IMPROVE THE TEXAS NEWBORN SCREENING PROGRAM

State law requires that every baby born in Texas receives testing through the Texas Newborn Screening Program unless a parent or guardian refuses screening for a child due to a conflict with religious tenets or practices. Newborn screening identifies infants who may have serious medical conditions for which treatments are available. The screening includes testing for several conditions that can lead to disabilities or death if they are not identified and treated early. For example, newborns with untreated galactosemia develop life-threatening complications within a few days after initiating milk feedings because they cannot metabolize milk sugar. Galactosemia can be fatal without prompt treatment and careful management. Screening tests are available for more than 60 disorders. More than 900 infants in Texas and 5,000 infants nationally are identified each year with a condition included in newborn screening panels.

The Department of State Health Services administers the Texas Newborn Screening Program, which includes testing, follow-up, and clinical care coordination. Limitations in how the fees for the Texas Newborn Screening Program are determined and updated result in these fees not fully covering program costs, which can affect the state's ability to identify and refer for care children who may have serious medical conditions. For example, failure in the newborn screening fee methodology to include the initial costs associated with adding conditions to the program affects how quickly the state can add federally recommended conditions. Failure to add conditions in a timely manner can hamper the early detection of disorders, which may harm children and their families, including leading to severe disabilities and death. In addition, the amount appropriated for newborn screening for Medicaid clients yields a per-screen amount that is less than the estimated newborn screening cost. Furthermore, the state does not meet performance targets related to the timeliness of newborn screening processes. To maximize the ability of the Texas Newborn Screening Program to identify children with serious medical conditions and refer them for appropriate care, the state should improve the methodology and process used to establish program fees, increase appropriations for newborn screening for Medicaid clients and for strategies to improve timeliness, and provide a method to fund the addition of new conditions to the program.

FACTS AND FINDINGS

- The Texas Newborn Screening Program includes screening for 55 conditions. Two of the conditions, hearing impairment and critical congenital heart disease, are detected through point-of-care screening, and the remaining 53 conditions are detected through screening performed on blood samples, also known as blood spot-based newborn screening.
- The Department of State Health Services provides newborn screening specimen collection kits for the blood spot-based testing at no cost to providers for patients covered by Medicaid or the Children's Health Insurance Program and for charity-care newborns. A charity-care newborn is a patient who is not insured or otherwise is unable to pay and is not eligible for coverage of newborn screening services by Medicaid, the Children's Health Insurance Program, or any other government program.
- Healthcare providers purchase newborn screening specimen collection kits from the Department of State Health Services to screen patients who have private insurance or those who self-pay. Statute authorizes the Health and Human Services Commission Executive Commissioner to set the fee amount collected by the Department of State Health Services for these kits. The Department of State Health Services has a methodology for determining the proposed fee amount. As of October 2018, the fee for the specimen collection kit for patients with private insurance or who self-pay is $55.24. These fee amounts are deposited into the General Revenue–Dedicated Account No. 524, Public Health Service Fees. The cost of screening for charity-care newborns contributes to the overall cost and is included in the kit fee for self-pay and privately insured patients.
- The state uses the Medicare rate for newborn screening set by the federal Centers for Medicare and Medicaid Services to determine the amount of state and federal Medicaid funds generated as a result of newborn screening for Texas Medicaid clients. The current rate is $211.51 per screen. The state uses General Revenue Funds to draw down Federal Funds that together

reimburse the state for screening Medicaid clients. These Medicaid funds are deposited into the Public Health Medicaid Reimbursements Fund, and total an estimated $241.8 million for the 2018–19 biennium.

- The Legislature appropriated $40.6 million from the Public Health Medicaid Reimbursements Fund to the Department of State Health Services for laboratory services for the 2018–19 biennium. Of this amount, the Department of State Health Services is spending an estimated $32.3 million for newborn screening for Medicaid clients. The Legislature appropriated the remaining amounts in the fund to mental health state hospitals, mental health community hospitals, nonlaboratory items at the Department of State Health Services, and other items at the Health and Human Services Commission.

CONCERNS

- The Department of State Health Services' methodology to determine the proposed fee for newborn screening specimen collection kits for self-pay and privately insured patients does not include all costs associated with operating the Texas Newborn Screening Program. These costs include certain staffing costs, initial costs associated with adding conditions to the program, and the cost of efforts to improve the timeliness of newborn screening processes.

- The Department of State Health Services does not evaluate the fee for newborn screening specimen collection kits regularly to address changes to screening costs, and the Health and Human Services Commission does not regularly update fee amounts. The Health and Human Services Commission last increased the kit fee for self-pay and privately insured patients in October 2016 from $33.60 to $55.24. Screening costs have increased since and exceed the revenue generated from this fee.

- According to the Department of State Health Services, the amounts allocated from the Public Health Medicaid Reimbursements Fund for newborn screening of Medicaid clients for the 2016–17 and 2018–19 biennia equate to a per-screen amount that is less than the 2016-estimated newborn screening cost of $55.24.

- The state does not meet performance targets for the timeliness of newborn screening processes. For example, during fiscal year 2017, the Department of State Health Services laboratory received 25.2 percent of initial-screen specimens and 12.3 percent of second-screen specimens within the targeted timeframe of one day after collection. The time that passes from specimen collection to reporting can affect the health outcomes of infants who have screened medical conditions. These conditions may manifest with acute symptoms during the first days of life and require immediate treatment to decrease the risk of morbidity and mortality.

- The state lacks a permanent funding mechanism to cover the initial costs associated with adding conditions to the Texas Newborn Screening Program. This lack of funding has delayed the addition of federally recommended conditions to the program. Failure to add conditions in a timely manner can prevent early detection of disorders, resulting in severe disabilities and death for some infants.

OPTIONS

- **Option 1:** Amend statute to require the Department of State Health Services to revise its methodology used to determine the proposed fee for newborn screening specimen collection kits to include all costs associated with operating the Texas Newborn Screening Program. The amended statute could require that the new methodology include the initial costs associated with adding conditions to the program and the cost of strategies to improve timeliness of newborn screening processes.

- **Option 2:** Amend statute to require the Department of State Health Services to evaluate annually the fee amount for newborn screening specimen collection kits and, if needed, to require the Health and Human Services Commission to consider updating the amount to ensure that the fee matches the program cost.

- **Option 3:** Increase appropriations in the 2020–21 General Appropriations Bill in Other Funds by $10.1 million from the Public Health Medicaid Reimbursements Fund to the Department of State Health Services in Strategy A.4.1, Laboratory Services, for newborn screening of Medicaid clients. The decrease of a like amount from the fund would be made in appropriations to the Health and Human Services Commission for other purposes, and an

increase in General Revenue Funds would restore the decrease. Amend Special Provisions Relating to All Health and Human Services Agencies in the 2020–21 General Appropriations Bill to specify the increased appropriations to the Department of State Health Services.

- **Option 4:** Increase appropriations in the 2020–21 General Appropriations Bill in Other Funds by $3.95 million from the Public Health Medicaid Reimbursements Fund to the Department of State Health Services in Strategy A.4.1, Laboratory Services to improve the timeliness of newborn screening processes, including expanding state-funded overnight courier service and provider education. The decrease of a like amount from the fund would be made in appropriations to the Health and Human Services Commission for other purposes, and an increase in General Revenue Funds would restore the decrease. Amend Special Provisions Relating to All Health and Human Services Agencies in the 2020–21 General Appropriations Bill to specify the increased appropriations to the Department of State Health Services.

- **Option 5:** Amend a rider in the 2020–21 General Appropriations Bill directing the Department of State Health Services to request from the Legislative Budget Board additional funds from the Public Health Medicaid Reimbursements Fund to pay for the initial costs associated with adding conditions to the Texas Newborn Screening Program if new conditions are identified outside of the biennial appropriations process. These funds would be in addition to the amounts appropriated to the Department of State Health Services for laboratory services from the Public Health Medicaid Reimbursements Fund in the 2020–21 General Appropriations Act and would result in a reduction in appropriations from the fund to other strategies at the Health and Human Services Commission.

DISCUSSION

Newborn screening, performed soon after birth, identifies infants who may have serious medical conditions. The screening includes testing for several conditions that can cause infants to develop mental and physical disabilities or die. Some untreated conditions may cause life-threatening complications within the first week of life. For example, untreated newborns with galactosemia develop life-threatening complications within a few days after initiating milk feedings because they cannot metabolize milk sugar. Galactosemia can be fatal without prompt treatment and careful management. A screening test does not confirm or rule out a particular condition, but screening identifies individuals who may have the condition so that definitive follow-up testing and treatment can occur.

Screening tests are available for more than 60 disorders. Each year, newborn screening identifies more than 5,000 infants in the U.S. with a condition included in the screening panels. Each state administers its own newborn screening program and may screen for a slightly different list of conditions. Parents also may choose to have their child screened for other conditions through newborn screening tests provided by private entities.

OVERVIEW OF THE TEXAS NEWBORN SCREENING PROGRAM

State law requires every infant born in Texas to receive testing through the Texas Newborn Screening Program (NSP) unless the child's parent or guardian objects on religious grounds. The Department of State Health Services (DSHS) administers the NSP, which includes testing, follow-up, and clinical care coordination.

Although newborn screening programs vary by state, national recommendations guide and support the development of state programs. The Recommended Uniform Screening Panel (RUSP) is a list of conditions recommended by the Secretary of the U.S. Department of Health and Human Services (DHHS) for states to include in their newborn screening programs. Ultimately, DHHS decides whether to add a condition to the RUSP, although the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) advises DHHS on which conditions to include. Disorders that are included on the RUSP are chosen based on evidence of potential net benefit of screening, the ability of states to screen for the disorder, and the availability of effective treatments.

DHHS recommends screening every newborn for all disorders on the RUSP, which includes 61 conditions, 35 core conditions and 26 secondary conditions, as of July 2018. Of the 35 core conditions on the RUSP, 33 are screened through blood testing and two are point-of-care screenings. Secondary conditions are detected during screening for core conditions. A condition on the newborn

FIGURE 1
CONDITIONS ON TEXAS NEWBORN SCREENING PANEL COMPARED TO FEDERAL PANEL, FISCAL YEAR 2018

PANEL	CORE CONDITIONS	SECONDARY CONDITIONS	TOTAL
Recommended Uniform Screening Panel	35	26	61
Texas Newborn Screening Program	31	24	55

NOTE: The Recommended Uniform Screening Panel is a list of conditions recommended by the Secretary of the U.S. Department of Health and Human Services for states to include in their newborn screening programs.
SOURCE: Legislative Budget Board.

screening panel is classified as a core condition if it meets the following requirements:

- a specific and sensitive test is available to detect it;
- the health outcomes of the condition are well-understood;
- an effective treatment is available; and
- identification of the condition could affect the family's future reproductive decisions.

To the extent that funding is available, Texas law requires that DSHS includes in the NSP the screenings for core and secondary conditions listed in the RUSP. State law excludes two RUSP conditions, galactose epimerase and galactokinase, from this requirement. As shown in **Figure 1**, the NSP does not include all conditions on the RUSP. As of November 2018, the NSP includes screening for 31 core conditions and 24 secondary conditions. Two of these 55 conditions, a hearing screen and a critical congenital heart disease screen, are detected through point-of-care screening. The remaining 53 conditions are detected through screening performed on blood samples, also known as blood spot-based newborn screening. Similarly to Texas' requirements, most states screen for the majority of disorders on the RUSP. Some states screen for additional disorders.

TEXAS NEWBORN SCREENING SPECIMEN COLLECTION AND PROCESSING

This report focuses on blood spot-based newborn screening, whereby the healthcare provider collects a child's blood sample and sends it to the DSHS public health laboratory in Austin for testing. The NSP's blood spot-based screening includes the following steps:

- specimen collection;
- transit of the specimen from the collection site to the DSHS laboratory;
- laboratory testing of the specimen; and
- reporting results to the healthcare provider.

During specimen collection, the healthcare provider collects the blood sample by taking a small amount of blood from the child's heel within 24 hours to 48 hours after birth and before leaving the birthing facility. A second sample is collected one week to two weeks later, usually at the child's first pediatric exam. In some cases, the first sample may not identify all abnormal screens, and a disorder may be detected only through the second screen. In both cases, the provider sends the specimen to the DSHS public health laboratory for testing. When testing is complete, the lab notifies providers of the results. If screening tests are abnormal for any disorder, DSHS clinical care coordination staff contact the healthcare provider and work with the provider and parents to ensure that the child receives recommended follow-up screens, confirmatory testing, and treatment, if needed. Infants who have an abnormal screening result or a confirmed diagnosis of a disorder on the panel and who meet other eligibility criteria may receive confirmatory testing and benefits, such as medications and follow-up care, at no cost or reduced cost through the NSP if funds are available. **Figure 2** shows the timeline from receipt of the specimen at the DSHS laboratory through reporting results to providers.

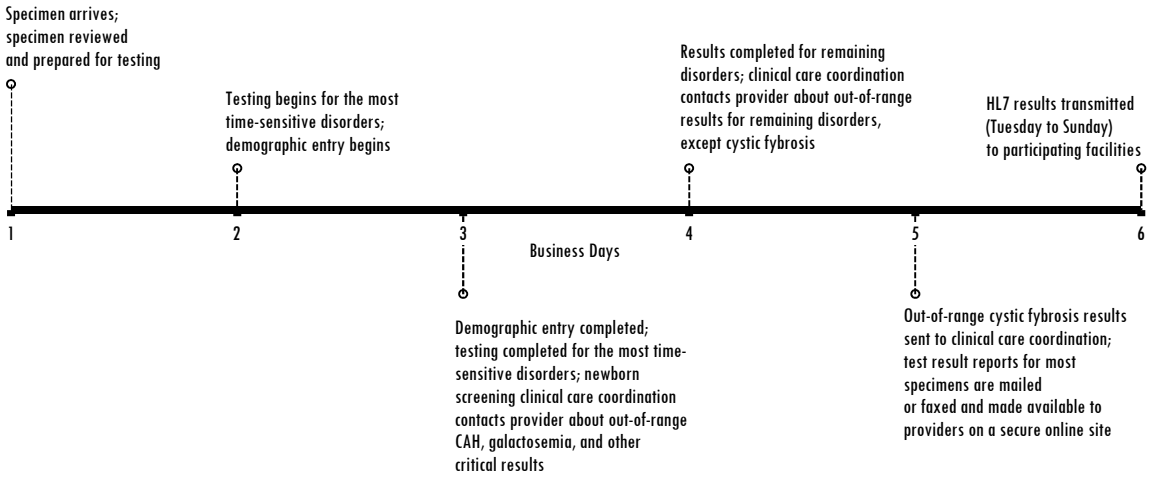
The DSHS public health laboratory receives approximately 800,000 newborn screening blood samples each year, or two samples for each of the approximately 400,000 Texas births. Of the approximately 20,000 abnormal screening results, about 900 core disorders are diagnosed each year.

METHODS OF FUNDING FOR THE TEXAS NEWBORN SCREENING PROGRAM

As shown in **Figure 3**, DSHS reports that the total cost to operate the NSP during the 2016–17 biennium was $85.9 million. This data does not include the cost to conduct the two point-of-care screenings.

NSP funding includes the following main sources:

FIGURE 2
TEXAS NEWBORN SCREENING SPECIMEN TIMELINE IN THE STATE LABORATORY, FISCAL YEAR 2018



NOTE: CAH=congenital adrenal hyperplasia; HL7=Health Level 7 standards for transfer of clinical data.
SOURCE: Department of State Health Services.

FIGURE 3
TEXAS NEWBORN SCREENING PROGRAM COSTS, 2016–17 BIENNIUM

(IN MILLIONS)	BLOOD-SPOT LABORATORY TESTING				
CATEGORY	SELF-PAY, PRIVATELY INSURED, AND CHARITY CARE	MEDICAID	CHIP (1)	CLINICAL CARE CASE MANAGEMENT CLIENTS	TOTAL
Cost (2)	$33.9	$41.6	$0.009	$10.4	$85.9

NOTES:
(1) Due to data limitations, Children's Health Insurance Program (CHIP) data is available only for fiscal year 2017.
(2) Amounts shown do not include the cost to provide state-funded overnight courier service to transport specimens from the collecting provider to the Department of State Health Services laboratory.
SOURCE: Department of State Health Services.

- a fee charged to healthcare providers who purchase newborn screening specimen collection kits from DSHS to screen patients that have private insurance or who self-pay;
- Medicaid funding appropriated to DSHS from the Public Health Medicaid Reimbursements Fund to screen newborns; and
- funds from CHIP, General Revenue Funds, and other Federal Funds.

Healthcare providers purchase newborn screening specimen collection kits from DSHS to screen privately insured patients or those who self-pay. The specimen-collection kit fee is $55.24, which includes $48.67 for laboratory testing and $6.57 for clinical care coordination. These amounts are deposited into the General Revenue–Dedicated Account No. 524, Public Health Service Fees (Account No. 524). According to DSHS, all the funds generated from newborn screening specimen collection kits are appropriated to DSHS for NSP costs. Providers then may bill private insurers to receive reimbursement for the cost of the kits. Each month, DSHS bills providers for the number of kits shipped to them in the previous month. DSHS requests that providers submit payment within 90 days, which is intended to give providers time to receive insurance payments for the cost of the kits before submitting payment to DSHS.

DSHS provides newborn screening specimen collection kits at no cost to providers for patients covered by Medicaid or CHIP and charity-care newborns. A charity-care newborn is one who is not insured or does not self-pay, and is not eligible for newborn screening service coverage by Medicaid, CHIP, or any other government program. Each quarter, DSHS analyzes data to determine if a patient tested with a no-cost kit is eligible for Medicaid. DSHS sends a voucher to HHSC

to request payment for those clients identified as Medicaid-eligible. HHSC then transfers Medicaid reimbursement funds for these clients to DSHS. The quarterly billing process is intended to ensure the most accurate identification of Medicaid-eligible clients, but it results in delayed Medicaid reimbursement to DSHS for the increased costs of adding new conditions to the NSP.

Texas uses the Medicare rate for newborn screening set by the federal Centers for Medicare and Medicaid Services to determine the amount of state and federal Medicaid funds generated as a result of newborn screening for Texas Medicaid clients. As of November 2018, the Medicare rate for a newborn screening specimen collection kit is $211.51 per screen. This rate is effective for specimens collected from April 1, 2018 through March 31, 2019. General Revenue Funds are used to draw down Federal Funds that together reimburse the state for screening Medicaid clients. Medicaid funds generated as a result of newborn screening are deposited into the Public Health Medicaid Reimbursements Fund, which totaled $180.8 million for the 2016–17 biennium. The Legislature appropriated some of these funds to DSHS to cover part of the newborn screening costs for Medicaid clients. The Legislature appropriated the remaining amounts in the fund to HHSC, mental health state hospitals, mental health community hospitals, and nonlaboratory items at DSHS.

Other funds used by DSHS for the NSP include CHIP, General Revenue Funds Match for Medicaid Administration, the federal Maternal and Child Health Block Grant, and General Revenue Funds Maintenance of Effort for the Maternal and Child Health Block Grant.

IMPROVE THE TEXAS NEWBORN SCREENING PROGRAM

DSHS' methodology to determine the proposed fee for newborn screening specimen collection kits for self-pay and privately insured patients does not include all costs associated with operating the NSP. These costs include certain staffing costs, the initial costs associated with adding conditions to the NSP, and the cost of efforts to improve the timeliness of newborn screening processes. The cost allocation methodology that DSHS uses to determine the NSP fee for newborn screening specimen collection kits for self-pay and privately insured patients has limitations. The methodology does not include all costs associated with operating the NSP, such as costs for staff who process the blood-spot cards.

After DHHS adds a condition to the RUSP, a state may require time to set up funding and lab infrastructure before screening begins. Costs for the addition include start-up costs, such as purchasing new testing equipment and supplies, and initial laboratory testing and clinical care coordination costs. When DSHS adds a condition to the NSP, the newborn screening fees paid by healthcare providers are increased. The fee is calculated to cover the laboratory testing and clinical care coordination costs associated with newborn screening. However, collection of fee revenue is delayed due to billing and data-matching considerations. This delay results in a period in which revenue is not yet available to cover the increased costs of testing for a new condition.

The agency must receive new funding during the biennial legislative appropriations process to cover start-up and initial-screening costs for adding a new condition to the NSP, which extends the amount of time required to add federally recommended conditions to the program. For example, DHHS added screening for X-ALD, a disease called adrenoleukodystrophy that is linked to the X chromosome, to the RUSP in February 2016. The Eighty-fifth Legislature, Regular Session, 2017, appropriated $1.2 million in Other Funds from the Economic Stabilization Fund to DSHS for fiscal year 2018 for onetime start-up costs to implement X-ALD testing 18 months after the condition was added to the RUSP. The estimated date for starting to screen for this condition in Texas is September 1, 2019. DSHS has requested $7.9 million in General Revenue Funds for the 2020–21 biennium for initial-screening costs for X-ALD.

Texas does not meet performance targets related to the timeliness of blood-spot specimen processing. For example, during fiscal year 2017, the DSHS laboratory received 25.2 percent of initial-screen specimens and 12.3 percent of second-screen specimens within the targeted timeframe of one day after collection. The cost of strategies that DSHS might consider implementing to improve the timeliness of NSP processes, such as expansion of state-funded overnight courier service, are not included in the methodology used to determine the fee for newborn screening specimen collection kits.

Option 1 would amend the Texas Health and Safety Code, Chapter 33, to require DSHS to revise its methodology used to determine the proposed fee for newborn screening specimen collection kits to include all costs associated with operating the NSP. The amended statute could require that the new methodology includes the initial costs associated with adding conditions to the NSP and the cost of strategies to improve timeliness of newborn screening processes. Chapter 33 authorizes the HHSC Executive Commissioner

to adopt fees for NSP. The Texas Health and Safety Code, Chapter 12 requires that the fee amount collected for a public health service must not exceed the cost to DSHS of providing it. According to DSHS, this provision prevents the state from adopting a fee for newborn screening that includes the costs associated with adding conditions to the NSP. The amended Chapter 33 could clarify that HHSC should set a fee for newborn screening specimen collection kits that includes the costs associated with adding conditions to the NSP, including start-up and initial laboratory testing costs. DSHS should be authorized to carry over these dedicated newborn screening funds into the following fiscal year. Sixteen states, including Alabama, Florida, Georgia, and Mississippi, charge fees for newborn screening specimen collection kits that support the initial cost of adding new conditions to their newborn screening panels. Option 5 would provide a method to fund the initial costs of adding new conditions to the NSP for Medicaid clients or until the fee amount for newborn screening specimen collection kits is revised to include these costs.

Neither DSHS nor HHSC regularly evaluates and updates the fee for newborn screening specimen collection kits to address changes to screening costs. DSHS is responsible for evaluating the fee, and HHSC is responsible for adopting it. The fee for newborn screening specimen collection kits for self-pay and privately insured patients was last increased in October 2016 from $33.60 to $55.24. Prior to the last fee change, the fee was last reviewed in 2011. Since the fee was last increased, screening costs have increased and exceed the revenue generated from this fee. For example, failure to update the fee amount regularly has resulted in fee revenue that does not fully cover costs associated with providing newborn screening to charity-care newborns, the cost of which is added to the cost of screening and included in the fee amount for self-pay and privately insured patients. Of the current $55.24 fee, $2.36 represents the amount intended to cover the cost of screening for charity-care newborns. Since the fee last was set, the percentage of screenings that are for charity-care newborns has increased. Option 2 would amend the Texas Health and Safety Code, Chapter 33, to require DSHS to evaluate annually the fee amount for newborn screening specimen collection kits and, if needed, to require HHSC to consider updating the amount to ensure that the fee matches the program cost.

According to DSHS, the amount allocated from the Public Health Medicaid Reimbursements Fund for newborn screening of Medicaid clients for the 2016–17 and 2018–19 biennia equates to a per-screen amount that is less than the 2016-estimated newborn screening cost of $55.24. From the $180.8 million that was deposited into the Public Health Medicaid Reimbursements Fund, the Legislature appropriated $96.6 million to DSHS for laboratory services for the 2016–17 biennium, but required a transfer of $57.4 million from DSHS' strategy in the General Appropriations Act to HHSC, resulting in $39.2 million remaining available for DSHS laboratory services. Of that amount, DSHS allocated $31.0 million for newborn screening for Medicaid clients for the 2016–17 biennium. According to DSHS, the $31.0 million amounts to $34.26 per screen, which is less than the 2016-estimated newborn screening cost of $55.24. The Legislature appropriated the remaining amounts in the fund to mental health state hospitals, mental health community hospitals, and nonlaboratory items at DSHS.

Medicaid funds that are generated as a result of newborn screening and are deposited into the Public Health Medicaid Reimbursements Fund are estimated to total $241.8 million for the 2018–19 biennium. The Legislature appropriated $40.5 million from the fund to DSHS for laboratory services. Of this amount, DSHS is estimated to use $32.3 million for newborn screening of Medicaid clients and $8.2 million for other laboratory operations. These operations include funding for Texas Health Steps testing, laboratory courier service for the NSP, influenza testing, foodborne outbreak testing, and special projects. Similarly to amounts for the 2016–17 biennium, according to DSHS, the $32.3 million is estimated to result in a per-screen amount of $36.91, which is less than the 2016-estimated newborn screening cost of $55.24. The Legislature appropriated the remaining amounts in the fund to nonlaboratory items at DSHS, mental health state hospitals, mental health community hospitals, and other items at HHSC.

During the 2016–17 and 2018–19 biennia, DSHS has used HIV rebates primarily to cover the difference between the cost and the amount available from the Public Health Medicaid Reimbursements for newborn screening of Medicaid clients. According to DSHS, use of HIV rebates will not be available for the 2020–21 biennium to fund newborn screening due to federal guidance that prohibits their use for this purpose. The amount of HIV rebates projected to be unavailable for the NSP for the 2020–21 biennium is $10.1 million.

Option 3 would increase appropriations in the 2020–21 General Appropriations Bill in Other Funds by $10.1 million from the Public Health Medicaid Reimbursements Fund to

FIGURE 4
TIMELINESS OF BLOOD-SPOT SPECIMEN PROCESSING IN THE TEXAS NEWBORN SCREENING PROGRAM
CALENDAR YEAR 2017

			TIME-CRITICAL CONDITIONS		TIME-SENSITIVE CONDITIONS	
SCREEN TYPE	AGE AT COLLECTION	COLLECTION TO LAB RECEIPT	LAB RECEIPT TO REPORTING	AGE AT REPORTING	LAB RECEIPT TO REPORTING	AGE AT REPORTING
Initial Screen						
Performance Target	1 to 2 days	1 day or less	1 day or less	5 days or less	3 days or less	7 days or less
Percentage of Specimens Compliant	88.6%	25.2%	69.2%	71.1%	84.6%	85.9%
Second Screen						
Performance Target	7 to 14 days	1 day or less	4 days or less	None	4 days or less	None
Percentage of Specimens Compliant	49.9%	12.3%	99.2%	N/A	92.6%	N/A

NOTE: Performance targets are based on statutory requirements, the federal Advisory Committee on Heritable Disorders in Newborns and Children recommendations, and the College of American Pathologists requirements. Timeframes shown are for the reporting of presumptive positive results. Collection of specimens before infants are 24 hours old could result in incorrect screening results because some disorders require 24 hours for detection. A day in this figure refers to a calendar day.
SOURCE: Department of State Health Services.

the Department of State Health Services in Strategy A.4.1, Laboratory Services, for newborn screening of Medicaid clients to cover the loss of HIV rebate funds. The decrease of a like amount from the Public Health Medicaid Reimbursements Fund would be made in appropriations to HHSC for other purposes, and an increase in General Revenue Funds would restore the decrease. Special Provisions Relating to All Health and Human Services Agencies in the 2020–21 General Appropriations Bill would be amended to specify the increased appropriations to DSHS. The appropriated amount is based on the current fee of $55.24 for newborn screening specimen collection kits set by HHSC.

As discussed for Option 1, the state does not meet performance targets related to the timeliness of blood-spot specimen processing, which can affect the health outcomes of infants who have screened medical conditions. According to the U.S. DHHS, evidence suggests a need for expedited screening, particularly for time-critical conditions. These conditions may manifest with acute symptoms in the first days of life and require immediate treatment to decrease the risk of morbidity and mortality. **Figure 4** shows how the timeliness of NSP processes compared to performance target times for calendar year 2017. One part of the process is transit time between specimen collection and delivery to the laboratory. The ACHDNC recommends the delivery of specimens to the laboratory within 24 hours of collection. During fiscal year 2017, the DSHS laboratory received 25.2 percent of initial-screen specimens and 12.3 percent of second-screen specimens within the targeted one-day timeframe. According to DSHS, the lack of statewide state-funded overnight courier service and certain hospital processes contribute to these shipping delays.

DSHS has taken steps to improve the timeliness of NSP processes. Currently, DSHS contracts with courier companies for next-day delivery of specimens from hospitals and clinics to the DSHS laboratory. However, the DSHS laboratory is closed and does not accept deliveries on Sunday. During calendar year 2017, 721 providers submitted 79.8 percent of newborn screening specimens using state-funded overnight courier service. The percent of specimens submitted to the DSHS laboratory within one day of collection is almost three times greater for specimens shipped using state-funded overnight courier service compared to specimens not shipped in this manner.

Approximately 1,500 newborn screening program submitters do not use state-funded overnight courier service due to funding limitations. Most of these providers pay the U.S. Postal Service to ship the small number of specimens they submit. According to DSHS, the annual cost to expand the existing six-day-per-week state-funded overnight courier service to all submitters is $1.1 million in All Funds. Including the annual $2.5 million in All Funds cost for the existing courier service, the total annual cost to provide this service to all submitters is $3.6 million in All Funds.

Despite the delivery of most newborn screening specimens overnight, the percentage of specimens received by the

DSHS laboratory within one day of collection remains low. According to DSHS, some providers who participate in state-funded overnight courier service do not fully use the service. For example, these providers may not request Saturday delivery, and some continue to pay the U.S. Postal Service to ship specimens. To address issues with timely transit of specimens, DSHS staffed a Transit Time Workgroup from fiscal years 2014 to 2016. The workgroup developed and implemented interventions to improve transit times, including the following activities:

- coordinated with providers that had high rates of delayed specimens to assess process workflows and provide targeted assistance;
- contacted providers to initiate the use of state-funded overnight courier service;
- recognized providers who met transit time and quality measures;
- developed and shared best-practice workflow based on processes used by providers with short transit times; and
- added courier service pick-up on Sundays.

DSHS discontinued the workgroup due to lack of resources. According to DSHS, the annual cost to reinstate the Transit Time Workgroup activities is $1.4 million in All Funds, in addition to some existing staff resources.

Option 4 would increase appropriations in the 2020–21 General Appropriations Bill in Other Funds by $3.95 million from the Public Health Medicaid Reimbursements Fund to DSHS in Strategy A.4.1, Laboratory Services, to improve the timeliness of newborn screening processes, including expanding state-funded overnight courier service and provider education. The decrease of a like amount in Other Funds from the Public Health Medicaid Reimbursements Fund would be made in appropriations to HHSC for other purposes, and an increase in General Revenue Funds would restore the decrease. Special Provisions Relating to All Health and Human Services Agencies in the 2020–21 General Appropriations Bill would be amended to specify the increased appropriations to DSHS.

As discussed previously for Option 1, Texas lacks a permanent funding mechanism to cover the initial costs associated with adding conditions to the NSP. Option 5 would amend a rider in the 2020–21 General Appropriations Bill directing DSHS to request from the Legislative Budget Board additional funds from the Public Health Medicaid Reimbursements Fund to pay for the initial costs associated with adding conditions to the NSP during the period outside of the biennial appropriations process. These funds would be in addition to the amounts appropriated to DSHS for laboratory services from the fund in the 2020–21 General Appropriations Bill and would result in a reduction in appropriations from the Public Health Medicaid Reimbursements Fund to other strategies at HHSC. If DSHS changes the fee methodology for specimen collection kits to include the initial costs associated with adding conditions to the NSP and HHSC adopts a revised fee as part of Option 1, DSHS' request for funding from the fund would be decreased.

FISCAL IMPACT OF THE OPTIONS

Options 1 to 5 would result in a net cost of $14.05 million in General Revenue Funds for the 2020–21 biennium to replace the use of Other Funds from the Public Health Medicaid Reimbursements Fund for non-NSP items. The options direct DSHS and HHSC to take steps to maximize the NSP's ability to identify children who may have a serious medical condition and refer them for appropriate care. These options would direct DSHS to revise the methodology used to determine the fee amount for newborn screening specimen collection kits, direct DSHS to annually evaluate and HHSC to update the fee amount, increase appropriations from the Public Health Medicaid Reimbursements Fund for newborn screening for Medicaid clients and for strategies to improve timeliness, and provide a method to fund adding new conditions to the NSP.

Options 1 and 2 could result in increased revenue to the General Revenue–Dedicated Account No. 524 if changes to the methodology and process used to establish fees result in higher fee amounts. This revenue gain likely would be offset by an identical cost for use of that fee revenue to operate the NSP. These amounts cannot be estimated at this time.

Option 3 would increase appropriations by $10.1 million in Other Funds for the 2020–21 biennium from the Public Health Medicaid Reimbursements Fund for newborn screening of Medicaid clients. It is assumed that a cost to General Revenue Funds in the same amount would result to replace the use of Other Funds for non-NSP items.

Option 4 would increase appropriations by $3.95 million in Other Funds for the 2020–21 biennium from the Public Health Medicaid Reimbursements Fund to improve the timeliness of newborn screening processes, including

expansion of state-funded overnight courier service and provider education. It is assumed that a cost to General Revenue Funds in the same amount would result to replace the use of Other Funds for non-NSP items.

Option 5 would not result in a net cost increase if amounts from the Public Health Medicaid Reimbursements Fund were used to pay the initial costs associated with adding conditions to the NSP. The potential amount cannot be estimated at this time. The funds used for this purpose would be greater than the amounts appropriated to DSHS for laboratory services from the fund in the 2020–21 General Appropriations Bill and would result in a reduction in appropriations from the fund to other strategies at HHSC.

The introduced 2020–21 General Appropriations Bill does not include any adjustments as a result of these options.