

IX. MAJOR ISSUES

A. Brief Description of Issue

Issue 1: Should the State continue to provide certain services offered in the private sector?

B. Background/Discussion

Some Department of State Health Services (DSHS) programs provide services that are currently provided through the private sector.

- DSHS State Hospitals provide acute and sub-acute inpatient mental health treatment to psychiatric patients statewide. Some of these services are currently contracted through the private sector.
- DSHS laboratories conduct clinical chemistry and microbiological tests that may also be available through laboratories in the private sector.

The State Hospital system provides care to 254 counties, some of which have few inpatient options. DSHS provides care for adults, forensic patients, geriatric patients, patients with cognitive and behavioral conditions, patients with multiple disabilities (hearing impaired, visually impaired), and children/adolescents. Clinical specialties provide assessment, evaluation, and treatment, including psychiatry, nursing, social work, psychology, education/rehabilitation services, nutrition, and spiritual care. Medical and dental clinics, x-ray and laboratory services, and other consultative services provide additional clinical support. Services are paid through general revenue funds, private payment, private third-party insurance, and Medicare and Medicaid programs.

Facilities located in Austin, Big Spring, Kerrville, Vernon/Wichita Falls, El Paso, Rusk, Terrell, San Antonio, and Harlingen provide inpatient care. Another facility in the State Hospital system, Texas Center for Infectious Diseases (TCID) in San Antonio, provides specialized care that is not found elsewhere in Texas and is rare in the entire country. TCID treats Hansen's disease and tuberculosis (TB), including multi-drug resistant TB. Finally, Waco Center for Youth (WCY) provides inpatient residential treatment for children ages 12-18. While there are private facilities that offer residential care, those facilities do not always serve children with mental illnesses that are as complex and treatment resistant as those children provided with care at WCY.

The DSHS laboratories, located in Austin and Harlingen, have historically provided testing services to support public health purposes, as well as to ensure access to laboratory testing for participants in DSHS programs. The DSHS laboratories provide testing for DSHS programs such as Texas Health Steps, the Rio Grande State Center Outpatient Clinic, HIV/STD/hepatitis surveillance, TB, and vaccine preventable disease programs. Private sector laboratories conduct many of the same tests performed by the DSHS laboratories in support of these programs.

C. Possible Solutions and Impact

State Hospitals

Texas and other states contract for inpatient psychiatric services through the private sector. The expansion of the private beds may benefit the State in the long term. Use of private beds may occur in two ways: (1) contract for a private entity to operate a DSHS facility, or (2) contract for use of a private entity's beds.

DSHS initiated an effort to privatize one State Hospital based on the 2012-13 General Appropriations Act, H.B. 1, 82nd Legislature, Regular Session, 2011 (Article II, DSHS, Rider 63). DSHS issued a request for proposal (RFP), and only one provider responded to the RFP. DSHS did not choose the provider because the provider was unable to demonstrate that it could provide the same level of care, particularly related to patient safety, with fewer resources than are currently provided in the State Hospital system. The prescriptive nature of the RFP, in keeping with the requirements of the rider, may have limited opportunities for contracting. For example, a future scenario might allow a contractor to increase facility capacity by 10 percent while keeping costs flat, instead of having to cut costs by 10 percent at static capacity. Still other ways to structure an RFP may exist that would yield an outcome beneficial to the State.

DSHS currently contracts with outside entities for psychiatric hospital services. This type of arrangement will continue to be advantageous in the future as the cost to maintain State Hospital facilities continues to grow. However, State Hospitals will still be a necessary adjunct to the private care facilities partially because there are currently not enough private facilities to serve all Texans needing inpatient psychiatric care. Additionally, many private facilities do not serve certain populations, such as patients with multiple disabilities, patients requiring longer-term care, patients needing forensic services, and patients with more complex psychiatric illnesses compounded by traumatic brain injury. Finally, far fewer child and adolescent psychiatric facilities are available in the state, and those serving children under age 8 are relatively rare outside of major urban areas.

A request for information could provide information on options for using the private sector in delivering psychiatric hospital services. Before expansion of private beds, DSHS will need to analyze the requirement that those private hospitals comply with the Continuity-of-Care rule in the Texas Administrative Code and other rules applicable to State Hospitals.

Laboratories

Some DSHS programs have considered contracting with private laboratories for certain testing services; however, such changes could impact response times and communication. When outbreaks occur, the DSHS laboratories work with the programs to ensure that specimens associated with the outbreak are given priority testing. If there is a public health risk, DSHS laboratory staff work beyond regular business hours to perform the testing. In addition, DSHS

program staff may communicate directly with testing staff regarding results and additional testing to support the investigation. These types of support are not typically available from private sector laboratories.

Currently, the DSHS Austin laboratory is a sole-source provider for laboratory specimens for initial lead screening and for chlamydia/gonorrhea testing as part of the Texas Health Steps program. If another DSHS program contracts out for chlamydia/gonorrhea testing, the DSHS laboratory may not be able to provide this test for the Texas Health Steps program, as it may no longer be financially feasible. DSHS would need to work with the Texas Health Steps submitters to find an appropriate alternative testing source.

DSHS laboratory staff is aware that certain infectious diseases require immediate action to investigate and prevent further disease spread. If the testing for these diseases is moved to a private sector laboratory, DSHS will need to put systems in place to ensure the timely provision of crucial result reports to epidemiological staff for follow-up.

IX. MAJOR ISSUES – CONTINUED

A. Brief Description of Issue

Issue 2: What is the best use of limited State Hospital resources?

B. Background/Discussion

DSHS State Hospitals provide acute and sub-acute inpatient mental health treatment to psychiatric patients statewide, some of which are contracted through hospitals in the private sector. Due to the great need for services, provision of inpatient hospitalization requires using both types of entities. Currently, full resources are not available to meet all the needs of the aging hospitals and the populations that they serve.

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C. Possible Solutions and Impact

One solution includes the ongoing assessment of the needs of Texas communities and the development of a response that alters the availability of civil and forensic psychiatric services specific to the various demographic and clinical populations requiring those services. This concept is currently being operationalized and integrated in a 10-year plan under development for both DSHS State Hospitals and Department of Aging and Disability Services State Supported Living Centers, as directed by the 2014-15 General Appropriations Act, S.B. 1, 83rd Legislature, Regular Session, 2013 (Article II, DSHS, Rider 83). Through creation of a long-term plan for the

provision of psychiatric services, the State can better determine future capacity needs, address population growth, contain costs, and accommodate changes in healthcare financing.

Another potential solution might include the continued expansion of contracting privatized beds, as described in Issue 1.

IX. MAJOR ISSUES – CONTINUED

A. Brief Description of Issue

Issue 3: Should DSHS have flexibility in its ability to oversee certain regulated entities?

B. Background/Discussion

DSHS has regulatory authority for many types of healthcare and consumer product delivery entities (e.g., hospitals, drug manufacturers, and distributors). However, statute's, sometimes narrow definitions, may limit companies seeking to do business in Texas. The provisions may impact entities seeking to provide additional options for patients/consumers. For healthcare facilities, the impetus is often to be able to bill for services as a facility instead of billing as an individual provider (e.g., physician, nurse practitioner). Examples include the following.

- Some entities decided a few years ago that they wanted to provide emergency care at the level of a hospital emergency department, but they did not want to provide inpatient care. There was no regulatory schema for this new type of healthcare facility. The change took two legislative sessions, but the Legislature ultimately passed a bill creating a new license type, free-standing emergency centers.
- Recently, DSHS has been asked to consider licensing a jail and a bulimia/anorexia residential clinic as hospitals.
- A number of entities that would probably be more appropriately licensed as ambulatory surgery centers (ASCs) have become licensed as hospitals because the type of surgeries they do might require their patients to stay longer than the 24-hour federal limit on ASCs.
- An example outside the healthcare facility strategy is compounding pharmacies that want to export products to other states. A number of compounding pharmacies that may meet the compounding requirements under the state pharmacy statute also seek to be licensed by DSHS as a drug manufacturer or distributor because other states require the Texas license for reciprocity. However, these compounding pharmacies may not meet the standards required for manufacturer or distributor licenses.

Universally, when an entity seeks a license that does not clearly align with its business model, DSHS is asked to waive many of the requirements, which are considered minimum standards. Some of these requirements are key elements for patient or consumer protection, such as emergency services, life safety code requirements, or good manufacturing principles. Some are federal requirements that cannot be waived. Historically, entities that meet the requirements are opposed to new entities receiving the same license without meeting the same requirements. For example, hospitals meeting the requirement for an on-site physician to provide emergency services oppose the efforts of some entities to change the requirements for physician coverage.

In addition to flexibility relating to entities that do not fit the current law and regulations, DSHS has likewise identified a need for flexibility in its ability to investigate entities that are not compliant with regulations. For instance, there is a growing trend in healthcare and consumer product delivery industries to hide control and ownership of companies through various privately held and specialized corporations and/or private partnerships. These complex organizations are often formed to shield assets and individuals from litigation and/or sanctions or to circumvent existing regulatory activities, challenging the success and ability of the agency to properly investigate and enforce regulatory requirements. In some cases, the owner of a problem business is out-of-state and fundamentally out of reach of Texas administrative laws.

A recent example is a physician who leased or purchased a number of rural hospitals, setting each up as a separate corporation that he wholly owned. Problems began to emerge in these facilities but the common ownership was not readily apparent. Two other examples include the following.

- An investigation led to a proposed enforcement action; however, the company investigated was owned by a second holding corporation and the manager was listed as the contact person. Further background work was needed to determine that the actual owner of the second holding corporation lived in California and had legal issues involving allegations of Centers for Medicare & Medicaid (CMS) fraud.
- A minority stakeholder was listed as an organization's contact person, while the principle stakeholder was a second corporation set up to shield the true company owners from having required criminal background checks done prior to the State issuing a license.

C. Possible Solutions and Impact

The issues described above are complex and are present across all of the major DSHS regulatory programs. Greater flexibility within statutes would allow DSHS to create new license "types" through the rulemaking process. However, this approach may be met with concern by the entities that meet the current requirements and would prefer that there not be such flexibility. In addition, federal entities such as CMS and the Food and Drug Administration have voiced concerns about the rapidly growing numbers of certain types of entities in Texas, which in many cases exceeds population growth.

Mandating greater ownership disclosure requirements could improve DSHS' ability to take regulatory action and to track individuals who may try to reenter a field in which they have already been disciplined or are a potential threat to consumers or patients. Additionally, as a part of the application process for business entities, the applicants could be required to list all persons having a five percent or greater share in the company. Other possible options to address this issue may exist in other states.

IX. MAJOR ISSUES – CONTINUED

A. Brief Description of Issue

Issue 4: Do certain functions currently housed at DSHS detract from the Department’s public health focus?

B. Background/Discussion

DSHS has identified a number of functions that are statutorily assigned to the agency, but which may not be directly related to the agency’s public health mission. These include certain regulatory functions, chemical reporting functions, and animal welfare functions.

Some licensing and regulatory programs housed within the DSHS Division for Regulatory Services:

- have no direct relationship to public health;
- have only an indirect relationship to public health;
- are regulated locally as well as regulated by DSHS;
- have voluntary regulation; or
- are more closely related to law enforcement functions than public health functions.

The following regulatory programs are examples of programs that have one or more of those characteristics: tanning beds, tattoo and body piercing, certified food managers, dyslexia therapists and practitioners, massage therapists, opticians’ registry, rendering, certificates of free sale, bedding, personal emergency response system providers, and code enforcement officers.

The Community Right-to-Know Program, also housed within the DSHS Division for Regulatory Services, administers state and federal requirements for facilities that hold hazardous substances or extremely hazardous substances. These facilities must annually report storage capacity to DSHS, local fire chiefs, and local emergency planning committees. The requirement applies to manufacturing facilities, non-manufacturing facilities, and public employers, including refineries, cities, and fertilizer plants. DSHS serves as an information repository for these reports and has no authority to oversee the amounts, locations, manner of storage, or types of chemicals stored at facilities. Nearly 68,000 facilities statewide submit annual reports. DSHS has inspection authority in the program, which is limited, discretionary, and related to failure to report. The intent of the statute is to encourage community awareness and emergency planning.

Through the years, DSHS has also been tasked in statute with many animal welfare duties. The statutes and associated rules are administered and implemented by the Zoonosis Control Branch (within the Division for Disease Control and Prevention Services) and Regional Zoonosis

Control Programs (within the Division for Regional and Local Health Services). The agency has generally been required to meet the mandates with existing personnel and fiscal resources. These mandates have included animal euthanasia training; animal control officer training; dog and cat sterilization; regulation of circuses, carnivals, and zoos; regulation of dangerous wild animals; and animal shelters. The mission of the Zoonosis Control Branch and the Regional Zoonosis Control Programs is to prevent the transmission of diseases from animals to humans through epidemiologic measures, intervention strategies, and educational efforts. DSHS addresses animal welfare mandates, using the same resources dedicated to the agency's public health responsibilities, which could impact the capacity of the agency to meet its public health mission.

C. Possible Solutions and Impact

Consideration could be given as to whether the functions described above should continue to be performed by state government and, if so, whether they are appropriately placed within the State's public health agency. Any movement of these programs to other agencies would impact each program's stakeholders and interest groups, who may or may not be supportive, and could result in a transfer of funding and staff resources from DSHS to other agencies.

IX. MAJOR ISSUES – CONTINUED

A. Brief Description of Issue

Issue 5: Do existing statutory caps on fees limit available funding?

B. Background/Discussion

Most programs within the DSHS Division for Regulatory Services are statutorily required to achieve cost recovery through fee revenue. The following 13 programs have statutory caps on their fees; all but hospital licensing and some asbestos licenses have fees at the statutory cap:

- asbestos removal licensure,
- abusable volatile chemical permit,
- bedding permit,
- bottled and vended water,
- emergency medical services,
- frozen desserts,
- hospital licensing,
- mammography systems certification,
- milk industry products permit,
- oyster sales certification,
- private psychiatric hospital and crisis stabilization units,
- special care facilities, and
- workplace (Tier II) chemical reporting.

Fee caps have sometimes challenged the agency's ability to ensure that the total cost of regulation is covered by fee revenue. Because most of the programs are at the cap, DSHS would not have the ability to adjust fees for these programs if costs increased. Currently, all but 2 of the 13 programs are generating fee revenues in amounts that exceed appropriations.

The *Operational Evaluation of the Division of Regulatory Services at DSHS*, as required by the 2012-13 General Appropriations Act, House Bill 1, 82nd Legislature, Regular Session, 2011 (Article II, DSHS, Rider 59), addressed the issue of fees assessed by regulatory programs. One of the report recommendations was that the Division for Regulatory Services develop a standardized decision-making process to evaluate new and existing fees across regulatory programs. The proposed redesign will require consideration of the statutory limits within which DSHS must operate.

C. Possible Solutions and Impact

Consideration could be given as to whether the statutory fee caps should be abolished and the agency should be given authority to set fees in amounts reasonable and necessary to cover program costs. This would ensure that, if program costs increase, the agency would have a mechanism to cover any shortfalls.

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