

**Department of State Health Services
Council Agenda Memo for State Health Services Council
February 26 -27, 2014**

Agenda Item Title: Amendments to rules concerning fee schedules for clinical testing, newborn screening, and chemical analysis

Agenda Number: 5.i

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Laboratory Services Section (LSS), in the Division for Disease Control and Prevention Services, supports public health programs by providing analysis of human, animal, and environmental specimens and samples.

For 2013, about 1.3 million specimens and environmental samples were tested by LSS, including:

- the testing of 261,000 specimens as part of the Texas Health Steps Program;
- the testing of 156,000 microbiological specimens associated with communicable diseases, foodborne outbreaks, tuberculosis, infectious agents, viruses, rabies, and other health threats;
- the testing of 31,000 drinking water samples;
- the testing of 63,000 samples at the South Texas Laboratory; and
- 746,000 samples for the screening of 400,000 newborns for 29 disorders.

The Laboratory is supported with \$34.5 million in general revenue, which includes \$9.7 million in Public Health Service Fees and \$14.7 million in Medicaid reimbursements. An additional \$4.1 million in federal funding is received from the Centers for Disease Control and Prevention, Assistant Secretary for Preparedness and Response, Food and Drug Administration, and the Environmental Protection Agency.

Summary:

The purpose of the amendments is to adjust the name of the submitter resource manual; remove technical definitions from rule and place in an online submitter resource manual; and adjust fee schedules for clinical testing, newborn screening, and chemical analysis. Proposed amendments are necessary because the fee schedules need to be updated to incorporate new laboratory tests, update test method references and fees, correct past errors in fee calculation, update to current actual costs using the standard formula, and to delete laboratory tests that are no longer performed by DSHS.

The DSHS “Manual of Reference Services” would be renamed “Laboratory Testing Services Manual.” The technical definitions in Section 73.51 would be removed and placed in the “Laboratory Testing Services Manual” on the DSHS LSS website, and the revised rule would contain both a cross-reference to that website and instructions for how people without Internet access can get a copy of the material. By maintaining the definitions on an agency website, the definitions can be modified as called for, as the underlying science advances, outside of the rulemaking process.

Some of the proposed rule changes in Sections 73.54 and 73.55 would increase fees in order to correct a cost calculation error in a previous rulemaking action; correct a typographical error from a previous rulemaking action; and capture current agency actual costs to reflect new technology and/or lower specimen volume. The proposed rules also delete low volume tests, which are defined as ordered less than 100 times in 2013; not considered a core public health test; and are readily available from commercial laboratories. The proposed fee changes reflect the DSHS’s current actual costs for providing services.

Key Health Measures:

The adjusted fee schedule reflects the Laboratory's current actual costs of testing and complies with legislation regarding the required fee and revenue recovery methodology. Adjusting the fee schedule will help ensure that the Laboratory is better positioned to generate enough revenue to maintain the current level of services to all providers. It is a statutory requirement to use the standardized formula to set fees to reflect the current actual cost, and DSHS does not have the discretion to use any other formula or method to derive its fee amounts.

The Laboratory reports two performance measures to the Texas Legislature that includes the number of laboratory tests performed and the average cost per test performed. The proposed amendments include adding 10 new tests; deleting 9 low-volume tests, reducing the fee of 7 tests; increasing the fee for 14 tests (1 of which will also be renamed for better clarity); and renaming 20 tests for better clarity (10 of those tests will also have the fee reduced). Below is a representation of some of the price changes. The largest price increase was 222%. This increase was due to an error in the application of the standardized cost calculation formula during a previous rulemaking in October 2012. The proposed new price is the current actual cost to the lab to perform the test.

Test	Current Price	Proposed Price	% Increase or Decrease
Cholesterol	\$4.07	\$5.18	27% increase
Glucose fasting and glucose random (2 separate test priced the same)	\$3.96	\$4.30	9% increase
Glucose post prandial (1 hour)	\$3.96	\$8.60	117% increase
Glucose post prandial (2 hour)	\$7.91	\$12.90	64% increase
Shiga toxin producing <i>E.coli</i> , PCR	\$36.60	\$117.90	222% increase
Definitive identification: <i>Campylobacter</i>	\$165.44	\$166.88	0.8% increase
All metals drinking water, EPA methods 200.7, 200.8, and 245.1 and SM 19 th edition 2340B	\$152.43	\$160.16	5% increase
High-density lipoprotein (HDL)	\$7.14	\$6.02	15% decrease
Definitive identification: bacillus	\$175.88	\$165.27	6% decrease
Definitive identification: <i>Haemophilus</i> ,	\$242.23	\$107.64	55% decrease
Schistosoma EIA	\$134.49	\$10.30	92% decrease
Strongylides EIA	\$73.45	\$16.89	77% decrease
Mumps: IgM	\$251.96	\$83.93	67% decrease
South Texas Laboratory			
PCR: Ricin	\$150.00	\$151.42	1% increase
PCR: Influenza A/H5	\$125.00	\$90.62	28% decrease

Summary of Input from Stakeholder Groups:

The LSS solicited preliminary feedback via email during the development of the proposed changes to these rules from the following stakeholders: Texas Medical Association, Texas Pediatric Association, Texas Hospital Association and Texas Association of Local Health Officials. Feedback provided by the stakeholders did not include substantive changes to these proposed rules. Once the rules are approved to be published in the *Texas Register*, a link to the publication will be posted on the DSHS LSS website.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item #5.i.

Approved by Assistant Commissioner/Director:		Janna Zumbrun	Date:	2-10-14
Presenter:	Grace Kubin	Program:	Director, Laboratory Services Section	Phone No.: 512-776-2468
Approved by CCEA:		Carolyn Bivens	Date:	2-11-14

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 73. Laboratories
Amendments §73.31, §73.41, §73.51, §73.54, §73.55

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §73.31, §73.41, §73.51, §73.54, and §73.55 concerning fee schedules for clinical testing, newborn screening, and chemical analysis.

BACKGROUND AND PURPOSE

This rule package concerns fees for laboratory services--specifically, specimen submission, sale of laboratory services, technical definitions associated with the sale of laboratory services, and fee schedules for clinical testing, newborn screening, and chemical analysis.

Proposed amendments to §73.51 would remove the technical definitions from these rules and replace them with a cross reference to the department's website where the definitions would then be located. The proposed revisions would provide alternative means of getting these definitions for those who do not have Internet access. Definitions for the technical terms in §73.51 change routinely as the science underlying them evolves, and so the department's Laboratory Services Section (LSS) believes that it makes more sense to move these definitions into the "Laboratory Testing Services Manual," with a rule providing a cross-reference to that document as well as providing information on how to obtain it. This would allow the technical terms to be updated as needed without going through the rulemaking process. This should not be controversial, and should actually help the department provide better service to its submitters because the manual--which lists the tests that the LSS offers and also outlines specimen collection and acceptance criteria--would then be kept current at all times. This helps reduce the chances of the department having to reject a specimen because the most up-to-date procedures for storage/shipping were not followed. Actual fee amounts would remain in the rules, and would not be impacted by this change in how technical definitions would be handled.

Some fee amounts in the fee schedules in these rule sections would change in this rulemaking action. Senate Bill (SB) 80, 82nd Legislature, Regular Session, 2011, required that the department: (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 the department's costs and update the fee schedule as needed in accordance with Texas Health and Safety Code, §12.032(c). In a past rulemaking action (adopted October, 2012), the LSS developed and documented a cost accounting methodology and determined the costs for each test performed listed in the fee schedule. The methodology for developing cost per test included calculating the specific costs of performing a test or analysis and the administrative and overhead cost necessary to operate the state laboratories in question. It is these figures together which

determined the revised fee amount for each of the tests in these fee schedules. In order to determine the specific cost for each test or analysis, LSS performed a work load unit study for every procedure or test offered by the laboratory. A work load unit was defined as a measurement of staff time, consumables and testing reagents required to perform each procedure from the time the sample enters the laboratory until the time the results are reported. More than 3,000 procedures performed by the department's LSS were included in this analysis. These procedures translated to approximately 700 different tests listed in the department fee schedule. It was understood at that time that the department would need to make periodic subsequent changes to its fee schedule in the rules in order to reflect changes in actual cost over time. Whenever such rulemaking actions are proposed, they employ the same fee calculation methodology mandates by law in 2011. In the current rulemaking proposal, this same approach was employed on a much smaller number of tests. These proposed fee changes reflect the department's current costs for providing the services at issue.

Proposed amendments to §73.54 and §73.55 are necessary because those fee schedules need to be updated to incorporate new laboratory tests, update test method references and fees, correct past errors in fee calculation, update to current actual costs using the standard formula, and to delete laboratory tests that are no longer performed by the department. For some of the tests proposed to be deleted, the current testing equipment or methodologies are no longer supported by the applicable manufacturers. Many of these changes to new testing methodologies will allow submitters to get faster and/or more accurate results.

Tests that will no longer be offered by the department are readily available elsewhere and only a few specific fees would be increased by virtue of these rule changes. The fee increases in the clinical chemistry section of §73.54 are: cholesterol increased from \$4.07 to \$5.18; glucose fasting from \$3.96 to \$4.30; glucose post prandial (1 hour) from \$3.96 to \$8.60; glucose post prandial (2 hour) from \$7.91 to \$12.90; glucose random from \$3.96 to \$4.30; glucose tolerance test (1 hour) from \$7.91 to \$8.60; glucose tolerance test (2 hour) from \$11.87 to \$12.90 glucose tolerance test 3 hour from \$15.82 to \$17.20; and Lipid panel from \$10.57 to \$15.04. These increases are due to new technology and lower specimen volume.

Updated work load unit studies were conducted for the definitive identification for *Campylobacter* at the Austin Laboratory and PCR Ricin for the South Texas Laboratory resulting in an increased fee for both tests. In §73.54, *Campylobacter* will increase from \$165.44 to \$166.88 and PCR for Ricin will increase from \$150.00 to \$151.42.

In §73.54, the fee for Shiga toxin producing *E.coli*. PCR increased from \$36.60 to \$117.90. This increase in price is necessary because an error was found in the existing rule text. The actual cost to perform the test is \$117.90. This increase was due to an error in application of the cost calculation formula for the fee adopted in October 2012. The error in the rule text must be corrected to ensure that the LSS-recoups the department's actual costs as called for in the cost calculation formula as required by law. The cost methodology used is as described in the Background and Purpose Section. The costs of the consumables were accidentally left out of the calculation and the price increase is the corrected price that reflects the ~~LSS~~ department's actual cost to perform the test under the proper application of the standard formula.

In §73.54, the fee for Metals in urine in the Emergency Preparedness section will increase from \$173.25 to \$176.25. This increase in price is necessary because an error was found in the existing rule text. The actual cost to perform the test is \$176.25. This increase was due to a typographical error for the fee adopted in October 2012. The error in the rule text must be corrected to ensure that the LSS recoups the department's actual costs as called for in the cost calculation formula as required by law. The cost methodology used is as described in the Background and Purpose Section.

In §73.54, the Acid Fast Bacilli section the fees for two tests were accidentally reversed during the same rulemaking action referenced immediately above. Direct detection by high-performance liquid chromatography (HPLC) was \$124.90 but will be amended to the correct fee of \$66.26; while identification of AFB isolates, HPLC was \$66.26, but will be amended to the correct fee of \$124.90.

In §73.55, the fee for all metals drinking water group, EPA methods 200.7, 200.8 and 245.1 and SM 19th edition 2340B will increase from \$152.43 to \$160.16. This fee increase is due to the addition of potassium as a metal to be identified in drinking water.

The proposed amendments comport with Texas Health and Safety Code, §12.031, §12.032, and §12.0122 that allow the department to charge fees to a person who receives public health services from the department, with fee amounts set to recover the department's costs for performing laboratory services.

SECTION-BY-SECTION SUMMARY

Existing §73.31(a) is proposed to be amended by changing the name of the "Manual of Reference Services" to its new name "Laboratory Testing Services Manual," as well as, adding the reference to the LSS's website (currently found at <http://www.dshs.state.tx.us/lab>) for the manual's location.

Existing §73.31(c) is proposed to be amended by updating the department's LSS phone number to (512)-776-7318 and by removing the website reference since it would now appear in subsection (a) of this section.

Existing §73.41(e) is proposed to be amended by changing the name of the "Manual of Reference Services" to its new name "Laboratory Testing Services Manual," as well as adding the reference to the LSS website (currently found at <http://www.dshs.state.tx.us/lab>) for the manual's location.

Existing §73.51 is proposed to be amended by removing the technical definitions from these rules and moving them into the "Laboratory Testing Service Manual," with the rule providing a cross-reference to that manual and detailing different methods for obtaining a copy of the manual. The reason for this proposed change, as discussed previously in the Background and Purpose Section, is to provide the flexibility to update these technical definitions in a timely manner (i.e., outside of the rulemaking process) as the science underlying the applicable terms evolves.

Existing §73.54(a)(1)(B)(iii), (iv), and (x) are proposed to be amended by increasing the fees to reflect both new technology being used for the tests and a decrease in testing volume experienced by department for these particular services: (iii) Cholesterol would increase from \$4.07 to \$5.18; (iv) Glucose: (I) glucoses fasting would increase from \$3.96 to \$4.30; (II) glucose post prandial (1 hour) would increase from \$3.96 to \$8.60; (III) glucose post prandial (2 hour) would increase from \$7.91 to \$12.90; (IV) glucose random would increase from \$3.96 to \$4.30; (V) glucose tolerance test (1 hour) would increase from \$7.91 to \$8.60; (VI) glucose tolerance test (2 hour) would increase from \$11.87 to \$12.90; (VII) glucose tolerance test (3 hour) would increase from \$15.82 to \$17.20; and (x) Lipid panel would increase from \$10.57 to \$15.04.

Existing §73.54(a)(1)(B)(viii) is proposed to be amended by decreasing the fee from \$7.14 to \$6.02 to reflect new technology.

The low volume tests in existing §73.54(a)(1)(B)(xi) and (x) are proposed for deletion to make more efficient use of LSS staff and to lower operational costs.

Existing §73.54(a)(2)(A)(vi)(I) is proposed to be amended by decreasing the fee from \$175.88 to 165.25. The fee reduction is due to decrease in identification time due to technician training.

Existing §73.54(a)(2)(A)(vi)(V) is proposed to be amended by increasing the fee from \$165.44 to \$166.88. The increase is due to changes in testing methodology. The new test method is slightly more expensive for the department to perform.

Existing §73.54(a)(2)(A)(vi)(VI) is proposed to be amended by deleting this subclause. This is a duplicate test and is more accurately placed in existing §73.54(a)(2)(A)(v). The remaining clauses will be renumbered accordingly.

Existing §73.54(a)(2)(A)(vi)(X), which would be renumbered as subclause (XI), is proposed to be amended by reducing the fee from \$242.23 to \$107.64 to reflect new technology.

Existing §73.54(a)(2)(A) is proposed to be amended by adding three new tests. These tests would be added by inserting 3 new clauses: (vii) Diphtheria screen priced at \$62.65, (xi) Group B streptococcus screen priced at \$48.32, and (xiii) Kirby Bauer priced at \$9.92. The remaining clauses will be renumbered accordingly. The new clauses more accurately reflect the components of this particular type of laboratory service.

Existing §73.54(a)(2)(A)(ix), which would be renumbered as clause (x), is proposed to be amended by updating the name of the test to “*Escherichia coli (E.coli)*, serotyping” to more accurately identify the test and by updating the fee from \$26.64 to \$25.71 due to the changes in technology used in the testing. Existing §73.54(a)(2)(A)(x)(I), which would be renumbered as subclause (xii)(I), is proposed to be amended by updating the name of the test to “Influenzae serotyping” to more accurately identify the test and by updating the fee from \$91.58 to \$79.64 due the changes in technology used in the testing.

Existing §73.54(a)(2)(A)(xii), which would be renumbered as clause (xv), is proposed to be amended by increasing the fee from \$36.60 to \$117.90. This increase in price is necessary because an error was found in the existing rule text. The actual cost to perform the test is \$117.90. This increase was due to an error in application of the cost calculation formula for the fee adopted in October 2012. The error in the rule text must be corrected to ensure that the LSS recoups the department's actual costs as called for in the cost calculation formula. The cost methodology used is as described in the Background and Purpose section in this preamble. The costs of the consumables were accidentally left out of the calculation and the price increase is the corrected price that reflects the department's actual cost to perform the test.

Existing §73.54(a)(2)(B)(ii)(II) and (VII) are proposed to be amended by updating the name of the test to more accurately reflect the test as currently performed. The name changes would be "Arsenic in urine, ICP-DRC (Dynamic reaction cell)-MS" and "Metals in urine (barium, beryllium, cadmium, lead, thallium, uranium), ICP/MS", respectively. Furthermore the fee for Metals in urine would be corrected from \$173.25 to \$176.25. In a previous rule amendment (adopted in October 2012) the fee was accidentally typed as \$173.25. The correct fee should be \$176.25.

Existing §73.54(a)(2)(C)(i)(I)(-c-) and (-d-)(-1-) are proposed to be amended by correcting the fee associated with each test. In a previous rules amendment (adopted in October 2012) the fees were accidentally reversed. Direct detection by high-performance liquid chromatography (HPLC) was \$124.90, but will be amended to the correct fee of \$66.26; while identification of AFB isolates, HPLC was \$66.26 but will be amended to the correct fee of \$124.90. Billing was not affected by this error. The correct fees were loaded in the billing system and the error only occurred in the rule text. Each of these fee amounts was reached using the standard calculation formula.

Existing §73.54(a)(2)(C)(v)(I)(-d-) is proposed to be amended by updating the name of the test to "Isoniazid, .02 mcg/ml" to more accurately identify the test. A new item (a)(2)(C)(v)(I)(-e-) Isoniazid, 1.0mcg/ml, priced at \$30.41, is proposed for addition to further clarify the different concentrations of Isoniazid used in agar proportion drugs testing. The remaining items would be renumbered accordingly.

Existing §73.54(a)(2)(C)(v)(I)(-f-) is proposed to be amended by correcting the spelling of "Ofloxacin."

Existing §73.54(a)(2)(C)(v) is proposed to be amended by deleting clauses (II) and (III), as the technology for these tests is no longer available. The remaining clauses would be renumbered accordingly.

Existing §73.54(a)(2)(C)(v)(IV), which would be renumbered as subclause (II), is proposed to be amended by reorganization of how the test is described in the rule, including adding new subitems to clarify the associated tests available. Existing §73.54(a)(2)(C)(v)(IV), would be renamed "MGIT drugs susceptibility test:" and two items (-a-) Primary Panel (includes Isoniazid 0.1mg/ml, 0.4 mcg/ml, Ethambutol, and Rifampin), priced at \$115.05; and (-b-) Individual MIGT primary drugs: would be added to specific testing. Additionally, 4 new

subitems would be added to (-b-) to allow submitters to order testing for individual drugs when the entire drug panel is not needed. These 4 subitems are: (-1-) Isoniazid, .01mcg/ml, priced at \$28.76; (-2-) Isoniazid, .04mcg/ml priced at \$28.76; (-3-) Ethambutol, priced at \$28.76; (-4-) Rifampin, priced at \$28.76.

Existing §73.54(a)(2)(E)(i) is proposed to be amended by reorganizing existing tests and adding new tests related to arbovirus testing to improve accuracy and readability, and to achieve consistency of format. Existing §73.54(a)(2)(E)(i)(I) is proposed to be renamed “Immunoglobulin G IgG (EIA).” The three viruses referenced in existing language are proposed to be broken out into individual tests to more accurately reflect how the department LSS currently handles testing for arbovirus Immunoglobulin IgG. These tests would be new items: (-a-) Dengue, priced at \$72.15; (-b-) St. Louis Encephalitis, priced at \$77.26; and (-c-) West Nile, priced at \$77.26. Existing §73.54(a)(2)(E)(i)(II) would be renamed “Immunoglobulin M (IgM) EIA.” The three viruses referenced in existing language are proposed to be broken out into individual tests to more accurately reflect how the lab currently handles testing for arbovirus Immunoglobulin IgM. These tests would be new items: (-a-) Dengue, priced at \$58.11; (-b-) St. Louis Encephalitis, priced at \$107.84; and (-c-) West Nile priced at \$107.84. Existing §73.54(a)(2)(E)(i)(III) PCR West Nile (WNV) and its corresponding fee are proposed to be deleted. This test is already listed in current rule and is more accurately placed in existing §73.54(c)(8)(A). The department proposes to add a new test at what would be §73.54(a)(2)(E)(i)(III). This test is called Immunoglobulin M (IgM) MIA (which includes: St. Louis Encephalitis and West Nile Virus), and its associated fee would be \$158.20, using the standard formula.

Existing §73.54(a)(2)(E)(ii), (iii), (v), (xvii), (xxii) and (xxiii) are proposed to be amended by updating the name of the tests, to more accurately identify them, and by updating their associated fees to reflect new technology: (ii) *Brucella* IgG, with the fee reduced from \$74.52 to \$44.10; (iii) Cat scratch Fever (*Bartonella*) IgG, indirect fluorescent antibody (IFA), with the fee reduced from \$171.30 to \$95.19; (v) *Ehrlichia* IFA, with the fee reduced from \$174.20 to \$131.31; (xvii) Q-fever IgG, with the fee reduced from \$234.97 to \$85.61; (xxii) Schistosoma EIA, with the fee reduced from \$134.49 to \$10.30; and (xxiii) Strongyloides EIA, with the fee reduced from \$73.45 to \$16.89.

Existing §73.54(a)(2)(E)(ix), (x), and (xv) are proposed to be amended by deleting the following low-volume tests: (ix) Hepatitis BeAb; (x) Hepatitis BeAg; (xv) Measles, mumps, rubella-*Varicella zoster* virus (MMR-VZV) Magnetic Immunoassay (MIA).

These tests are proposed for deletion to make more efficient use of LSS staff and to lower operational costs. The remaining clauses will be renumbered accordingly. As stated above, these tests are readily available at other laboratories in the state.

Existing §73.54(a)(2)(E)(xvi)(I) and (II), which would be renumbered as clause (xv), is proposed to be amended by updating the name of the tests to “IgG” and “IgM” respectively. The fee for IgM is also proposed to be decreased from \$251.96 to \$83.93 to reflect the implementation of new technology which has lowered the cost of performing the test.

New §73.54(a)(2)(E)(xvi) is proposed to be amended to include a new test, Pertussis Toxin IgG, priced at \$89.86.

Existing §73.54(a)(2)(E)(xix) is proposed to be amended by reorganizing the existing test under new subclauses to improve readability, accuracy and to achieve consistency of format. Existing §73.54(a)(2)(E)(xix) would be renamed to “*Rickettsia* panel:” and two new subclauses would be added to this clause to outline the individual tests available and the fees associated with those items: (I) Rocky Mountain spotted Fever (RMSF) IgG, priced at \$42.93, and (II) Typhus fever IgG, priced at \$42.93. This proposed change would more accurately reflect current testing in the department laboratories.

Existing §73.54(a)(2)(E)(xxi) and (xxvi) are proposed to be renamed and moved within the subparagraph to be alphabetically arranged to improve accuracy and organization. Existing (xxi) Rubleoa would be renamed “Measles” and would be moved to §73.54(a)(2)(E)(xiv) with subclauses (I) IgG priced at \$21.36 and (II) IgM priced with a reduced fee of \$85.60 from \$210.24. Existing (xxvi) Tularemia would be renamed “*Francisella tularensis*” and move to §73.54(a)(2)(E)(vi) with subclauses (I) IgG priced at \$61.15, and a new test added (II) IgM priced at \$122.30. The remaining clauses would be renumbered accordingly.

Existing §73.54(a)(2)(E)(xxiv)(I) is proposed for deletion. LSS has implemented a new screening process for syphilis and this existing reflex test is no longer in the testing algorithm. The remaining subclauses will be renumbered accordingly.

Existing §73.54(a)(2)(E)(xxvii) is proposed to be amended by reorganizing the existing test under new subclauses to improve readability, accuracy, and to achieve consistency of format. Existing §73.54(a)(2)(E)(xxvii), which is currently listed as the *Varicella zoster* test, would be moved to proposed subclause (I) and be renamed “IgG.” Under the proposed reorganization, the new test for Immunoglobulin M is proposed to be added at subclause (II), be listed as “IgM priced,” with a fee of \$147.84 which was calculated using the standard formula.

Section 73.54(a)(2)(F)(ii) and all subclauses are proposed for deletion. These tests are more appropriately placed, from an organizational perspective, in existing §73.54(c)(8)(A). The remaining clauses will be renumbered accordingly.

Existing §73.54(a)(2)(F)(xi), which would be renumbered as clause (x), is proposed to be amended by correcting grammatical format errors by adding semicolons instead of periods to allow for consistency of format.

New §73.54(a)(2)(F)(xii) is proposed to add a new test for 2012 Novel Coronavirus, priced at \$78.92.

Existing §73.54(b)(1)(E) is proposed to be amended by updating the name of the test to “KOH exam for skin, hair, nails” to more accurately identify the test.

Existing §73.54(b)(3)(D)(vii) and (ix) are proposed to be amended by updating the fees associated with the tests. The fee for (vii) Influenza A/H5 would decrease from \$125.00 to

\$90.62, and the fee for (ix) Ricin would increase from \$150.00 to \$151.42. Both tests recently had an updated cost calculation conducted that resulted in the price change. These adjustments are necessary for the department to recoup cost of performing the testing.

Existing §73.54(b)(6)(D) is proposed for deletion. This test is a duplication of (b)(1)(F) and is more accurately placed in paragraph (1) Bacteriology.

Existing §73.54(b)(7)(B) and (I) are proposed to be amended by updating the name of the test to “Follicle stimulating hormone (FSH)” and “Thyroid stimulating hormone (TSH),” respectively, to more accurately identify the tests.

Existing §73.54(c)(1) is proposed for deletion. This low-volume test is proposed for deletion to make more efficient use of LSS staff and to lower operational costs. Subsequent paragraphs will be renumbered accordingly.

Existing §73.54(c)(4)(C), which would be renumbered to be (3)(C), is proposed to be amended by updating the name to “Yeast and mold enumeration” to more accurately reflect the test.

Existing §73.54(c)(5)(E)(i), which would be renumbered to be (4)(E)(i), is proposed to be amended by updating the name to “Charm 3SL-S beta lactam test” to more accurately reflect the test.

Existing §73.54(c)(6) is proposed to be moved to new (c)(8) for alphabetical consistency of text. Remaining paragraphs would be renumbered accordingly.

Existing §73.54(c)(7)(C) is proposed to be amended by updating the name to “Fecal Coliforms (MPN)” to more accurately describe the test.

Existing §73.55(2)(A)(i)(XV) is proposed to be amended by decreasing the fee from \$135.47 to \$53.75. New pricing reflects increase in volume which reduces operational cost.

Existing §73.55(2)(B)(iii)(I) is proposed to be amended by increasing the fee from \$152.43 to \$160.16. The increase is due to the addition of potassium as a new element to the testing.

Existing §73.55(2)(C)(xii) is proposed to be amended by removing method 502.2 from the name of the test. This older method is being discontinued. The new name of the test would be “trihalomethanes, EPA method 524.2.”

FISCAL NOTE

Dr. Grace Kubin, Director, LSS, has determined that for each year of the first five year years the sections are in effect, there will be fiscal implications to the state as a result of administering the sections as proposed. It is impossible to predict the volume of testing LSS will receive under a revised fee schedule as well as the actual resulting revenues, but this rulemaking proposal reflects the fee calculation methodology derived and implemented in the larger rulemaking action, that was adopted in October of 2012, which revised the entire LSS fee schedule,

consistent with Senate Bill (SB) 80, 82nd Legislature, Regular Session, 2011. SB 80 requires the LSS to develop and document a cost accounting methodology to determine costs for each test performed. The department has an ongoing obligation to ensure its laboratory fees reflect this calculation formula, using a reasonable number of periodic rulemaking actions to make needed adjustments. Because this proposed rulemaking would reduce fees for some tests, the volume of those same tests may increase and thus result in a net increase in revenue. Some fees are being lowered to reflect cost savings that the department recently realized through changes in technology. The increased fees would result in increased revenues to the department unless the increase results in a substantial decrease of orders for that test.

A portion of the fee revenues will be used to pay the bond debt on the laboratory building at the department's Central Office main campus, as required by the General Appropriations Act (GAA). Dr. Kubin has also determined that there may be an increased financial burden placed on local health departments, health care providers, and others that submit specimens for testing. Some of the impacted external submitters may be small or micro-businesses. However, the fees for some tests would go down under the proposed rule amendments, and so the fiscal impact would be determined by the combination of tests ordered by the particular submitter. Some submitters may see their testing costs go down, depending on the tests they order. However, the department by law must set its fees to recoup actual cost, according to the standard calculation formula, and does not have the discretion to deviate from this formula when rule writing, regardless of the possible impacts to submitters.

MICRO-BUSINESS AND SMALL BUSINESSES IMPACT ANALYSIS

Varieties of entities, and some few persons, approach the department to purchase laboratory services. Many of those services are currently included in department rules with fee schedules which list amounts for each service. The proposed amendments in this rulemaking proposal include some fees which would be increased. As discussed previously, those proposed increases in fees are necessary for several reasons: to correct previous fee calculation errors; and to reflect the current actual cost to the department for providing these services. The revised fee amounts would properly reflect the methodology used in previous rulemaking actions, which was designed to recoup the department's costs related to providing the service in its laboratories. As directed by law, since 2011 the department has used the same calculation formula to determine its actual cost to perform lab services.

Some of these proposed amendments would also decrease fee amounts for specific tests. The fee increases may not be offset by the fee decreases, for a particular submitter, and thus may have an adverse economic impact on such a small or micro-business. Since these increased fees will potentially impact all submitters (ie., anyone who might order a test, alone or in combination with other tests), the department's analysis under the Economic Impact Statement in this preamble will also serve to satisfy the Small Business Impact Analysis required by Texas Government Code, §2006.002(a).

Texas Government Code, Chapter 2006, was amended by the 80th Legislature, Regular Session, 2007, (House Bill (HB) 3430) to require that, before adopting a rule that may have an adverse

economic effect on small businesses, a state agency must first prepare an Economic Impact Statement and a Regulatory Flexibility Analysis.

The definition of a “small business” for purposes of this requirement was codified at Texas Government Code, §2006.001(2). Under this definition, a “small business” is an entity that is: for profit, independently owned and operated; and have fewer than 100 employees or less than \$6 million in annual gross receipts. Independently owned and operated businesses are self-controlling entities that are not subsidiaries of other entities or otherwise subject to control by other entities (and are not publicly traded).

Dr. Kubin has determined that there may be an adverse economic effect on those small businesses who submit specimens or samples to the LSS for analysis using any of the tests which would experience a fee increase under the proposed amendments. Therefore, the following two analyses have been performed:

--ECONOMIC IMPACT STATEMENT

The Economic Impact Statement in this preamble does not explicitly distinguish between “micro-businesses” and “small businesses.” The department believes that some of the health care providers impacted by this proposed rule will be “micro-businesses” as well as “small businesses,” and thus the department’s analyses regarding the latter will also be applicable to the former. While it is true that a micro-business may be inherently somewhat less able to absorb new increased fees than a small business, the department believes that all businesses periodically experience increases in the cost of doing business. The revised fees in this package of proposed amendments were derived using the mandated methodology in SB 80. Since some fees went up and some fees went down, the impact on a particular submitter will vary depending on, among other things, what particular tests are ordered by that submitter.

The LSS does not collect information on the size of a submitter’s business, and so it does not have direct data at hand to definitely determine what percentage of its usual submitters are small or micro-businesses. However, the department has made an estimate, using an approach suggested in the Texas Office of the Attorney General guidance document associated with HB 3430. A review of The North American Industry Classification System (NAICS) on the U.S. Census Bureau website revealed four classifications that appear to represent all the submitter types for the LSS. Specific information on the number of small businesses listed for each of these codes in 2007 (is the most recent data) was found on the Texas Comptroller of Public Accounts website. The NAICS codes that represent submitters to the LSS include: "6221" - General Medical and Surgical Hospitals (364 businesses listed of which 56 are defined as small businesses), "6214"- Outpatient Care Centers (578 businesses listed of which 442 are defined as small businesses), "6223" - Specialty (except Psychiatric and Substance Abuse) Hospitals (116 businesses listed of which 80 are defined as small businesses), and "2213" - Water, Sewage and Other Systems (927 businesses listed of which 852 are defined as small businesses). The total number of businesses listed for these four classification codes is 1985. Of that number, only 1439 of the businesses listed (physician, clinics, hospitals and public water systems) are small businesses that could be affected by these rule amendments. This estimate corresponds to approximately 14% of the total number of submitters who submitted specimens to the LSS from

January 1, 2012 through June 30, 2013, extrapolating based on the assumptions and data discussed above. The department believes that most of these 1430 small or micro-businesses are contractors for department programs such as Texas Health Steps and HIV Prevention. Therefore, the economic impact would be to the department program which hires each contractor, and it is those department programs which would ultimately have to absorb the fee increases. Subtracting these contractors from the total, the department believes this leaves a much smaller number of non-department contractor small and micro-businesses that could be impacted by any fee increases.

--REGULATORY FLEXIBILITY ANALYSIS

Texas Government Code, Chapter 2006, was amended by the 80th Legislature, Regular Session, (2009), (HB 3430) to require, as part of the rulemaking process, state agencies to prepare a Regulatory Flexibility Analysis that considers alternative methods of achieving the purpose of the rule. The department has considered several options for minimizing the adverse impacts on small businesses.

Option 1 - Maintain fees at their current level. The department cannot implement this option because SB 80 from 2011 requires the department to develop, document and implement procedures for setting fees for laboratory services, including updating and implementing a documented cost allocation methodology that determines actual costs for each test offered, as well as analyzing the department's costs and updating the fee schedules as needed in accordance with Texas Health and Safety Code, §12.032(c). The fee revisions included in these proposed amendments to the rules were derived using that methodology required by SB 80, consistent with Texas Health and Safety Code, §12.032. Keeping the fees at the current level would not reflect the use of the required methodology, and thus would not reflect the actual cost to the department to perform the tests in question.

Option 2 - Allow an exemption from these proposed increases for small and micro-businesses. Texas Health and Safety Code, §12.031, §12.032, and §12.0122 allow the department to charge fees to a "person" who receives public health services from the department, with the fee amount reflecting that which is necessary for the department to recover costs for performing laboratory services. Public health service fees generated by laboratory testing are appropriated to the LSS and are used to purchase supplies and equipment necessary for testing and to pay salaries of LSS personnel (as well as to service the bond debt for the main department's laboratory building in Austin). If the department were to allow an exemption from any fees for small and micro-businesses, the reduction in revenues generated would impact the department's ability to maintain the current level of laboratory services. Such a fee structure would also not reflect the SB 80 methodology discussed at Option 1. Additionally, Texas Health and Safety Code, §12.032(e), states that the department may not fail to provide the service at issue if the submitter can demonstrate a financial inability to pay. So, if a small or micro-business could demonstrate, through submission of appropriate financial documentation that it truly was unable to pay for the one laboratory service at issue that would be an option for such a business. It should be noted, though, that an inability to pay is not the same thing as not having budgeted sufficient funds to pay, for example. The submitter would have to demonstrate, to the department's satisfaction

(through submission of tax returns and other documentation), that it simply did not have the funds at all to pay for the service in question.

Option 3 - Change fees back to the level which preceded the 2011 comprehensive rulemaking revision to the overall LSS fee schedule. Texas Health and Safety Code, §12.031, §12.032, and §12.0122 allow the department to charge fees to a person who receives public health services from the department, and those fees cannot exceed the amount which is necessary for the department to recover costs for performing laboratory services. Public health service fees generated by laboratory testing are appropriated to the LSS and are used to purchase supplies and equipment necessary for testing and to pay salaries of LSS personnel (as well as to service the bond debt for the main department's laboratory building in Austin). If the department were to decrease these fees back to the level prior to the 2011 rulemaking action, as opposed to increasing the fees as proposed in these amendments, the reduction in revenues generated would have a negative impact on the department's ability to maintain the current level of laboratory services. Such a fee structure would also not reflect the SB 80 methodology discussed at Option 1, and thus would not reflect the actual cost to the department to perform the tests in question.

IMPACT ON LOCAL EMPLOYMENT

There is no anticipated negative impact on local employment.

TAKINGS IMPACT ASSESSMENT

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

PUBLIC BENEFIT

Dr. Kubin has also 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 the continued operation of the department's laboratories, which perform important public health activities every day. The public would also benefit by the department adjusting its fees to recover the costs associated with providing these laboratory services, which is money for LSS operations that would then reduce the amount of funding required to come from the public's tax dollars (i.e. General Revenue). The public would also benefit from the proposed changes designed to improve clarity, readability and user-friendliness of the rules, in that there is a public benefit whenever a state improves the efficiency of its operations. The public will also benefit from the list of laboratory services currently available being updated for accuracy.

PUBLIC COMMENT

Comments on the proposal may be directed to Amy Schlabach, Laboratory Services Section, Mail Code 1947, P.O. Box 149347, Austin, Texas 78714-9347, (512) 776-6191 or by email at

amy.schlabach@dshs.state.tx.us. Comments will be accepted for 30 days following the date of publication of this proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The amendments are authorized under Texas Health and Safety Code, §12.031 and §12.032 which allow the department to charge fees to a person who receives public health services from the department, §12.034 which requires the department to establish collection procedures, §12.035 which required the department to deposit all money collected for fees and charges under §12.032 and §12.033 in the state treasury to the credit of the department's public health service fee fund, and §12.0122 which allows the department 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 the department and for the administration of Texas Health and Safety Code, Chapter 1001.

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

Legend: (Proposed Amendments)

Single Underline = Proposed new language

[Bold, Print, and Brackets] = Current language proposed for deletion

Regular print = Current language

(No change.) = No changes are being considered for the designated subdivision

§73.31. Specimen Submission.

(a) Specimens submitted to the Department of State Health Services (department) shall meet the requirements specified in the department's Laboratory Testing Services Manual **[Manual of Reference Services]** (manual) and other written instructions established by the department. The manual is posted on the department's website (currently found at <http://www.dshs.state.tx.us/lab>).

(b) (No change.)

(c) The manual and other written instructions may be obtained upon request from the Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756-3199, (512) 776-7318 **[(512) 458-7318 or online at <http://www.dshs.state.tx.us/lab>]**.

§73.41. Sale of Laboratory Services.

(a) - (d) (No change.)

(e) Fees. 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 in the Laboratory Testing Services Manual (currently found at <http://www.dshs.state.tx.us/lab>). **[Manual of Reference Services at <http://www.dshs.state.tx.us/lab>]**

(f) (No change.)

§73.51. Technical Definitions Associated with the Sale of Laboratory Services.

Technical definitions associated with the sale of laboratory services can be found in the Laboratory Testing Services Manual. This manual is available online (currently found at <http://www.dshs.state.tx.us/lab>), and may otherwise be obtained as described in §73.31 of this title (relating to Specimen Submission).

[The following words and terms, when used in this section shall have the following meaning.]

[(1) All metals drinking water group--Aluminum, antimony, arsenic, barium, beryllium, total hardness (calculated), cadmium, calcium, chromium, copper, iron, lead, magnesium, manganese, mercury, nickel, selenium, silver, sodium, thallium, and zinc.]

[(2) Chlorinated pesticides and polychlorinated biphenyls (PCBs) in drinking water.]

[(A) Regulated compounds--Alachlor, aroclor 1016, aroclor 1221, aroclor 1232, aroclor 1242, aroclor 1248, aroclor 1254, aroclor 1260, atrazine, chlordane, endrin, heptachlor, heptachlor epoxide, hexachlorobenzene, hexachlorocyclopentadiene, lindane, methoxychlor simazine and toxaphene.]

[(B) Non-Regulated compounds--Aldrin, butachlor, dieldrin, etolachlor, metribuzin, propachlor, trifluralin.]

[(3) Gamma emitting isotopes--Gamma emitting isotopes with energies ranging from 59 keV to 1836 keV.]

[(4) ICP/ICP-MS drinking water metals group--Aluminum, arsenic, barium, beryllium, calcium, total hardness (calculated), chromium, copper, iron, lead, magnesium, manganese, nickel, silver, sodium, and zinc.]

[(5) Reagent water metal suitability group--cadmium, chromium, copper, iron, lead, manganese, nickel and zinc.]

[(6) Routine water mineral group--Alkalinity, chloride, conductance, fluoride, nitrate, pH, sulfate, and total dissolved solids.]

[(7) Volatile organic compounds (VOC).]

[(A) In air--1,1,1-Trichloroethane, 1,2,4-trimethylbenzene, 1,4-dichlorobenzene, 2-ethoxy ethyl acetate, 2-heptanone, 2-propanol, acetone, alpha-pinene, benzene, butoxy ethanol, butyl acetate, chloroform, cumene (isopropyl benzene), cyclohexane, cyclohexanone, ethanol, ethyl acetate, ethyl methacrylate, ethylbenzene, heptane, hexachloroethane, isoamyl acetate, iso-butanol, limonene, m/p-xylene, methyl ethyl ketone (MEK), methyl isobutyl ketone, methyl methacrylate, naphthalene, n-propyl acetate, o-xylene, phenol, sec-butanol, styrene, tetrachloroethylene, tetrahydrofuran, toluene, trichloroethylene.]

[(B) In drinking water.]

[(i) Regulated compounds--1,1,1-Trichloroethane, 1,1,2-trichloroethane, 1,1-dichloroethylene, 1,2,4-trichlorobenzene, 1,2-dichloroethane, 1,2-dichloropropane, benzene, carbon tetrachloride, cis-1,2-dichloroethylene, dichloromethane, ethylbenzene, monochlorobenzene, o-dichlorobenzene, para-dichlorobenzene, styrene, tetrachloroethylene, toluene, trans-1,2-dichloroethylene, trichloroethylene, vinyl chloride, xylenes (total).]

[(ii) Monitored compounds--1,1,1,2-tetrachloroethane, 1,1,2,2-tetrachloroethane, 1,1-dichloroethane, 1,1-dichloropropene, 1,2,3-trichlorobenzene, 1,2,3-

trichloropropane, 1,2,4-trimethylbenzene, 1,3,5-trimethylbenzene, 1,3-dichlorobenzene, 1,3-dichloropropane, 2,2-dichloropropane, 2-chlorotoluene, 4-chlorotoluene, 4-isopropyltoluene, bromobenzene, bromochloromethane, bromodichloromethane, bromoform, bromomethane, chloroethane, chloroform, chloromethane, cis-1,3-dichloropropene, dibromochloromethane, dibromomethane, dichlorodifluoromethane, hexachlorobutadiene, isopropylbenzene, naphthalene, n-butylbenzene, n-propylbenzene, s-butylbenzene, t-butylbenzene, trans-1,3-dichloropropene, trichlorofluoromethane.]

[(iii) Other compounds--2-Butanone (MEK), 2-hexanone, 4-methyl-2-pentanone (MIBK), acetone, acrylonitrile, carbon disulfide, ethyl methacrylate, iodomethane, methyl methacrylate, methyl-t-butyl ether (MTBE), tetrahydrofuran, vinyl acetate.]

[(8) Trihalomethanes (THM)--Bromodichloromethane, bromoform, chloroform, dibromochloromethane, trichloromethanes, and total THM.]

[(9) Carbamate insecticides.]

[(A) Regulated compounds--Aldicarb, aldicarb sulfone, aldicarb sulfoxide, carbofuran, oxamyl.]

[(B) Monitored compounds--Baygon, carbaryl, 3-hydroxycarbofuran, methiocarb, methomyl.]

[(10) Dibromochloropropane (DBCP) and ethylene dibromide (EDB).]

[(A) Regulated compounds--Ethylene dibromide, dibromochloropropane.]

[(B) Non-regulated compound--1,2,3-Trichloropropane.]

[(11) Haloacetic acids.]

[(A) Regulated compounds--Dibromoacetic acid, dichloroacetic acid, monobromoacetic acid, monochloroacetic acid, trichloroacetic acid, total of the 5 regulated haloacetic acids (HAA5).]

[(B) Monitored compounds--Bromochloroacetic acid, dalapon.]

[(12) Chlorophenoxy herbicides.]

[(A) Regulated compounds--2,3-Dichlorophenoxyacetic acid (2,4-D), 2(2,4,5-Trichlorophenoxy)propionic acid (2,4,5-TP)(Silvex), dalapon, dinoseb, pentachlorophenol, picloram.]

[(B) Non-Regulated compounds--2,4,5-Trichlorophenoxyacetic acid (2,4,5-T), 4,(2,4-Dichlorophenoxy)butyric acid (2,4,-DB), 3,5-dichlorobenzoic acid, acifluofen, bentazon, chloramben, dicamba, dichlorprop, quinclorac.]

[(13) Polycyclic Aromatic Hydrocarbon (PHA)/Phthalates, Synthetic Organic Contaminants Group 5 (SOC 5).]

[(A) Regulated Compounds--Alachlor, alpha-chlordane, atrazine, benzo(a)pyrene, chlordane, di(2-ethylhexyl)adipate, di(2-ethylhexyl)phthalate, endrin, gamma-chlordane, heptachlor, heptachlor epoxide, hexachlorobenzene, hexachlorocyclopentadiene, lindane, methoxychlor, pentachlorophenol, simazine, toxaphene, trans-nonachlor.]

[(B) Monitored Compounds--2,2',3,3',4,4',6-heptachlorobiphenyl, 2,2',3',4,6-pentachlorobiphenyl, 2,2',4,4',5,6 hexachlorobiphenyl, 2,2',3,3',4,5',6,6',-octachlorobiphenyl, 2,2',4,4'-tetrachlorobiphenyl, 2,4,5-trichlorobiphenyl, 2,3-dichlorobiphenyl, 2-chlorobiphenyl, acenaphthene, acenaphthylene, aldrin, anthracene, benzo(a)anthracene, benzo(b)fluoranthene, benzo(g,h,i)perylene, benzo(k)fluoranthene, bromacil, butachlor, butylbenzylphthalate, chrysene, dibenz(a,h)anthracene, dieldrin, diethylphthalate, dimethylphthalate, di-n-butylphthalate, fluorene, indeno(1,2,3-cd)pyrene, metolachlor, metribuzin, naphthalene, phenathrene, prometon, propachlor, pyrene, trifluralin.]

[(14) Semi-Volatile Organic Compounds.]

[(A) Pesticides--Alachlor, aldrin, atrazine, bromacil, butachlor, alpha-chlordane, gamma-chlordane, trans-nonachlor chlordane, dieldrin, heptachlor, hexachlorobenzene, hexachlorocyclopentadiene, lindane, methoxychlor, metolachlor, metribuzin, pentachlorophenol, promethon, propachlor, simazine, trifluralin.]

[(B) Polycyclic Aromatic Hydrocarbons (PAHs)--Acenaphthene, acenaphthylene, anthracene, benzo(a)anthracene, benzo(a)pyrene, benzo(b)fluoroanthene, benzo(g,h,i)perylene, benzo(k)fluoranthene, chrysene, dibenz(a,h)anthracene, fluorene, indeno(1,2,3,c,d,)pyrene, naphthalene, phenanthrene, pyrene.]

[(C) PCBs--2-Chlorobiphenyl, 2,3-dichlorobiphenyl, 2,4,5-trichlorobiphenyl, 2,2',4,4'-tetrachlorobiphenyl, 2,2',3',4,6-pentachlorobiphenyl, 2,2',4,4',5,6'-hexachlorobiphenyl, 2,2',3,3',4,4',6-heptachlorobiphenyl, 2,2',3,3',4,5',6,6'-octachlorobiphenyl.]

[(D) Phthalates--butylbenzylphthalate, di(2-ethylhexyl)adipate, di(2-ethylhexyl)phthalate, diethylphthalate, dimethylphthalate, di-n-butylphthalate.]

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

(a) Tests performed on clinical specimens, Austin Laboratory.

(1) Biochemistry and genetics.

(A) (No change.)

(B) Clinical chemistry.

(i) - (ii) (No change.)

(iii) Cholesterol--~~\$5.18~~ [**\$4.07**].

(iv) Glucose:

(I) glucose fasting--~~\$4.30~~ [**\$3.96**];

(II) glucose post prandial (1 hour)--~~\$8.60~~ [**\$3.96**];

(III) glucose post prandial (2 hour)--~~\$12.90~~ [**\$7.91**];

(IV) glucose random--~~\$4.30~~ [**\$3.96**];

(V) glucose tolerance test 1 hour--~~\$8.60~~ [**\$7.91**];

(VI) glucose tolerance test 2 hour--~~\$12.90~~ [**\$11.87**]; and

(VII) glucose tolerance test 3 hour--~~\$17.20~~ [**\$15.82**].

(v) - (vii) (No change.)

(viii) High-density lipoprotein (HDL)--~~\$6.02~~ [**\$7.14**].

(ix) Lead--\$3.47.

(x) Lipid panel (consists of cholesterol, triglycerides, high density lipoprotein (HDL), and low density lipoprotein (LDL))--~~\$15.04~~ [**\$10.57**].

[(xi) Red blood cell antigens, other than ABO or Rh(D)--\$260.70.]

[(xii) RH typing--\$20.51.]

(C) (No change.)

(2) Microbiology.

(A) Bacteriology. Charges for bacteriology testing will be based upon the actual testing performed as determined by suspect organisms, specimen type and clinical history provided.

(i) - (v) (No change.)

(vi) Definitive identification:

(I) bacillus--\$165.27 [**\$175.88**];

(II) - (IV) (No change.)

(V) *Campylobacter*--\$166.88 [**\$165.44**];

[(VI) enteric bacteria--**\$243.97**];

(VI) [(VII)] Gonorrhea/Chlamydia (GC/CT):

(-a-) GC/CT, amplified RNA probe--\$20.28;

probe--\$37.66; and
(-b-) GC culture confirmation by amplified or direct

(-c-) GC screen--\$44.54.

(VII) [(VIII)] gram negative rod--\$261.00;

(VIII) [(IX)] gram positive rod--\$226.12;

(IX) [(X)] *Haemophilus*--\$107.64 [**\$242.23**];

(X) [(XI)] *Legionella*--\$265.57;

(XI) [(XII)] *Neisseria*--\$141.84;

(XII) [(XIII)] pertussis--\$287.98;

(XIII) [(XIV)] *Staphylococcus*--\$188.88;

(XIV) [(XV)] *Streptococcus*--\$258.91; and

(XV) [(XVI)] *Vibrio*--\$228.15.

(vii) Diphtheria screen--\$62.65.

(viii) [(vii)] Enteric bacteria:

(I) culture confirmation--\$158.53;

(II) *Shigella* serotyping--\$120.38; and

(III) *Salmonella* serotyping--\$86.63.

(ix) [(viii)] Enterohaemorrhagic *Escherichia Coli* (EHEC), shiga-like toxin assay--\$38.60.

(x) [(ix)] *Escherichia coli* (*E.coli*), serotyping--\$25.71 [O157:H7, culture confirmation-\$26.64].

(xi) Group B streptococcus screen--\$48.32.

(xii) [(x)] *Haemophilus*:

(I) *Influenzae* serotyping--\$79.64 [culture confirmation, serological--\$91.58]; and

(II) isolation from clinical specimen--\$100.18.

(xiii) Kirby Bauer--\$9.92.

(xiv) [(xi)] *Neisseria meningitides*, serotyping--\$167.48.

(xv) [(xii)] Shiga toxin producing *E.coli*, PCR--\$117.90 [\$36.60].

(xvi) [(xiii)] Toxic shock syndrome toxin I assay (TSST 1)--\$125.25.

(xvii) [(xiv)] *Vibrio cholerae*, serotyping--\$32.73.

(B) Emergency preparedness.

(i) (No change.)

(ii) Chemical Threat agent Analysis.

(I) (No change.)

(II) Arsenic [Arsenic/selenium] in urine, ICP-DRC (Dynamic reaction cell)- MS--\$176.62.

(III) - (VI) (No change.)

(VII) Metals in urine (barium, beryllium, cadmium, lead, thallium, uranium) [(**antimony, barium, beryllium, cadmium, cesium, cobalt, lead, molybdenum, platinum, titanium, tungsten, uranium**)], ICP/MS--\$176.25 [**\$173.25**].

(VIII) - (XI) (No change.)

(C) Mycobacteriology/mycology.

(i) Acid fast bacilli (AFB).

(I) Clinical specimen, AFB isolation and identification.

(-a-) - (-b-) (No change.)

(-c-) Direct detection by high-performance liquid chromatography (HPLC)--\$66.26 [**\$124.90**].

(-d-) Identification of AFB isolate.

(-1-) HPLC--\$124.90 [**\$66.26**];

(-2-) - (-4-) (No change.)

(-e-) - (-g-) (No change.)

(II) (No change.)

(ii) - (iv) (No change.)

(v) *Mycobacterium tuberculosis* (*M. tuberculosis*) complex drug susceptibility.

(I) Agar proportion drugs.

(-a-) Capreomycin--\$30.41.

(-b-) Ethambutol--\$30.41.

(-c-) Ethionamide--\$30.41.

(-d-) Isoniazid, 0.2 mcg/ml--\$30.41.

(-e-) Isoniazid, 1.0 mcg/ml--\$30.41.

(-f-) [(-e-)]Kanamycin--\$30.41.

(-g-) [(-f-)] Ofloxacin [**Ofloxacin**]--\$30.41.

(-h-) [(-g-)] Rifabutin--\$30.41.

(-i-) ~~[(**-h-**)] Rifampin--\$30.41.~~

(-j-) ~~[(**-i-**)] Streptomycin--\$30.41.~~

[(II) Primary drug, BACTEC.]

[[(-a-) Ethambutol--\$37.40.]

[(-b-) Isoniazid--\$37.40.]

[(-c-) Rifampin--\$37.40.]

[(-d-) Pyrazinamide (PZA)--\$98.76.]

[(III) Secondary drug, BACTEC.]

[(-a-) Ethionamide--\$23.24.]

[(-b-) Kanamycin--\$23.24.]

[(-c-) Ofloxacin--\$23.24.]

[(-d-) Rifabutin--\$23.24.]

[(-e-) Streptomycin--\$23.24]

[(II) [(IV)] MGIT drug susceptibility test [primary panel--\$115.05].

(-a) primary panel (includes Isoniazid 0.1mcg/ml and 0.4 mcg/ml, Ethambutol, and Rifampin)--\$115.05; and

(-b-) Individual MGIT primary drugs:

(-1-) Isoniazid, 0.1 mcg/ml--\$28.76.

(-2-) Isoniazid, 0.4 mcg/ml--\$28.76.

(-3-) Ethambutol--\$28.77.

(-4-) Rifampin--\$28.76.

[(III) [(V)] MGIT PZA susceptibility test--\$77.17.

(D) (No change.)

(E) Serology.

(i) Arbovirus:

(I) Immunoglobulin G (IgG) EIA: [(includes: Dengue, St. Louis Encephalitis, West Nile Virus--\$147.78;]

(-a-) Dengue--\$72.15;

(-b-) St. Louis Encephalitis--\$77.26; and

(-c-) West Nile--\$77.26.

(II) Immunoglobulin M (IgM) EIA: [(includes: Dengue, St. Louis Encephalitis, West Nile Virus)--\$82.45; and]

(-a-) Dengue--\$58.11;

(-b-) St. Louis Encephalitis--\$107.84; and

(-c-) West Nile--\$107.84.

(III) Immunoglobulin M (IgM) MIA (includes: St. Louis Encephalitis and West Nile Virus)--\$158.20 [PCR West Nile Virus (WNV)--\$57.87].

(ii) *Brucella* IgG--\$44.10 [\$74.52].

(iii) Cat scratch fever (*Bartonella*) IgG, indirect fluorescent antibody (IFA)--\$95.19 [\$171.30].

(iv) Cytomegalovirus (CMV):

(I) IgG--\$23.23; and

(II) IgM--\$24.26.

(v) *Ehrlichia* IFA [indirect fluorescent antibody (IFA)]--\$131.31 [174.20].

(vi) *Francisella tularensis*:

(I) IgG--\$61.15; and

(II) IgM--\$122.30.

(vii) [(vi)] Hantavirus IgG/IgM--\$362.05.

(viii) [(vii)] Hepatitis A:

(I) IgM--\$44.04; and

(II) total--\$34.45.

(ix) [(viii)] Hepatitis B:

(I) core antibody--\$36.06;

(II) core IgM antibody--\$44.75;

(III) surface antibody (Ab)--\$28.34; and

(IV) surface antigen (Ag)--\$18.47.

[(ix) Hepatitis BeAb--\$109.20.]

[(x) Hepatitis BeAg--\$195.14.]

(x) [(xi)] Hepatitis C (HCV)--\$25.68.

(xi) [(xii)] Human immunodeficiency virus (HIV):

(I) serum, multi spot--\$40.74; and

(II) HIV Combo Ag/Ab EIA--\$7.90.

(xii) [(xiii)] Human immunodeficiency virus-1 (HIV-1):

\$14.32;

(I) enzyme immunoassay (EIA) Dried Blood Spots (DBS)--

(II) enzyme immunoassay (EIA) oral fluid--\$69.99;

(III) Nucleic acid amplification test (NAAT)--\$7.79;

(IV) western blot serum--\$277.23;

(V) western blot DBS--\$277.23; and

(VI) western blot oral--\$324.71.

(xiii) [(xiv)] Lyme (*Borrelia*) IgG/IgM Panel--\$706.25.

[(xv) Measles, mumps, rubella - *Varicella zoster virus* (MMR-VZV) Magnetic Immunoassay (MIA)--\$345.63.]

(xiv) Measles:

(I) IgG--\$21.36; and

(II) IgM--\$85.60.

(xv) [(xvi)] Mumps:

(I) [epidemic parotitis] IgG--\$22.62; and

(II) [epidemic parotitis] IgM--\$83.93 [**\$251.96**].

(xvi) Pertussis Toxin IgG--\$89.86.

(xvii) Q-Fever IgG--\$85.61 [**\$234.97**].

(xviii) QuantiFERON (tuberculosis serology)--\$53.66.

(xix) *Rickettsia* panel; [(includes: Rocky Mountain spotted fever and typhus)--\$134.14.]

and

(I) Rocky Mountain spotted Fever (RMSF) IgG--\$42.93;

(II) Typhus fever IgG--\$42.93.

(xx) Rubella:

(I) IgM--\$24.77; and

(II) screen--\$22.33.

[(xxi) Rubeola:]

[(I) IgM--\$210.24; and]

[(II) screen (IgG)--\$21.35.]

[(xxi) [(xxii)] Schistosoma EIA [enzyme immunoassay (EIA)]--\$10.30 [**\$134.49**].

[(xxii) [(xxiii)] Strongyloides EIA --\$16.89 [enzyme immunoassay (EIA)--\$73.45].

[(xxiii) [(xxiv)] Syphilis:

absorbed (FTA-ABS)--\$80.20;]

\$27.02;

[(I) Confirmation fluorescent treponemal antibody

(I) **[(II)] Confirmation particle agglutination (TP-PA)--**

(II) **[(III)] Rapid plasma reagin (RPR):**

(-a-) screen (qualitative)--\$2.89; and

(-b-) titer (quantitative)--\$12.88;

(III) **[(IV)] Screening, IgG--\$7.57.**

(xiv) **[(xxv)] Toxoplasmosis--\$23.23.**

[(xxvi) Tularemia (*Francisella tularensis*)--\$54.53.]

(xv) **[(xxvii)] *Varicella zoster* virus (VZV); [--\$19.70.]**

(I) **IgG--\$19.70; and**

(II) **IgM--\$147.84.**

(xvi) **[(xxviii)] *Yersinia pestis* (Plague), serum--\$237.18.**

(F) Virology.

(i) (No change.)

[(ii) Arbovirus identification, PCR:]

[(I) Eastern Equine Encephalitis (EEE)--\$60.39;]

[(II) St. Louis Encephalitis (SLE)--\$60.18;]

[(III) Western Equine Encephalitis (WEE)--\$60.41;

and]

[(IV) West Nile virus--\$57.87.]

(ii) **[(iii)] Arbovirus identification, direct fluorescent antibody**

(DFA)--\$152.93.

(iii) **[(iv)] Coxsackievirus, DFA--\$84.37.**

(iv) [~~(v)~~] Culture:

(I) Supplemental Cell Culture--\$135.46; and

(II) reference--\$96.66.

(v) [~~(vi)~~] Dengue, real-time PCR--\$215.52.

(vi) [~~(vii)~~] Echovirus, DFA--\$115.80.

(vii) [~~(viii)~~] Electron microscopy (includes observation, electron microscopy and photography)--\$527.91.

(viii) [~~(ix)~~] Enterovirus:

(I) DFA--\$162.96; and

(II) PCR--\$393.27.

(ix) [~~(x)~~] *Herpes Simplex virus* 1 and 2, identification, DFA--\$96.52.

(x) [~~(xi)~~] Influenza: [.]

(I) Influenza A/B identification, DFA--\$54.02; [.]

(II) Influenza surveillance with culture--\$248.00; [.]

(III) Influenza pyrosequencing for antiviral resistance--\$13.11; and [.]

(IV) Influenza surveillance without culture (typing, PCR)--\$131.32.

(xi) [~~(xii)~~] Norovirus (Norwalk-like virus) PCR--\$55.77.

(xii) 2012 Novel Coronavirus--\$78.92.

(xiii) - (xxi) (No change.)

(b) Tests performed on clinical specimens, South Texas Laboratory. Specimens that must be sent to a reference lab for testing will be billed at the reference laboratory price plus a \$3.00 handling fee.

(1) Bacteriology.

(A) - (D) (No change.)

(E) KOH exam [**except**] for skin, hair, nails--\$7.85.

(F) - (G) (No change.)

(2) (No change.)

(3) Emergency Preparedness.

(A) - (C) (No change.)

(D) PCR.

(i) - (vi) (No change.)

(vii) Influenza A/H5--\$90.62 [**125.00**];

(viii) Multiple Agent Panel--\$169.39;

(ix) Ricin--\$151.42 [**150.00**]; and

(x) *Yersinia pestis*--\$58.41.

(4) - (5) (No change.)

(6) Microbiology.

(A) - (C) (No change.)

[(D) Wet mount, vaginal--\$9.14.]

(7) Special chemistry.

(A) Ferritin--\$22.31.

(B) Follicle stimulating [**stimulating**] hormone (FSH)--\$15.10.

(C) - (H) (No change.).

(I) Thyroid stimulating hormone (TSH) [, **prenatal**]-\$9.41.

(J) Tri-iodothyronine (T3), free--\$19.10.

(8) (No change.)

(c) Non-clinical testing, Austin Laboratory.

[(1) *Legionella*, culture--\$265.48.]

(1) [(2)] Bat identification--\$3.52.

(2) [(3)] Entomology:

(A) insect identification--\$20.86;

(B) mosquito identification for surveillance--\$17.66; and

(C) mosquito larvae identification--\$6.04.

(3) [(4)] Food.

(A) Bacterial identification.

(i) Bacillis:

(I) identification--\$101.16; and

(II) enumeration, most probable number (MPN)--\$245.53.

(ii) *Campylobacter* identification--\$145.40.

(iii) *Clostridium perfringens* identification--\$217.06.

(iv) *Cronobacter sakazakii*--\$115.17.

(v) *Escherichia coli*.

(I) *E.coli* 0157 identification--\$121.52.

(II) Non-0157 STEC--\$295.02.

(III) *E.coli* enumeration (MPN)--\$180.97.

(vi) *Listeria* identification--\$150.75.

(vii) *Salmonella* identification--\$66.07.

(viii) *Shigella* identification--\$119.40.

(ix) *Staphylococcus* identification--\$127.28.

- (x) *Yersinia* identification--\$62.48.
 - (B) *Staphylococcus* enterotoxin detection--\$90.80.
 - (C) Yeast and mold enumeration [(MPN)]--\$128.50.
 - (D) Standard plate count--\$67.38.
- (4) [(5)] Milk and dairy.
- (A) Aflatoxin--\$65.63.
 - (B) Bacterial counts:
 - (i) coliform count, milk--\$33.97;
 - (ii) coliform count, containers--\$41.28;
 - (iii) standard plate count, milk--\$22.14; and
 - (iv) standard plate count, container--\$44.33.
 - (C) Dairy water--\$16.19.
 - (D) Freezing point--\$26.59.
 - (E) Growth inhibitors.
 - (i) Charm 3SL-S [SL-6] beta-lactam test--\$81.14.
 - (ii) Charm SLBL beta-lactam test--\$58.91.
 - (iii) Charm II sulfonamide test--\$51.69.
 - (iv) Charm II tetracycline test--\$55.15.
 - (v) Delvo test--\$25.60.
 - (F) Phosphatase--\$37.82.
 - (G) Somatic cell counts.
 - (i) Direct microscope somatic cell count (DMSC):
 - (I) bovine (cow)--\$50.83; and

(II) caprine (goat)--\$58.54.

(ii) Optical somatic cell count (OSCC):

(I) bovine (cow)--\$51.05; and

(II) caprine (goat)--\$51.05..)

[(6) *Yersinia pestis* (plague), Nobuto--\$8.57.]

(5) [(7)] Shellfish.

(A) Bay water--\$25.76.

(B) Brevetoxin identification--\$242.95.

(C) Fecal Coliforms, [*E.coli*, **identification and enumeration**] (MPN)--
\$151.43.

(D) Standard plate count--\$67.38.

(E) *Vibrio* identification--\$211.47.

(F) *Vibrio* identification and enumeration (MPN)--\$478.70.

(6) [(8)] Virology.

(A) Arbovirus:

(i) culture from mosquito--\$44.25;

(ii) Eastern Equine Encephalitis (EEE), mosquitoes, PCR--\$60.39;

(iii) St. Louis Encephalitis (SLE), mosquitoes, PCR--\$60.18;

(iv) Western Equine Encephalitis (WEE), mosquitoes, PCR--
\$60.41; and

(v) West Nile Virus (WNV), mosquitoes, PCR--\$57.87.

(B) Rabies:

(i) detection, DFA--\$72.99;

(ii) detection, DFA, cell culture--\$158.77;

(iii) molecular typing--\$181.05; and

(iv) monoclonal typing--\$31.19.

(7) [(9)] Water.

(A) Heterotrophic plate count (HPC) bacteria in water (Simplate)--\$84.86.

(B) Potable water--\$16.19.

(C) Surface water, (MPN) (Quanti-tray)--\$257.66.

(8) *Yersinia pestis* (plague), Nobuto--\$8.57.

(d) - (e) (No change.)

§73.55. Fee Schedule for Chemical Analyses.

Fees for chemical analyses and physical testing.

(1) (No change.)

(2) The following fees apply to analysis of drinking water samples.

(A) Inorganic parameters.

(i) Individual tests:

(I) - (XIV) (No change.)

(XV) cyanide, total, QuickChem 10-204-00-1-X--\$53.75

[\$135.47];

(XVI) - (XXVII) (No change.)

(ii) (No change.)

(B) Metals analysis. A preparation fee applies to all drinking water samples analyzed by inductively coupled plasma (ICP) or by inductively coupled plasma-mass spectrometry (ICP-MS) with turbidity greater than or equal to 1 Nephelometric Turbidity Unit (NTU) or that contains visible particles. The total analysis cost includes the per-element or per-group fee and any required sample preparation fee.

(i) - (ii) (No change.)

(iii) Group Fees:

(I) all metals drinking water group, EPA methods 200.7, 200.8, and 245.1 and SM 19th edition 2340B--~~\$160.16~~ [**\$152.43**];

(II) - (IV) (No change.)

(C) Organic compounds:

(i) - (xi) (No change.)

(xii) trihalomethanes, EPA method [**methods 502.2 or**] 524.2--\$50.13;

(xiii) - (xiv) (No change.)

(D) (No change.)

(3) - (9) (No change.)