



**TO:** Health and Human Services Commission  
Executive Council

**DATE:** December 6, 2018

**FROM:** Dr. Grace Kubin, PhD, Director of Laboratory  
Services Section

**AGENDA ITEM: 2.b**

**SUBJECT:** Fee Schedule for Clinical Testing, Newborn Screening and  
Chemical Analyses

**BACKGROUND:**  Federal  Legislative  Other: Program Initiative

This rule project proposes to amend §73.41, concerning Sale of Laboratory Services, repeal §73.54, concerning Fee Schedule for Clinical Testing and Newborn Screening, and §73.55, concerning Fee Schedule for Chemical Analyses, in Texas Administrative Code (TAC), Title 25, Part 1, Chapter 73 to direct stakeholders to visit the Laboratory Services Section (LSS) website to view the most current LSS Public Fee Schedule.

The repeal of §73.54 and §73.55 removes the Fee Schedule for Clinical Testing and Newborn Screening, as well as Chemical Analyses, from TAC. Future changes to the LSS Public Fee Schedule will be posted on the LSS website and may include: (1) the addition of new tests or deletion of low volume tests as needed; (2) fee increases for existing tests, an individual test fee would not be increased more than once per year; (3) decreases in fees for existing tests will be made as necessary; and (4) test changes in the event of a declared public health emergency or outbreak. These changes will be made based on the business needs of the LSS or public health needs. Proposed changes will allow for stakeholder input prior to the implementation date as well as LSS customer communication regarding all changes to the LSS Public Fee Schedule. The only exception is in the case of a declared public health emergency or outbreak.

Changes to available laboratory testing and related pricing may include implementation of new testing methodologies in the DSHS LSS, updating fees to reflect the cost of testing, and elimination of certain low volume tests to make more efficient use of staff time and to reduce costs. Updating the LSS Public Fee Schedule directly through the LSS website will help facilitate a more targeted and specific stakeholder and customer notification of upcoming changes and will ensure the most accurate LSS Public Fee Schedule will be available to the public.

Senate Bill (S.B.) 80, 82nd Legislature, Regular Session, 2011, required that DSHS: (1) develop, document, and implement procedures for setting fees for laboratory services, including updating and implementing a documented cost allocation methodology that determines reasonable costs for the provision of laboratory tests; and (2) analyze DSHS' costs and update the LSS Public Fee Schedule as needed in accordance with Texas Health and Safety Code, §12.032(c). Although S.B. 80 expired in 2013, the DSHS LSS continues to use a methodology approved by DSHS Executive Management for the determination of fees. A key component of the current fee change process is to notify all LSS stakeholders of the proposed changes and request feedback on the suggested fee increases. Any change in fees will be posted on the LSS website for at least 90 days to allow for stakeholder feedback and LSS customer communication regarding all changes to the LSS Public Fee Schedule.

All of the proposed amendments comply with the Texas Health and Safety Code, §§12.031, 12.032, and 12.0122 that allow DSHS to charge fees to a person who receives public health services from DSHS (which explicitly includes laboratory services), in an amount that recovers the cost to DSHS for providing that service.

#### **ISSUES AND ALTERNATIVES:**

If rules §73.54 and §73.55 are not repealed, DSHS LSS would continue to follow the TAC change process and therefore, could not add or remove tests or change prices except through the extensive rule review and approval process. This has a potentially negative impact on public health including an inability to provide testing for emerging infectious diseases and a loss of revenue for the agency when there are cost increases.

#### **STAKEHOLDER INVOLVEMENT:**

The proposed rule amendment and repeals were sent to external stakeholders for informal comment via the following methods on Monday, August 20, 2018:

- Posting on the HHS rulemaking website: <https://hhs.texas.gov/laws-regulations/policies-rules/health-human-services-rulemaking>.
- Posting on the LSS web notices/correspondence & bulletins pages for Clinical Chemistry, Newborn Screening, Microbiological Sciences, South Texas, and the Austin Laboratory.  
<https://www.dshs.texas.gov/lab/correspondencebulletins.shtm>
- Information has also has been sent via the GovDelivery/Listserv.

Comments were received from stakeholders and reviewed by health and human services staff and taken into consideration.

March of Dimes acknowledged the rule change will allow the LSS flexibility adjusting the fees.

Texas Public Health Coalition (TPHC), Cure Spinal Muscular Atrophy (Cure SMA), and the Texas Hospital Association (THA) request that the proposed rules ensure stakeholder feedback and adequate time to review any future changes. Both TPHC and THA requested a 90-day notification period to stakeholders related to any fee changes.

**FISCAL IMPACT:**

None

**SERVICES IMPACT STATEMENT:**

The proposed rule amendment and repeals will result in a more targeted and specific stakeholder and customer notification of upcoming public fee changes and will ensure the most accurate LSS Public Fee Schedule will be available to the public.

**RULE DEVELOPMENT SCHEDULE:**

December 6, 2018	Present to HHSC Executive Council
December 2018	Publish proposed rules in Texas Register
April 2019	Publish adopted rules in Texas Register
April 2019	Effective date

## PROPOSED PREAMBLE

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (DSHS), proposes an amendment to §73.41, concerning Sale of Laboratory Services; and the repeal of §73.54, concerning Fee Schedule for Clinical Testing and Newborn Screening; and the repeal of §73.55, concerning Fee Schedule for Chemical Analyses.

## BACKGROUND AND PURPOSE

The purpose of the amendment to §73.41 is to inform stakeholders that future changes to the Laboratory Services Section (LSS) Public Fee Schedule will be posted on the LSS website at [www.dshs.texas.gov/lab](http://www.dshs.texas.gov/lab). The repeal of §73.54 and §73.55 removes the Fee Schedule for Clinical Testing and Newborn Screening, as well as Chemical Analyses, from rules in Texas Administrative Code (TAC) Title 25.

Future changes to the LSS Public Fee Schedule will be posted on the LSS website and may include: (1) the addition of new tests or deletion of low volume tests as needed, (2) fee increases for existing tests, an individual test would not be increased more than once per year, (3) decreases in fees for existing tests will be made as necessary, and (4) test changes in the event of a declared public health emergency or outbreak. These changes will be made based on the business needs of the LSS, or public health needs. Proposed changes will allow for stakeholder input prior to the implementation date as well as LSS customer communication regarding all changes to the LSS Public Fee Schedule. The only exception is in the case of a declared public health emergency or outbreak.

Senate Bill (S.B.) 80, 82nd Legislature, Regular Session, 2011, required that DSHS: (1) develop, document, and implement procedures for setting fees for laboratory services, including updating and implementing a documented cost allocation methodology that determines reasonable costs for the provision of laboratory tests and (2) analyze DSHS' costs and update the fee schedule as needed in accordance with Texas Health and Safety Code, §12.032(c). Although S.B. 80 expired in 2013, the DSHS LSS continues to use a methodology approved by DSHS Executive Management (Chief Financial Officer and Deputy Chief Financial Officer) for the determination of fees. A key component of the current fee change process is to notify all LSS stakeholders of the proposed changes and request feedback on the suggested fee increases. The LSS longstanding practice to engage stakeholders has included direct communication, LSS website and list-serve postings. Under the new proposed process, the LSS will continue to include

time for stakeholder feedback and ample communication. Specifically, any change in fees will be posted on the LSS website for at least 90 days to allow for stakeholder feedback and LSS customer communication regarding all changes to the LSS Public Fee Schedule. The LSS will continue to use the same methods of outreach and communication with stakeholders in order to ensure timely and inclusive stakeholder involvement in the fee change process.

All of these proposed amendments comply with the Texas Health and Safety Code, §§12.031, 12.032, and 12.0122 that allow DSHS to charge fees to a person who receives public health services from DSHS (which explicitly includes laboratory services), in an amount that recovers the cost to DSHS for providing that service.

#### SECTION-BY-SECTION SUMMARY

The proposed amendment to §73.41, concerning Sale of Laboratory Services, adds language clarifying that future changes to the LSS Public Fee Schedule will be found on the LSS website at [www.dshs.texas.gov/lab](http://www.dshs.texas.gov/lab). The rule references to §73.54 and §73.55 are being removed from the rule text and replaced with the link to the revised website. New §73.41(f) describes that changes to available laboratory testing and related pricing may include implementation of new testing methodologies (such as Zika or other emerging diseases) in the DSHS LSS, updating fees to reflect the cost of testing, and elimination of certain low volume tests to make more efficient use of staff time and to reduce costs. Any change in fees will include processes for stakeholder input as well as LSS customer communication regarding all changes to the LSS Public Fee Schedule. Updating the LSS Public Fee Schedule directly through the LSS website will help facilitate effective cost recovery and allow offering of emerging laboratory testing to respond to public health threats on a broader scale, and will ensure the most accurate LSS Public Fee Schedule and information will be available to the public.

Sections 73.54 and 73.55 are proposed for repeal as the content of the rules will be provided on the LSS website.

#### FISCAL NOTE

Dr. Grace Kubin, Director, LSS, has determined that for each year of the first five years that the sections will be in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed. Information posted on the LSS website will clearly layout the fiscal impact of any changes on specific fees.

## GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined that during the first five years that the sections will be in effect:

(1) the proposed rules will not create or eliminate a government program;

(2) implementation of the proposed rules will not affect the number of employee positions;

(3) implementation of the proposed rules will not require an increase or decrease in future legislative appropriations;

(4) the proposed rules will not affect fees paid to the agency. This specific change only impacts the process for updating fees and tests in the LSS Public Fee Schedule, but does not impact the fees themselves;

(5) the proposed rules will not create a new rule;

(6) the proposed rules will not expand or limit, but will repeal two existing rules;

(7) the proposed rules will not change the number of individuals subject to the rule; and

(8) the proposed rules will not affect the state's economy.

## SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Dr. Kubin has also determined that there will be very little or no adverse economic effect on small businesses, micro-businesses, or rural communities. The only impact would be if a business does not have easy access to internet services in order to review the online Public LSS Fee Schedule, they would have to request and receive the fee schedule via US mail. The rules do not impose any additional costs on small businesses, micro-businesses, or rural communities that are required to comply with the rules.

## ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the sections as proposed.

There is no anticipated negative impact on local employment.

#### COSTS TO REGULATED PERSONS

Texas Government Code, §2001.0045 does not apply to these rules because the rules are necessary to protect the health, safety, and welfare of the residents of Texas. The rule change in and of itself does not have a fiscal impact. Information posted on the LSS website will clearly layout the fiscal impact of any changes on specific fees. Any proposed changes to costs of regulated persons would be communicated to the public and allow for stakeholder feedback prior to the implementation of the new fee.

#### PUBLIC BENEFIT

Dr. Kubin has determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections will be as mentioned in the Section-by-Section Summary, will facilitate effective cost recovery and allow the offering of emerging laboratory testing to respond to public health threats on a broader scale, and will ensure the most accurate LSS Public Fee Schedule and information will be available to the public.

#### TAKINGS IMPACT ASSESSMENT

DSHS has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code, §2007.043.

#### PUBLIC COMMENT

Questions about the content of this proposal may be directed to Martha Thompson at (512) 776-6191 in the DSHS Laboratory Services Section.

Written comments on the proposal may be submitted to the Laboratory Services Section, P.O. Box 149347, Mail Code 1947, Austin, Texas 78714-9347 or physical address 1100 West 49th Street, Austin, Texas 78756; by fax (512) 776-7406; or by email to [hhsrulescoordinationoffice@hhsc.state.tx.us](mailto:hhsrulescoordinationoffice@hhsc.state.tx.us). When faxing or emailing comments, please indicate "Comments on Proposed Rules 18R067" in the subject line.

Comments are accepted for 30 days following publication of the proposal in the Texas Register. If the last day to submit comments falls on a weekend or a holiday, comments must be postmarked, shipped, faxed or emailed before midnight on the following business day to be accepted.

#### STATUTORY AUTHORITY

The amendment and repeals are authorized under Texas Health and Safety Code, §12.031 and §12.032 which allow DSHS to charge fees to a person who receives public health services from DSHS; §12.034 which requires DSHS to establish collection procedures; §12.035 which requires the DSHS to deposit all money collected for fees and charges under §12.032 and §12.033 in the state treasury to the credit of DSHS' public health service fee fund; §12.0122 which allows DSHS to enter into a contract for laboratory services; and Texas Government Code, §531.0055, and Texas Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code, Chapter 1001.

The amendment and repeals affect the Texas Health and Safety Code, Chapters 12 and 1001; and Texas Government Code, Chapter 531.

This agency hereby certifies that this proposal has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

TITLE 25        HEALTH SERVICES  
PART 1         DEPARTMENT OF STATE HEALTH SERVICES  
CHAPTER 73    LABORATORIES

**§73.41. Sale of Laboratory Services.**

(a) Purpose. This section details the procedures concerning the sale of laboratory services by the Department of State Health Services (department). Particular services, [~~Certain of these services are set out by rule~~] with specific charges for each listed service, are found on the Laboratory Services Section (LSS) website (www.dshs.texas.gov/lab) [~~as found in §73.54 and §73.55 of this title (relating to Fee Schedule for Clinical Testing and Newborn Screening and Fee Schedule for Chemical Analyses)~~]. Provision of those listed services by the department may or may not involve a contract, at the department's discretion. Other services[~~;~~] not found in the LSS Public Fee Schedule [~~those fee schedules;~~] that the department elects to sell will be memorialized in a contract between the department and the purchaser of such services [~~service(s)~~]. Entities which the department may contract with for the sale of laboratory services are limited to those found at Health and Safety Code, §12.0122. At the department's discretion, tests designated to be performed at a particular department laboratory may be performed at any of the department laboratories.

(b) Definition of laboratory services. Laboratory services include the sale of the following services: the evaluation and [~~and/or~~] testing of samples, and the subsequent reporting of test or evaluation results for samples submitted to the laboratory; certification, accreditation or approval of milk and shellfish laboratories and milk analysts; and special projects. Laboratory Services, as limited by Health and Safety Code, §12.0122, do not include services related to tissue and cytology specimens [~~except for pap smears for recipients under federally funded programs~~].

(c) Charges. Fees for the sale of laboratory services to the public found on the LSS website [~~in the fee schedules at §73.54 and §73.55 of this title~~] were calculated to recover the department's costs associated with such activities. When laboratory services outside of the LSS Public Fee Schedule [~~those fee schedules~~] are sold under this section, the contract executed for that sale shall include charges for the services in question which recover the department's costs associated with such activities.

(d) Other contracts. This section does not affect department contracts that are not governed by Health and Safety Code, §12.0122.

(e) Fees. The LSS Public Fee Schedule [A schedule of all fees] is available upon request from the Department of State Health Services, 1100 West 49th Street, Austin, TX 78756-3199, (512) 776-7318. It is also available online at <http://www.dshs.texas.gov/lab> [~~in the Laboratory Testing Services Manual (currently found at <http://www.dshs.state.tx.us/lab>)~~].

(f) Future updates for laboratory services and fees. Changes to the LSS Public Fee Schedule will be posted on the LSS website and made based on the business needs of the LSS and the public health needs of the department. Changes to available laboratory testing and related pricing may include implementing new testing methodologies in the LSS, updating fees to reflect the cost of testing, and eliminating certain low volume tests to make more efficient use of staff time and to reduce costs. Any change in fees will be posted on the LSS website for at least 90 days to allow for stakeholder input as well as LSS customer communication regarding all changes to the LSS Public Fee Schedule. After the period for stakeholder notification and input, changes and amendments affecting the LSS Public Fee Schedule will be added to the LSS Public Fee Schedule as soon as practicable. Changes may include the following:

(1) the addition of new tests or deletion of low volume tests as needed;

(2) an increase in fees for existing tests may be applied to a test individually or collectively, but an individual test fee would not be increased more than once per year;

(3) a decrease in fees for existing tests as needed; or

(4) a change to the LSS Public Fee Schedule in response to a declared public health emergency or outbreak situation. This change may not include a formal process to receive stakeholder input before implementing a new test in order to ensure a rapid public health action. In the event of a declared public health emergency or outbreak, the LSS may implement tests as required without contract provisions or posting in the LSS Public Fee Schedule.

(g) [(f)] Payment of charges.

(1) The department will determine whether a charge must be paid with submission of the specimen or whether the department will bill later for the charge, unless otherwise stated in this section.

(2) A charge paid is non-refundable.

(3) Failure to pay a charge in a timely manner may result in the department's refusal to accept specimens or samples until all delinquent charges are paid.

TITLE 25                   HEALTH SERVICES  
PART 1                     DEPARTMENT OF STATE HEALTH SERVICES  
CHAPTER 73               LABORATORIES

The full text of the repealed rules for §73.54 and §73.55 can be viewed here:

**§73.54. Fee Schedule for Clinical Testing and Newborn Screening.**

[http://texreg.sos.state.tx.us/public/readtac\\$ext.TacPage?sl=R&app=9&p\\_dir=&p\\_rloc=&p\\_tloc=&p\\_ploc=&pg=1&p\\_tac=&ti=25&pt=1&ch=73&rl=54](http://texreg.sos.state.tx.us/public/readtac$ext.TacPage?sl=R&app=9&p_dir=&p_rloc=&p_tloc=&p_ploc=&pg=1&p_tac=&ti=25&pt=1&ch=73&rl=54)

**§73.55. Fee Schedule for Chemical Analyses.**

[http://texreg.sos.state.tx.us/public/readtac\\$ext.TacPage?sl=R&app=9&p\\_dir=&p\\_rloc=&p\\_tloc=&p\\_ploc=&pg=1&p\\_tac=&ti=25&pt=1&ch=73&rl=55](http://texreg.sos.state.tx.us/public/readtac$ext.TacPage?sl=R&app=9&p_dir=&p_rloc=&p_tloc=&p_ploc=&pg=1&p_tac=&ti=25&pt=1&ch=73&rl=55)