias.
Local health jurisdictions	Local health jurisdictions inspect and permit retail food service establishments. Some jurisdictions also test and issue certificates to food service managers.	Food and Drug Safety provides training to local health jurisdictions, including standardization of local inspectors to ensure uniform inspections. Food and Drug Safety works jointly with local jurisdictions on food-borne illness investigations and assists local health jurisdictions

Name	Description	Relationship to DSHS
		with the adoption and update of their local ordinances. DSHS serves as a model to the local jurisdictions in the inspection and enforcement of retail food safety laws and rules. DSHS staff gives numerous presentations to local and state groups of sanitarians.
Municipal public health laboratories	Municipal public health laboratories analyze both clinical and public health-related samples, usually submitted from within their own jurisdictional boundaries.	The Milk and Dairy Group contracts with the larger municipal laboratories in Texas to conduct bacteriological and antibiotic residue analyses of over 131,000 samples each year.

Federal Units of Government

Name	Description	Relationship to DSHS
FDA	FDA oversees all food safety in the United States other than meat and poultry, sets standards, approves food additives, and approves new drugs and medical devices. FDA also oversees importation of these food and drug products.	DSHS administers state laws and regulations that, in most cases, are identical to those enforced by FDA. DSHS looks to FDA for advice on approved food additives and approval of new drugs and devices. DSHS shares lists of regulated establishments with FDA and conducts inspections for FDA. FDA audits inspections DSHS conducts for FDA and the qualifications of DSHS inspectors. FDA also oversees the work of the Milk and Dairy Group and the Seafood Group, which must meet specific standards in order for Texas producers to ship their products in interstate commerce. FDA also provides model standards for the Food Establishments Group (retail).
USDA, FSIS	FSIS inspects all amenable species of livestock, meat, and poultry, listed as subject to federal inspection, that are scheduled for interstate	DSHS receives 50 percent of program funding from FSIS and receives program audits by FSIS to ensure that the state Meat Safety inspections remain “equal to” the

Name	Description	Relationship to DSHS
	shipment. FSIS establishes all regulations dealing with the safety and labeling of amenable species of meat and poultry, regulations that are preemptive upon the states.	federal meat and poultry inspection standards.

- K. If contracted expenditures are made through this program please provide:**
- a short summary of the general purpose of those contracts overall;
 - the amount of those expenditures in fiscal year 2012;
 - the number of contracts accounting for those expenditures;
 - top five contracts by dollar amount, including contractor and purpose;
 - the methods used to ensure accountability for funding and performance; and
 - a short description of any current contracting problems.

DSHS established contracts in this program for the following:

- milk and dairy sample laboratory analysis,
- fish and shellfish tissue laboratory analysis,
- rapid response team for food-borne outbreak, and
- food processing and technology course training.

Amount of contracted expenditures in fiscal year 2012: \$853,331

Number of program contracts: 26 (includes contracts with no expenditures)

The top five contracts for the program are as follows.

Amount Expended FY 12	Contractor	Purpose
\$173,968	Tarrant County	Milk and dairy laboratory sample analysis
\$90,630	Northeast Texas Public Health District	Milk and dairy laboratory sample analysis
\$78,363	Texas Agrilife Research	Support for RRT cooperative agreement grant from USDA
\$47,422	City of San Antonio	Milk and dairy laboratory sample analysis
\$45,576	City of Houston	Milk and dairy laboratory sample analysis

To ensure accountability, the assigned contract manager monitors contract performance and takes action to resolve performance and compliance issues as needed. Additionally, staff in the Chief Financial Office audits each invoice to confirm accuracy. The accounting system includes

edits to match invoices with purchase orders and verification of receipt of goods and services. Staff in the Chief Operating Office performs targeted financial compliance reviews and provides consultative services and technical assistance on financial management of contracts. Assigned contract managers use an automated contract management system, SOURCE.Net, to document contractor information, contract management activities, and monitoring of reports. DSHS has no known contracting problems.

L. Provide information on any grants awarded by the program.

The program does not award grants.

M. What statutory changes could be made to assist this program in performing its functions? Explain.

DSHS suggests the following statutory changes to assist the program in performing its functions.

Chapter 431 and 437, Texas Health and Safety Code – DSHS recommends revision to provide DSHS with authority to suspend a license issued under these chapters for repeated serious violations without the prerequisite that the violations pose an imminent health hazard.

Section 431.021, Texas Health and Safety Code – DSHS recommends revision to make it a violation for a flea market operator to allow the sale of illegal foods, drugs, or medical devices from the premises under the operator’s control.

Section 431.048, Texas Health and Safety Code – DSHS recommends revision to reference the administrative penalty option for contested cases.

Section 38.15, Texas Penal Code – DSHS recommends revision to add additional protection of inspectors in health-related fields from physical abuse and/or verbal abuse and threats.

N. Provide any additional information needed to gain a preliminary understanding of the program or function.

The preceding discussion is sufficient to gain a preliminary understanding of the program.

- O. Regulatory programs relate to the licensing, registration, certification, or permitting of a person, business, or other entity. For each regulatory program, if applicable, describe:**
- **why the regulation is needed;**
 - **the scope of, and procedures for, inspections or audits of regulated entities;**

- **follow-up activities conducted when non-compliance is identified;**
- **sanctions available to the agency to ensure compliance; and**
- **procedures for handling consumer/public complaints against regulated entities.**

Regulation of the persons licensed, certified, and inspected by Food and Drug Safety is necessary for the protection of health and safety of the citizens of Texas and the citizens of the United States with respect to products sold in interstate commerce.

Food and Drug Safety operates within the parameters established by statute and according to rules adopted to enforce these laws. Where possible, Food and Drug Safety uses uniform procedures for conducting inspections, including report forms, evidence development, and review of reports. Each area utilizes a risk assessment procedure to determine inspection frequency. Areas utilize procedure manuals for directing the activities of the inspection staff and, in a number of cases, also use federal procedure manuals to maintain uniformity with federal counterparts.

When Food and Drug Safety observes non-compliance, the program may implement one or more of the following: place establishments on escalated re-inspection frequencies; issue warning letters; and/or voluntarily destroy or place adulterated foods, drugs, and devices under embargo. Statutes and rules do not allow livestock slaughter and meat and poultry processing facilities to operate and/or enter their products into commerce on a daily basis, unless the inspector-in-charge at the facility finds them in compliance. Many of the areas within Food and Drug Safety have embargo authority to remove adulterated and significantly misbranded foods, drugs, and devices from commerce and destroy adulterated foods and drugs, as well as obtain summary closure of a facility in the case of the existence of an imminent health hazard.

Food and Drug Safety has a risk module for handling consumer complaints, which requires investigating concerns involving illness or injury within 24 hours. Staff enters all complaints into a database for tracking and assignment. DSHS forwards complaints related to entities not under DSHS direct jurisdiction, such as those against restaurants or grocery stores, to the appropriate jurisdiction for investigation. Staff forwards those received from prison inmates to the Texas Department of Criminal Justice for investigation.

P. For each regulatory program, if applicable, provide the following complaint information. The chart headings may be changed if needed to better reflect your agency's practices.

Department of State Health Services Food and Drug Safety Exhibit 11: Information on Complaints Against Regulated Persons or Entities Fiscal Years 2011 and 2012		
	FY 2011	FY 2012
Total number of regulated persons	13,638	3,110
Total number of regulated entities	51,770	50,807
Total number of entities inspected	17,937	18,786
Total number of complaints received from the public*	1,443	1,340
Total number of complaints initiated by agency	143	75
Number of complaint investigations pending from prior years	95	130
Number of complaints found to be non-jurisdictional	94	110
Number of jurisdictional complaints found to be without merit	537	674
Number of complaints resolved	1,144	856
Average number of days for complaint resolution	313	400
Complaints resulting in disciplinary action:**		
administrative penalty	66	64
reprimand	0	0
probation	0	0

* Represents all complaints received, including public, external sources, and internal sources.

** Because staff takes the majority of disciplinary actions as the result of routine inspections, reporting only disciplinary actions as a result of complaints would provide an inaccurate picture of the total disciplinary actions taken.

VII. GUIDE TO AGENCY PROGRAMS - CONTINUED

A. Provide the following information at the beginning of each program description.

Name of Program or Function	Environmental Health
Location/Division	8407 Wall Street, Austin - Regulatory Services Division (RSD)
Contact Name	Kathryn C. Perkins, Assistant Commissioner, RSD
Actual Expenditures, FY 2012	\$7,125,585
Number of Actual FTEs as of June 1, 2013	108.9
Statutory Citation for Program	Chapters 141, 341, 343, 345, 385, 485, 501-502, and 505-507, Texas Health and Safety Code; Chapters 1954, 1955, and 1958, Texas Occupations Code; Sections 2165.301-2165.305, Texas Government Code

B. What is the objective of this program or function? Describe the major activities performed under this program.

The Environmental Health Program has as its primary objective to design and implement risk assessment and risk management regulatory programs for consumer products, occupational and environmental health hazards, and public health sanitation. Major activities include the following.

Asbestos Program

The Asbestos Program conducts licensing, inspections, and enforces state and federal rules and statutes pertaining to asbestos in public buildings, schools, and commercial and industrial facilities. The Asbestos Program operates through fees generated from licensing and abatement notifications. Through federal grants administered by the U.S. Environmental Protection Agency (EPA), the Asbestos Program enforces the asbestos National Emission Standard for Hazardous Air Pollutants, dedicated to ensuring safe removal of asbestos in facilities, and the Asbestos Hazard Emergency Response Act, which applies to management of asbestos materials in schools.

Abusable Volatile Chemicals Program

The Abusable Volatile Chemicals Program provides for licensure, inspection, outreach and education, and enforcement of rules and statutes pertaining to restriction of minors from purchasing inhalant-abuse products and to proper signage for retail establishments that sell abusable volatile chemicals. The Abusable Volatile Chemical Program operates through fees generated from permitting of retail facilities that sell regulated products.

Bedding Program

The Bedding Program provides for licensure, inspection, outreach and education, and enforcement of rules and statutes pertaining to new, remanufactured, and used bedding products to ensure the health and safety of the consumer. Regulations provide the consumer with a safe, properly manufactured and labeled bedding product, and sanitary conditions in manufacturing plants and germicidal treatment facilities. The Bedding Program operates through fees generated from licensing of bedding manufacturers and germicidal treatment operators.

Hazardous Products Program

The Hazardous Products Program conducts licensing, inspections, and enforces rules and statutes pertaining to consumer products to ensure that manufacturers and others inform consumers of product hazards and label products properly, including children's products regulated by the U.S. Consumer Product Safety Improvement Act. The Hazardous Products Program operates through fees generated from registration of manufacturers, repackagers, and private label distributors of consumer products.

Environmental Lead Program

The Environmental Lead Program certifies, inspects, and enforces rules and statutes to ensure safe work practices for controlling hazards of lead-based paint. The program operates with fees generated through licensing, abatement notifications, and a federal grant administered by the EPA.

Environmental Home Investigations Program

The Environmental Home Investigations Program provides public assistance and conducts field investigations in homes of children with elevated blood lead levels. Upon conclusion of the investigation, the program notifies the medical provider, parent, and homeowner of potential sources of lead as well as recommendations to mitigate the exposure of the child to environmental lead. DSHS relocated the program to the Prevention and Preparedness Services Division (now the Disease Control and Prevention Services Division) in 2010, and the environmental health strategy is providing funding for positions on a temporary basis until fully funded by Medicaid reimbursement.

Community Right to Know (Tier II Chemical Inventory Reports) Program

The Community Right to Know Program conducts inspections and enforces rules relating to the requirement to submit annual reports of hazardous chemical inventories (called Tier II Chemical Inventory Reports) to ensure that chemical manufacturers inform the public, and to facilitate emergency response planning. The Community Right to Know Program operates through fees generated from submission of the Tier II Chemical Inventory Reports.

Worker Right to Know (Hazard Communication for Public Employers) Program

The Worker Right to Know Program provides for outreach, inspection, and enforcement of the Texas Hazard Communication Act. This act requires public employers to develop and maintain a written hazard communication program and provide information and training to employees

who routinely work with hazardous chemicals in the workplace. The Worker Right to Know Program operates through fees generated from Tier II Chemical Inventory Reports submitted under the Community Right to Know Program as allowed by statute.

Public Health Sanitation Program

The Public Health Sanitation Program provides complaint investigations and enforcement of public health nuisances as allowed by statute in areas of the state without a local health department (LHD) for the following conditions: breeding places for flies in a populous area, rat harborage in a populous area, and conditions or places that can transmit disease to or between humans.

Public Pools and Spas Program

The Public Pools and Spas Program performs complaint investigations of public swimming pools and spas for compliance with minimum construction, operation, safety, and maintenance standards in areas of the state without a LHD. Local law enforcement officials make referrals for the enforcement of the public pool and spa rules.

Public Interactive Water Features Program

The Public Interactive Water Features Program performs complaint investigations of public interactive water features for compliance with sanitation and safety standards and for enforcement by closure in areas of the state without a LHD.

Economically Distressed Area Program (EDAP)

The EDAP investigates water and wastewater services in economically distressed areas. According to Section 17.933, Texas Water Code, DSHS functions in an investigatory manner to determine if a nuisance dangerous to the public health and safety exists as defined by Section 341.011, Texas Health and Safety Code. If DSHS finds a public health nuisance, the area may be eligible for federal funding to install or repair public sanitation equipment, such as wastewater treatment facilities.

Mold Remediation Program

The Mold Remediation Program conducts licensing and inspections and enforces rules and statutes relating to mold remediation projects to ensure that consumers receive services that meet regulatory standards. The Mold Program operates through fees generated from licensing and notifications submitted for mold remediation projects.

Youth Camps Program

The Youth Camp Program provides for licensure, inspection, outreach and education, and enforcement of rules and statutes pertaining to youth camps. The program ensures safe facilities and practices for the lodging, feeding, daily activities, and care of children. Youth camp inspections may cover multiple components of the youth camp facility, including swimming pools, public interactive water features, food service facilities, playgrounds, and private water supplies. The Youth Camp Program operates through fees generated from the licensing of youth camps.

C. What evidence can you provide that shows the effectiveness and efficiency of this program or function? Provide a summary of key statistics and performance measures that best convey the effectiveness and efficiency of this function or program.

With the functional alignment of activities as described in Question E, the Environmental Health Program accomplishes a variety of environmental inspections using common resources, including personnel and equipment. As a result of the increase in efficiency, DSHS has improved access to the regulated community, shortened response times, fostered consistencies in enforcement, and increased regulatory coverage. DSHS demonstrates evidence of this increase in efficiency by the numbers of inspections conducted before and after functional alignment. In fiscal year 2004 (prior to the reorganization), centrally directed programs in Environmental Health conducted 11,008 inspections. During the first year of the reorganization, the number of inspections did not significantly change (10,973), but in fiscal year 2006, the centrally directed programs conducted 15,594 inspections.

Centrally Directed Inspections by Fiscal Year								
FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
11,008	10,973	15,594	19,495	13,593	13,417	13,297	12,291	12,124

Cross-utilization of personnel in the inspection program was a primary factor in increased number of inspections from 2005 to 2007. For example, asbestos inspectors conducted abusable-volatile-chemical (AVC) inspections while on travel status to investigate asbestos complaints. In addition, environmental health inspectors received training to conduct bedding, AVC, and product safety inspections.

In fiscal years 2006 and 2009, these new efficiencies were evident as citizens were repatriating housing facilities in the aftermath of hurricanes Rita, Katrina, and Ike. On an emergency basis, DSHS assisted federal and local governments by ensuring safe living conditions for residents returning to impacted areas and for those transferred to alternative housing. During one 6-week period, DSHS' environmental inspectors in the affected area conducted over 600 housing inspections in addition to routine inspections conducted under other environmental programs. In addition, the RSD's environmental health technical expert served as a liaison for the Centers of Disease Control and Prevention (CDC), Federal Emergency Management Administration, U.S. Fish and Wildlife Service, and U.S. Department of Defense in the assessment of vector problems in the affected areas. This measure enabled federal, state, and local resources to provide aerial spraying needed to reduce the proliferation of mosquitoes that hampered recovery efforts and to prevent the spread of mosquito-borne illnesses, such as St. Louis encephalitis and West Nile infection, after heavy rains and flooding from Hurricane Ike.

The above examples demonstrate that the consolidation of programs into functional units provides the opportunity to expand Environmental Health's risk matrix to assess the needs of the public on a broader scale and provide public health services more efficiently. As such, the

program applies the risk-based approach to prioritize all functional activities, rather than limiting the prioritization to within each discrete activity.

The Environmental Health Program has implemented further improvements in program efficiency with the application of the Regulatory Automated System (RAS). This system replaces outdated and obsolete databases designed for specific functions in each regulatory program. The new system provides authorized Environmental Health employees with real-time access to licensing, enforcement, and inspection data. This innovation reduces the personnel time required to extract and utilize information for the benefit of the public. The Environmental Health Program has recently implemented online systems for the provision of public access to information and license renewals. This measure has increased licensing efficiency by reducing the staff time required to process applications.

In 2011 and 2012, a retraction in program size and capabilities due to staff reductions and a reassessment and redirection of inspection resources contributed to the decrease in the number of inspections for centrally directed programs in the Environmental Health Program. The program refocused inspection resources to areas with clear DSHS obligations and elevated risk to public health.

D. Describe any important history regarding this program not included in the general agency history section, including how the services or functions have changed from the original intent.

2001 – The legislatively mandated Business Practices Evaluation Report of 2001 finds that the Texas Department of Health needs a complete reordering of the administrative and organizational infrastructure in order to function efficiently. In response to findings, Environmental Health undergoes staff reorganizations that centralize inspection teams within programs and combines certain programs according to functionality.

2003 – The Legislature passes three bills that add or change functions in Environmental Health. Senate Bill 329 directs DSHS to initiate a new program to regulate mold remediation. The Mold Program ensures that DSHS properly trains, licenses, and ensures adherence to work-practice standards with companies and individuals performing regulated mold remediation activities. Senate Bill 599 transfers the responsibility for conducting indoor air quality investigations in state facilities from the Texas Building and Procurement Commission to DSHS. This change eliminates redundancies between the two agencies, but increases the scope of activities for Environmental Health. House Bill 2292 requires a two-year term for each license issued by DSHS, with the exception of youth camp licenses that require a one-year term. In addition, this law requires DSHS to charge licensing fees in amounts necessary to recover from its license holders all necessary costs to administer and enforce the program.

2004 – DSHS undergoes further reorganization, creating functional units dedicated to inspections, enforcement, and licensing activities. This new functional structure consolidates

programmatic responsibilities to a unit dedicated to policy development, standards, and quality assurance. This reorganization improves availability of services to the regulated community and helps standardize quality assurance across programs.

2009 – Senate Bill 968 authorizes DSHS to begin regulating sanitation at interactive water features and fountains and to adopt rules for the new program.

2010 – Environmental lead investigations become a Texas Medicaid benefit for Texas Health Steps clients with an elevated blood level demonstrating medical necessity. The program locates in another division, but the environmental health strategy is providing funding for positions on a temporary basis until fully funded by Medicaid reimbursement.

2011 – Senate Bill 1414 authorizes DSHS to implement a requirement for training and examination programs on warning signs of sexual abuse and child molestation for employees of higher education campus programs hosting children.

2012 – The Environmental Health strategy previously provided food service sanitation inspections upon request from childcare facilities in areas of the state without a LHD. Environmental Health transfers this inspection activity to the Texas Department of Family and Protective Services and notifies childcare facilities of the change.

E. Describe who or what this program or function affects. List any qualifications or eligibility requirements for persons or entities affected. Provide a statistical breakdown of persons or entities affected.

The Environmental Health Program performs activities that protect public health and consumers of products, impacting most people in Texas either directly or indirectly. The qualifications and eligibility requirements for persons and entities holding licenses vary according to statute. Licenses that qualify the license holder to conduct or oversee projects involving hazardous materials require specialized training, formal education, and relevant work experience. The table below represents the combined numbers of individuals and firms holding licenses, certifications, or permits.

Program	Holders of Licenses, Certificates, or Permits in Fiscal Year 2012
Asbestos	7,078
Environmental Lead	1,009
Mold	3,777
Youth Camps	546
Abusable Volatile Chemicals	22,461
Hazardous Products	1,252
Bedding	4,939
Total	41,062

Additionally, RSD received 63,579 Tier II Chemical Reports during fiscal year 2012.

F. Describe how your program or function is administered. Include flowcharts, timelines, or other illustrations as necessary to describe agency policies and procedures. Indicate how field/regional services are used, if applicable.

RSD administers the Environmental Health Program and organizes the program functionally into the Environmental and Consumer Safety Section, which includes the Policy, Standards, and Quality Assurance (PSQA) Unit and the Inspection Unit, and the Health Care Quality Section, which includes the Regulatory Licensing Unit. The Enforcement Unit and the health service regional inspectors are also in the Environmental Health Program. The PSQA Unit coordinates activities that facilitate policy development, rule interpretation, legislative inquiry, standards development, quality assurance, grants, contracts, and program accountability. The PSQA Unit performs these activities with input and direct interaction with experts from each of the other functional units.

The Regulatory Licensing, Inspection, and Enforcement Units each have designated groups for performing their respective duties within the Environmental Health Program. In the Inspection Unit, the Notifications Group performs the administrative functions of receipt of project notifications; data entry; sorting; and disseminating of information on asbestos, lead, and mold abatement projects for the facilitation of inspection scheduling and prioritization. This function is integral to the risk assessments used in each abatement program. In addition, the Notifications Group receives and processes notification fees collected under each abatement program.

Centrally directed inspectors conduct inspections for the following programs: Asbestos, Abusable Volatile Chemicals, Bedding, Hazardous Substances, Environmental Lead, Community Right to Know, Worker Right to Know, and Mold Remediation. Staff conducts the inspections in accordance with a risk assessment designed for each activity in order to provide a fair, consistent, and effective compliance approach within the regulated community. Inspectors report these activities weekly to the Inspection Unit. Thereafter, staff turns in all associated paperwork, such as checklists, sample results, and report narratives, within timelines prescribed by each activity. Group managers in the Inspection Unit receive and review the work according to standards prior to forwarding to the PSQA Unit. Specialists in the PSQA Unit review the findings of each inspection to determine whether to proceed with enforcement action; if so, specialists forward the recommendation to the Enforcement Unit. The Enforcement Unit, with support from the Office of General Counsel, handles the due process requirements associated with prosecuting cases.

Regionally directed inspectors who report to the DSHS health service region directors conduct inspections for the following programs: Public Health Sanitation, Public Pools and Spas, Public Interactive Water Features, Public Schools and School Cafeterias, EDAP, and Youth Camps. Staff conducts inspections in accordance with policies, procedures, and risk-management criteria

administered through the PSQA Unit in Austin. The regionally directed inspectors submit reports to the PSQA Unit for review and possible referral to the Enforcement Unit.

The program has organizational charts and descriptions of units for review located at: <http://www.dshs.state.tx.us/orgchart/regulatory.shtm>

G. Identify all funding sources and amounts for the program or function, including federal grants and pass-through monies. Describe any funding formulas or funding conventions. For state funding sources, please specify (e.g., general revenue, appropriations rider, budget strategy, fees/dues).

Funding Source	Amount
Federal	\$1,006,313
General Revenue	\$3,367,834
General Revenue-Dedicated	\$2,626,438
Other	\$125,000

H. Identify any programs, internal or external to your agency, that provide identical or similar services or functions to the target population. Describe the similarities and differences.

External Programs

Name	Similarities	Differences
EPA	EPA administers and enforces federal asbestos regulations.	EPA serves as an oversight agency to DSHS. EPA performs limited numbers of asbestos compliance inspections.
Texas Commission on Environmental Quality (TCEQ)	TCEQ administers and enforces asbestos (waste) regulations pertaining to landfill requirements.	DSHS has jurisdiction over asbestos abatement projects but not the landfill requirements that result from those projects.
Texas Water Development Board (TWDB) and TCEQ	TWDB and TCEQ administer the EDAP.	DSHS conducts the required inspections, while TWDB and TCEQ provide oversight and funding.
Occupational Safety and Health Administration (OSHA)	OSHA is involved in enforcement of regulations regarding field sanitation in places of temporary employment.	DSHS only has jurisdiction in work areas that have less than 11 employees; OSHA has jurisdiction in areas having 11 or more employees.
U.S. Consumer Product Safety	CPSC administers and enforces federal hazardous substance	DSHS requires hazardous substance manufacturers,

Name	Similarities	Differences
Commission (CPSC)	labeling requirements.	repackagers, distributors, and importers to register and pay fees prior to distributing products in the state.

I. Discuss how the program or function is coordinating its activities to avoid duplication or conflict with the other programs listed in Question H and with the agency’s customers. If applicable, briefly discuss any memorandums of understanding (MOUs), interagency agreements, or interagency contracts.

The Environmental Health Program works closely with its federal partners to ensure program policies and procedures are consistent at the state and federal level and to remove duplication of effort. The EPA shares regulatory clarifications and policy interpretations with Environmental Health staff and holds meetings as needed to ensure staff uphold the federal intent of the asbestos and lead regulations. DSHS submits progress reports to EPA as part of its asbestos and environmental lead grant requirements that facilitate communication of program activities. EPA delegated separate portions of the federal asbestos regulation to DSHS and to the TCEQ, so the agencies generated a memorandum of understanding between TCEQ and the legacy Texas Department of Health to outline their respective responsibilities and prevent duplication. Similarly, DSHS works closely with other state agencies in programs involving overlapping jurisdictions. In EDAP, for example, DSHS limits its activities to performing site investigations, while the TWDB and TCEQ perform administrative and funding activities.

J. If the program or function works with local, regional, or federal units of government include a brief description of these entities and their relationship to the agency.

Local Units of Government

Name	Description	Relationship to DSHS
LHDs	Local agencies provide healthcare services to their respective constituents.	DSHS performs public health sanitation inspections only in areas where there is no capability through a LHD.

Federal Units of Government

Name	Description	Relationship to DSHS
EPA	DSHS performs asbestos and environmental lead activities under grants from EPA.	EPA administers the grants and serves as an oversight agency to DSHS.

K. If contracted expenditures are made through this program please provide:

- a short summary of the general purpose of those contracts overall;
- the amount of those expenditures in fiscal year 2012;
- the number of contracts accounting for those expenditures;
- top five contracts by dollar amount, including contractor and purpose;
- the methods used to ensure accountability for funding and performance; and
- a short description of any current contracting problems.

The program does not have any contracts.

L. Provide information on any grants awarded by the program.

The program does not award grants.

M. What statutory changes could be made to assist this program in performing its functions? Explain.

DSHS suggests the following statutory changes to assist the program in performing its functions.

Chapter 502, Texas Health and Safety Code (Texas Hazard Communication Act) – DSHS recommends a revision to update the definition of “hazardous chemical” and “material safety data sheet” in the Act for consistency with newly revised definitions in the OSHA’s Hazard Communication Standard, codified as 29 Code of Federal Regulations, Section 1910.1200.

Chapters 505, 506, and 507, Texas Health and Safety Code – DSHS recommends deleting the provision in all four statutes that allows non-compliant entities, including repeat offenders, as many as three opportunities to come into compliance before DSHS can take any action. Because of these provisions, DSHS has never assessed an administrative penalty for violations of these statutes. DSHS finds approximately one-third of all facilities covered by the Emergency Planning and Community Right-to-Know Act (EPCRA) Tier II that are inspected annually out of compliance by failing to notify their local fire departments, emergency planning committees, and DSHS of their potentially hazardous chemicals as required. This revision will enable DSHS to collect penalty fees for first-time violations, a percentage of which DSHS can provide as grants to local emergency planning committees to assist them in fulfilling their responsibilities under EPCRA.

Chapter 505, Texas Health and Safety Code (Manufacturing Facility Community Right-To-Know Act) – DSHS recommends a change in the amount of available administrative penalties from \$500 maximum per violation per day (not to exceed \$5,000 for each violation) to up to \$5,000 per violation per day, to provide DSHS with more discretion in assigning penalties.

Chapter 507, Texas Health and Safety Code (Non-manufacturing Facilities Community-Right-To-Know Act) – DSHS recommends a revision to the amount of available administrative penalties from \$50 maximum per violation per day (not to exceed \$1,000 for each violation) to up to \$1,000 per violation per day to provide DSHS with more discretion in assigning penalties.

N. Provide any additional information needed to gain a preliminary understanding of the program or function.

The preceding discussion is sufficient to gain a preliminary understanding of the program.

O. Regulatory programs relate to the licensing, registration, certification, or permitting of a person, business, or other entity. For each regulatory program, if applicable, describe:

- **why the regulation is needed;**
- **the scope of, and procedures for, inspections or audits of regulated entities;**
- **follow-up activities conducted when non-compliance is identified;**
- **sanctions available to the agency to ensure compliance; and**
- **procedures for handling consumer/public complaints against regulated entities.**

The Environmental Health Program is broad in scope and continues to grow with an increasing number of programs and licensees. The program is founded on a variety of statutes and regulations that share the objective of protecting the citizens from harm in the areas of hazardous materials and consumer products. These statutes and regulations are essential for ensuring compliance with the health, safety, and consumer protection standards developed by DSHS and its oversight agencies. DSHS establishes eligibility requirements for licensing, certification, and training in accordance with state and/or federal statutes to protect the public from exposure to hazardous materials and provide the consumer access to professional services of the highest possible standards.

The Environmental Health Program bases inspection activities on a risk assessment to ensure the utilization of allocated resources for maximum benefit to health, safety, and consumer protection. The program develops standardized inspection methodology for each activity, including the use of standard forms, checklists, and attachments necessary to document the findings of each type of inspection. Initial and recurring training for all inspectors reinforces this methodology and ensures that staff conducts inspections consistently across the regions of the state.

Staff completes inspections and audits of license holders and regulated abatement projects on a routine basis or in response to a complaint, tip, or referral. Internal or external sources provide information to the PSQA Unit that, upon review, requests the Inspection Unit to

conduct an investigation of a regulated project or a license holder’s activities to determine compliance with applicable regulations.

Compliance history is an important criterion used in prioritizing inspections in the programs involving abatement of hazardous materials. This information consistently and reliably directs the inspection staff to conduct follow-up inspections of violators. Although the conditions surrounding a previous violation may no longer exist, follow-up inspections are important to assess the licensee’s progress in complying with all of the regulations pertinent to the license.

Staff also performs follow-up inspections in facilities under consumer product regulations as determined by the facility’s compliance history. Environmental Health balances the decision to conduct follow-up inspections in these programs with the need for the program to have broad coverage in many different retail facilities. Staff considers the compliance history and the risk to the public when deciding to conduct follow-up inspections at specific establishments.

The Environmental Health Program seeks to ensure compliance through a balance of compliance assistance and enforcement actions. Overall, Environmental Health operates under an enforcement policy that uses the minimum necessary sanctions to achieve the compliance objective. Sanctions may include detention and destruction of products, administrative penalties, and license suspension and/or revocation as well as referrals for civil and criminal prosecution.

The Environmental Health Program gives complaint investigations top priority and investigates these within the timelines of the applicable statute. The PSQA Unit serves as a repository to the public for complaint intake; however, personnel within all functional units may receive and refer complaints when called upon. The PSQA Unit maintains a complaint log to monitor timeliness responses to complaints.

P. For each regulatory program, if applicable, provide the following complaint information. The chart headings may be changed if needed to better reflect your agency’s practices.

Department of State Health Services Environmental Health Exhibit 11: Information on Complaints Against Regulated Persons or Entities Fiscal Years 2011 and 2012		
	FY 2011	FY 2012
Total number of entities inspected *	20,240	18,709
Total number of complaints received from the public	457	396
Total number of complaints initiated by agency**	2,823	2,528
Number of complaints pending from prior years***	85	27
Number of complaints found to be non-jurisdictional***	17	5

Department of State Health Services Environmental Health Exhibit 11: Information on Complaints Against Regulated Persons or Entities Fiscal Years 2011 and 2012		
	FY 2011	FY 2012
Number of jurisdictional complaints found to be without merit***	203	174
Number of complaints resolved***	330	271
Average number of days for complaint resolution***	194	159
Complaints/inspections resulting in disciplinary action:****		
administrative penalty	660	695
reprimand	0	0
probation	1	0
suspension	0	0
revocation	0	0
other	470	114

* The regulated community far exceeds the total number of licensees within the programs. It includes all retail facilities, schools, construction projects, demolition projects, certain workers, employers, and owners of businesses, facilities, and Health and Human Service System agencies. Some of the regulated entities are under DSHS' jurisdiction only for the duration of an activity, for example, during a mold remediation project or the demolition of a structure.

** Complaints initiated by the agency include program-generated complaints resulting from inspections that reveal deficiencies.

*** These measures represent complaints received from the public.

**** Because staff implements the majority of disciplinary actions as the result of routine inspections, reporting only disciplinary actions taken as a result of complaints would provide an inaccurate picture of the total disciplinary actions taken.

VII. GUIDE TO AGENCY PROGRAMS - CONTINUED

A. Provide the following information at the beginning of each program description.

Name of Program or Function	Radiation Control
Location/Division	8407 Wall Street, Austin - Regulatory Services Division (RSD)
Contact Name	Kathryn C. Perkins, Assistant Commissioner, RSD
Actual Expenditures, FY 2012	\$7,815,605
Number of Actual FTEs as of June 1, 2013	125.8
Statutory Citation for Program	Chapter 401, Texas Health and Safety Code

B. What is the objective of this program or function? Describe the major activities performed under this program.

Radiation Control has the following primary objectives.

- Design and implement a risk assessment and risk management regulatory program for all sources of radiation.
- Protect and promote public health and safety through a comprehensive program of regulation, education, and enforcement to minimize unnecessary radiation exposure to the public, radiation workers, and releases into the environment.

Major activities include the following.

Radioactive Materials Licensing and Inspection

RSD staff licenses, sets standards, inspects, and takes enforcement actions for users of radioactive material at medical, industrial, educational, and research facilities. They also conduct incident and complaint investigations. For regulation of these radioactive materials, the DSHS program must be compatible to that of the U.S. Nuclear Regulatory Commission (NRC) since the Governor of Texas entered into an agreement with NRC in 1963 whereby the federal government relinquished authority over certain radioactive materials to the State. Texas became what is called an "agreement state" when the Governor entered into this agreement.

X-ray and Laser Program

RSD staff registers the use of x-ray machines and lasers; and inspects the users of these sources of radiation at medical, industrial, educational, entertainment, and research facilities and for aesthetic treatment. This includes registration and inspection of laser hair-removal facilities and certification of individuals who perform laser hair-removal procedures. Staff also conducts incident and complaint investigations.

Radiological Emergency Response and Preparedness

RSD staff prepares and updates Annex D to the State of Texas Emergency Management Plan and prepares site-specific radiological emergency response plans. Additionally, staff conducts Federal Emergency Management Agency (FEMA)-graded full-scale exercises at the state's two nuclear utility facilities and the U.S. Department of Energy (DOE) nuclear weapons facility, Pantex. Staff conducts environmental monitoring around major radioactive material use facilities and investigations of radiological accidents and complaints. Staff also provides some radiological emergency response training to first responders in local governments; provides the responders with radiation detection instruments, such as Geiger counters; and provides radiological response support for state emergency operations.

Mammography Facility Certification and Accreditation Programs

The Mammography Facility Certification and Accreditation Programs certify and accredit mammography facilities and inspect these facilities in accordance with the requirements in state law and of the U.S. Food and Drug Administration (FDA), Mammography Quality Standards Act.

C. What evidence can you provide that shows the effectiveness and efficiency of this program or function? Provide a summary of key statistics and performance measures that best convey the effectiveness and efficiency of this function or program.

Radiation Control works closely with other federal agencies to evaluate the effectiveness and efficiency of activities.

NRC audits the radioactive material regulatory program to assure adequacy and compatibility with the federal requirements. During a routine program review in February 2010, NRC found DSHS' radiation program to be "adequate to protect public health and safety" and "satisfactory" in all areas. Radiation Control has been a national leader in the regulation of radiation and had always received NRC's highest rating of "satisfactory" except when, in the early 2000s, the loss of many technical staff due to non-competitive salaries caused NRC to put the state under heightened oversight. Radiation Control greatly improved its performance after filling all technical staff vacancies. The Legislature's creation of a new classification of "health physicist" and the resulting salary increase helped DSHS to fill the vacancies. Radiation Control also modified the inspection program and placed more emphasis on timely reporting of incidents involving radioactive materials to NRC. The next NRC program review will occur in 2014.

Radiation Control has completed successful full-scale emergency response exercises, graded by the Federal Emergency Management Agency (FEMA), at the state's two nuclear utility facilities every year for the past 12 years. These exercises validate training of emergency response team members and include a demonstration of specific evaluation areas identified by FEMA. FEMA issues findings in the form of a final report on the evaluation of each area.

The FDA, Division of Mammography Quality Radiation Program granted the legacy agency Texas Department of Health (TDH) approval as an accreditation body in April 1999. Texas joined two other states (Arkansas and Iowa) and the American College of Radiology as approved accreditation bodies. FDA has approved the agency to accredit mammography units that utilize film-screen mammography, full-field digital mammography, and computed radiography mammography. The FDA provides oversight to the Mammography Accreditation Program by performing an annual evaluation; Texas has successfully passed the FDA performance evaluation for the past nine years.

The FDA approved the State of Texas as a Certifying Agency under the Mammography Quality Standards Act (MQSA) States as Certifiers provision, effective September 1, 2008. The FDA delegates many aspects of the MQSA certification program to qualified states that have applied for and received FDA approval as a certifying body. The FDA provides oversight to the Mammography Certification Program by performing an annual evaluation of the State of Texas Certifying Agency Program. The Mammography Certification Program successfully passed the performance evaluation conducted by the FDA in 2012. DSHS adequately and appropriately fulfills its responsibilities as an FDA-approved Certifying Agency.

Radiation Control also uses key statistics to evaluate program activities, such as the inspection of x-ray facilities. The number of new x-ray facilities has steadily grown as the Texas economy improved. As of May 31, 2013, DSHS had inspected 2,956 x-ray facilities, leaving an additional 3,571 x-ray inspections due. Because of the growing numbers of facilities that are subject to regulation and the static number of inspectors, regulatory programs have developed a risk-based matrix to ensure that the licensees and registrants posing the highest risk receive the most attention through inspections and follow-up visits.

D. Describe any important history regarding this program not included in the general agency history section, including how the services or functions have changed from the original intent.

1947 – The legacy agency TDH first becomes involved in radiological health activities. TDH conducts one of the nation’s first extensive surveys demonstrating the radiation hazards of shoe-fitting fluoroscopes. In the early 1950s, TDH conducts a series of short courses on radiological hazards at various locations throughout the state.

1961 – The Legislature adopts the Texas Radiation Control Act, codified as Chapter 401, Texas Health and Safety Code. The Act establishes the Texas Radiation Advisory Board and designates TDH as the Radiation Control Agency.

1963 – An agreement between the Governor of Texas and the U. S. Atomic Energy Commission becomes effective. Under the agreement, Texas assumes all licensing and regulatory authority over radioactive materials in the state, with the exception of special nuclear material in excess of a critical mass and radioactive material utilized by federal agencies.

1981 – The Legislature passes legislation allowing TDH to regulate uranium mill tailings and low-level radioactive waste and creates the Radiation and Perpetual Care Fund. The legislature designates the fund primarily for financial security that is required of uranium and low-level radioactive waste licensees. The Legislature also creates the Bureau of Radiation Control with an additional 100 staff to regulate all sources of radiation.

1989 – The Legislature revised Chapter 401, Texas Health and Safety Code (Texas Radiation Control Act), to establish the regulatory framework and authority for the state agencies that regulate sources of radiation, encompassing the use, possession, and disposal of such sources.

2001 – Since the terrorist attacks on September 11, 2001, the security of radioactive sources experiences heightened awareness. The federal government requires the NRC and agreement states to implement increased controls over certain types of radioactive material possessed in large quantities. Approximately 240 of approximately 1950 licensees in Texas possess such material and must establish procedures to minimize the likelihood that the radioactive material could be stolen or accessed for malevolent purposes.

2001 – The Legislature establishes the Radiation and Perpetual Care Account to replace the Radiation Perpetual Care Fund to ensure funding for decontamination, decommissioning, stabilization, reclamation, maintenance, surveillance, control, storage, and disposal of radioactive materials in cases where a company cannot meet its legal obligation to restore the site.

2003 – The Legislature requires the term of each license issued by DSHS to be two years and requires DSHS to charge licensing fees that would cover all necessary costs to administer and enforce the program.

2004 – DSHS undergoes reorganization, creating functional units dedicated to inspections, enforcement, and licensing activities. The functional model improves availability of services to the regulated community and helps standardize quality assurance across programs.

2007 – House Bill 2285 removes the requirement that the term of the licenses be tied to the two-year fee requirement. Senate Bill 1604 mandates transfer of the uranium and radioactive waste processing regulatory authority to the Texas Commission on Environmental Quality (TCEQ).

2009 – House Bill 449 creates a regulatory program for laser hair removal. The legislation requires licensing of laser hair removal facilities and certification of individuals performing laser hair removal procedures.

2013 – Senate Bill 347 establishes a new \$100 million cap for the Perpetual Care Account and Environmental Radiation and Perpetual Care Account. The bill requires DSHS to use assessed fees for emergency planning and response to transportation accidents involving low-level radioactive waste; however, no appropriation is made.

E. Describe who or what this program or function affects. List any qualifications or eligibility requirements for persons or entities affected. Provide a statistical breakdown of persons or entities affected.

Radiation Control impacts companies that use radioactive materials, medical x-ray, and laser procedures; and individuals that receive diagnostic or therapeutic x-ray or laser procedures. Radiation Control also impacts users of lasers for entertainment, and facilities and individuals who perform laser hair removal. Radiation Control training affects first responders to radiological accidents and members of the public living near one of the foregoing operations.

Number of Licenses, Registrant, and Mammography Certification Fiscal Year 2012		
Type of License/Certification	Number of Licenses	Number of Locations
Radioactive Material Licensees	1,606	2,267
General Licenses	273	392
X-Ray Registrants	16,717	19,829
Laser Registrants	1,979	2,241
Mammography Certifications	686	686
Laser Hair Individual Certifications	1,072	N/A
Laser Hair Removal Facilities	81	N/A
Laser Hair Removal Training Providers	13	N/A
Industrial Radiographer Certifications	3,831	N/A

F. Describe how your program or function is administered. Include flowcharts, timelines, or other illustrations as necessary to describe agency policies and procedures. Indicate how field/regional services are used, if applicable.

RSD administers Radiation Control. The Regulatory Licensing Unit, Radiation Safety Licensing Branch conducts licensing and registration activities. Radioactive material licensing processes must be compatible with those of the NRC; the mammography certification and accreditation process must be compatible with the FDA requirements. DSHS performs x-ray registration activities in accordance with policies and regulation requirements. Staff reviews applications to confirm satisfaction of regulatory requirements in order to assure the safe use of these sources of radiation. This includes registration of laser hair removal facilities and certification of individuals who perform laser- hair removal procedures. Staff also conducts incident and complaint investigations. DSHS staff prepares examinations for individual industrial radiographers; administers and grades them; provides exam results to the individuals as

required by 25 Texas Administrative Code, Section 298.225; and provides successful applicants a certification identification card. A number of other states also use the tests through a contract between DSHS and the Conference of Radiation Control Program Directors.

The Environmental and Consumer Safety Section, Radiation Policy/Standards/Quality Assurance (PSQA) Group coordinates rules development with input from the radiation licensing, inspection, and other program staff. The PSQA Group also coordinates stakeholder participation in the rulemaking process. The group develops radiation standards based on health and safety considerations and compatibility with national standards developed by state and federal cooperative task forces for the multiple disciplines regulated. The PSQA Group also performs technical quality assurance reviews of inspection and investigation reports. The PSQA Group receives and reviews all associated paperwork, such as checklists, sample results, and report narratives, according to established standards in order to verify technical accuracy and completeness. The PSQA Group issues findings of inspections and investigations, including violations, based upon the inspection and investigation reports received. The PSQA Group prepares and presents cases that involve violations warranting enforcement to the Enforcement Unit.

The Environmental and Consumer Safety Section, Radiation Inspection Branch performs inspections of the licensees and registrants to assure that the sources of radiation are received, stored, used, and disposed of in accordance with the rules and permit requirements. The branch bases inspection frequency for each category of use on the risk posed by the source of radiation authorized and the past compliance record on the users. The branch conducts investigations of radiation accidents, incidents, and complaints and performs environmental monitoring around major radioactive material licensee facilities to assure that any releases of radioactive material to the environment are below release limits in the radiation rules. The branch also prepares and updates the state emergency response plans for response to accidents at nuclear facilities and conducts annual exercises at these facilities to assure that the plans, staffing, and resources are adequate. In addition, the branch provides radiological emergency response training and detection equipment along the Interstate 20 corridor and in the counties surrounding the fixed nuclear facilities.

In the Inspection Unit, the group managers, under the direction of the manager of the Radiation Inspection Branch, ensure that staff administers the inspection program consistently, and in accordance with agency and program policies. Group managers report the inspection activities to the PSQA Group where specialists review the findings of each inspection to determine if enforcement action is warranted; if warranted, the specialists refer the case to the Enforcement Unit.

The Enforcement Unit, with support from the Office of General Counsel, escalates enforcement actions and handles the due process requirements associated with prosecuting cases.

Radiation Control performs the regulatory functions for all areas of the state and is not involved with local health departments other than to provide expertise to them on an as-needed basis.

The program has organizational charts and descriptions of units for review located at: <http://www.dshs.state.tx.us/orgchart/regulatory.shtm>.

G. Identify all funding sources and amounts for the program or function, including federal grants and pass-through monies. Describe any funding formulas or funding conventions. For state funding sources, please specify (e.g., general revenue, appropriations rider, budget strategy, fees/dues).

Funding Source	Amount
Federal	\$439,610
General Revenue	\$6,586,745
General Revenue-Dedicated	\$723,216
Other	\$66,034

H. Identify any programs, internal or external to your agency, that provide identical or similar services or functions to the target population. Describe the similarities and differences.

External Programs

Name	Similarities	Differences
TCEQ	DSHS regulates all users of radioactive material, but not the final disposal of low-level radioactive waste or uranium mining facilities.	TCEQ is responsible for regulating the disposal of low-level radioactive waste, all uranium mining including the underground portion of <i>in situ</i> uranium mining (Underground Injection Control Program), and the disposal of non-oil and gas Natural Occurring Radioactive Material (NORM).
Texas Railroad Commission (RRC)	DSHS regulates the use of NORM and decommissioning of facilities and sites with NORM contamination.	RRC is responsible for regulating the surface exploration for uranium ore and the disposal of oil and gas NORM.

I. Discuss how the program or function is coordinating its activities to avoid duplication or conflict with the other programs listed in Question H and with the agency's customers. If applicable, briefly discuss any memorandums of understanding (MOUs), interagency agreements, or interagency contracts.

DSHS and TCEQ have a memorandum of understanding (MOU), as required by Section 401.414, Texas Health and Safety Code, to clarify their respective jurisdictions under the statute. The agencies are currently revising this MOU with a tentative completion date of June 2014. DSHS and RRC have a MOU, as required by Section 401.414, Texas Health and Safety Code, to clarify their respective jurisdictions under the statute. This MOU became effective January 2, 2012.

J. If the program or function works with local, regional, or federal units of government include a brief description of these entities and their relationship to the agency.

Local Units of Government

Name	Description	Relationship to DSHS
County and local officials	County and local officials are involved with emergency response to nuclear reactor accidents and radiological emergency preparedness to radiological incidents in their areas.	DSHS Radiation Control technical experts advise the county judges and other local officials on emergency actions necessary to protect public health during routine graded exercises and in the event of a real emergency. DSHS also consults with and provides limited services to county judges and local emergency management officials regarding radiological plans, training, and instrumentation used to protect public health during radiation accidents and other emergencies.

Federal Units of Government

Name	Description	Relationship to DSHS
NRC	NRC has authority over radioactive materials but may delegate certain authority to states.	Texas is an agreement state with NRC. NRC provides regulatory guidance and policy concerning radioactive materials regulation and oversees the state's adequacy and compatibility with federal requirements.
FDA	FDA enforces the federal Mammography Quality Standards Act.	DSHS performs mammography certifications, accreditations, and inspections as a Certifying Agency under FDA, Mammography Quality Standards Act States as Certifiers provision. FDA approved the State of Texas Mammography Accreditation Program as an accreditation body.

Name	Description	Relationship to DSHS
Environmental Protection Agency (EPA)	EPA provides standards of human exposure to radiation.	EPA coordinates environmental monitoring for radioactive materials with DSHS and develops environmental radiation standards for environmental release limits and occupational radiation exposure standards.
FEMA	FEMA develops requirements for emergency response to nuclear facility accidents. The Radiological Emergency Preparedness Program provides FEMA approved radiological training.	FEMA grades full-scale exercises conducted by the state, county, and local government staff at the state's two nuclear utility facilities. DSHS staff provides recommendations to local and county officials after evaluating the radiological releases during exercises or in actual events. FEMA provides standards, goals, and objectives for radiological training.
DOE	DOE provides standards, goals, objectives, and audits for radiological training.	DSHS provides DOE-approved radiological training to first responders along the Interstate 20 corridor. DOE also funds DSHS emergency response activities for the Pantex nuclear weapons production facility near Amarillo.

K. If contracted expenditures are made through this program please provide:

- a short summary of the general purpose of those contracts overall;
- the amount of those expenditures in fiscal year 2012;
- the number of contracts accounting for those expenditures;
- top five contracts by dollar amount, including contractor and purpose;
- the methods used to ensure accountability for funding and performance; and
- a short description of any current contracting problems.

The program does not have any contracts.

L. Provide information on any grants awarded by the program.

The program does not award grants.

M. What statutory changes could be made to assist this program in performing its functions? Explain.

The program does not have any statutory changes to suggest.

N. Provide any additional information needed to gain a preliminary understanding of the program or function.

Industrial, educational, and medical facilities make use of radioactive material and x-ray machines for the benefit of Texas citizens. Examples of the beneficial uses of radiation include diagnostic nuclear medicine studies, emergency exit lighting, nondestructive testing of critical components in passenger aircraft, pipeline radiography, sterilization of surgical bandages, treatment of cancer, and highway construction materials testing. Regulatory oversight of these uses of radioactive materials and x-ray machines ensures continuation of the beneficial uses and minimizes unnecessary radiation exposure to occupational workers and the public in Texas.

O. Regulatory programs relate to the licensing, registration, certification, or permitting of a person, business, or other entity. For each regulatory program, if applicable, describe:

- **why the regulation is needed;**
- **the scope of, and procedures for, inspections or audits of regulated entities;**
- **follow-up activities conducted when non-compliance is identified;**
- **sanctions available to the agency to ensure compliance; and**
- **procedures for handling consumer/public complaints against regulated entities.**

DSHS is the lead agency for all radioactive material, mammography certification, x-ray, and laser regulatory and safety efforts in the state to protect workers, the public, and the environment. Radiation Control protects the public health and safety with regulation permitting requirements and routine inspections that result in improved compliance, less unnecessary exposure to sources of radiation, and secure sources of radioactive material.

In order to allocate resources for maximum benefit to public health and consumer safety, Radiation Control bases inspection activities on a risk assessment of the potential harm from each category of sources of radiation. Radiation Control uses a standardized inspection methodology when conducting inspections. Inspection methodology includes standard forms, checklists, and attachments necessary to document the findings of each type of inspection. Radiation Control reinforces standard inspection methodology with initial and recurring training for all inspectors to ensure that staff conducts inspections consistently across the state. The PSQA Unit provides training and oversight of inspection documentation with audits, as necessary, to assess the quality standards.

Paralleling the growth in industry and medicine in Texas, the use of radiation has increased significantly. Industrial, medical, and educational facilities in Texas use radiation sources. Additionally, the state has two nuclear utility facilities. Excessive exposure to radiation presents a public and occupational health hazard. Radiation is a known carcinogen. Currently, no federal program exists to protect the public from impacts associated with all types and origins of radiation exposure.

Procedures for inspection of licensee and registrant performance include observation of operations, review of documentation, surveys of radiation levels, and evaluation of radiation exposures. Inspections that reveal violations of regulatory requirements result in the issuance of a notice of violation that requires corrective action to prevent reoccurrence. Radiation Control staff reviews corrective actions during the following inspection. Sanctions of violators that are available include administrative penalties, emergency orders (cease and desist, impoundment), and modification/revocation of licenses.

Radiation Control also conducts activities as the lead agency for radiological emergency response for the state and responds to any nuclear reactor accident or radiological terrorist threat.

Radiation Control receives complaints in writing or by telephone and investigates all complaints based on program guidelines or administrative review. The primary emphasis of an investigation is to assure that health and safety issues are resolved. After complaints are resolved and closed, Radiation Control files the information collected, reports of actions taken, and makes the information available as open records.

P. For each regulatory program, if applicable, provide the following complaint information. The chart headings may be changed if needed to better reflect your agency's practices.

Department of State Health Services Radiation Control Exhibit 11: Information on Complaints Against Regulated Persons or Entities Fiscal Years 2011 and 2012		
	FY 2011	FY 2012
Total number of regulated entities	25,105	26,258
Total number of entities inspected	5,879	7,932
Total number of complaints received from the public	59	69
Total number of complaints initiated by agency	74	72
Number of complaints pending from prior years*	11	9
Number of complaints found to be non-jurisdictional	1	1
Number of jurisdictional complaints found to be without merit	55	40

Department of State Health Services Radiation Control Exhibit 11: Information on Complaints Against Regulated Persons or Entities Fiscal Years 2011 and 2012		
	FY 2011	FY 2012
Number of complaints resolved	73	72
Average number of days for complaint resolution	53	56
Complaints/inspections resulting in disciplinary action:**		
administrative penalty	43	63
reprimand	N/A	N/A
probation	6	1
suspension	1	2
revocation	72	49
other	0	11
Number of environmental samples collected***	639 (1,968)	619 (2,024)

* Some complaints from the previous year were resolved during the timeframe given.

** Because staff takes the majority of disciplinary actions as the result of routine inspections, reporting only disciplinary actions taken as a result of complaints would provide an inaccurate picture of the total disciplinary actions taken. These numbers also include enforcement actions resulting from referrals from licensing (e.g., fee delinquencies).

*** The number in parenthesis includes environmental radiation monitors.

VII. GUIDE TO AGENCY PROGRAMS - CONTINUED

A. Provide the following information at the beginning of each program description.

Name of Program or Function	Healthcare Professionals
Location/Division	8407 Wall Street, Austin - Regulatory Services Division (RSD)
Contact Name	Kathryn C. Perkins, Assistant Commissioner, RSD
Actual Expenditures, FY 2012	\$6,876,437
Number of Actual FTEs as of June 1, 2013	116.2
Statutory Citation for Program	Chapters 12 (Subchapter H), 773, and 781, Texas Health and Safety Code; Chapters 110, 203, 352, 353, 401-403, 451, 455, 502, 503-505, 601-605, 701, 1952, and 1953, Texas Occupations Code; Sections 521.371 – 521.377, Texas Transportation Code; Article 42.12, Sections 13(h) and 13(j), Texas Code of Criminal Procedure; Section 106.115, Alcoholic Beverage Code

B. What is the objective of this program or function? Describe the major activities performed under this program.

Healthcare Professionals has the primary objective to issue licenses, certifications, and other registrations of healthcare professionals, and to ensure compliance with standards.

Regulatory Programs and Activities with Governor-Appointed Boards with Independent Rulemaking Authority

The following healthcare professionals have boards with independent rulemaking authority:

- athletic trainers,
- audiologists, counselors, dietitians, fitters and dispensers of hearing instruments,*
- marriage and family therapists,
- medical physicists,*
- midwives and associated training programs (Board is appointed by DSHS Commissioner and has rulemaking authority),*
- orthotists and prosthetists and associated facilities,
- sex offender treatment providers,
- social workers, and
- speech-language pathologists.

*These three boards have quasi-independent rulemaking authority, in that their final rules require approval by the HHSC Executive Commissioner for adoption.

Regulatory Programs and Activities that do not have Governor-Appointed Boards with Independent Rulemaking Authority

The following healthcare professionals do not have boards with independent rulemaking authority:

- chemical dependency counselors and associated training entities,
- code enforcement officers,
- contact lens dispensers,
- dyslexia practitioners and therapists,
- emergency medical services personnel and associated firms,
- massage therapists and associated establishments and training programs,
- medical radiologic technologists and associated training programs,
- offender education programs and instructors,
- opticians,
- perfusionists,
- personal emergency response system providers,
- respiratory care practitioners, and
- sanitarians.

For regulation of all the healthcare professions and programs listed above, DSHS evaluates credentials and qualifications; administers or recognizes examination requirements; processes initial and renewal applications for licensure, permitting, certification, and specialty recognition; and issues and renews licenses, permits, and certifications. DSHS staff also provides intake and processing for consumer complaints, investigates the complaints, and determines proposed violations and sanctions. Healthcare Professionals establishes program policy, procedure, and standards for the regulation of these healthcare professions; handles stakeholder relations; provides public information and education; develops curriculum; and provides training.

For independent rulemaking boards, Healthcare Professionals coordinates the rulemaking activities and handles board and committee relations and support. For healthcare professions governed by these boards, Healthcare Professionals also issues notices of violation and holds enforcement/settlement conferences.

For regulation of healthcare professions without independent rulemaking, Healthcare Professionals coordinates and initiates rulemaking by the HHSC Executive Commissioner. Additionally, Healthcare Professionals coordinates the enforcement review committee to determine violations and sanctions, issues notices of violation, coordinates informal conferences and hearings, and issues final orders.

Medical Review for Driver Licensing and Concealed Handgun Licensing

DSHS staff reviews referrals from the Texas Department of Public Safety (DPS) that relate to driver's license applicants and concealed handgun license applicants, renders an opinion regarding whether a person is capable of safely operating a motor vehicle or is capable of exercising sound judgment with respect to proper use and storage of a handgun, and makes recommendations to DPS. Effective September 1, 2013, this will include referrals that relate to applicants for private security commissions. The DSHS Commissioner appoints Medical Advisory Board members, all of whom by law must be physicians and optometrists.

C. What evidence can you provide that shows the effectiveness and efficiency of this program or function? Provide a summary of key statistics and performance measures that best convey the effectiveness and efficiency of this function or program.

Continuous improvement, resulting in more efficient and effective customer and licensing service, is a management priority for Healthcare Professionals. Improvement and quality assurance activities include the following.

- Since October 2002, the Professional Licensing and Certification (PLC) Unit surveys license holders biennially to assess the level of satisfaction with the license renewal process, the ability of the program staff to communicate effectively and courteously, the quality of program written materials, and the quality of the program websites. The PLC Unit uses the survey information as a basis for improving the license renewal process, staff training, and public information. The unit maintains the data by unit, by program, by question, and by time period. For example, survey respondents from the professional counselor licensing program reported an overall satisfaction rate of 93.4 percent in fiscal year 2012.
- The PLC Unit regularly monitors telephone call volume and service to ensure quality. RSD has divided the PLC Unit into five customer service groups for purposes of receiving phone calls. The unit tracks the average length of call, number of calls transferred, and average wait time both in real time and cumulatively, and implements staffing adjustments as necessary. During fiscal year 2012, the PLC Unit received 19,560 calls (approximately 1630 per month).
- In 2006, DSHS implemented a consolidated licensing database system within the PLC Unit (Project Phase I). The system, License Ease, integrates licensing, inspection, and enforcement functions for the programs. Implementation of the system was the culmination of an information technology (IT) project involving DSHS IT staff and contracted staff from Versa, Inc. The project included a majority of the programs within the RSD. Implementation activities included business planning, configuration, data migration, and staff training. A number of obsolete systems were retired upon the successful implementation of the system.
- In 2010, the consolidated system, License Ease, migrated to Versa Regulation. In 2011, the first professional licensing renewal transactions occurred through Versa Online.
- The PLC Unit regularly assesses components of individual programs to ensure that processes and requirements are both reasonable and streamlined to the extent possible. For

example, DSHS revised the Drug Offender Education Program curriculum after a study of best practices.

- Healthcare Professionals staff regularly assesses information relating to the programs to ensure that it remains current, accurate, and useful to consumers and license holders. DSHS redesigned program websites in 2005 to meet Health and Human Services System standards and to improve the consistency and availability of information regarding the programs. Boards, committees, and staff regularly review and update consumer brochures and other information.
- DSHS has fully implemented statutory modifications and management recommendations from the 2005 Sunset Advisory Commission reviews of six boards within the PLC Unit, including jurisprudence examinations for new licensure applicants.
- DSHS has fully implemented statutory modifications and management recommendations from the 2011 Sunset Advisory Commission reviews of two boards within the PLC Unit, including criminal history fingerprinting requirements for new and renewal applicants.
- The PLC Unit conducts rule reviews in accordance with the Administrative Procedure Act to ensure that rules reflect current policy, legal, and programmatic considerations. As required by law, the program conducts reviews of the 23 sets of rules every four years.
- In 2005, four programs in the PLC Unit established and implemented ongoing continuing education provider audits. These audits ensure that approved continuing education providers are providing quality education in compliance with program rules.
- In 2006, the State Auditor's Office conducted a review of the use of criminal history background information within three programs in the PLC Unit. While there were no significant adverse findings, the programs successfully implemented the resulting management recommendations by increasing the use of risk-based criminal history checks.

Continuous improvement and appropriate targeting of resources in investigations and inspections are ongoing activities. The PLC Unit prioritizes complaints by severity level, and conducts investigations in a manner that optimizes the use of travel funds and staff resources.

D. Describe any important history regarding this program not included in the general agency history section, including how the services or functions have changed from the original intent.

1997 – The Legislature adds a level of regulation, licensed paramedic, to the emergency medical services (EMS) area. In addition to other standards, a licensed paramedic must hold a post-secondary degree. Other levels of EMS certification include emergency care attendant, emergency medical technician (EMT) basic, and EMT intermediate.

2001 – The Legislature creates the Governor's EMS and Trauma Advisory Council (GETAC) to advise the legacy Texas Department of Health (TDH) on rules regarding EMS and trauma systems. GETAC serves as a gathering point for stakeholder input on rules regarding the licensing, certification, and enforcement of EMS personnel and entities.

2003 – Healthcare Professionals begins the process of reorganizing along functional lines as a means to improve overall program functioning, provide greater flexibility to meet current and anticipated future workload demands, increase staff knowledge and expertise, and realize efficiencies in the use of program resources.

2004 – Healthcare Professionals completes a formal project to make licensing services available through the Texas Online portal. Online services currently include application for licensure, renewal of licensure, and change of address. Additionally, the regulation of offender education programs and chemical dependency counselors, formerly at the legacy Texas Commission on Alcohol and Drug Abuse, merged with Healthcare Professionals at DSHS.

2005 – The Legislature creates a subcommittee of GETAC on stroke systems. Additionally, H.B. 1126 prohibits DSHS from licensing gurney cars as a type of ambulance. Gurney cars are vehicles that have no medical equipment nor medically trained personnel. These types of vehicles are appropriate for non-emergency transfer of ambulatory persons or those using a wheelchair but may compromise the safety of patients who are so ill as to require transport by stretcher.

2006 – Healthcare Professionals completes the change from one-year to two-year licensing, as mandated by legislation in 2003. This requirement does not apply to all licensing programs; for example, the EMS personnel certification period is four years. Healthcare Professionals also participates in a formal project to consolidate licensing database software and implement a common licensing database system.

2008 – DSHS completes a four-year criminal history check review of all EMS-certified licensees.

2009 – The Legislature establishes a bar or mandatory revocation of an EMS license or certification for persons convicted or placed on a deferred community supervision for certain crimes, including a person that had to register as a sex offender after September 1, 2009. Additionally, H.B. 461 creates the licensing program for dyslexia practitioners and dyslexia therapists, as well as the Dyslexia Licensing Advisory Committee.

E. Describe who or what this program or function affects. List any qualifications or eligibility requirements for persons or entities affected. Provide a statistical breakdown of persons or entities affected.

Healthcare Professionals directly affects allied health, mental health, and emergency medical services professionals and providers, as well as consumers of those services in Texas. The functions of the Medical Advisory Board (MAB) protects citizens from the risks posed by persons who have conditions that render them incapable of operating a motor vehicle safely or of properly storing and using a handgun.

Each regulatory program’s enabling statute and associated rules establish qualifications and eligibility requirements for persons seeking to practice in the regulated profession or occupation. The requirements may include a range of educational, experience, and examination requirements, in addition to a review of a person’s criminal history to determine fitness for licensure.

There are approximately 225,000 persons and entities regulated through Healthcare Professionals.

Profession	Total Regulated Population FY 2012
Athletic trainers	2,868
Audiologists	1,205
Chemical dependency counselors and associated training entities	8,961
Code enforcement officers	2,206
Contact lens dispensers	176
Emergency medical services personnel	63,833
Emergency medical services firms and first responder organizations	1,802
Emergency medical services education programs	517
Counselors, professional	19,435
Dietitians	4,828
Dyslexia therapists and practitioners	973
Fitters and dispensers of hearing instruments	754
Marriage and family therapists	3,291
Massage therapists and associated establishments and training programs	29,596
Medical physicists	614
Medical radiologic technologists and associated training programs	27,844
Midwives and associated training programs	219
Offender education programs and instructors	2555
Opticians	129
Orthotists and prosthetists and associated facilities	837
Perfusionists	366
Personal emergency response system providers	249
Respiratory care practitioners	14,230
Sex offender treatment providers	498
Social workers	22,066
Speech-language pathologists	15,465
Sanitarians	1,241

The MAB receives approximately 5,700 referrals annually from DPS in accordance with Section 12.092(b), Texas Health and Safety Code. DPS requests assistance in determining whether an applicant for a driver's license or a license holder is capable of safely operating a motor vehicle, or whether an applicant for or holder of a license to carry a concealed handgun is capable of exercising sound judgment with respect to the proper use and storage of a handgun. A DPS referral is the only qualification or eligibility requirement for review by the MAB. A license applicant referred by DPS is required to supply medical records and information necessary for the MAB to render an opinion regarding the person.

F. Describe how your program or function is administered. Include flowcharts, timelines, or other illustrations as necessary to describe agency policies and procedures. Indicate how field/regional services are used, if applicable.

Five units within RSD administer Healthcare Professions. The division divides each unit into groups with specialized licensing, policy, education, standards, or enforcement functions. The PLC Unit houses licensing, policy, education, and quality assurance functions for 22 mental health, allied health, and health-related professions, as well as offender education programs. The Regulatory Licensing Unit houses the Board and the licensing functions related to EMS, as well as other licensing functions that are not part of this program. The Patient Quality Care Unit houses compliance and quality assurance for EMS licensing, as well as other functions not included within this program. The Enforcement Unit has responsibility for all enforcement functions within RSD, including Healthcare Professionals. The EMS/Trauma Systems Coordination Office houses policy and education functions for EMS licensing, as well as other EMS and trauma-related functions in the EMS/Trauma Program. DSHS licenses the ambulance services according to their designated capability levels under Healthcare Professionals. RSD combines investigations against EMS personnel with the investigations against EMS providers, plus EMS provider surveys and inspections. Healthcare Facilities performs these investigations.

A unique administrative feature within the PLC Unit is the presence of 11 licensing boards with independent rulemaking and enforcement authority. The Governor appoints members to 10 of the boards. These regulatory boards are statutorily mandated and are administratively attached to DSHS. DSHS provides staff, facilities, and infrastructure necessary to accomplish the mission and functions of each board. PLC program specialists serve as executive directors for the boards and coordinate meetings, rulemaking, stakeholder relations, and enforcement actions.

The functions of Healthcare Professionals are primarily in the DSHS central office in Austin. EMS has a central office with statewide oversight over the licensing, compliance, and enforcement regulatory functions. Four zone compliance offices (Central, North, East, and South) are located in DSHS regional offices for compliance field staff. A close relationship exists between the regulation of the providers and the personnel, which enhances regulatory effectiveness and efficiency across the state.

The Council on Sex Offender Treatment (CSOT) is a Governor-appointed council that has been administratively attached to the PLC Unit since 1997. In 1983, the 68th Legislature created the CSOT due to the rising rate of sexual crimes and extremely high recidivism rates for untreated sexual offenders. Over the past two decades, CSOT’s core function as a regulatory entity has expanded due to the increased public awareness and concern for community safety. Today, CSOT has three primary functions, as described by Chapter 110, Texas Occupations Code:

- public and behavioral health by advocating for the management and treatment of sex offenders;
- regulatory by administering a licensure program for sex offender treatment providers, establishing the rules and regulations regarding the treatment of sex offenders, and maintaining a list of sex offender treatment providers; and
- educational by the dissemination of information to the public regarding the treatment and management of sex offenders.

The program has organizational charts and descriptions of units for review located at: <http://www.dshs.state.tx.us/orgchart/regulatory.shtm>.

G. Identify all funding sources and amounts for the program or function, including federal grants and pass-through monies. Describe any funding formulas or funding conventions. For state funding sources, please specify (e.g., general revenue, appropriations rider, budget strategy, fees/dues).

Funding Source	Amount
Federal	\$815,380
General Revenue	\$3,418,958
General Revenue-Dedicated	\$1,500,819
Other	\$1,141,280

H. Identify any programs, internal or external to your agency, that provide identical or similar services or functions to the target population. Describe the similarities and differences.

No other state government programs, internal or external, engage in the specific regulation authorized by the enabling statutes for Professionals. Other state programs and agencies regulate professions and occupations, but not the specific occupations that this program regulates.

I. Discuss how the program or function is coordinating its activities to avoid duplication or conflict with the other programs listed in Question H and with the agency’s customers. If applicable, briefly discuss any memorandums of understanding (MOUs), interagency agreements, or interagency contracts.

Not applicable.

J. If the program or function works with local, regional, or federal units of government include a brief description of these entities and their relationship to the agency.

Local Units of Government

Name	Description	Relationship to DSHS
Local school districts	Local school districts may employ athletic trainers that DSHS regulates.	The Athletic Trainer Licensing Program interacts regularly with school districts throughout the state to disseminate information regarding licensure and enforcement actions.
Local law enforcement	Local law enforcement agencies enforce the laws in their jurisdictions. Licensed healthcare professionals may be the subject of law enforcement investigations.	Healthcare Professionals cooperates, as appropriate, with local investigations into allegations against license holders and may propose enforcement action either in conjunction with other agencies or in response to information received from other agencies or units of government.
Local city and county governments	Local city and county governments operate EMS and may have local EMS ordinances.	The EMS Program coordinates with local city and county governments regarding EMS regulation, especially if the local unit has an EMS ordinance.

K. If contracted expenditures are made through this program please provide:

- a short summary of the general purpose of those contracts overall;
- the amount of those expenditures in fiscal year 2012;
- the number of contracts accounting for those expenditures;
- top five contracts by dollar amount, including contractor and purpose;
- the methods used to ensure accountability for funding and performance; and
- a short description of any current contracting problems.

The program does not have any contracts.

L. Provide information on any grants awarded by the program.

The program does not award any grants.

M. What statutory changes could be made to assist this program in performing its functions? Explain.

DSHS suggests the following statutory change to assist the program in performing its functions.

Chapter 773, Texas Health and Safety Code – DSHS recommends a revision to this statute to:

- provide authority to assess an administrative penalty against individuals;
- create two categories of provider licensure: one license for non-emergency medical transport providers and another license for 911 emergency providers;
- provide increased authority to assess an administrative penalty for licenses up to \$10,000 per day per violation;
- add EMS initial education and continuing education programs to the type of licenses for which DSHS can assess an administrative penalty;
- clarify that DSHS has authority to regulate licensed and unlicensed activity; and
- provide ambulance detention authority to DSHS.

N. Provide any additional information needed to gain a preliminary understanding of the program or function.

Eight of the eleven Governor-appointed licensing boards that Healthcare Professionals provides administrative support have separate Sunset review dates in their enabling statutes. The three boards that do not have separate Sunset review dates are the CSOT, Advisory Board of Athletic Trainers, and the Texas Board of Licensure for Professional Medical Physicists.

During the 1992-1993 review cycle, the Sunset Advisory Commission reviewed seven boards (speech-language pathologist and audiologist, marriage and family therapist, professional counselor, dietitian, social worker, midwifery, and hearing aid fitter and dispenser). As a result of the review, the Texas Legislature abolished the Texas Board of Examiners in the Fitting and Dispensing of Hearing Aids as an independent state agency and replaced it with an independent board administratively attached to the RSD. The Legislature continued the other boards for an additional 12 years with certain modifications to their enabling statutes.

In 1997, the 75th Legislature placed the CSOT within the legacy TDH as a result of a Sunset Advisory Commission review. The CSOT was formerly an independent state agency.

During the 2004-2005 review cycle, the Sunset Advisory Commission reviewed six boards (marriage and family therapist, professional counselor, midwifery, perfusionist, dietitian, and social worker). The Legislature abolished the perfusionist board and replaced it with an advisory committee. The Legislature continued the other five boards for an additional 12 years with certain modifications to their enabling statutes.

During the 2010-2011 review cycle, the Sunset Advisory Commission reviewed two boards (fitter and dispenser of hearing instruments, and speech-language pathologist and audiologist). The Legislature continued the boards until 2017 with certain modifications to their enabling statutes.

During the 2016-2017 review cycle, the Sunset Advisory Commission is scheduled to review the following nine boards and programs: marriage and family therapist, professional counselor, midwifery, perfusionist, dietitian, social worker, fitter and dispenser of hearing instruments, orthotics and prosthetics, and speech-language pathologist and audiologist.

O. Regulatory programs relate to the licensing, registration, certification, or permitting of a person, business, or other entity. For each regulatory program, if applicable, describe:

- **why the regulation is needed;**
- **the scope of, and procedures for, inspections or audits of regulated entities;**
- **follow-up activities conducted when non-compliance is identified;**
- **sanctions available to the agency to ensure compliance; and**
- **procedures for handling consumer/public complaints against regulated entities.**

The regulation of allied health, mental health, and emergency medical occupations is a means to protect and promote public health, safety, and welfare. The regulation helps ensure that consumers are availing themselves of the services of qualified and competent providers.

Most of Healthcare Professionals license holders are individuals who are not subject to inspection, but are subject to audit processes regarding continuing education compliance. They are subject, however, to investigation when consumers or agency staff files allegations of wrongdoing. Healthcare Professionals staff verifies suspected violations of law or rule through an investigation and presents the results to the Enforcement Review Committee (or the appropriate committee of an independent board) for consideration and imposition of proposed disciplinary action, if appropriate.

License holders selected for continuing education audit are subject to Texas criminal history background checks, except those license holders who have undergone fingerprint-based criminal history checks. DSHS also performs these checks on all new licensure applicants.

When the agency identifies non-compliance, DSHS may take a number of follow-up actions. In an enforcement matter, DSHS may require the license holder to complete additional education

in addition to enforcement sanctions, such as probation or suspension. In some enforcement matters, the regulatory authority may require another license holder to supervise reporting requirements. Program staff monitors these enforcement orders for compliance. If Healthcare Professionals receives another complaint, or if the problem appears to be unresolved, DSHS can re-investigate and refer to the appropriate committee for review.

The Legislature has authorized DSHS and the independent boards attached to DSHS to impose a broad range of enforcement sanctions to ensure compliance with the enabling statutes and rules. These sanctions vary somewhat by program, but generally include application or renewal application denial, administrative penalties, emergency suspension, reprimand, suspension, probation, or revocation. Additionally, DSHS and independent boards may use agreed orders, requirements for additional education, practice limitations, and/or other appropriate measures to resolve contested cases.

DSHS may conduct inspections and audits of facilities and business entities regulated through Healthcare Professionals if authorized by statute and/or upon receipt of a jurisdictional consumer complaint. The scope of inspections is set out in the applicable statute or rules.

DSHS audits EMS personnel for compliance with certification and licensing standards. This includes continuing education compliance as well as in-depth criminal history evaluations. Beginning in September 2004, the EMS Program implemented a 100 percent criminal history review of all initial and renewal certificates; DSHS staff evaluates applicants' criminal history through DPS. On January 1, 2010, DSHS began requiring a fingerprint-based criminal background check for all EMS initial applicants, which is a state and federal check for criminal activity. This was a result of legislation that passed in 2009 establishing a bar or mandatory revocation of an EMS license or certification for persons convicted or placed on a deferred community supervision for certain crimes, including a person that had to register as a sex offender after September 1, 2009.

P. For each regulatory program, if applicable, provide the following complaint information. The chart headings may be changed if needed to better reflect your agency's practices.

Department of State Health Services Healthcare Professionals Professional Licensing and Certification Unit Exhibit 11: Information on Complaints Against Regulated Persons or Entities Fiscal Years 2011 and 2012		
	FY 2011	FY 2012
Total number of regulated persons	152,520	157,986
Total number of regulated entities	2,615	2,620
Total number of entities inspected	420	453
Total number of complaints received from the public	1309	1,194
Total number of complaints initiated by agency*	N/A	N/A

Department of State Health Services Healthcare Professionals Professional Licensing and Certification Unit Exhibit 11: Information on Complaints Against Regulated Persons or Entities Fiscal Years 2011 and 2012		
	FY 2011	FY 2012
Number of complaints pending from prior years	N/A	N/A
Number of complaints found to be non-jurisdictional	83	81
Number of jurisdictional complaints found to be without merit	330	280
Number of jurisdictional complaints resolved	1,051	994
Average number of days for complaint resolution	265	263
Complaints resulting in disciplinary action:		
administrative penalty	50	58
reprimand	38	15
probation	51	38
suspension	10	28
revocation	33	14
other (letters of warning, cease and desist letters, denials, and surrenders)	480	489

* DSHS staff enters all complaints, regardless of source, into a consolidated database. Staff estimates that DSHS initiates no more than 10 percent of complaints.

Department of State Health Services Healthcare Professionals EMS Providers* Exhibit 11: Information on Complaints Against Regulated Persons or Entities Fiscal Years 2011 and 2012		
	FY 2011	FY 2012
Total number of regulated persons	65,287	66,133
Total number of regulated entities (providers, education programs, and first responder programs)	2,232	2,319
Total number of entities inspected (complaint investigations)	2,046	1,954
Total number of complaints received from the public	71	64
Total number of complaints initiated by agency	187	493
Number of complaints pending from prior years	312	515
Number of complaints found to be non-jurisdictional	0	2
Number of jurisdictional complaints found to be without merit**	N/A	N/A
Number of complaints resolved***	246	202
Average number of days for complaint resolution	91	65
Complaints resulting in disciplinary action:		

Department of State Health Services Healthcare Professionals EMS Providers*		
Exhibit 11: Information on Complaints Against Regulated Persons or Entities Fiscal Years 2011 and 2012		
	FY 2011	FY 2012
administrative penalty	85	173
reprimand	69	112
probation	8	11
suspension	41	35
revocation	47	75
other	16	17

Numbers are based on state performance measure reports.

* These numbers include complaint investigations against both EMS providers and EMS personnel.

** N/A=information in this category is not collected by database in this manner.

*** Resolved=investigation completed and case referred to Enforcement Review Committee.

VII. GUIDE TO AGENCY PROGRAMS - CONTINUED

A. Provide the following information at the beginning of each program description.

Name of Program or Function	Healthcare Facilities
Location/Division	8407 Wall Street, Austin - Regulatory Services Division (RSD)
Contact Name	Kathryn C. Perkins, Assistant Commissioner, RSD
Actual Expenditures, FY 2012	\$9,351,689
Number of Actual FTEs as of June 1, 2013	114.6
Statutory Citation for Program	Chapters 222, 241, 243, 244, 245, 248, 251, 254, 464, 466, and 577, Texas Health and Safety Code; Chapter 74, Subchapter C, Civil Practice and Remedies Code

B. What is the objective of this program or function? Describe the major activities performed under this program.

Healthcare Facilities has the primary objective of implementing programs to license/certify non-long-term care facilities, monitor compliance, enforce rules/regulations, and provide technical assistance to healthcare facilities. Major activities include the following.

Licensed Only Facilities (Abortion Facilities, Birthing Centers, Crisis Stabilization Units, Special Care Facilities, and Substance Abuse Treatment Facilities)

Healthcare Facilities staff assists in the development and implementation of licensing rules, issues licenses, and conducts surveys and complaint investigations to determine compliance with state licensing rules and regulations, and cite applicable violations.

Licensed and Medicare-Certified Facilities (Ambulatory Surgical Centers, End-Stage Renal Disease Facilities, Freestanding Emergency Medical Care Facilities, Hospitals-General and Special, and Hospitals-Psychiatric)

Healthcare Facilities staff assists in the development and implementation of licensing rules, makes licensing decisions, and makes recommendations regarding certification of these facilities to the Centers for Medicare & Medicaid Services (CMS). When facilities are in compliance with Medicare Conditions of Participation, these providers are allowed to seek Medicare reimbursement for care provided to consumers. Healthcare Facilities staff performs surveys and complaint investigations to determine compliance with state and federal rules and regulations, and cites applicable violations.

Medicare-Certified Only Facilities (Comprehensive Outpatient Rehabilitation Facilities, Clinical Laboratories, Outpatient Physical Therapy or Speech Pathology Services, Portable X-Ray Services, and Rural Health Clinics)

Healthcare Facilities staff makes recommendations to CMS regarding the certification of these facilities. When they are determined to be in compliance with Medicare Conditions of Participation, these providers can seek Medicare reimbursement for care provided to consumers. Healthcare Facilities staff conducts surveys and complaint investigations of these facilities to determine compliance with state and federal regulations and cites applicable violations. Healthcare Facility staff assists in certifying community mental health centers, although staff does not survey the facilities.

Healthcare Facilities staff also supports the Texas Medical Disclosure Panel (TMDP), which is administratively attached to DSHS by statute. TMDP determines which risks and hazards related to medical care and surgical procedures healthcare providers or physicians must disclose to their patients and establishes the general form and substance of the disclosure. TMDP is composed of nine members appointed by the DSHS Commissioner. Six members must be licensed physicians and three members must be licensed attorneys.

C. What evidence can you provide that shows the effectiveness and efficiency of this program or function? Provide a summary of key statistics and performance measures that best convey the effectiveness and efficiency of this function or program.

During fiscal year 2012, the Healthcare Facilities staff conducted 1,737 complaint investigations and 3,655 surveys/inspections, and issued 3,774 initial and renewal licenses. Staff determined that approximately 94 percent of all healthcare facilities complied with applicable statutes and rules at the time of their surveys/inspections.

DSHS is the designated state agency in Texas to conduct non-long-term care surveys [Medicare and Clinical Laboratory Improvement Amendments of 1988 (CLIA) Medicare surveys in Texas]. As part of the “Section 1864 Agreement” (Social Security Act, Section 1864) between Texas and the federal government, CMS requires DSHS to submit quarterly reports related to workload, full-time equivalents, staff training, and initial surveys. CMS provides a Mission and Priority Document as part of the annual process for requesting federal funding. DSHS then estimates the workload that staff can accomplish, based on the expected level of funding that CMS will provide. DSHS plans its workload and scheduling priorities, based on a mandated federal survey frequency for each provider type. The CMS Dallas regional office and DSHS are in frequent communication regarding the survey operations and workload activities.

CMS provides an annual evaluation related to survey activities called the State Performance Standards System (SPSS) Report. CMA conducts the evaluation for both the non-long-term care and the CLIA programs. This review focuses on three areas related to state agency performance of Medicare activities (frequency, quality, and enforcement). The CMS criteria pertains to the frequency of non-long-term care surveys, accuracy and frequency of data entry,

documentation of deficiencies, prioritizing complaints and incidents, timeliness of complaint and incident investigations, timeliness of immediate jeopardy actions, and adherence to the Conditions of Participation. The CLIA SPSS criteria are similar but relate specifically to laboratory surveys. CMS prepares a report for DSHS, identifying any unmet review criteria. After a discussion regarding findings, DSHS and CMS reach a final decision regarding the SPSS Report. DSHS must submit a plan of correction for any areas of operation that CMS identified as needing improvement. Staff training may occur as part of the corrective action plan.

The group managers in Healthcare Facilities perform limited quality assurance (QA) reviews of statements of deficiency, reports of contact, and various correspondence. In addition, QA staff has developed a surveyor procedure manual and a QA program for healthcare facility compliance activities. The QA program develops criteria for random sampling of survey documents to determine compliance with the CMS Principles of Documentation and the criteria established by the SPSS. After QA completes an analysis of survey documents, staff receives feedback and training, as needed. The goal is to improve the effectiveness and efficiency of compliance activities. The success of state and federal enforcement actions provide a form of QA for compliance activities as well.

D. Describe any important history regarding this program not included in the general agency history section, including how the services or functions have changed from the original intent.

2003 – Senate Bill 1152 requires Healthcare Facilities to provide regulated entities the option of renewing licenses via Texas Online, the official e-government website. The Legislature also mandates that the term of each license issued by state agencies be two years. This requirement applies to licenses, permits, registrations, and certificates issued or renewed on or after January 1, 2005. The requirement applies to all activities within Healthcare Facilities.

Legislation that passes in 2003 also eliminates the Texas Commission on Alcohol and Drug Abuse, and the substance abuse treatment facilities program became part of DSHS.

2009 – House Bill 1357 requires DSHS to regulate freestanding emergency medical care facilities. The rules for these facilities become effective June 1, 2010, and require facilities to be licensed by September 1, 2010.

2013 – Several bills are enacted during the 83rd Legislature that affect health facilities: S.B. 793 relates to newborn screening requirements for hospitals and birthing centers; S.B. 944 relates to criminal history checks for certain hospital staff; S.B. 945 relates to hospital staff identification badges; S.B. 1191 relates to hospitals and sexual assault survivors and a website list of all hospitals identified in a community plan; and S.B. 1643 relates to certain controlled substances. Additionally, H.B. 705 relates to emergency services personnel and enhanced criminal penalty; H.B. 729 relates to access by facilities to certain criminal history; H.B. 740

relates to newborn screening in a hospital; and H.B. 1376 relates to hospital and freestanding emergency centers advertising their rates for services.

E. Describe who or what this program or function affects. List any qualifications or eligibility requirements for persons or entities affected. Provide a statistical breakdown of persons or entities affected.

In general, Healthcare Facilities regulation directly impacts any consumer who seeks healthcare services in Texas by ensuring that proper policies and procedures, equipment, facilities, and trained personnel are available to deliver care and services in a safe manner.

The licensed-only facilities are abortion facilities, birthing centers, crisis stabilization units, special care facilities, substance abuse treatment facilities, and freestanding emergency medical care facilities.

Type of Facility	Number Licensed as of June 17, 2013
Abortion Facilities	36
Birthing Centers	61
Crisis Stabilization Unit	3
Freestanding Emergency Medical Care Facilities	64
Special Care Facilities	14
Substance Abuse Treatment Facilities	579

To operate in Texas, these facilities must have a license. To obtain a license, a facility must complete a multi-page license application properly, submit any required documentation, pay the required licensing fee, and pass an architectural/life safety code and health survey, if applicable. A license is valid for two years, with the exception of freestanding emergency medical care centers, which are licensed annually. For a facility to retain its license, it must demonstrate that it is in substantial compliance with the current state licensing laws and rules, based on the results of any survey, complaint, or incident investigation and follow-up visit.

The licensed and Medicare-certified facilities are ambulatory surgical centers, end-stage renal disease (ESRD) facilities, hospitals-general and special, and hospitals-psychiatric.

Type of Facility	As of June 17, 2013	
	Number of Licensed Facilities	Number of Medicare-Certified Facilities
Ambulatory Surgical Centers	422	314
End-Stage Renal Disease Facilities	561	400
Hospitals-General and Special	647	535
Hospitals-Psychiatric*	38	38

* Six State Hospitals in Texas are not licensed but are Medicare-certified.

To operate in Texas, these facilities must have a license. To obtain a license, a facility must complete a multi-page license application properly, pay the required licensing fee, and pass an architectural/life safety code and health survey, if applicable. A license is valid for two years.

A provider’s participation in the federal Medicare program is voluntary. Each facility must have certification for the appropriate Medicare program in order to serve clients who are eligible for this program. Once DSHS finds the facility in compliance with state and federal regulations, DSHS recommends to CMS that the facility be certified. For a facility to retain its license and certification, the results of any survey, complaint, or incident investigation and follow-up visit must indicate that the facility is in substantial compliance with the current state and federal laws and rules.

The Medicare-certified only facilities are comprehensive outpatient rehabilitation facilities, clinical laboratories, outpatient physical therapy or speech pathology services, portable x-ray services, and rural health clinics.

Type of Facility	Number Licensed as July 17, 2013
Comprehensive Outpatient Rehabilitation Facilities	67
Clinical Laboratories	20,461
Outpatient Physical Therapy or Speech Pathology Services	230
Portable X-ray Services	42
Rural Health Clinics	322

F. Describe how your program or function is administered. Include flowcharts, timelines, or other illustrations as necessary to describe agency policies and procedures. Indicate how field/regional services are used, if applicable.

The Regulatory Licensing Unit, Healthcare Facility Group handles all licensing functions. The Patient Quality Care Unit, which is comprised of six Health Facility Compliance Groups across the state, conducts all compliance functions (state and federal). The Enforcement Unit, Consumer Safety Group handles all healthcare facility enforcement functions.

Healthcare Facilities staff conducts surveys and complaint investigations of healthcare facilities that are State-licensed only. Pursuant to the Section 1864 Agreement between the U.S. Department of Health and Human Services (DHHS) and Texas, two state agencies have responsibility for licensing healthcare facilities. The Texas Department of Aging and Disability Services (DADS) regulates long-term care facilities such as assisted living facilities, nursing homes, intermediate care facilities for persons with intellectual disabilities or related conditions, home health, and hospice. DSHS Healthcare Facilities staff is responsible for the non-long-term care survey and certification activities funded through the Title XVIII Medicare program. CMS funds these activities through an annual grant provided to the State of Texas. Healthcare Facilities staff conducts activities under the direction of the State Operations

Manual (SOM), in conjunction with specific directives provided by the CMS Dallas Regional Office and DSHS policies/procedures. The goal of survey and certification activity is to assure the quality of healthcare services delivery by participating providers and suppliers by verifying compliance with minimum requirements established under state law and the Medicare Conditions of Participation. Complaint and incident investigations are also part of these compliance activities.

Healthcare Facilities staff is also responsible for the survey and certification activities performed for the CLIA program, which is funded on a user fee basis, and is an annual grant from CMS. Healthcare Facilities staff carries out this activity under the direction of the SOM, in conjunction with specific directives provided by the CMS Dallas Regional Office and DSHS policies/procedures. The overall goal is to conduct survey and certification activities in a manner that validates laboratories meet the minimum standards under the CLIA program, while assuring that the health and safety of consumers are protected.

For state licensing, Medicare, and CLIA healthcare facility compliance activities, the Patient Quality Care Unit (PQCU) is responsible for scheduling surveys, hiring qualified survey staff, operating within federal budget allocations, and assuring that CMS and DSHS policies/procedures are followed. PQCU also provides data entry of the Medicare and CLIA surveys and information into the federal database systems, provides information to the public concerning rules and regulations, and submits selected survey documents to the Austin central office or the CMS Dallas Regional Office. PQCU consists of five zone offices across the state, located in the following cities: Houston, San Antonio, Arlington, Tyler, and Austin. There are two groups in Austin, one being exclusive to CMS work for certified-only facilities. The Substance Abuse Compliance Group in Austin handles all inspections and compliance activities for substance abuse treatment facilities and narcotic treatment programs.

A healthcare facility must be licensed in Texas if required by state law. The healthcare facility must pass an initial health survey, submit construction plans for review, and pass a final construction inspection and a life safety code survey (if applicable) to obtain a Medicare provider number, which allows the facility to submit healthcare-related claims to CMS for reimbursement. In addition, the provider usually must have a Medicare provider number before the facility can become a Medicaid provider. According to funding availability and prioritized workload, DSHS staff periodically conducts on-site surveys at health facilities to ensure continuing compliance with the applicable state and federal rules and regulations. When DSHS staff inspects a facility, or investigates a complaint and violations are determined, staff refers the matter to RSD, Enforcement Unit for possible state enforcement action, or to CMS for federal action.

The program has organizational charts and descriptions of units for review located at: <http://www.dshs.state.tx.us/orgchart/regulatory.shtm>.

For more information, see:

- <http://www.cms.hhs.gov/CertificationandCompliance/>
- <http://www.cms.hhs.gov/SurveyCertificationEnforcement/>
- <http://www.cms.hhs.gov/GuidanceforLawsAndRegulations/>

G. Identify all funding sources and amounts for the program or function, including federal grants and pass-through monies. Describe any funding formulas or funding conventions. For state funding sources, please specify (e.g., general revenue, appropriations rider, budget strategy, fees/dues).

Funding Source	Amount
Federal	\$5,565,433
General Revenue	\$2,688,887
General Revenue-Dedicated	\$1,097,369
Other	\$0

H. Identify any programs, internal or external to your agency, that provide identical or similar services or functions to the target population. Describe the similarities and differences.

External Programs

Name	Similarities	Differences
DADS	DADS promulgates the licensing rules for nursing facilities, assisted living facilities, intermediate care facilities for the individuals with intellectual disabilities or related conditions, adult daycare centers, and home and community support services agencies. DADS licenses these facilities, surveys them for compliance with state and federal regulations, and conducts complaint investigations for violations alleged to have been committed by facility staff.	DSHS does not regulate long-term healthcare facilities. DSHS regulates the non-long-term care healthcare facilities in Texas.
CMS	CMS maintains a panel of psychiatric consultant surveyors under contract to conduct initial	DSHS does not conduct these surveys, but does conduct federal complaint investigations in

Name	Similarities	Differences
	and recertification surveys of the two special conditions for psychiatric hospitals. CMS conducts two main types of surveys to validate state surveys: <ul style="list-style-type: none"> • comparative surveys, in which a CMS team or contractor conducts an independent survey within 60 days of the state survey (to compare results); and • observational surveys, in which a CMS team or contractor accompanies the state team to observe conditions at the facility, as well as the process of the state team. 	psychiatric hospitals, as authorized by CMS. DSHS does not validate CMS surveys. There is open communication between agencies to discuss and resolve differences of opinion and to seek written interpretation.
CMS Approved Accreditation Organizations, for example, The Joint Commission (TJC)	TJC conducts surveys of health facilities. TJC awards accreditation for a provider type; the request for certification flows through DSHS to CMS. CMS approves the certification or deemed status.	TJC may announce some surveys. TJC is a private organization receiving compensation from facilities for conducting surveys. TJC has its own standards. Not all health facilities in Texas have or seek TJC accreditation and/or deemed status.

I. Discuss how the program or function is coordinating its activities to avoid duplication or conflict with the other programs listed in Question H and with the agency’s customers. If applicable, briefly discuss any memorandums of understanding (MOUs), interagency agreements, or interagency contracts.

The Social Security Act mandates the establishment of minimum health and safety standards, which providers and suppliers participating in the Medicare and Medicaid programs must meet. The Secretary of the DHHS has designated CMS to establish standards and the compliance aspects of these programs. Section 1864(a) of the Social Security Act directs the Secretary to use the help of state health agencies or other appropriate agencies when determining whether healthcare entities meet federal standards. This helping function is termed “provider certification.”

Agreements between the DHHS Secretary and states stipulate that designated agencies performing provider certification will keep necessary and appropriate records to be provided as

required and employ management methods, personnel procedures, equal opportunity policies, and merit system procedures in accordance with agreed upon or established practices. The Secretary agrees to provide funds for the reasonable and necessary costs to the states for performing the functions authorized by the agreements. The lifetime of the agreements is unlimited, but either of the parties may terminate the agreement under specific conditions. State governors have the prerogative to propose modification of the agreements to allow for variations in organizational location of responsibilities with the state for federal programs and for state health facilities licensure. The state agency cannot re-delegate responsibility for evaluation and certification; however, the agency may assign subsidiary functions, such as the performance of surveys and investigations, to other state government units or other agencies, with the express approval of the DHHS Secretary. Modification or renegotiation of the agreement may be necessary if the reorganization of a state government affects the responsibilities of the designated agency, or in any way affects the arrangement previously recognized by the Section 1864 Agreement.

Effective September 1, 1999, the Texas Department of Human Services became the designated state agency for the Section 1864 Agreement. Effective September 1, 2004, the DADS assumed this responsibility. DADS is responsible for the Medicare survey and certification activities in nursing facilities, intermediate care facilities for individuals with intellectual disabilities or related conditions, and home and community support services agencies. As part of the 1864 Agreement, DSHS is responsible for the non-long-term care survey and certification activities, exclusive of home and community support services.

J. If the program or function works with local, regional, or federal units of government include a brief description of these entities and their relationship to the agency.

Federal Units of Government

Name	Description	Relationship to DSHS
CMS	CMS administers the standards compliance aspects of the Medicare and Medicaid programs.	DSHS is responsible for the non-long-term care survey and certification activities.

K. If contracted expenditures are made through this program please provide:

- a short summary of the general purpose of those contracts overall;
- the amount of those expenditures in fiscal year 2012;
- the number of contracts accounting for those expenditures;
- top five contracts by dollar amount, including contractor and purpose;
- the methods used to ensure accountability for funding and performance; and
- a short description of any current contracting problems.

The program does not have any contracts.

L. Provide information on any grants awarded by the program.

The program does not award any grants.

M. What statutory changes could be made to assist this program in performing its functions? Explain.

DSHS suggests the following statutory changes to assist the program in performing its functions.

Chapter 241, Texas Health and Safety Code – DSHS recommends revision of this statute to clarify the definition of general hospital, special hospital, and hospital premises. DSHS also recommends a revision to change the administrative hearing process for emergency orders and to allow the State Office of Administrative Hearings to conduct administrative hearings for regulatory contested and informal cases, instead of DSHS.

Chapter 241, 251, and 243, Texas Health and Safety Code – DSHS recommends a revision to increase authority up to \$25,000.00 per violation per day for administrative penalties.

General Appropriations Act – The Narcotic Treatment Program (NTP), currently in the Food and Drug funding strategy, is more closely related to substance abuse facility regulation in the Health Care Facility funding strategy. NTPs provide an approved narcotic drug (methadone) for maintenance and/or detoxification and rehabilitative services to opium-addicted individuals.

N. Provide any additional information needed to gain a preliminary understanding of the program or function.

Texas has gained a reputation for its model survey program for ESRD facilities, which is performed under state licensing rules and state funding. The health and safety risks inherent with dialysis treatment necessitate close scrutiny of these providers. ESRD surveys have become a higher workload priority for the CMS in recent years. The state and federal regulations require DSHS to work closely with the ESRD network related to quality assurance and data provided by these facilities.

- O. Regulatory programs relate to the licensing, registration, certification, or permitting of a person, business, or other entity. For each regulatory program, if applicable, describe:**
- why the regulation is needed;
 - the scope of, and procedures for, inspections or audits of regulated entities;

- **follow-up activities conducted when non-compliance is identified;**
- **sanctions available to the agency to ensure compliance; and**
- **procedures for handling consumer/public complaints against regulated entities.**

Licensing of healthcare facilities is necessary to protect the health and safety of consumers receiving care and services in those facilities. A license issued by DSHS establishes the right of that healthcare facility to operate in Texas, subject to ongoing compliance with applicable state statutes, rules, and regulations. The statutes and rules establish minimum health and safety standards that facilities must meet and maintain in order to provide healthcare services to patients. These standards include provisions for administration; qualifications, orientation, training, continuing education, and evaluation of staff; medical staff requirements; clinical records including confidentiality and security of records; quality assurance requirements; emergency equipment and medical protocols; infection control surveillance; equipment sterilization standards; nursing, pharmaceutical, radiology, laboratory, and dietary services; physical plant and fire safety codes; and disposal of hazardous waste.

Healthcare Facilities staff verifies a facility's compliance with minimum standards through periodic on-site inspections, complaint investigations, follow-up inspections, and document review. In addition, Healthcare Facilities must comply with the applicable state and federal regulations in order to obtain and maintain Medicare or CLIA certification.

Applicable health and safety codes authorize statewide on-site inspections to verify compliance with statutes, rules, and corrective action plans. DSHS conducts inspections of regulated entities through on-site inspections, via mail, and by desk reviews. Staff may conduct on-site inspections for issuance of an initial license, renewal of a license, following a change of ownership, when the facility has not demonstrated compliance with standards, or in response to a complaint. DSHS conducts inspections for initial or license renewal purposes by performing a standard-by-standard review of all aspects of a facility's operation in order to determine compliance with licensing standards. This may include an on-site inspection as well as a desk review inspection. DSHS conducts Medicare and CLIA surveys and investigations according to the State Operations Manual developed by CMS. Certain health facilities undergo life safety code surveys, in addition to the health surveys. DSHS has procedures for inspections and complaint investigations of substance abuse facilities and NTPs.

The surveyor completes both a statement of deficiencies and a survey report documenting any deficiencies cited. The facility must prepare an acceptable plan of correction that includes the date that the facility expects to have the deficiency corrected. The surveyor may conduct on-site verification of corrections. If an immediate threat to patient health and safety exists, the surveyor may remain on site until the facility addresses the threat. The surveyor may refer the healthcare facility for state and/or federal enforcement action, if appropriate.

Facilities that endanger the health and safety of their patients by failing to demonstrate ongoing compliance with licensing rules and standards are subject to enforcement action

including injunctive relief, criminal and civil penalties, reprimand, administrative penalties, denial, suspension, and revocation of license. Medicare-certified and CLIA facilities are subject to termination for serious and/or recurring non-compliance.

Staff receives complaints against substance abuse facilities, NTPs, and non-long-term care facilities both by verbal and written communication. A complaint may be anonymous. To assure continuous intake of complaint information, DSHS maintains a 24-hour, toll-free hotline. Information and instructions on filing a complaint are on the DSHS website. The steps for handling consumer/public complaints against regulated entities are as follows.

1. Evaluate allegations to determine if a potential violation exists.
2. Evaluate allegations to determine if a referral to another regulatory body is appropriate.
3. Authorize an investigation if a potential violation exists.
4. Send referral letters to other regulatory bodies, as appropriate.
5. Notify complainant, if known, of whether an investigation will ensue and/or if staff made a referral to another regulatory body that has jurisdiction.
6. Conduct an investigation by going on-site, via mail or desk review, as appropriate.
7. Determine regulatory violations, if indicated. Notify complainant of investigative findings, if allowed per state and federal rules and regulations.
8. Take state enforcement action against a healthcare facility, as appropriate, or refer to CMS for termination process.

P. For each regulatory program, if applicable, provide the following complaint information. The chart headings may be changed if needed to better reflect your agency's practices.

Department of State Health Services Healthcare Facilities Licensing Exhibit 11: Information on Complaints Against Regulated Persons or Entities Fiscal Years 2011 and 2012		
	FY 2011	FY 2012
Total number of regulated persons	N/A*	N/A*
Total number of regulated entities**	2,966	2,995
Total number of entities inspected	492	507
Total number of complaints received from the public	1,436	1,627
Total number of complaints initiated by agency	58	54
Number of complaints pending from prior years	0	0
Number of complaints found to be non-jurisdictional***	385	436

Department of State Health Services Healthcare Facilities Licensing Exhibit 11: Information on Complaints Against Regulated Persons or Entities Fiscal Years 2011 and 2012		
	FY 2011	FY 2012
Number of jurisdictional complaints found to be without merit	671	781
Number of complaints resolved	1,172	1,350
Average number of days for complaint resolution****	38	41
Complaints resulting in disciplinary action:*****		
administrative penalty	10	17
reprimand	0	0
probation	1	3
suspension	0	0
revocation	0	0
other	3	0

Healthcare Facilities data is based on state performance measure reporting.

* N/A=Data not collected or tracked

** Does not include substance abuse facilities, NTPs or EMS; EMS excluded here since reported under Healthcare Professions

*** Based on Healthcare Facility complaint staff knowledge and experience, for every complaint logged into CMS Automated Survey Processing Environment Complaints/Incidents Tracking System (ACTS), approximately three more complaints are received that are non-jurisdictional.

**** Healthcare Facilities data from ACTS report (intake date to exit date)

***** These disciplinary actions are for all Healthcare Facilities, including EMS providers (EMS personnel are reported under the Professional Licensing Strategy), substance abuse, and NTPs.

**Department of State Health Services
Substance Abuse Licensing
Exhibit 11: Information on Complaints Against Regulated Persons or Entities
Fiscal Years 2011 and 2012**

	FY 2011	FY 2012
Total number of regulated persons	N/A*	N/A*
Total number of regulated entities	579	579
Total number of entities inspected	277	367
Total number of complaints received from the public	369	353
Total number of complaints initiated by agency	2	2
Number of complaints pending from prior years	4	0
Number of complaints found to be non-jurisdictional	34	23
Number of jurisdictional complaints found to be without merit	N/A*	N/A*
Number of complaints resolved**	349	334
Average number of days for complaint resolution	53	42
Complaints resulting in disciplinary action:		
administrative penalty	0	1
reprimand	0	0
probation	0	0
suspension	0	0
revocation	0	0
other	0	0

* N/A=Data not collected or tracked

** Resolved=Closed, referred, or non-jurisdictional complaints

**Department of State Health Services
Narcotic Treatment Program (NTP) Licensing
Exhibit 11: Information on Complaints Against Regulated Persons or Entities
Fiscal Years 2011 and 2012**

	FY 2011	FY 2012
Total number of regulated persons	N/A*	N/A*
Total number of regulated entities	74	83
Total number of entities inspected/surveyed	41	43
Total number of complaint investigations conducted	10	16
Total number of complaints received	10	21
Total number of complaints initiated by agency	N/A*	N/A*
Number of complaints pending from prior years	4	13
Number of complaints found to be non-jurisdictional	0	1
Number of jurisdictional complaints found to be without merit	0	8
Number of complaints resolved**	1	34
Average number of days for complaint resolution	53	103
Complaints resulting in disciplinary action:		
administrative penalty	1	1
reprimand	0	0
probation	0	0
suspension	0	0
revocation	0	0
other	0	0

* N/A=Data not collected or tracked

** Resolved=Closed, referred, or non-jurisdictional complaints