05/01/2018: Report has been attached, please see below.

STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

March 1, 2018

SENT VIA ELECTRONIC MAIL

The Honorable Louis Pate, Chair
Joint Legislative Oversight Committee on
Health and Human Services
North Carolina General Assembly
Room 311, Legislative Office Building
Raleigh, NC 27603

The Honorable Josh Dobson, Chair
Joint Legislative Oversight Committee on
Health and Human Services
North Carolina General Assembly
Room 301N, Legislative Office Building
Raleigh, NC 27603

The Honorable Donny Lambeth, Chair
Joint Legislative Oversight Committee on
Health and Human Services
North Carolina General Assembly
Room 303, Legislative Office Building
Raleigh, NC 27603

Dear Chairmen:

Session Law 2017-57, Section 11E.2.(a), requires the Department of Health and Human Services, Division of Public Health, to review the current fee schedule for medical and environmental services provided by the State Laboratory of Public Health (SLPH) and report any recommended strategies for addressing its structural budget deficit. The report is due on or before March 1, 2018.

On behalf of Secretary Cohen, the Department of Health and Human Services is notifying you that this report will be delayed as the Department continues to work to finalize the requirements for this report. We will submit the report on or before April 1, 2018.

Should you have any questions concerning this report, please contact Danny Staley, Director for the Division of Public Health, at 919-707-5000 or Danny.Staley@dhhs.nc.gov.

Sincerely,

Mandy Cohen, MD, MPH
Secretary

cc: Danny Staley
Theresa Matula
Lisa Wilks
reports@ncleg.net
Deborah Landry
Rod Davis
Leah Burns
Mark Benton
Marjorie Donaldson
Christen Linke Young
LT McCrimmon
Susan Perry-Manning
Kolt Ulm
Pam Kilpatrick
Matt Gross
Joyce Jones

WWW.NCDHHS.GOV
TEL 919-855-4800 • FAX 919-715-4645
LOCATION: 101 BLAIR DRIVE • ADAMS BUILDING • RALEIGH, NC 27603
MAILING ADDRESS: 2001 MAIL SERVICE CENTER • RALEIGH, NC 27699-2001

STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

March 1, 2018

SENT VIA ELECTRONIC MAIL

Mr. Mark Trogdon, Director
Fiscal Research Division
Suite 619, Legislative Office Building
Raleigh, NC 27603-5925

Dear Director Trogdon:

Session Law 2017-57, Section 11E.2.(a), requires the Department of Health and Human Services, Division of Public Health, to review the current fee schedule for medical and environmental services provided by the State Laboratory of Public Health (SLPH) and report any recommended strategies for addressing its structural budget deficit. The report is due on or before March 1, 2018.

On behalf of Secretary Cohen, the Department of Health and Human Services is notifying you that this report will be delayed as the Department continues to work to finalize the requirements for this report. We will submit the report on or before April 1, 2018.

Should you have any questions concerning this report, please contact Danny Staley, Director for the Division of Public Health, at 919-707-5000 or Danny.Staley@dhhs.nc.gov.

Sincerely,

for MLCC

Mandy Cohen, MD, MPH
Secretary

cc: Danny Staley
Theresa Matula
Lisa Wilks
reports@ncleg.net
Deborah Landry
Rod Davis
Leah Burns
Mark Benton
Marjorie Donaldson
Christen Linke Young
LT McCrimmon
Susan Perry-Manning
Kolt Ulm
Pam Kilpatrick
Matt Gross
Joyce Jones

STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

March 29, 2018

SENT VIA ELECTRONIC MAIL

The Honorable Louis Pate, Chair
Joint Legislative Oversight Committee on
Health and Human Services
North Carolina General Assembly
Room 311, Legislative Office Building
Raleigh, NC 27603

The Honorable Josh Dobson, Chair
Joint Legislative Oversight Committee on
Health and Human Services
North Carolina General Assembly
Room 301N, Legislative Office Building
Raleigh, NC 27603

The Honorable Donny Lambeth, Chair
Joint Legislative Oversight Committee on
Health and Human Services
North Carolina General Assembly
Room 303, Legislative Office Building
Raleigh, NC 27603

Dear Chairmen:

Session Law 2017-57, Section 11E.2.(a), requires the Department of Health and Human Services, Division of Public Health, to review the current fee schedule for medical and environmental services provided by the State Laboratory of Public Health (SLPH) and report any recommended strategies for addressing its structural budget deficit. The report is due on or before March 1, 2018.

On behalf of Secretary Cohen, the Department of Health and Human Services is notifying you that this report will be delayed as the Department continues to work to finalize the requirements for this report. We will submit the report on or before May 1, 2018.

Should you have any questions concerning this report, please contact Danny Staley, Director for the Division of Public Health, at 919-707-5000 or Danny.Staley@dhhs.nc.gov.

Sincerely,

Mark T. Benton

Mandy Cohen, MD, MPH
Secretary

cc: Danny Staley, Theresa Matula, Lisa Wilks, reports@ncleg.net, Deborah Landry, Rod Davis, Leah Burns, Mark Benton, Marjorie Donaldson, Christen Linke Young, LT McCrimmon, Susan Perry-Manning, Kolt Ulm, Pam Kilpatrick, Matt Gross, Joyce Jones

STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

March 29, 2018

SENT VIA ELECTRONIC MAIL

Mr. Mark Trogdon, Director
Fiscal Research Division
Suite 619, Legislative Office Building
Raleigh, NC 27603-5925

Dear Director Trogdon:

Session Law 2017-57, Section 11E.2.(a), requires the Department of Health and Human Services, Division of Public Health, to review the current fee schedule for medical and environmental services provided by the State Laboratory of Public Health (SLPH) and report any recommended strategies for addressing its structural budget deficit. The report is due on or before March 1, 2018.

On behalf of Secretary Cohen, the Department of Health and Human Services is notifying you that this report will be delayed as the Department continues to work to finalize the requirements for this report. We will submit the report on or before May 1, 2018.

Should you have any questions concerning this report, please contact Danny Staley, Director for the Division of Public Health, at 919-707-5000 or Danny.Staley@dhhs.nc.gov.

Sincerely,

Mark T. Benton

for Mandy Cohen, MD, MPH
Secretary

cc:

Danny Staley	Deborah Landry	Marjorie Donaldson	Kolt Ulm
Theresa Matula	Rod Davis	Christen Linke Young	Pam Kilpatrick
Lisa Wilks	Leah Burns	LT McCrimmon	Matt Gross
reports@ncleg.net	Mark Benton	Susan Perry-Manning	Joyce Jones

Strategies for Addressing the Structural Budget Deficit in the State Laboratory of Public Health

Session Law 2017-57, Section 11E.2. (a)

Report to

The North Carolina General Assembly

By

North Carolina Department of Health and Human Services

May 1, 2018

Introduction and Background

The Department of Health Humans Services' (DHHS) State Laboratory of Public Health (SLPH) has experienced a budget shortfall of approximately $4 million in each of the last two state fiscal years (State Fiscal Year 2015-16 and State Fiscal Year 2016-17). Session Law 2017-57 Section 11E.2. (a) directs the Department of Health and Human Services (DHHS) to prepare a report to the North Carolina General Assembly (NCGA) by March 1, 2018 that addresses:

1. Any service the SLPH currently provides at no cost for which it should begin charging a fee, along with recommendations for each new fee sufficient to cover both the direct and indirect costs of the service.
2. Implementation of a billing system for services provided by the SLPH.
3. Strategies to improve billing accuracy to increase the SLPH's Medicaid reimbursement rate.
4. The feasibility of modifying the Medicaid State Plan to allow the SLPH to engage in cost settlement, like the approaches used by local health departments.
5. Identification of measures to ensure that local health departments collect and report all data needed to ensure accurate and timely billing of SLPH services.
6. Proposals on alternative funding options to support the operating costs of the SLPH.

This report provides a history of the SLPH structural operating budget shortfall and addresses the elements of the legislative reporting requirements.

History of the SLPH Structural Operating Budget Shortfall and SFY 2018-19 Projections

The SLPH budget shortfall in SFY 2015-16 totaled $3,923,383, and the shortfall in SFY 2016-17 totaled $3,877,459.

Several historical factors over time have contributed to the structural operating budget shortfall at the SLPH that was realized for SFY 2015-16 and SFY 2016-17. These include:

1. In SFY 2015-16, financial support for the Newborn Screening (NBS) test narrowed from two revenue streams to one. Prior to this point, the NBS program had been largely supported by Medicaid receipts and, to a lesser extent, by individual fees. Beginning in SFY 2015-16, the SLPH was no longer able to bill Medicaid for Newborn Screening (NBS) services, so reimbursement changed to NBS fees only.
2. New equipment maintenance contracts for laboratory instrumentation and equipment purchased in 2012 (part of funding for the new SLPH facility at 4312 District Drive, Raleigh, NC) expired, beginning in SFY 2016-17, and have not been funded on a recurring basis since that time.
3. Inflationary costs of healthcare items such as laboratory supplies, reagents, kits, and consumables have not been funded on a recurring basis.
4. Replacement costs of laboratory instrumentation and equipment that has "aged out" have not been funded on a recurring basis.

5. Acquisition of laboratory instrumentation and equipment required for providing services to properly detect new and emerging health threats (i.e., hepatitis C virus, hexavalent chromium, antimicrobial resistance, etc.) has not been funded on a recurring basis.

The NC General Assembly has provided recurring funding to partially offset the $4 million structural deficit to the overall SLPH budget over the last two state fiscal years. In SFY 2016-17, $1 million was appropriated and in SFY 2017-18, an additional $1 million was appropriated (both were funded on a recurring basis). And in SFY 2017-18, the legislature provided $2 million in non-recurring appropriations to temporarily assist with the continued budget shortfall while DHHS studied this issue and completed this legislative report.

- These new appropriations reduced the shortfall by one-half (i.e., $2M).
- The costs for the equipment maintenance contracts for laboratory instrumentation and equipment is estimated to be $327K for non-NBS SLPH equipment.
- Before factoring in costs related to the Newborn Screening Program, the SLPH's revised, recurring budgetary shortfall is estimated to be approximately $2.3M annually ($4M less $1M less $1M plus $0.327M).

Beginning in SFY 2018-19, SLPH projects increased operational costs of the NBS program. This will further contribute to the SLPH's structural operating budget shortfall. The increased costs are related to increased supply and reagent costs, NBS specimen shipping costs and NBS equipment maintenance contracts (in addition to the equipment maintenance contracts referenced above).

- Increased NBS Program Direct Costs including supply and reagent costs, follow up costs, and NBS specimen shipping costs are approximately $612,000.
- Increased NBS equipment maintenance agreements are approximately $670,800.
- Increased NBS equipment replacement are $980,400.

Therefore, the projected recurring SLPH structural operating budget shortfall for SFY 2018-19 is approximately $2.3M for non-NBS Programs plus approximately $2.26M in new operational costs for the Newborn Screening Program. The combined impact of both generates a SLPH-wide, annual shortfall of approximately $4.56 million.

Review of Current Services and Fees Provided by SLPH

Primary Function

The primary function of the SLPH is to support public health programs. Its services are directed at the prevention and control of disease and the improvement of the community's health and to offer disease assessments to epidemiologists and disease control personnel. Testing functions carried out by SLPH are not 'services,' but essential 'disease assessments' which are key steps in the prevention and control of disease and necessary for the identification and investigation of outbreaks and the assessment of community illness.

Unlike a clinical laboratory (such as LabCorp), a public health laboratory is focused on the health of the community and not always with that of any individual patient. Whereas a commercial clinical laboratory completes clinical laboratory testing addressing an individual's personal health, a public health laboratory does not generally complete clinical testing, unless such testing serves an overarching function to protect the public's health or to substantially impact the state's return on investment of its healthcare resources.

Newborn screening (NBS) and private well water testing are the only existing SLPH clinical laboratory testing for individual citizens that serve a larger public health function because:

- NBS testing serves to identify newborns for conditions for which death or lifelong health consequences may result and, for those conditions that produce lifelong health consequences, for which excessive costs to the state's healthcare resources would occur. NBS testing is consistent with the prevention role of the state's public health system.
- Since 2007, all newly drilled private wells in North Carolina must be certified for the absence of chemical and biological agents that would have negative impacts on the public's health. Given that approximately half of North Carolina's residents use private wells for drinking water, private well water testing protects the health of the state's population through widespread prevention of waterborne and infectious diseases, "blue baby syndrome' (secondary to nitrates) and health conditions related heavy metal (lead and copper) contamination of water.

Also, unlike commercial clinical and environmental laboratories (which are largely for-profit entities), the SLPH is committed to providing cost-based services, without generating additional for-profit revenues.

Core Test Functions

North Carolina Administrative Code (10A NCAC 42B) establishes that the SLPH provide essential disease assessments for the following specialties: 1) Clinical Chemistry (10A NCAC 42B .0102), 2) Newborn Screening (10A NCAC 42B .0102), 3) Environmental Sciences (10A NCAC 42B .0103), 4) Laboratory Improvement (10A NCAC 42B .0104), 5) Microbiology (10A NCAC 42B .0105), and 6) Virology (10A NCAC 42B .0106). The core functions of these specialties include:

- Examination of specimens for the identification of disease outbreaks, with isolation and identification of an agent causing a disease.
- Reference services, including those for identification of rare and unusual microorganisms, such as agents of Ebola, Zika, plague, anthrax, and brucellosis.
- Testing for diseases of public health importance that are too rare and unusual to be identified by other laboratories, such as rabies, botulism, and drug-resistant tuberculosis.
- Testing for diseases that are prevalent in populations traditionally not willing to approach private medicine due to issues of confidentiality or inability to pay, such as testing for sexually transmitted infections.

- Population surveillance studies, such as NBS, immune status screening for infectious diseases, screening for risk factors, including chronic hepatitis C virus screening, and screening for chronic diseases such as blood lead intoxication.
- Environmental testing, including microbiological, chemical and radiological analyses for quality of water.
- Discovery of new and emerging pathogens in what is or may become an outbreak situation (such as Zika virus, hepatitis C virus) or efforts that incorporate fundamental scientific advances into a public health setting.
- Centralization of data for rapid transmission to epidemiologists, infectious disease specialists, and other decision-makers. The public health laboratory is a center where information from all types of laboratories is collected, analyzed, and transmitted.
- Training of personnel in clinical and other laboratories and regulation, certification, and licensing of laboratories (all means by which the public health laboratory protects the health of the public by setting standards for laboratory testing and training technical personnel).

Submitters Requesting Tests from SLPH

At SLPH, disease assessments and testing are performed for a variety of agencies, organizations and submitters in North Carolina. In 2017, SLPH conducted 2,168,114 tests:

- 58% of the tests conducted were for hospital submitters (primarily NBS)
- 32% were for local health department submitters (for private drinking water and a variety of other tests)
- 8% were for private medical offices
- 2% of submitters were made up of other laboratories, universities/colleges, public water suppliers/authorities, other state agencies, correctional/detention facilities, veterinary hospitals, dental offices, schools/head start agencies, and local law enforcement (*See Figure 1*). For those specimen submissions, *Figure 2* demonstrates the number of tests performed by each SLPH Testing Unit.

Figure 1. Number of Tests Submitted to SLPH by Submitter Type in 2017

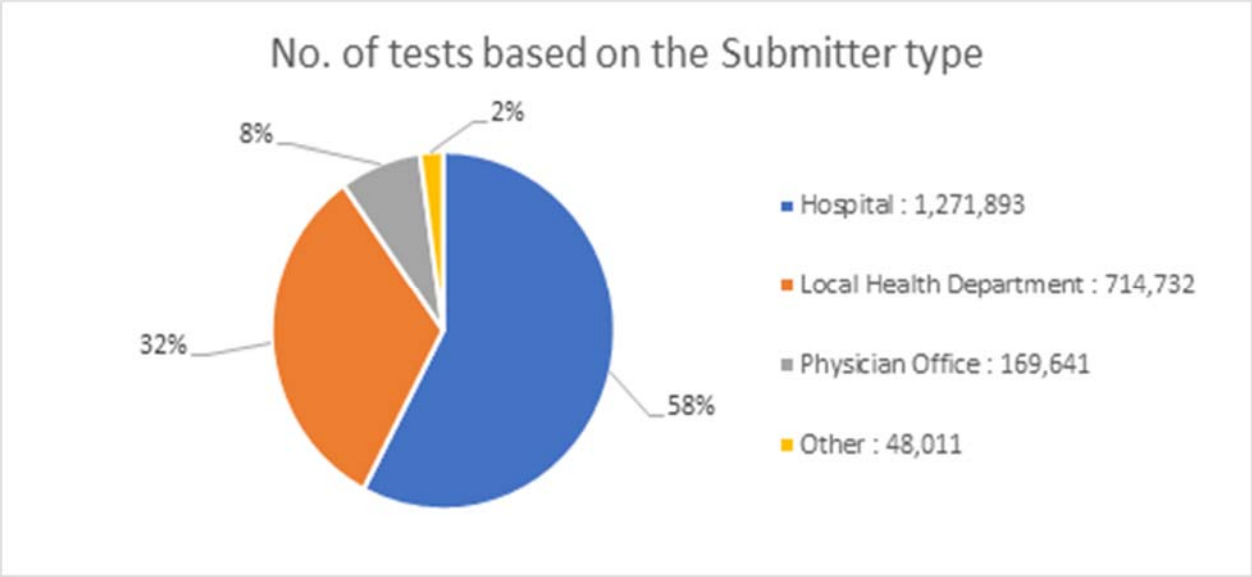
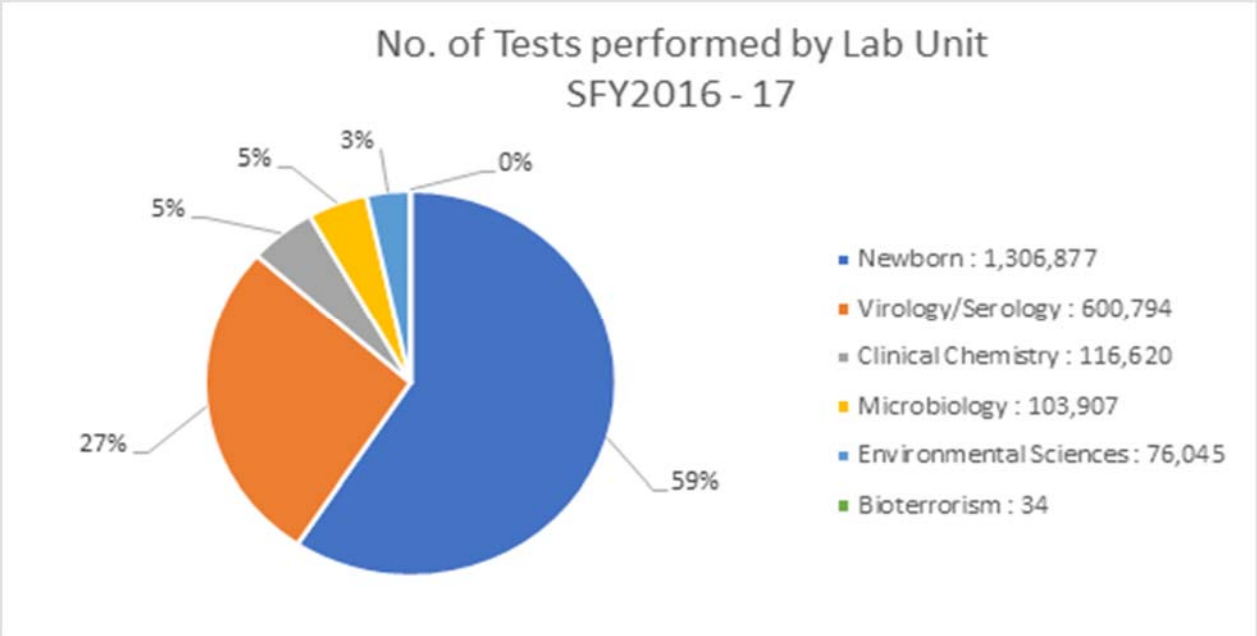


Figure 2. Number of Tests Performed by SLPH Unit



SLPH conducts well over 200 different analyses on both clinical and environmental samples. However, because of the nature of testing performed, the source of specimens and samples, the role of government in providing public safety and public health assurance, and SLPH's unique ability to carry out rare or specialized assessments, there are few opportunities to charge a fee.

Current SLPH Test Fees

Newborn Screening (NBS) and private well water (potable) testing are the only existing tests for which the SLPH currently has statutory authority to charge a fee to the submitters. In addition to these two testing programs, SLPH is authorized to file claims to Medicaid for reimbursement of clinical laboratory testing for Medicaid eligible recipients.

DHHS believes the NBS and private well water testing programs are the only two testing programs in North Carolina for which it is appropriate for the state's public health laboratory to charge a fee to the submitter. That is because NBS and well water testing represents the majority of the tests performed by the SLPH and based on the following:

- State and local governments play a vital role in assuring the conditions in which North Carolina citizens can be healthy by ensuring a strong local public health system. North Carolina's state and local public health enterprise works to reduce the risk of diseases (through investigation of communicable disease and food-related outbreaks) and to ensure citizens' safety from environmental contaminants (through the private well water testing program and testing for environmental contaminants related to elevated child blood lead levels). These functions are completed while also allowing flexibility for local health departments (LHDs) to serve a clinical services safety net function in their communities.
- North Carolina's 85 LHDs are the primary customers for the SLPH because of the variety and volume of testing requested of the SLPH, as well as related to their role in local communicable disease control, food-borne illness investigations, environmental health, and emergency response. LHDs order laboratory tests from the SLPH for a variety of public health reasons. Some of the testing requests have no payer source for the work performed while a public health need exists to complete the investigation or analysis (such as foodborne outbreak investigations, rabies testing, and influenza surveillance). Other test requests may have a payer source for reimbursement. However, DHHS recommends that further analysis of third party payer billing be undertaken to include: 1) assessment of the impact private insurance billing will have on local public health workflow, 2) estimation of the influence that private insurance billing will have on patient's confidentiality concerns related to sexually transmitted infections and other privacy matters, 3) an understanding of the structural and IT needs and cost for a functional SLPH billing system (addressed in paragraph below), and 4) determination if charging the LHD for services or billing third party payers directly is more cost effective.

  In late 2017, SLPH staff conducted a survey of five neighboring states (GA, SC, TN, VA, WV) who were asked to identify tests for which fees were charged and tests for which fees were not charged (*See Table 1*). Feedback from this survey indicates there are relatively few tests for which these other states' State Laboratories of

Public Health charge a fee. Exceptions are universally limited to new born screening (NBS) and drinking water tests.

Table 1. Survey of Fees Charged by Southeast State Public Health Laboratories

State Public Health Lab	Fee Charged	No Fee Charged
NC	**NBS, drinking water**	**Microbiology, Virology, Serology, Molecular Epidemiology, Biological and Chemical Terrorism, Rabies**
GA	No response to date	No response to date
SC	NBS, drinking water	Clinical Microbiology, Virology, Food Microbiology, Biological & Chemical Terrorism (All funded by Appropriations)
TN	NBS, drinking water, Sexually Transmitted Diseases (STDs, Dept. of Corrections), Environmental testing (DEQ)	Bacteriology, Mycology, Parasitology, Virology, Rabies, Serology, Molecular Biology, Enterics, Food testing (All funded by Appropriations)
VA	NBS, drinking water, Tuberculosis (TB), Lab Certification	All others funded by Appropriations
WV	NBS, Environmental water testing, Hepatitis testing	Microbiology, Food Microbiology, Emerging Pathogens, Biological & Chemical Terrorism, TB, STDs, Milk testing, Rabies testing, Arbovirus surveillance (Funded by Appropriations and Grants)

SLPH Billing System and Enhanced Billing Data Accuracy

SLPH currently maintains a "homegrown" billing software application that was developed years ago using internal information technology (IT) resources. This system is used to generate invoices for NBS, private well water testing, and Specimen-Sample Collection devices sold to customers prior to specimen-sample acquisition. Additionally, SLPH utilizes a DHHS-approved Medicaid Fee Schedule to submit fee-for-service (FFS) claims to Medicaid to reimburse for

clinical laboratory testing conducted on Medicaid-eligible recipients. In SFY 2016-17, 25% (N=645,488) of non-NBS clinical specimens tested were from Medicaid-eligible patients.

Currently, SLPH does not submit claims for patients covered by private insurers (i.e. Blue Cross/Blue Shield) because it does not have a billing system to submit such claims to private insurers. With the implementation of Medicaid managed care in 2019, the SLPH is aware that it will have to purchase or internally develop the capability to bill the new managed care firms. While that technology will also permit the SLPH to bill commercial or private payers, it is unlikely that this enhanced capability will generate a lot of new revenue. That because efforts dating back to 2014 to improve billing have demonstrated only meager improvements in reimbursement. Additional information regarding those efforts in 2014 are detailed below.

DHHS State Lab Rebill Task Force

To further improve this process, SLPH completed a business case for financial stability in February 2014 with the DHHS Division of Medical Assistance (DMA). DHHS formed the DHHS Lab Rebill Task Force, consisting of staff from the DHHS Divisions of Medical Assistance, Information Technology (ITD), and Public Health (DPH), to analyze SLPH billing practices and generate recommendations to address policies and practices impacting the financial stability of SLPH. The DHHS Lab Rebill Task Force summarized the outcomes of their activities in a document that highlighted some of the billing and data accuracy problems faced by SLPH and made certain recommendations (See *Appendix 1. DHHS Lab Rebill Task Force Outcomes*). The DHHS Lab Rebill Task Force recommendations centered on the following areas:

1. Improved billing processes to use more reliable eligibility inquiry mechanisms (270/271 Healthcare Eligibility Benefit Inquiry)
2. Enhanced collection of mandatory data elements billing (for example, Family Planning's Annual Exam Date)
3. A corrected Taxonomy End Date
4. Overall recommendation for implementing an online service request form (electronic test order and reporting, or ETOR

For Task Force recommendations 1-3, in SFY 2015-16, the SLPH retroactively collected reimbursement of funds to the maximum extent allowable by Medicaid. This resulted in approximately $5 million of revenues generated primarily for NBS Medicaid claims which were deposited in Fund 1993 (Prior Year Adjustments). The SLPH continues to use changes made based on these Task Force recommendations as part of its current business practices.

National Provider Identifier

To be in compliance with federal law, beginning in November 2016, the submission of Ordering Provider National Provider Identifier (NPI) was mandated with all Medicaid claims. SLPH modified its test requisition forms to collect the Ordering Provider NPI details. Initially, only

40% of the requisition forms received from test submitters contained the required Ordering Provider NPI and name, and therefore, these Medicaid claims were denied. Consequently, SLPH hired temporary employees to individually call submitters to retrieve the Ordering Provider NPI details. Due to this manual process, NCSLPH was able to obtain 80% of required NPI information for Medicaid billing submission. However, a structural improvement to meet the NPI requirement and maximize Medicaid claim reimbursement will only be achieved through Electronic Test Ordering (ETOR), which will require submitters to enter NPI information and assess the validity of the NPI information prior to test submission. As previously noted, implementation of ETOR was recommended by the DHHS State Lab Rebill Task Force in 2014.

Local Health Department Payer Mix and Third-Party Billing

Since SLPH does not currently submit billing claims to private, third-party insurers, DPH surveyed its primary customers, local health departments (LHDs), in 2018 to assess their client payer mix to assist in assessment of the proportion of SLPH clients that have private, third-party insurance for which the SLPH could bill. As of February 2018, fifty-five (55) of 85 LHDs responded to this survey, and the results indicated that 11% of LHD clients were insured by a third party or contract payer (*see Table 2*).

Table 2. Payer mix of patients from NC local health departments

Unduplicated Patient total	Number of Medicaid patients	Number of self-pay-uninsured patients	Number of third party or contract payer patients
336,244	105,731 (31%)	192,907 (57%)	38,482 (11%)

Assessment of routine LHD services suggests that unduplicated patients seeking services from LHDs in Family Planning, Sexually Transmitted Diseases (STDs) services, and Prenatal Care are patients for which clinical specimens are tested by SLPH. However, other routine clinical services provided by LHDs (such as Child Health and Adult Health services) may be more likely to have lab tests that are performed by private reference laboratories. Preliminary data suggests that a minority of third party or contract payer patients at LHDs are actually tested by SLPH (in other words, a small portion of the 11% of third party or contract payer patients). SLPH conducted nearly 600,000 clinical tests in SFY 2016-17 (of which nearly 80% were for HIV/STIs). Further exploration is required to assess the potential revenue that could be generated by the subcategory of third party or contract payer patients that are tested by SLPH.

Furthermore, this survey emphasizes that, although 500,000 North Carolinians were covered through subsidized health insurance in the Marketplace, the LHDs and other safety net organizations still care for mostly the uninsured or working poor who would benefit from efforts to address the health care coverage gap. This would, in turn, enhance revenues to the

SLPH when those recipients receive clinical services for which samples are submitted to the SLPH.

Billing Technology

The DHHS Information Technology Division and the Division of Public Health are working collaboratively with the cabinet-level Department of Information Technology to further improve billing practices and accuracy through a technology-based solution. This process, initiated in December 2017, will study potential solutions for both billing and electronic test order and reporting (ETOR) for the SLPH and will determine if there would be a return for such solutions. It is anticipated both studies could require approximately up to 12 months to complete.

Feasibility of Modifying the Medicaid State Plan to Allow the SLPH to Engage in Cost Settlement

As the state moves forward with Medicaid transformation, fewer things will be paid for through a Fee-for-Service model, and the US Centers for Medicare and Medicaid Services (CMS) has indicated that cost settlement is not an option in a managed care model in NC. Therefore, obtaining CMS' approval of cost settlement for the SLPH is highly unlikely.

DHHS examined options to states provided under *42 CFR 438.6 – Special contract provisions related to payment*, and concluded the following:

- Local health departments (LHDs) are currently cost settled (at the federal share only, or roughly 66% of cost) for Medicaid services provided. For services covered under the Medicaid Waiver and currently cost settled (like LHDs), additional payments in lieu of cost settlement can be provided. However, such payments cannot be provided to the SLPH because it is currently reimbursed using an established fee schedule.
- DHHS has determined it can contractually require Prepaid Health Plans (PHPs) to provide payment for state mandated services (such as those provided by the SLPH NBS program) at a DHHS-approved rate.
    - A contractual relationship between SLPH and PHPs would require SLPH to invoice PHPs for services provided.
    - As previously noted, the current SLPH Billing System is not capable of this billing function and requires an assessment of needed capabilities for billing 3rd party payors (see reference in previous section on SLPH Billing System and Enhanced Billing Data Accuracy).

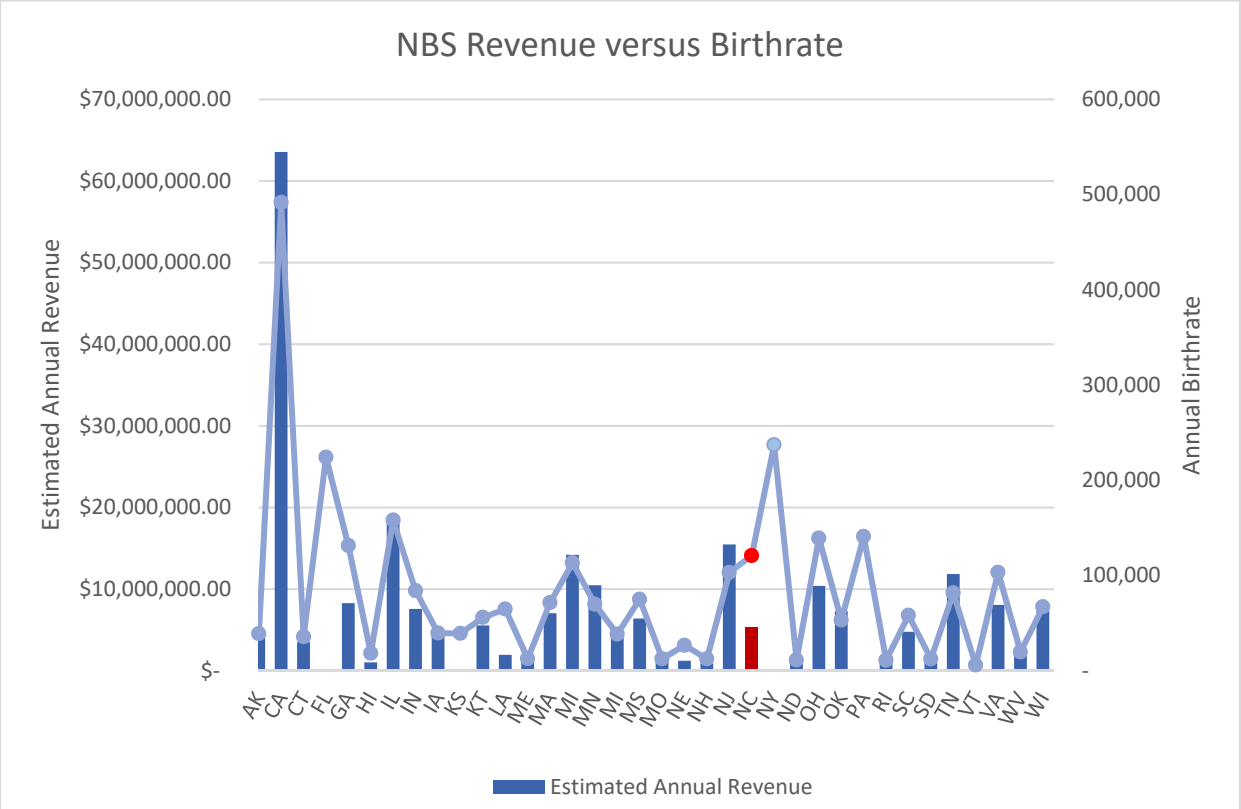
Alternative Funding Options to Support SLPH Operating Costs

Revenue to Support the NBS Program

SLPH is currently authorized to charge a fee of $44 per newborn to all hospitals and birthing centers in NC that submit NBS specimens to SLPH for screening. This fee no longer covers the cost of operating the NBS Program. The funding necessary to operate the NBS Program has increased due to supply, reagent, and consumable costs, the cost of shipping newborn specimens from NC hospitals to SLPH and ensuring necessary short-term follow up for new disorders added to the NBS program. SLPH is the only laboratory in NC that conducts screening of all newborns (120,000 annually) for metabolic and other hereditary and congenital disorders as recommended by the U.S. Department of Health and Human Services and the federal Recommended Uniform Screening Panel (RUSP).

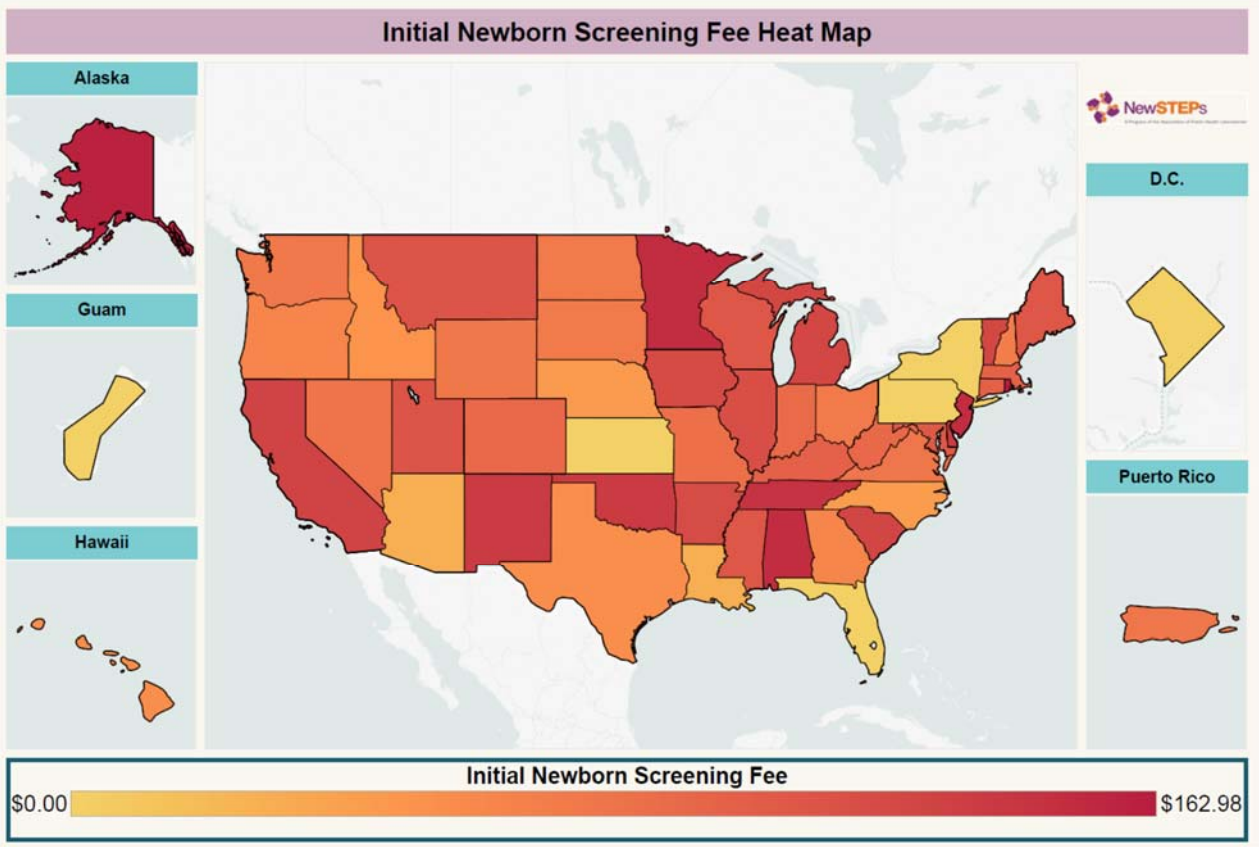
SLPH has surveyed other State Public Health Laboratories to assist in the comparative assessment of the current NBS Fee of $44. *Figure 3* demonstrates the relationship between annual NBS revenues and annual birthrates by state. NC's annual revenue for the NBS program is disproportionately low based on the state's birthrate when compared to nearly all other states that currently charge a fee for NBS (*see red bar and data point for NC in Figure 3*).

Figure 3. NBS Revenues vs. Birthrate by State (for states that charge a NBS fee)



Further, *Figure 4* demonstrates a heat map of NBS fees by state. The average initial fee charged for NBS in the United States is $98.36. The NBS fee for North Carolina is $44 (see *Appendix 2* for NBS Fees by State).

Figure 4. Initial Newborn Screening Fee Heat Map



The SLPH's NBS program serves a core governmental statewide public health function in protecting the health and welfare of newborns and in reducing excessive costs to the state's healthcare resources. Any adjustment to the NBS Fee would require modification of General Statute 130A-125(c) *Screening of Newborns for metabolic and other hereditary and congenital disorders*.

Appropriations

The change in 2015 to the NBS revenue streams resulted in an approximately $4 million annual shortfall in SLPH revenues. The NC General Assembly provided $1 million in recurring appropriations in SFY 2016-17 and another $1 million in recurring appropriations in SFY 2017-18 to offset this loss of Medicaid receipts. The recurring appropriations reduced the structural budget deficit for the SLPH to approximately $2 million. Also, in SFY 2017-18, the legislature provided $2 million in non-recurring appropriations to temporarily assist with the continued budget shortfall while DHHS studied this issue and completed this legislative report.

In SFY 2018-19, SLPH will realize a new expense of approximately $327K for laboratory instrumentation and equipment maintenance agreements previously supported by COPS funding (from SLPH Facility Construction funds purchased in 2012 for the new SLPH facility). Therefore, the combined SFY 2018-19 budget shortfall for routine operating expenses at the SLPH will total approximately $2.3M. Recurring appropriations could be used to address this SLPH structural budget shortfall.

Equipment Replacement and Inflationary Costs

The shortfall funding requirement above only addresses projected funding requirements for SFY 2018-19. It does not address inflationary increases for personnel and operational expenditures beyond SFY 2018-19.

Furthermore, the shortfall amounts do not address equipment replacement recommendations. Specifically:

- The SLPH has over $20 million in fixed assets, mainly in scientific equipment.
- To maintain laboratory equipment reliability, and to meet technologic laboratory advances, a 5-year replacement equipment schedule is an industry standard recommendation.
- Over the years, existing equipment funds in the SLPH's budget have been reallocated instead to equipment maintenance and repair costs.
- Aside from some limited, federal grant equipment funds that are targeted to only a few laboratory test units and for limited purposes, the SLPH budget does not currently have the funding to support a 5-year equipment replacement schedule. Approximately $4 million per year (one fifth, or 20% of the total SLPH equipment inventory) is needed to adequately fund the replacement schedule, of which $980,400 per year is specific to NBS equipment.

The current SLPH budget does not currently have the funding to meet the industry recommended 5-year equipment replacement schedule, or inflationary personnel and operational requirements.

Summary

Starting in SFY 2018-19, SLPH anticipates a total recurring structural operating budget shortfall annually of approximately $4.56M, which consists of the following elements:

1. An annual SLPH-wide recurring shortfall of approximately $2.3M, secondary to primarily the ongoing loss of Medicaid receipts plus expiring equipment maintenance agreements purchased in 2012.
2. Increased operational costs of the NBS program of approximately $2.26M annually consisting of increased NBS Program Direct Costs including supply and reagent costs, equipment maintenance costs, and NBS specimen shipping costs.

Therefore, the projected SLPH structural operating budget shortfall for SFY 2018-19 is $2.3M non-Newborn Screening Programs plus $2.26M for the Newborn Screening Program, for a combined SLPH-wide shortfall of approximately $4.56M.

Funding Options to Consider for Support of SLPH Operating Costs

As discussed earlier in the report, many SLPH tests and services are performed to protect and promote the health of the entire state.

Consideration could be given to increasing the NBS fee by at least $18.86 per test, from the current $44 per test to $62.86 per test to cover NBS requirements anticipated for SFY 2018-19. Based on annual NBS testing of 120,000 newborns, an increased fee of $62.86 per test could generate approximately $2.26M in net, new revenue annually and would cover the costs of the NBS program that are not covered by the current fee:

- $49.10 per test to cover increased unbudgeted operational costs of the NBS program totaling approximately $612,000 in net, new revenue annually.
- $5.59 per test to fund the NBS program's unbudgeted recurring equipment maintenance costs of approximately $670,800 annually.
- $8.17 per test to cover the NBS program's unbudgeted costs of equipment replacement based on an industry recommended 5-year replacement schedule. This would generate approximately $980,400 in net, new revenue annually and reflects the cost of replacing one fifth (20%) of the NBS program's total equipment inventory each year. This is a conservative estimate and uses only current equipment acquisition cost without factoring in actual amount equipment replacement cost, which is unknown at the present time.

Adding 3 new screening tests (MPS-I, Pompe Disease, and X-ALD) to the NBS panel as recommended in the Haley Hayes NBS Bill (SB190) would increase the NBS fee an additional $16. The amounts in the above fee increase scenario does not reflect the impact of costs to the NBS program if SB190 is enacted, including a $16 fee increase (recurring) and recurring and non-recurring appropriations.

Appendix 1. DHHS State Lab Rebill Task Force Outcomes

State Lab Rebill Task Force Outcomes

Summary

The Rebill Task Force was constituted to bill/ rebill NCTracks for services rendered by the North Carolina State Laboratory of Public Health (NCSLPH). During the months of April and May 2014, the Task Force submitted $9.9 million in claims (new bills and rebills) for Family Planning Waiver and Medicaid services rendered from September 2011 through December 2013. These claims were largely denied by NCTracks with a payment of $62,426.

The en masse denial of the claims by NCTracks impacts NCSLPH's financial stability. The problem is compounded because of the Local Health Departments not submitting, in many instances, information required for billing and routing, inadvertently or not, service requests for mostly uninsured recipients to NCSLPH.

After a meeting with DMA on Wed, 5/21/2014, the Task Force's effort was considered concluded. Details on the principal and ancillary outcomes from the effort are listed below. A perusal of these outcomes underlines the multifaceted policy, process, and industry challenges facing the NCSLPH.

Principal Outcome 1: Unpaid FPW Claims

Family Planning Waiver (FPW) services were rebilled to the tune of $1.97 million for the September 2011 through December 2013 period. Based upon discussions with the prior DMA CFO, the Task Force expected three NCTracks edits to be lifted for FPW claims resulting in a payment of $1.7 million. The three edits are related to timely submission, Annual Exam Date, and a 30-day limit for providing services. The expectation was also set that FPW services unreimbursed by NCTracks after lifting these three edits would be paid out of State funds.

With the denial of these FPW claims, any payment is contingent upon a favorable DMA determination.

Principal Outcome 2: Unpaid Medicaid Claims

While scouring the system for FPW claims, the Task Force identified a huge tranche of unbilled/never billed Medicaid claims. These services, numbering about 1.2 million for the September 2011 through March 2013 period, were never invoiced since the recipients' Medicaid IDs were not provided to NCSLPH by the Local Health Departments (LHDs). The Task Force located Medicaid IDs for 381,906 service lines using the NCTracks 270/ 271 eligibility enquiry process and submitted these claims for the first time to the tune of $7.87 million. These claims were primarily denied by the timeliness edit.

Unlike with the FPW claims, there was no agreement with the prior DMA CFO that these would be paid but only that DMA would evaluate the issue once the total claim amount was ascertained. If the NCTracks timely edit is lifted for these Medicaid claims, a payment in the region of $1.6 million is expected.

Principal Outcome 3: Never Billed Medicaid Claims

Not all of the 1.2 million service lines referenced in the earlier section were invoiced. About 800,000 service lines were never invoiced since the Medicaid IDs could not be located. Since invoicing 381,906 service lines resulted in billing for $7.87 million, an extrapolation suggests about $15 million of (primarily) Medicaid services can never be invoiced.

Apart from the principal outcomes noted above, the Task Force's effort resulted in some ancillary outcomes that are listed below.

Ancillary Outcome 1: Eligibility Enquiry

Identification of recipients is necessary before NCTracks can be invoiced for services rendered to the Local Health Departments (LHDs). The State Lab (NCSLPH) relied on a rudimentary screen scraping process to identify recipients. Non-identification of recipients led to revenue loss. The Task Force revised the NCSLPH's billing process to use the more reliable 270/ 271 eligibility enquiry mechanism.

The above measure resulted in the number of identified recipients increasing from 15% to 33% leading to more claims being submitted to NCTracks. The availability of the 270/ 271 process also helps with billing of services for New Born Screening.

Ancillary Outcome 2: Annual Exam Date

Family Planning Waiver (FPW) services require submission of an Annual Exam Date (AED) when a claim is submitted to NCTracks. The absence of AED is one of the major reasons for FPW claims being denied. The Task Force communicated with the LHDs and monitored the NCSLPH system (StarLIMS) to improve the AED collection rate to 47% as of April 2014.

Ancillary Outcome 3: Date of Service

FPW claims require the date of service to be within 30 days of the AED. The Task Force analyzed the impact of switching the date of service from "date of reporting" to "date of collection" and determined that the gain was negligible based on a sampling of some FPW rebills. The FPW rebills from this effort thus used the date of reporting as the date of service. This also enabled NCTracks to correctly detect duplicate claim submissions.

Ancillary Outcome 4: Taxonomy End Date

Upon submission of NCSLPH rebills, it was discovered that all labs were having claims denied due to a legacy to NCTracks data conversion issue wherein the taxonomy for labs was end dated as of 6/30/13. This issue was resolved by NCTracks based on a DMA memo.

Ancillary Outcome 5: Data Elements Uncertainty

FPW claims require the modifier "FP" and procedure code "V25.09" for claims to be paid by NCTracks. However, regarding other data elements, there was no definitive and reliable information on the correct values required by HIS vs. NCTracks. HIS is the claims billing system maintained by DIRM. NCSLPH will have to continue to work with HIS and NCTracks to refine the data elements and values needed for specific business scenarios until a comprehensive and reliable understanding is obtained.

A suggested process improvement was for NCSLPH to bypass HIS and to submit 837 claims direct to NCTracks. This suggestion was not pursued owing to the potential complexity of the switch and necessary discussions and approvals.

Ancillary Outcome 6: Decreased HIS Rejection Rate

NCSLPH sends claims data to HIS, operated by DIRM, and which in turn sends 837 claims to NCTracks. In a typical batch file transmission to HIS, about 10% of the records are rejected. By the time the Task Force's effort concluded, this rejection rate was brought down to less than 1% on average.

Ancillary Outcome 7: Delayed SPA

The delay in switching from the Family Planning Waiver (FPW) to State Plan Amendment is causing additional financial hardship because of non-reimbursement for HIV lab services (CPT code 87389), which if added to the current FPW would yield over $21,500 per month. The SPA was originally scheduled for a May 2014 implementation and is likely delayed by about six months.

Ancillary Outcome 8: Contacting LHDs

The Task Force had discussed the option of contacting LHDs to garner AEDs to submit FPW claims. This approach was negated early 2014.

Ancillary Outcome 9: Online Service Request Form

One tool to ensure collection of AEDs is to deploy an online service request form to the LHDs (and move away from the current paper-based process). While this would improve collection of AEDs, it would not alleviate other problems (30-day limit, non-submission of Medicaid IDs, and lack of insurance coverage).

Ancillary Outcome 10: Temporary Exemption Request

NCSLPH had filed a request with DMA in January 2014 seeking exemption from policies leading to FPW claims being denied. This request was discussed but not approved.

Ancillary Outcome 11: Financial Stability Request

NCSLPH filed a business case for financial stability in February 2014 with DMA. The document and ensuing discussions highlighted some of the problems faced by NCSLPH and made certain recommendations. These recommendations are reproduced below.

1. The relevant North Carolina State Plan Amendment (SPA), a successor to the "Be Smart Family Planning Waiver" program, must be revised immediately
    a. to exempt NCSLPH claims from the following:
        i. Annual Exam Date (AED)
        ii. Date of Laboratory Service within 30 days of AED
        iii. Approved CPT codes can only be ordered once every 365 days from AED
    b. If the AED must be a required field, then the SPA must allow the NCSLPH to use the Date of Collection as the AED when the patient has an MAFDN (FPW) benefit plan.
2. NCSLPH must be reimbursed for any test ordered from the allowable list of Family Planning CPT codes. The accountability to assess medical necessity of care options and the patient's health insurance benefit plans should rest solely with the healthcare provider that renders direct patient care and not with NCSLPH.
3. The HIS requirements to include data not required to conduct regulatory-compliant laboratory testing nor required for claims processing should be lifted for claims submitted by NCSLPH.
4. NCSLPH must be reimbursed from State dollars for all bonafide services provided but not paid by Medicaid.
5. Legislative and/ or monetary mechanisms must be instituted to enforce compliance by healthcare providers with policies and processes impacting the financial stability of NCSLPH.

Appendix 2. National Newborn Screening (NBS) Fees Report (Published by NewSteps)

NBS Fees Report

State/NBS Program	Initial Screen Fee	Repeat Screen Fee	Second Screen Fee	Fee Notes
Alabama	$150.00	Not Provided	Not Provided	
Alaska	$159.50	Included in the initial fee	$0.00	The fee is for 2 complete screens and 3 screens for NICU. Single use cards are $100.
Arizona	$30.00	Not Provided	$65.00	
Arkansas	$121.00	$121.00	Not Provided	Fee is charged for each satisfactory specimen submitted for testing (initial and repeat).
California	$129.25	Included in the initial fee	Not Provided	All of the areas in the Fee Use Details marked "unknown" are covered by the NBS fee, but the percentages are not disclosed.
Colorado	$92.00	Included in the initial fee	$0.00	
Connecticut	$98.00	Included in the initial fee	Not Provided	not applicable since money collected goes into general funds

State/NBS Program	Initial Screen Fee	Repeat Screen Fee	Second Screen Fee	Fee Notes
Delaware	$135.00	Included in the initial fee	Not Provided	
District of Columbia	$0.00	Included in the initial fee	Not Provided	
Florida	$0.00	$0.00	Not Provided	In addition to the hospital fees Florida bills Medicaid and private insurance for screening tests. Hospitals are billed $15 per live birth--not for screening specimens.
Georgia	$63.00	Included in the initial fee	Not Provided	GA NBS program does not charge for two repeats when babies are admitted to a NICU. There is no charge for second screens when there is an out-of-range result on the initial screen. There is also no charge to the PCP for second screens when the initial screen from the hospital is Unsatisfactory.
Guam	$0.00	Not Provided	Not Provided	Public Health is not involved with setting fees or collecting them. The hospitals deal with billing and paying for screening.
Hawaii	$55.00	Included in the initial fee	Not Provided	
Idaho	$51.00	$49.00	Not Provided	

State/NBS Program	Initial Screen Fee	Repeat Screen Fee	Second Screen Fee	Fee Notes
Illinois	$118.00	$118.00	Not Provided	
Indiana	$90.00	Included in the initial fee	Not Provided	ISDH contracts with the IU NBS Lab. $60 of each $90 NBS fee stays with the lab, so in addition to lab tests, part of this $60 pays for part of the initial short-term follow-up as well as the courier service and other costs the lab incurs (ie IT support, administration, etc). $30 of each $90 NBS goes to ISDH for follow-up services, LTFU, IT support, and short-term follow-up of CCHD.
Iowa	$122.00	Included in the initial fee	Not Provided	
Kansas	$0.00	Not Provided	Not Provided	
Kentucky	$99.00	Included in the initial fee	Not Provided	
Louisiana	$30.00	Not Provided	Not Provided	
Maine	$110.00	Included in the initial fee	Not Provided	

State/NBS Program	Initial Screen Fee	Repeat Screen Fee	Second Screen Fee	Fee Notes
Maryland	$106.00	Included in the initial fee	Not Provided	Fee is per baby regardless of the number of specimens received
Massachusetts	$98.45	Included in the initial fee	Not Provided	
Michigan	$125.16	$117.11	Not Provided	EHDI Fee from purchase of NBS card + CDC/HRSA
Minnesota	$150.00	$150.00	Not Provided	$10 goes to MN Hands & Voices and $5 goes to the Deaf Mentor/Adult Role Model program – we don't see this at all in the program. This $15 was tacked on to our fee not by us, but by the Deaf and Hard of Hearing Commission.
Mississippi	$110.00	$110.00	Not Provided	Birthing facilities are billed $100 per screen. If there is poor specimen collection yielding an unacceptable specimen to use, birthing facilities are billed $200.
Missouri	$85.00	$85.00	Not Provided	
Montana	$112.25	$112.25	Not Provided	Only one screen required for most infants.

State/NBS Program	Initial Screen Fee	Repeat Screen Fee	Second Screen Fee	Fee Notes
Nebraska	$45.50	Included in the initial fee	Not Provided	$35.50 of fee covers all initial testing and requested repeats, filter paper, shipping, data management and results reporting. $10 of fee is returned to the State Program to subsidize the metabolic foods and formula program.
Nevada	$81.00	Included in the initial fee	Not Provided	
New Hampshire	$71.00	$71.00	Not Provided	
New Jersey	$150.00	Included in the initial fee	Not Provided	
New Mexico	$138.00	Included in the initial fee	Not Provided	Initial fee includes the second screen as well as a third NICU screen in applicable
New York	$0.00	Not Provided	Not Provided	Because NYS does not charge a fee, the "fee use details" are not applicable.
North Carolina	$44.00	Included in the initial fee	Not Provided	

State/NBS Program	Initial Screen Fee	Repeat Screen Fee	Second Screen Fee	Fee Notes
North Dakota	$75.00	Included in the initial fee	Not Provided	
Ohio	$74.61	$74.61	Not Provided	
Oklahoma	$137.28	Not Provided	Not Provided	
Oregon	$64.00	Included in the initial fee	$0.00	
Pennsylvania	$0.00	Included in the initial fee	Not Provided	
Puerto Rico	$78.00	Included in the initial fee	Not Provided	
Rhode Island	$162.98	Not Provided	Not Provided	The initial fee includes dried blood spot, hearing and developmental assessment screening.
South Carolina	$127.00	Included in the initial fee	Not Provided	

State/NBS Program	Initial Screen Fee	Repeat Screen Fee	Second Screen Fee	Fee Notes
South Dakota	$75.00	Included in the initial fee	Not Provided	
Tennessee	$145.00	Included in the initial fee	Not Provided	Fees charged for screening support the lab and follow-up activities. Fee is split 2/3rd (lab) and 1/3 (follow-up). Fees support IT, LIMS, Courier, EHDI, and Administration as well. Data on amount spent on these activities are unknown however are covered under the fee.
Texas	$55.24	$55.24	$55.24	
Utah	$112.16	Included in the initial fee	$0.00	
Vermont	$125.00	Included in the initial fee	Not Provided	Current fee ($125) implemented 10/01/16
Virginia	$78.00	Included in the initial fee	Not Provided	
Washington	$76.10	Included in the initial fee	$0.00	Clinic subsidy fee = $8.40 used to support the specialty clinics that provide medical care to babies identified with a newborn screening condition.

State/NBS Program	Initial Screen Fee	Repeat Screen Fee	Second Screen Fee	Fee Notes
West Virginia	$91.37	Not Provided	Not Provided	Initial fee includes a repeat screen fee when applicable.
Wisconsin	$109.00	Not Provided	Not Provided	
Wyoming	$77.00	Included in the initial fee	Not Provided	