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February 8, 2024

MEMORANDUM

TO: The Honorable L. Louise Lucas
Chair, Senate Finance & Appropriations Committee

The Honorable Ghazala F. Hashmi
Chair, Senate Education and Health Committee

The Honorable Luke E. Torian
Chair, House Appropriations Committee

The Honorable Mark D. Sickles
Chair, House Health, Welfare and Institutions Committee

FROM: Karen Shelton, MD
State Health Commissioner, Virginia Department of Health

Joseph Damico
Director, Department of General Services

SUBJECT: Evaluation of the Virginia Newborn Screening Program Funding Model

This report is submitted in compliance with the 2023 Virginia Acts of the Assembly – Chapter 386, which states:

> *That the Department of Health and the Department of General Services shall convene a work group to evaluate the current funding model for the Commonwealth's newborn screening program… The Department of Health and the Department of General Services shall report their findings and recommendations to the Chairmen of the House Committees on Appropriations and Health, Welfare and Institutions and the Chairmen of the Senate Committees on Education and Health and Finance and Appropriations by December 1, 2023.*

Should you have any questions or need additional information, please feel free to contact me at (804) 864-7002.

KS/AJ
Enclosure

Pc: The Honorable John Littel, Secretary of Health and Human Resources

EVALUATION OF THE VIRGINIA NEWBORN SCREENING PROGRAM FUNDING MODEL

REPORT TO VIRGINIA GENERAL ASSEMBLY

2023

VIRGINIA DEPARTMENT OF HEALTH
DEPARTMENT OF GENERAL SERVICES

PREFACE

During the 2023 Virginia General Assembly Session, Delegate Kathleen Murphy introduced HB2224 to amend and reenact §§ **2.2-1104** and **32.1-65** of the Code of Virginia, relating to newborn screening tests; Division of Consolidated Laboratory Services; fees prohibited. The bill, promulgated as Chapter 386 of the 2023 Virginia Acts of the Assembly, directs the Department of Health (VDH) and the Department of General Services (DGS) to convene a work group to evaluate the current funding model for Virginia's Newborn Screening Program. The bill directs the departments to report their findings and recommendations to the General Assembly by December 1, 2023.

WORKGROUP MEMBERS

Department of General Services/Division of Consolidated Laboratory Services
Denise M, Toney, Ph.D. (HCLD), Director, Division of Consolidated Laboratory Services
Newborn Bloodspot Screening Advisory Committee
William Wilson, M.D., Chair
Parent Advocate
Julie Murphy
Virginia Chapter of the American Academy of Pediatrics
Nayef Chahin, M.D., Neonatologist Representative
Virginia Department of Health
Vanessa Walker Harris, M.D., Director, Office of Family Health Services
Virginia Department of Medical Assistance Services
Lisa Stevens, Payor
Virginia Hospital and Healthcare Association
Abraham Segres, Vice President of Quality and Patient Safety
Virginia Midwife Alliance
Chrissy Owen, CPM, President
Virginia Rare Disease Council
Jana Monaco, Vice Chair

WORKGROUP SUPPORT STAFF

Department of General Services (DGS)/Division of Consolidated Laboratory Services (DCLS)
Emily Hopkins, MS, Director Laboratory Operations, DGS/DCLS
Leigh Emma Lion, MS, NBS Group Manager, DGS/DCLS
Paul Hetterich, MS, NBS Group Manager, DGS/DCLS
Keith Kellam, NBS Informatics Senior Scientist, DGS/DCLS
Jessica Hendrickson, Policy Analyst, Department of General Services (DGS)

Virginia Department of Health (VDH)
Christen Crews, MSN, RN, NBS and Birth Defects Surveillance Programs Manager
Jennifer Macdonald, MPH, BSN, RN, Division Director, Child and Family Health
Mary Lowe, BSN, RN, Newborn Bloodspot Screening Program Nurse Supervisor
Parker Parks, MPH, Newborn Screening Epidemiologist
Rebecca Edelstein, MSW, Policy Analyst

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EXECUTIVE SUMMARY

During the 2023 Virginia General Assembly Session, Delegate Kathleen Murphy introduced HB2224 to amend and reenact §§ 2.2-1104 and 32.1-65 of the Code of Virginia, relating to newborn screening tests; Division of Consolidated Laboratory Services; fees prohibited. The bill, promulgated as Chapter 386 of the 2023 Virginia Acts of Assembly, directed the Department of Health (VDH) and the Department of General Services (DGS) to convene a workgroup (the Workgroup) to evaluate the current funding model for Virginia's Newborn Screening Program (NBS Program). The bill directed the departments to report their findings and recommendations to the General Assembly by December 1, 2023.

An expert workgroup of stakeholders met from July to September 2023 to review the current funding model for newborn screenings, hear presentations from other state newborn screening programs on alternative funding models, and allow for public comment and input from the workgroup members. The findings of the Workgroup's evaluation of newborn screening program funding models are listed below.

FINDINGS

The priority of the Workgroup was to ensure that cost was not a barrier for newborn screening and that all babies born in the Commonwealth of Virginia receive a newborn screening test. The Workgroup issued a stakeholder survey on the current NBS funding model, evaluated seven different potential funding models, and concluded that:

1. There is currently a lack of consensus on reimbursement for newborn screenings and wide variations in reimbursement amount across providers. The Workgroup identified areas of opportunity for training and technical assistance regarding proper newborn screening collection and billing.

2. All of the NBS Program funding models that the Workgroup assessed have their own unique advantages and disadvantages, and the best model for Virginia will depend on the priorities of the General Assembly. As a result, the Workgroup does not recommend a specific newborn screening program funding model. The Workgroup has included their analysis of each model in this report.

INTRODUCTION

WORKGROUP MANDATE

Chapter 386 of the 2023 Acts of Assembly mandated that the Department of Health and Department of General Services establish the Virginia Newborn Screening Funding Model Workgroup (Workgroup) (Appendix A). Chapter 386 required the Workgroup to evaluate the current fee-for-service funding model for the Commonwealth's Newborn Screening Program (NBS), survey and evaluate alternative funding models (including those used by other states), and prepare alternative funding models to the current funding model for the General Assembly. The Workgroup was tasked to report its findings and recommendations to the General Assembly by December 1, 2023.

WORKGROUP ACTIVITIES

The Department of Health (VDH) and the Department of General Services Division of Consolidated Laboratory Services (DCLS) NBS program staff collaborated on convening the Workgroup to include expert stakeholders as members, relevant presentations, survey dissemination, data analysis, and moderation of Workgroup discussion. A series of three Workgroup meetings were held monthly from July to September 2023 with meetings open to the public and minutes posted for the public on Virginia's Regulatory Town Hall (Appendix D).

JULY 24, 2023, IN-PERSON MEETING

The initial meeting of the Workgroup was held in-person on July 24, 2023, with Dr. Vanessa Walker Harris (VDH) and Dr. Denise Toney (DCLS) presiding as Co-Chairs of the Workgroup. Christen Crews, NBS and Birth Defects Surveillance Programs Manager (VDH), provided a presentation on HB2224 and the resulting Chapter 386 of the 2023 Acts of Assembly, Virginia's Newborn Screening Program, the current regulations governing the NBS program, details on NBS operations, the current funding model, and the funding history of Virginia's NBS program. Additionally, the group reviewed the proposed timeline for the Workgroup deliverables and final report. Emily Hopkins, Director of Laboratory Operations (DCLS), provided the Workgroup with a data review, including an overview of other newborn screening program funding models, fee comparisons, and 2021 birth data in Virginia (**Error! Reference source not found.**).

The Workgroup identified key areas to consider when evaluating alternative funding models including fiscal impact to stakeholders and families; necessary data to make informed decisions supporting potential fee model changes; potential effects on timeliness of reporting NBS results; Virginia's ability to implement new disorders or new technologies; and impacts on staff recruitment or retention. It was noted that the Health Resources and Services Administration's Title V Maternal and Child Health (MCH) Block Grant covers some operational costs of Virginia's Early Hearing Detection and Intervention Program (VA EHDI) and Critical Congenital Heart Disease (CCHD) Newborn Screening Program, but does not cover dried-blood spot screening. Representatives from Kansas and New York NBS programs presented their respective programs and funding structures. The Workgroup adjourned with action items including assimilating more information on how insurance is billed for newborn screening reimbursement and rescheduling with Arizona NBS Program for their funding model presentation.

AUGUST 16, 2023, VIRTUAL MEETING

The Workgroup discussed concerns with the current NBS Program Funding Model and several members voiced issues with the model relevant to their constituencies (including hospitals, out of hospital birth providers (OOH), parents of children diagnosed through newborn screening, and clinical providers). Detailed discussions occurred about the current funding model of Virginia's NBS program, how fees are determined, the entities involved in the review and approval of fee changes, the scope of testing and support services covered by the fee, the allowance for stakeholder input, and examples of alternative funding sources investigated by Virginia's Program. As a result of these discussions, members identified new funding model considerations.

The group discussed different data sources on NBS reimbursement, including the Virginia Health Information's (VHI) All-Payer Claims Database (APCD) and the dissemination of a Workgroup survey to stakeholders around the Commonwealth as a potential source of information about NBS-related claims made by Virginians using commercial, Medicaid, and Medicare coverage. Prior to this meeting, eight of nine Workgroup members had reviewed and approved a draft version of the stakeholder survey, entitled the NBS Reimbursement Stakeholder Survey (Appendix F). The Workgroup discussed action items, including that the survey would be finalized and disseminated to stakeholders (including hospitals, out-of-hospital birth providers, and pediatricians) after the meeting, allowing for at least 2 weeks for participation. The group elected that they would review the stakeholder survey responses at the next meeting and would also summarize the survey responses in their final report to the General Assembly.

SEPTEMBER 27, 2023, IN-PERSON MEETING

During the final Workgroup meeting, Christen Crews, VDH, presented to members a review of the information, data, and discussions from previous Workgroup meetings. Emily Hopkins, DCLS, shared the data analysis of the NBS Reimbursement Stakeholder Survey with the Workgroup members (Appendix G). The Workgroup members discussed the NBS Reimbursement Stakeholder Survey findings, including findings on reimbursement, reasons for providers not collecting the newborn screen, NBS compliance, and targeted education to providers for NBS collection or reimbursement. Workgroup members expressed that there will always be a challenge around submitting claims, particularly for providers who may not trust that they will be reimbursed either partially or completely for screenings.

The group discussed several visualizations of the different potential NBS program funding models (Appendix H), including benefits, barriers, and limitations of each model. Dr. Denise Toney, Co-Chair, reminded the Workgroup that the newborn screening collection fee covers more than just the actual testing of the dried blood spot card. It also covers NBS staff (VDH and DCLS) salaries; courier services; NBS information technology (IT) support; secondary screening and genetic variant testing and interpretation for selected disorders; advancements in technology; education; contracts with specialists; and other NBS programmatic activities. The group discussed how their priority is to ensure that cost is not a barrier for NBS and that all babies born in the Commonwealth of Virginia receive a newborn screen. The Workgroup voted to share the findings of all funding models discussed without a formal recommendation to inform legislators of potential options.

REPORT OUTLINE

The remainder of the report includes content to inform newborn screening funding in Virginia. It provides an overview of the importance of newborn screening to public health, national oversight of newborn screening disorders, a history of newborn screening in Virginia, and current programmatic operations and funding of the Virginia Newborn Screening Programs (VNSP). The report concludes with potential newborn screening program funding models, including priorities, advantages, and disadvantages, as well as other Workgroup findings.

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EVALUATION OF VIRGINIA'S NEWBORN SCREENING PROGRAM FUNDING MODEL

Newborn Screening Background

The goal of newborn screening is to detect potentially fatal or disabling conditions in newborns as early as possible to allow for prompt medical evaluation and treatment to reduce or eliminate negative health consequences. The Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) is charged with advising the U.S. Department of Health and Human Service's Secretary on topics relating to reducing or preventing morbidity and mortality in newborns who are at risk. They do so by evaluating and recommending metabolic and genetic disorders most appropriate for population based universal newborn screening. The ACHDNC identifies a standardized list of core disorders and makes recommendations for states to adopt screening as part of their state universal NBS Program by reviewing criteria and current research evidence.

Disorders on the Recommended Uniform Screening Panel (RUSP) are selected based on an evaluation of the potential benefits of the screening, the ability of states to perform the laboratory testing, the ability of states to perform the screening, and the availability of treatments. An expert review is completed by a disorder specific workgroup and reported to the ACHDNC, including clinical presentation, treatment outcomes, technologies, policies, guidelines, and standards. If the ACHDNC recommends adding a disorder, the ACHDNC sends information to the Secretary of Health and Human Services for consideration. As of October 2023, the RUSP includes 37 primary or core conditions. Additional disorders are currently undergoing evidence review for consideration of addition to the RUSP.

Virginia's Newborn Screening Programs (VNSP)

Virginia's Newborn Screening Programs (VNSP) include the Virginia Newborn Bloodspot Screening Program (VNBSP), Virginia Early Hearing Detection and Intervention Program (VA EHDI), and the Virginia Critical Congenital Heart Disease (CCHD) Newborn Screening Program. The VNBSP operates as a partnership between the Department of General Services' Division of Consolidated Laboratory Services (DCLS) and the Virginia Department of Health (VDH) to screen each baby born in Virginia for certain rare and potentially life-threatening metabolic and genetic disorders through dried bloodspot testing (NBS-DBS). DCLS provides the oversight for sample collection, transport, testing and reporting of newborn screening results to providers and VDH VNBSP. VDH VNBSP provides program oversight, notifies healthcare providers of results needing immediate intervention, and provides case management including diagnostic testing, education, and referral for care coordination. DCLS also provides testing for the VA EHDI's Hearing Targeted Cytomegalovirus Screening Program (CMV), whereas VDH provides program oversight, patient follow-up, and case management.

Newborn screening in Virginia, first mandated in 1966, is required by the Code of Virginia (§ 32.1-65) which states:

> *"In order to prevent intellectual disability and permanent disability or death, every infant who is born in the Commonwealth shall be subjected to screening tests for various disorders consistent with, but not necessarily identical to, the uniform condition panel recommended by the U.S. Secretary of Health and Human Services and the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children. Any infant whose parent*

> *or guardian objects thereto on the grounds that such tests conflict with his religious practices or tenets shall not be required to receive such screening tests. The physician or certified nurse midwife in charge of the infant's care after delivery shall cause such tests to be performed. The screening tests shall be performed by the Division of Consolidated Laboratory Services or any other laboratory the Department of Health has contracted with to provide such service. Screening tests for time-critical disorders identified by the U.S. Department of Health and Human Services and the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children shall be performed seven days a week."*

In the maternal and infant health field, newborn screening programs are regarded as one of the largest and most successful public health programs by screening newborns for timely intervention of certain diseases and medical conditions. The critical keys to the success of NBS Programs include the rapid laboratory screening of potential indicators for disorders, prompt medical follow-up, and effective early diagnosis and treatment. The ability of the VNBSP to evaluate the inclusion of new disorders on the RUSP enables Virginia to expand the core newborn screening panel to improve health outcomes and reduce infant mortality. Conditions identified by NBS require prompt medical attention to prevent negative long-term outcomes, including disability or even death. Since Virginia's inception of NBS in 1966, many new testing technologies have been incorporated into the program; testing turnaround times have been reduced from days to hours; the number of NBS-DBS disorders tested for in Virginia has increased from a single disorder to thirty-three (33) core disorders; and targeted screening for congenital cytomegalovirus with hearing loss was implemented in 2020 (Appendix C).

The VNSP VA EHDI and CCHD programs are mainly funded from federal grants. The legislative mandate for this report is related to the fiscal impact of the Fee-for-Service (FFS) NBS Program Funding Model that currently funds all operations of the VNSP that include DCLS NBS laboratory testing and VDH (see Figure 1 depicting the NBS programs and their funding streams). The VNSP VNBSP and CMV programs are currently funded by charging a fee to hospitals, healthcare entities, and midwives for the purchase of dried blood spot collection devices. The 1976 National Genetics Services Act assisted with the development of genetic services in Virginia, and in 1981, Congress incorporated the genetic services originally covered under that act into the newly established Title V Block Grant Program. The Title V block grant program funds a variety of comprehensive maternal, infant, child, and adolescent health programs within the VDH Division of Child and Family Health (DCFH). The block grant did provide some support for VDH VNBSP follow-up services through 2002; however, budget constraints required reallocation of funds. From 1966 to 1992, the VNBSP was financially supported as a general funded program with funding provided by the Virginia General Assembly. An Enterprise or FFS funding model was established in 1992 to fund NBS activities in Virginia. Revenue from the sale of the NBS-DBS collection devices provides funding for the majority of Virginia's VNBSP activities and a variety of other program specific services that include but are not limited to the following activities:

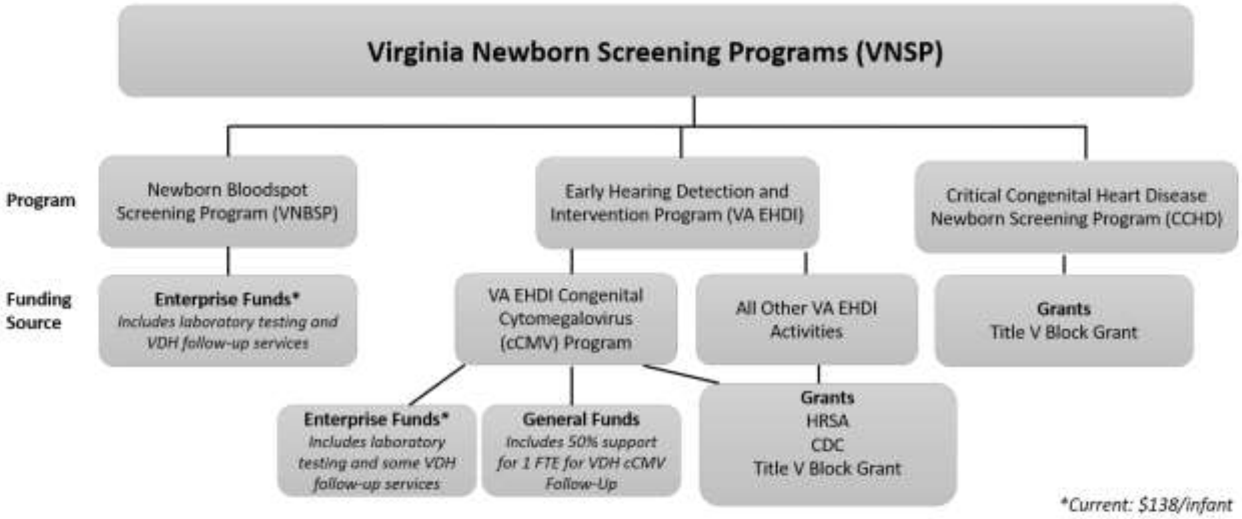
- laboratory screening (DCLS) and specialized NBS nurses (VDH) providing notification, follow-up, and consultation services for 33 different core metabolic and genetic NBS-DBS disorders and variant interpretations;
- program operations seven days per week ,365 days per year to ensure timely reporting and follow-up of abnormal and critical results;
- operation of a contracted courier service to pick up samples from hospitals and birthing centers throughout the state seven days a week;

- provision of complimentary (no cost) pre-paid commercial shipping labels to out of hospital and midwife providers;
- contracts with four regional pediatric genetic centers to provide 24/7 consultation for NBS-DBS results or related clinical questions;
- secondary testing for congenital adrenal hyperplasia (CAH) to reduce the number of false positive screens;
- secondary genetic sequencing and variant characterization for two lysosomal storage disorders (Pompe Disease and Mucopolysaccharidosis Type 1 (MPS-1);
- secondary genetic sequencing for cystic fibrosis transmembrane reductance regulator (CFTR) for elevated immunoreactive trypsinogen (IRT) identified on screening to reduce the number of false positive screens;
- complimentary (no-cost) collection device cards for newborns requiring repeat testing to resolve indeterminants and/or insufficient sample submissions;
- development of educational resources for parents and providers;
- development and access to a NBS portal to allow for real-time access to newborn screening results by healthcare providers including pediatricians, nurse practitioners, and midwives;
- provision of complimentary (no-cost) collection device cards as requested by local health departments;
- funding support for the Metabolic Formula Distribution and Purchase plan for those affected by metabolic disorders;
- laboratory testing for congenital cytomegalovirus (CMV) for infants who fail their initial hearing screen before hospital discharge; and
- follow-up services for CMV including ensuring diagnostic testing, education, and referral coordination.

DCLS receives about 103,000 NBS-DBS samples and performs more than 4 million newborn screening tests each year. The VNBSP operates seven days a week, including holidays, as mandated in 2019 by Chapter 531 of the 2018 Virginia Acts of Assembly. DCLS screens for all time-sensitive NBS-DBS disorders daily, to ensure timely reporting and medical intervention. A statewide courier service picks up the NBS-DBS and CMV samples from hospitals to ensure the timely and safe arrival of samples to the laboratory. The VDH VNBSP and CMV Follow-Up staff follow-up on abnormal test results for more than 20,000 infants each year, ensuring that babies with abnormal test results receive appropriate follow-up and are referred to appropriate specialty care. DCLS can perform repeat tests on infants up to 6 months of age.

In the current Virginia FFS model, hospitals, midwives, and other medical care providers purchase NBS-DBS collection devices from DCLS in advance (i.e., prior to birth) to be available for use as needed. Hospitals purchase the kits in bundles of 10 collection device cards. Midwives and other medical care providers, who experience lower birth rates, have the option to purchase the collection device cards individually. The current NBS fee cost is $138, though this fee can change over time based on addition of new disorders or expansion of services. The fee for the newborn screening collection device cards is determined by a cost analysis performed when a disorder is being reviewed by the Virginia Newborn Screening Advisory Committee (NBS AC) or legislatively mandated for consideration to be added to Virginia's core disorder newborn screening panel. The cost analysis could include, but is not limited to, the costs associated with the addition of the disorder(s) to the core newborn screen: test evaluation and validation, laboratory equipment, test reagents and supplies, personnel (DCLS laboratory and VDH Follow-Up), technical modifications to the laboratory information management system and NBS portal, reporting, training, and education. The annual programmatic operating cost, birth rate, and start-up costs for new disorders/technologies are reviewed and shared with stakeholders and the Governor's office to be approved by the Department of Planning and Budget. Stakeholders have an opportunity to provide input regarding the fee increase when the program is evaluating the addition of new disorders through the NBS AC or Virginia's Regulatory Town Hall. DCLS and VDH are held to the review of all proposed fee changes by the Department of Planning and Budget and must provide detailed justifications for any fee changes with the requirement to ensure fiscal solvency without profit. All reserve funding or additional cash on hand is held in the NBS Enterprise fund account to be used for only Program expenses or to offset startup costs when new disorders are being proposed to be added to the screening panel. The Program has requested state general funds in the past for new disorders or legislative mandates to add new disorders, however requests have been denied due to an alternative funding model in place for supporting program operations. The Program does seek grant opportunities to fund or offset costs associated with the implementation of new disorders or advancements in technology.

Figure 1
Virginia Newborn Screening Programs Funding Structure



Virginia's Administrative Code 12VAC-71-100 further defines the responsibilities of the newborn dried blood spot testing laboratory [DCLS] stating:

> *"F. The testing laboratory [DCLS] shall manage the distribution of newborn dried-blood-spot screening specimen collection kits.*
> *G. The testing laboratory [DCLS] is authorized to set the fee charged to birthing hospitals and physicians for purchase of newborn dried-blood-spot screening specimen collection kits in consultation with the department and in accordance with applicable state statutes and regulations."*

FINDINGS

The priority of the Workgroup was to ensure that cost was not a barrier for newborn screening and that all babies born in the Commonwealth of Virginia receive a newborn screen. As tasked by the legislative mandate, the Workgroup surveyed stakeholders, evaluated other state NBS program funding models, and discussed various potential NBS program funding models for Virginia. The Workgroup's findings are as follows:

1. The Workgroup Survey findings demonstrated a lack of consensus on reimbursement for newborn screening, wide variations in reimbursement amount across providers, and identified areas of opportunity for training and technical assistance to providers regarding proper newborn screening collection and billing.

2. The Workgroup evaluated and discussed various newborn screening program funding models. The Workgroup concluded that all of the NBS Program Funding models that the Workgroup assessed have their own unique advantages and disadvantages, and the best model for Virginia will depend on the priorities of the General Assembly. Although the Workgroup did not recommend a specific NBS Program Funding Model, it concluded that the two most promising funding models for specifically ensuring that cost is not a barrier for newborn screening and that all babies born in the Commonwealth of Virginia can equitably receive a newborn screen without the variable of birth location are the Pool of Funds (POF) and the Insurance Fund. A description of each model and the Workgroup's analysis of each model's advantages, disadvantages, and priorities are as follows:

A. Fee-for-Service (FFS) Model

The majority of state newborn screening programs in the United States use a FFS funding model. In this model, the NBS program charges a fee to the hospital, healthcare provider and/or midwife for the costs associated with Newborn Screening. The costs range from $81.00 to $235.00 depending on the number of disorders included in the NBS screen, and whether other programmatic services (i.e., courier, secondary testing, variant analysis) are included in the fee. Across NBS programs, there is no standardized requirement for what services programs include in the established fee or how programs collect the fee from providers. Some programs require the providers to pay to receive the NBS collection kit, while other programs will bill the submitters monthly for the number of NBS received to be tested. Additionally, some NBS programs charge for a repeat NBS test or secondary/variant testing; Virginia does not charge any additional fee for repeat screens or additional testing.

The level of reimbursement providers receive for NBS varies from entity to entity based on a number of factors including, but not limited to, birth provider type (hospital or out of hospital birth), availability of health care or other insurance plans, billing process (global billing or service), and the provider's negotiated reimbursement rate with individual insurance providers. Furthermore, entities that bill insurance do not always receive full reimbursement for the costs of newborn screening and must absorb the remaining costs as "unrecovered debt." Providers with smaller practices may not be willing to collect the initial newborn screen due to concerns of not receiving reimbursement and having to absorb the remaining costs. In this model, there is also the potential for the NBS costs to be passed on to the family. This can also occur for births at an out-of-network facility, an out-of-network provider (most OOH providers or midwives), self-pay, uninsured, or if insurance deductibles have not been met. As such, some families may be reluctant to agree to having newborn screening performed on their newborns due to the cost.

In discussing this model, the Workgroup finds the following advantages and disadvantages of the FFS model:

- Advantages of FFS model:
    - No impact to the state budget.
    - Program is able to adjust NBS fee to meet budgetary requirements and implementation timelines for the addition of new disorders and advances in NBS operations.
    - The ability to combine the costs associated with support services (ie. Courier) into one fee instead of billing separately.
    - The ability to carry-over cash on hand at the end of the fiscal year to offset start-up costs associated with validation and implementation of new disorders.
- Disadvantages of FFS model:
    - Potential for NBS costs to be passed to the family.
    - Risk of lack of compliance for NBS due to fiscal impact for families and providers.
    - Hospitals typically include NBS fee in global billing for birth and their budget is negatively impacted by NBS fee increases or low reimbursement.
    - Some OOH providers will require the families to file for insurance reimbursement.

B. **Insurance Fund Model**

A few states have incorporated the use of an Insurance Fund Model, whereby insurance companies operating within the state financially contribute a specified amount of funding into a state fund based on the number of subscribers from the previous year. This allotment is then appropriated to the specified programs, and unspent funds at the end of the fiscal year revert to the state fund. NBS is provided at no cost to providers and families, even if the infant is uninsured or self-pay. There would be no potential cost to the family in this model. The current program operating expenses (~$14 million annually) can be used as baseline for projected fiscal impact; however, this amount is subject to change. The full fiscal impact of this model is unknown, as potential administrative costs to the program may increase and the costs to insurance companies for implementation and management have not been evaluated by the Workgroup.

In discussing this model, the Workgroup finds the following advantages and disadvantages of the Insurance Fund model:

- Advantages of Insurance Fund model:
    - No potential cost to the family or provider for the NBS.
    - Family or provider does not need to file for reimbursement of NBS.

    - Compliance with NBS not affected by cost.
- Disadvantages of Insurance Fund model:
    - Operating budget of the program is based on allotted amount from state which may not cover all costs.
    - Competing priority areas may limit fund appropriations.
    - No carryover to offset or fund implementation of new disorders or other budgetary adjustments (unspent monies revert to Fund at end of fiscal year).
    - Potential delays in implementing new disorders due to projected funding shortfalls.
    - Other states with this model have shared challenges with a flat budget to include the difficulties in meeting budgetary needs for implementation of new disorders, and the need to pursue supplemental grant funding which is not a sustainable funding source.

C. State General Funds (GF)

This model would rely on the state to appropriate 100% of program operation costs through state general funds. There would be no potential cost to the family in this model. This model would provide equity regardless of income, access to insurance, or selected birthing provider.

In discussing this model, the Workgroup finds the following advantages and disadvantages of the GF model:

- Advantages of GF model:
    - No cost to the family or provider for the NBS.
    - Family or provider does not need to file for reimbursement of NBS.
    - Compliance with NBS not affected by cost.
- Disadvantages of GF model:
    - Significant fiscal impact to state budget for essential program operations (~$14 million annually).
    - Potential delays in implementing new disorder due to state budget cycle and the need to request and receive appropriation and funding increases.
    - Operating budget of the program is based on allotted amount from state which may not cover all costs.
    - Competing priority areas may limit fund appropriations.
    - No carryover for implementation of new disorders or other budgetary adjustments (unspent monies revert to state treasury at end of fiscal year).

D. Pool of Funds (POF) Model: Fee-for-Service and State General Funds

This model would be the combination of the current FFS model with the creation of a “NBS pool of funds” (POF) established by general funds with the goal of reducing/eliminating cost barriers to the NBS. In this model, an estimate of projected costs would need to be calculated and a budget amendment for general fund (GF) appropriations approved. Once the POF is exhausted, then no additional funds would be available until the next fiscal year. The structure of the POF would need to be established with guidelines and logistics for reimbursement. One point to consider would be whether to focus on the OOH births, uninsured, self-pay, or to expand to include families that are not covered completely from insurance. According to VDH Vital Statistics, in 2021, 1,687 infants were identified as having an OOH birth ($232,806 NBS fee) and 13,104 of total births in Virginia had insurance carrier indicated as "Other, Not Reported, or Self Pay" (~$1.8 million NBS fee). The amount needed from GF could change annually or as new disorders were added, and future fee increases could impact the amount needed from appropriations.

In discussing this model, the Workgroup finds the following advantages and disadvantages of the POF model:

- Advantages of POF model:
  - Potentially decreased or no cost to the family or provider for the NBS.
  - Compliance with NBS not affected by cost.
  - Program able to adjust NBS fee to meet budgetary requirements for the addition of new disorders and advances in NBS operations.
- Disadvantages of POF model:
  - Potential for NBS costs to be passed to some families if the POF becomes exhausted for fiscal year, creating inequities for families delivering babies towards the end of the fiscal year.
  - Some providers may not bill insurance to avoid work of reimbursement.
  - Does not address stakeholder concerns regarding fiscal burden of NBS on the hospitals.

E. **Fee-for-Service with Limits on Annual Increase (FFS Cap Max)**

This model would revise the existing FFS Funding Model by imposing a cap on the maximum percentage increase of the NBS fee in a year. This would address the fiscal concerns expressed by hospitals or providers related to NBS fee increases. However, this would not address the fiscal impact to families or midwives and other out of hospital providers. This model would also result in potential implementation delays for new disorders. Since the program could only increase the fee incrementally each year, the program would have to delay adding any new disorders whose cost to screen would exceed the cap that year.

In discussing this model, the Workgroup finds the following advantages and disadvantages of the FFS Cap Max model:

- Advantages of FFS Cap Max model:

    - Hospitals and providers could budget for potential NBS fee increases.
  - Disadvantages of FFS Cap Max model:
    - Does not address stakeholder concerns regarding fiscal burden of NBS on the families, midwives or out of hospital providers.
    - Risk of lack of compliance with NBS due to fiscal impact for families and providers.
    - Potential implementation delays for new disorders to meet budget requirements for operations.

F. **Fee-for-Service with Annual Increase (FFS Annual Increase)**

The existing FFS Funding Model could be revised to improve the ability of hospitals and other insurance-accepting facilities to recover full costs by instituting an annual "flat-rate" fee increase as opposed to aligning the increases to the addition of new disorders or programmatic changes. In this model, the Program would accrue the revenue in a non-reverting fund and this funding would be used by the Program in the future for required expansion or addition of new disorders.

In discussing this model, the Workgroup finds the following advantages and disadvantages of the FFS Annual Increase model:

  - Advantages to FFS Annual Increase model:
    - Hospitals and providers could budget for annual NBS fee increases.
  - Disadvantages to FFS Annual Increase model:
    - Does not address stakeholder concerns regarding fiscal burden of NBS on the families, midwives and out of hospital providers.
    - Risk of lack of compliance with NBS due to fiscal impact for families and providers.
    - Potential delay of implementation of new disorders to acquire funds to meet budget requirements for operations.

G. **Hybrid Model: Fee-for-Service with Partial General Funds**

This funding model would involve "unbundling" the services included in the current FFS model so that the NBS fee would only cover costs needed for testing (collection cards, testing reagents, supplies) to have the minimal cost for birth providers. The additional programmatic costs, such as staffing, equipment, maintenance fees, IT/LIMS modifications, courier services, education, would be covered by General Funds.

In discussing this model, the Workgroup finds the following advantages and disadvantages of the Hybrid model:

  - Advantages of Hybrid model:
    - Reduce fiscal burden of NBS fee on hospital and birth providers.
  - Disadvantages of Hybrid model:

- Potential for significant fiscal impact to state budget as most of the programmatic costs are associated with staffing, equipment, and maintenance fees.
- Difficulty in "unbundling" the NBS fee and dividing funding sources as there is crossover and many components required for NBS operations to occur.
- Does not address stakeholder concerns regarding potential fiscal burden of NBS on the families.
- Risk of lack of compliance with NBS due to fiscal impact for families and providers.
- Potential delay of implementation of new disorders for appropriation of additional General Funds to increase programmatic budget.
- Risk of continuity of operations with staff recruitment and retention.
- Inability to carry-over funding between fiscal years to offset startup costs for implementation of new disorders.

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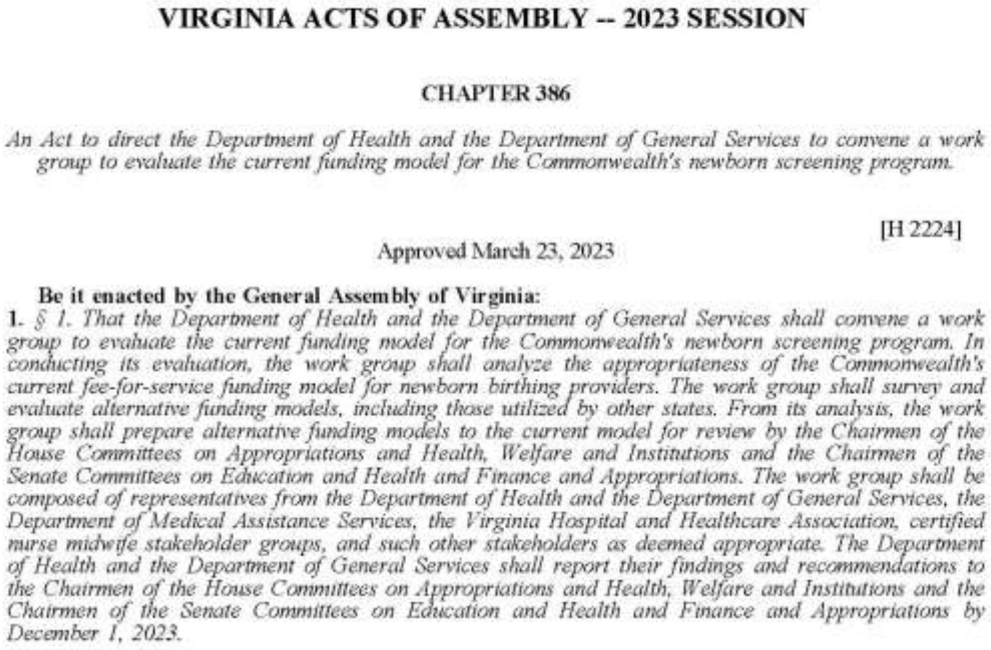
APPENDIX A – CHAPTER 386 OF THE 2023 ACTS OF ASSEMBLY



VIRGINIA ACTS OF ASSEMBLY -- 2023 SESSION

CHAPTER 386

An Act to direct the Department of Health and the Department of General Services to convene a work group to evaluate the current funding model for the Commonwealth's newborn screening program.

[H 2224]

Approved March 23, 2023

Be it enacted by the General Assembly of Virginia:

1. *§ 1. That the Department of Health and the Department of General Services shall convene a work group to evaluate the current funding model for the Commonwealth's newborn screening program. In conducting its evaluation, the work group shall analyze the appropriateness of the Commonwealth's current fee-for-service funding model for newborn birthing providers. The work group shall survey and evaluate alternative funding models, including those utilized by other states. From its analysis, the work group shall prepare alternative funding models to the current model for review by the Chairmen of the House Committees on Appropriations and Health, Welfare and Institutions and the Chairmen of the Senate Committees on Education and Health and Finance and Appropriations. The work group shall be composed of representatives from the Department of Health and the Department of General Services, the Department of Medical Assistance Services, the Virginia Hospital and Healthcare Association, certified nurse midwife stakeholder groups, and such other stakeholders as deemed appropriate. The Department of Health and the Department of General Services shall report their findings and recommendations to the Chairmen of the House Committees on Appropriations and Health, Welfare and Institutions and the Chairmen of the Senate Committees on Education and Health and Finance and Appropriations by December 1, 2023.*

APPENDIX B – ACRONYMS, ABBREVIATIONS, AND TERMS

ACHDNC - Advisory Committee on Heritable Disorders in Newborns and Children
APCD - All-Payer Claims Database
CAH - Congenital Adrenal Hyperplasia
CCHD – Critical Congenital Heart Disease
CF – Cystic Fibrosis
CFTR – Cystic Fibrosis Transmembrane Conductance Regulator
CMV – Hearing Targeted Congenital Cytomegalovirus Program
DCFH – Division of Child and Family Health
DCLS – Division of Consolidated Laboratory Services
DGS – Department of General Services
DMAS – Department of Medical Assistance Services
DPB – Department of Planning and Budget
False Positive – a screened abnormal result with confirmatory testing indicating negative ("normal") results.
FFS – Fee for Service
Genetic Disorder – an inherited medical condition caused by variation(s) in DNA.
GF – General Fund
HB – House Bill
IRT – Immunoreactive Trypsinogen
LIMS – Laboratory Information Management System
Metabolic Disorder – a medical condition involving dysfunction of metabolic processes in the body.
MCH – Maternal and Child Health
NBS – Newborn Screening
NBS-DBS – Newborn Screening Dried Blood Spot
OOH – Out of Hospital Birth Provider
POF – Pool of Funds
Repeat Screen – additional NBS-DBS specimen(s) submitted if need for follow-up is indicated.
RUSP – Recommended Uniform Screening Panel
Secondary Screen – targeted reflex testing for specific NBS disorders to reduce false positives.
VA EHDI – Virginia Early Hearing Detection and Intervention Program
VDH – Virginia Department of Health
VHHA – Virginia Hospital and Healthcare Association
VMA- Virginia Midwives Alliance
VNBSP – Virginia Newborn Bloodspot Screening Program
VNSP – Virginia Newborn Screening Programs

APPENDIX C – VIRGINIA NEWBORN SCREENING LABORATORY TESTS

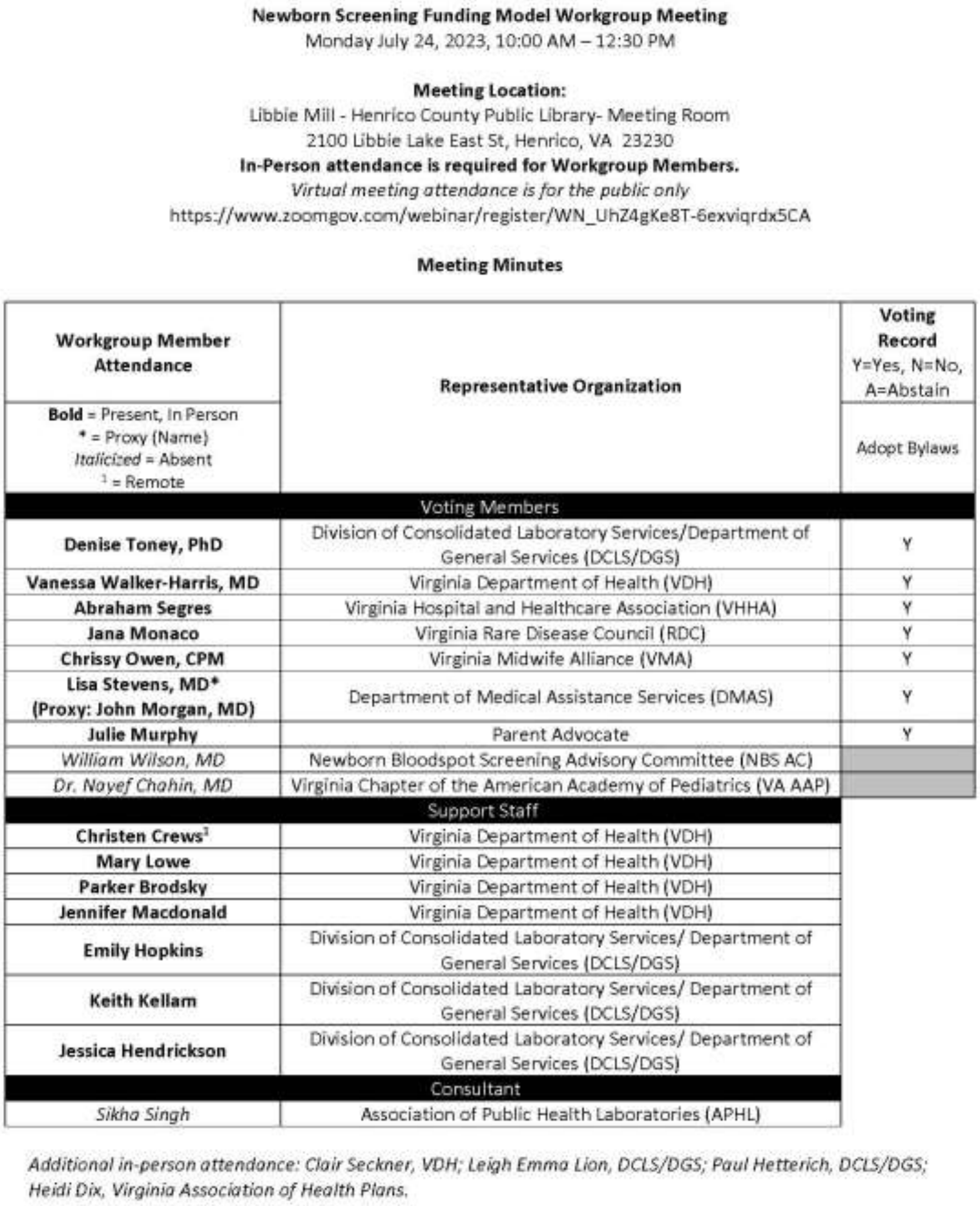
Dried Blood Spot (DBS)

- 3-Hydroxy-3Methylglutaryl-COA Lyase Deficiency (HMG)
- Argininosuccinic Aciduria (ASA)
- Beta-Ketothiolase Deficiency (BKT)
- Biotinidase Deficiency (BIOT)
- Carnitine Uptake Deficiency (CUD)
- Citrullinemia (CIT)
- Congenital Adrenal Hyperplasia (CAH)
- Cystic Fibrosis (CF)
- Galactosemia (GALT)
- Glutaric Acidemia Type I (GA-1)
- Homocystinuria (HCU)
- Congenital Hypothyroidism (CH)
- Isovaleric Acidemia (IVA)
- Long Chain Hydroxyacy-CoA Dehyrogenase Deficiency (LCHADD)
- Maple Syrup Urine Disease (MSUD)
- Medium Chain Acyl -CoA Dehydrogenase Deficiency (MCADD)
- Methylmalonyl Adenosyl-Cobalamine Synthesis Defects (Cbl A& B)
- Methylcrotonyl-CoA Carboxylase Deficiency (3MCC)
- Methylmalonyl-CoA Mutase Deficiency (MUT)
- Mucopolysaccharidosis Type 1 (MPS-1)
- Multiple CoA Carboxylase Deficiency (MCD)
- Phenylketonuria (PKU)
- Pompe
- Propionic Acidemia (PROP)
- Severe Combined Immunodeficiency (SCID)
- Sickle Beta Thalassemia (Hb SBThal)
- Sickle Cell Anemia (Hb SS)
- Sickle Hemoglobin C Disease (Hb SC)
- Spinal Muscular Atrophy (SMA)
- Tri-functional Protein Deficiency (TFP Deficiency)
- Tyrosinemia I (TYR I)
- Very Long Chain Acyl-CoA Dehydrogenase Deficiency (VLCADD)
- X-linked Adrenoleukodystrophy (X-ALD)

Hearing

- Targeted Congenital Cytomegalovirus (CMV)

APPENDIX D – WORKGROUP MEETING MINUTES



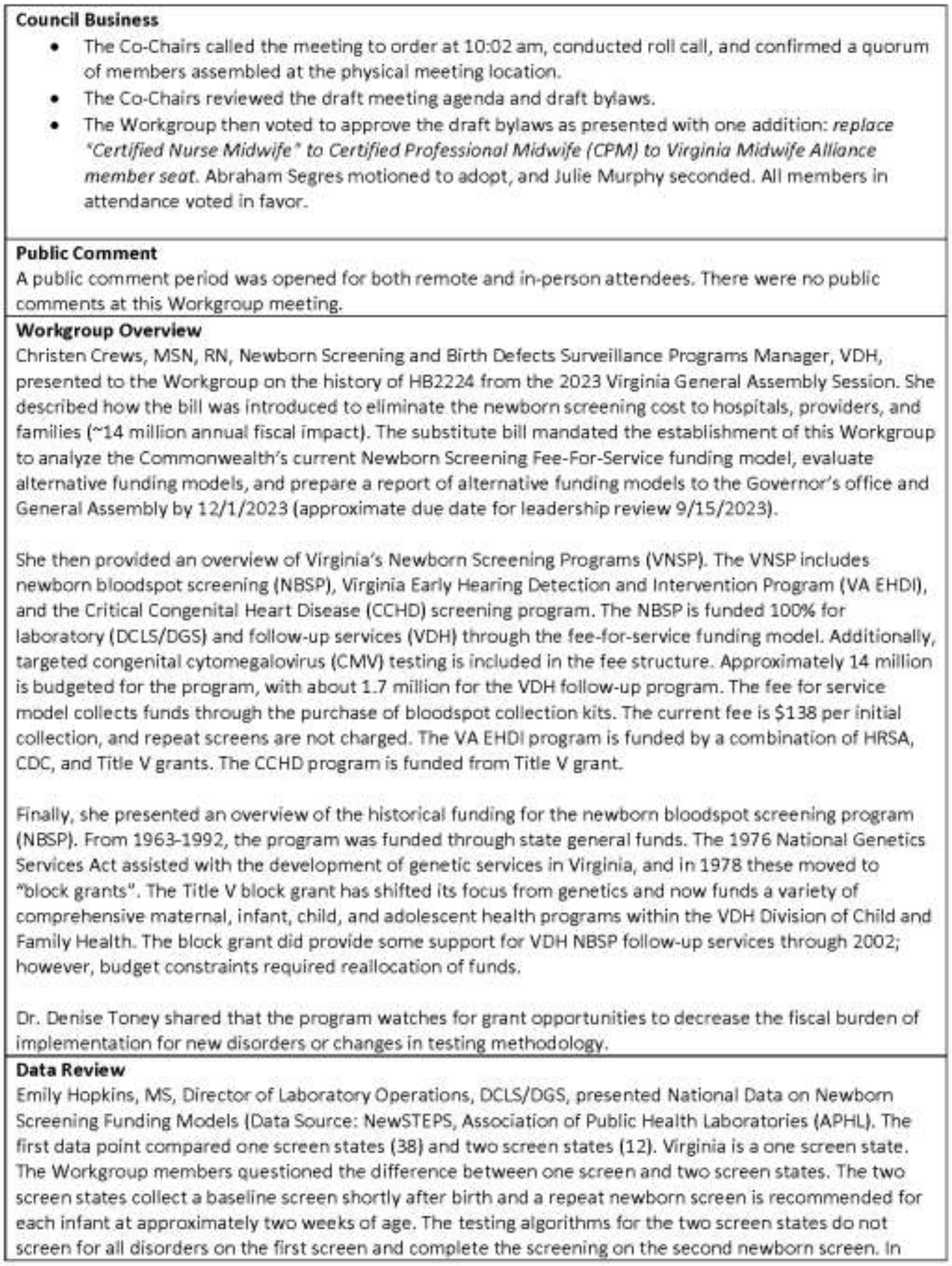
Newborn Screening Funding Model Workgroup Meeting
Monday July 24, 2023, 10:00 AM – 12:30 PM

Meeting Location:
Libbie Mill - Henrico County Public Library- Meeting Room
2100 Libbie Lake East St, Henrico, VA 23230
In-Person attendance is required for Workgroup Members.
Virtual meeting attendance is for the public only
https://www.zoomgov.com/webinar/register/WN_UhZ4gKe8T-6exviqrdx5CA

Meeting Minutes

Workgroup Member Attendance	**Representative Organization**	**Voting Record** Y=Yes, N=No, A=Abstain
Bold = Present, In Person * = Proxy (Name) *Italicized* = Absent [1] = Remote		Adopt Bylaws
	Voting Members	
Denise Toney, PhD	Division of Consolidated Laboratory Services/Department of General Services (DCLS/DGS)	Y
Vanessa Walker-Harris, MD	Virginia Department of Health (VDH)	Y
Abraham Segres	Virginia Hospital and Healthcare Association (VHHA)	Y
Jana Monaco	Virginia Rare Disease Council (RDC)	Y
Chrissy Owen, CPM	Virginia Midwife Alliance (VMA)	Y
Lisa Stevens, MD* (Proxy: John Morgan, MD)	Department of Medical Assistance Services (DMAS)	Y
Julie Murphy	Parent Advocate	Y
William Wilson, MD	Newborn Bloodspot Screening Advisory Committee (NBS AC)	
Dr. Nayef Chahin, MD	Virginia Chapter of the American Academy of Pediatrics (VA AAP)	
	Support Staff	
Christen Crews[1]	Virginia Department of Health (VDH)	
Mary Lowe	Virginia Department of Health (VDH)	
Parker Brodsky	Virginia Department of Health (VDH)	
Jennifer Macdonald	Virginia Department of Health (VDH)	
Emily Hopkins	Division of Consolidated Laboratory Services/ Department of General Services (DCLS/DGS)	
Keith Kellam	Division of Consolidated Laboratory Services/ Department of General Services (DCLS/DGS)	
Jessica Hendrickson	Division of Consolidated Laboratory Services/ Department of General Services (DCLS/DGS)	
	Consultant	
Sikha Singh	Association of Public Health Laboratories (APHL)	

Additional in-person attendance: Clair Seckner, VDH; Leigh Emma Lion, DCLS/DGS; Paul Hetterich, DCLS/DGS; Heidi Dix, Virginia Association of Health Plans.



Council Business

- The Co-Chairs called the meeting to order at 10:02 am, conducted roll call, and confirmed a quorum of members assembled at the physical meeting location.
- The Co-Chairs reviewed the draft meeting agenda and draft bylaws.
- The Workgroup then voted to approve the draft bylaws as presented with one addition: *replace "Certified Nurse Midwife" to Certified Professional Midwife (CPM) to Virginia Midwife Alliance member seat.* Abraham Segres motioned to adopt, and Julie Murphy seconded. All members in attendance voted in favor.

Public Comment

A public comment period was opened for both remote and in-person attendees. There were no public comments at this Workgroup meeting.

Workgroup Overview

Christen Crews, MSN, RN, Newborn Screening and Birth Defects Surveillance Programs Manager, VDH, presented to the Workgroup on the history of HB2224 from the 2023 Virginia General Assembly Session. She described how the bill was introduced to eliminate the newborn screening cost to hospitals, providers, and families (~14 million annual fiscal impact). The substitute bill mandated the establishment of this Workgroup to analyze the Commonwealth's current Newborn Screening Fee-For-Service funding model, evaluate alternative funding models, and prepare a report of alternative funding models to the Governor's office and General Assembly by 12/1/2023 (approximate due date for leadership review 9/15/2023).

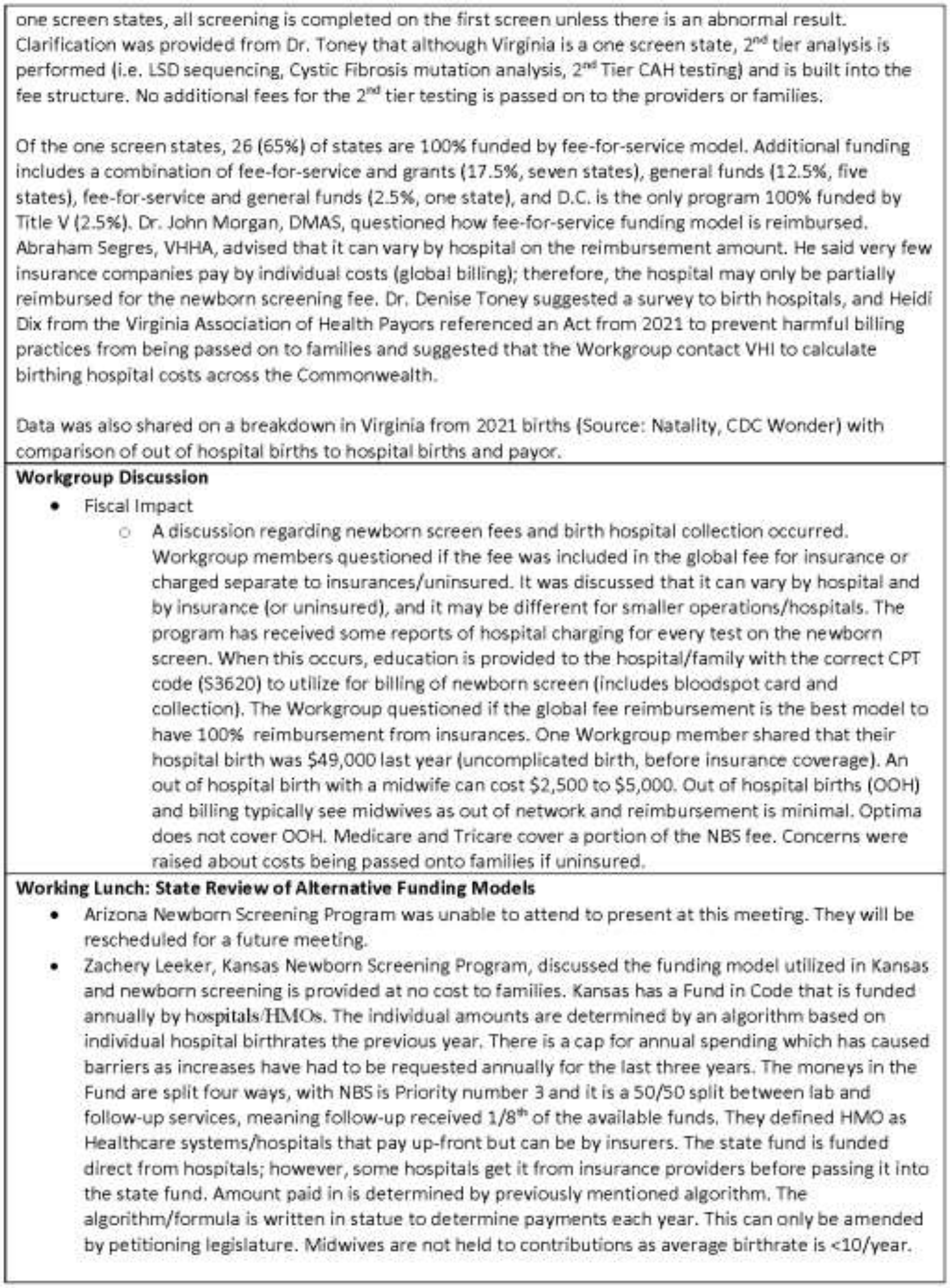
She then provided an overview of Virginia's Newborn Screening Programs (VNSP). The VNSP includes newborn bloodspot screening (NBSP), Virginia Early Hearing Detection and Intervention Program (VA EHDI), and the Critical Congenital Heart Disease (CCHD) screening program. The NBSP is funded 100% for laboratory (DCLS/DGS) and follow-up services (VDH) through the fee-for-service funding model. Additionally, targeted congenital cytomegalovirus (CMV) testing is included in the fee structure. Approximately 14 million is budgeted for the program, with about 1.7 million for the VDH follow-up program. The fee for service model collects funds through the purchase of bloodspot collection kits. The current fee is $138 per initial collection, and repeat screens are not charged. The VA EHDI program is funded by a combination of HRSA, CDC, and Title V grants. The CCHD program is funded from Title V grant.

Finally, she presented an overview of the historical funding for the newborn bloodspot screening program (NBSP). From 1963-1992, the program was funded through state general funds. The 1976 National Genetics Services Act assisted with the development of genetic services in Virginia, and in 1978 these moved to "block grants". The Title V block grant has shifted its focus from genetics and now funds a variety of comprehensive maternal, infant, child, and adolescent health programs within the VDH Division of Child and Family Health. The block grant did provide some support for VDH NBSP follow-up services through 2002; however, budget constraints required reallocation of funds.

Dr. Denise Toney shared that the program watches for grant opportunities to decrease the fiscal burden of implementation for new disorders or changes in testing methodology.

Data Review

Emily Hopkins, MS, Director of Laboratory Operations, DCLS/DGS, presented National Data on Newborn Screening Funding Models (Data Source: NewSTEPS, Association of Public Health Laboratories (APHL). The first data point compared one screen states (38) and two screen states (12). Virginia is a one screen state. The Workgroup members questioned the difference between one screen and two screen states. The two screen states collect a baseline screen shortly after birth and a repeat newborn screen is recommended for each infant at approximately two weeks of age. The testing algorithms for the two screen states do not screen for all disorders on the first screen and complete the screening on the second newborn screen. In



one screen states, all screening is completed on the first screen unless there is an abnormal result. Clarification was provided from Dr. Toney that although Virginia is a one screen state, 2nd tier analysis is performed (i.e. LSD sequencing, Cystic Fibrosis mutation analysis, 2nd Tier CAH testing) and is built into the fee structure. No additional fees for the 2nd tier testing is passed on to the providers or families.

Of the one screen states, 26 (65%) of states are 100% funded by fee-for-service model. Additional funding includes a combination of fee-for-service and grants (17.5%, seven states), general funds (12.5%, five states), fee-for-service and general funds (2.5%, one state), and D.C. is the only program 100% funded by Title V (2.5%). Dr. John Morgan, DMAS, questioned how fee-for-service funding model is reimbursed. Abraham Segres, VHHA, advised that it can vary by hospital on the reimbursement amount. He said very few insurance companies pay by individual costs (global billing); therefore, the hospital may only be partially reimbursed for the newborn screening fee. Dr. Denise Toney suggested a survey to birth hospitals, and Heidi Dix from the Virginia Association of Health Payors referenced an Act from 2021 to prevent harmful billing practices from being passed on to families and suggested that the Workgroup contact VHI to calculate birthing hospital costs across the Commonwealth.

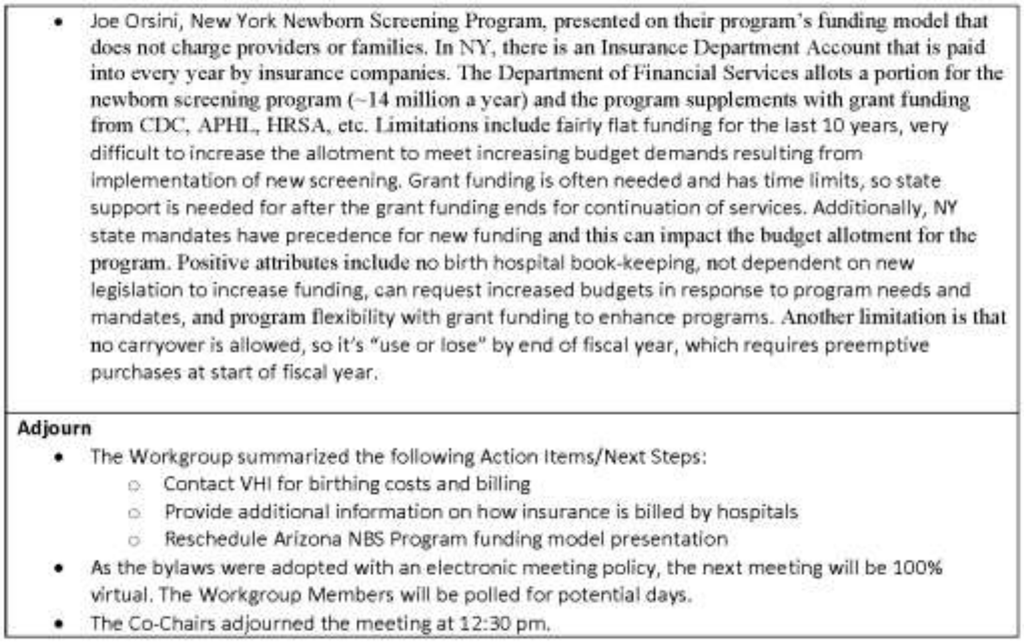
Data was also shared on a breakdown in Virginia from 2021 births (Source: Natality, CDC Wonder) with comparison of out of hospital births to hospital births and payor.

Workgroup Discussion

- Fiscal Impact
  - A discussion regarding newborn screen fees and birth hospital collection occurred. Workgroup members questioned if the fee was included in the global fee for insurance or charged separate to insurances/uninsured. It was discussed that it can vary by hospital and by insurance (or uninsured), and it may be different for smaller operations/hospitals. The program has received some reports of hospital charging for every test on the newborn screen. When this occurs, education is provided to the hospital/family with the correct CPT code (S3620) to utilize for billing of newborn screen (includes bloodspot card and collection). The Workgroup questioned if the global fee reimbursement is the best model to have 100% reimbursement from insurances. One Workgroup member shared that their hospital birth was $49,000 last year (uncomplicated birth, before insurance coverage). An out of hospital birth with a midwife can cost $2,500 to $5,000. Out of hospital births (OOH) and billing typically see midwives as out of network and reimbursement is minimal. Optima does not cover OOH. Medicare and Tricare cover a portion of the NBS fee. Concerns were raised about costs being passed onto families if uninsured.

Working Lunch: State Review of Alternative Funding Models

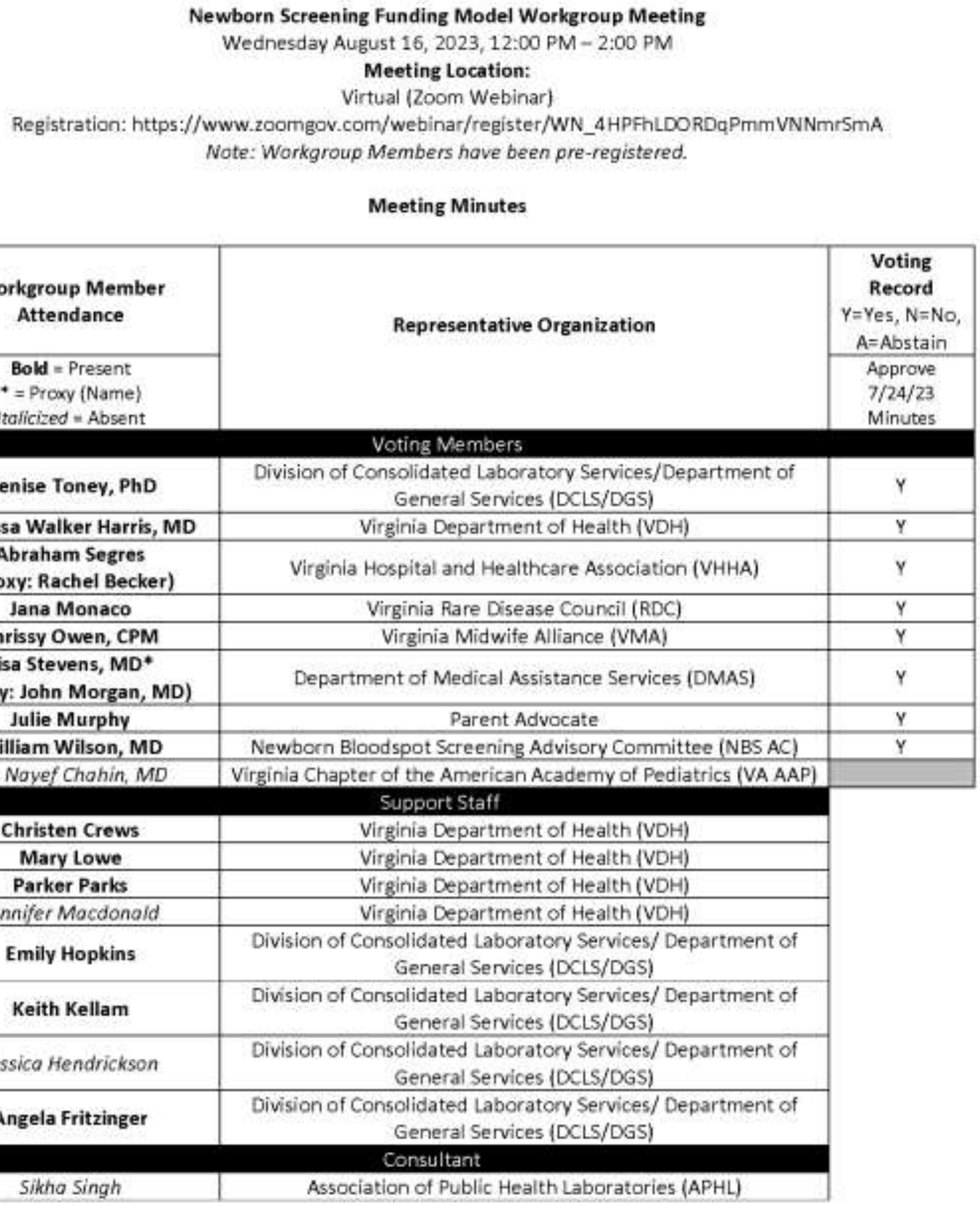
- Arizona Newborn Screening Program was unable to attend to present at this meeting. They will be rescheduled for a future meeting.
- Zachery Leeker, Kansas Newborn Screening Program, discussed the funding model utilized in Kansas and newborn screening is provided at no cost to families. Kansas has a Fund in Code that is funded annually by hospitals/HMOs. The individual amounts are determined by an algorithm based on individual hospital birthrates the previous year. There is a cap for annual spending which has caused barriers as increases have had to be requested annually for the last three years. The moneys in the Fund are split four ways, with NBS is Priority number 3 and it is a 50/50 split between lab and follow-up services, meaning follow-up received 1/8th of the available funds. They defined HMO as Healthcare systems/hospitals that pay up-front but can be by insurers. The state fund is funded direct from hospitals; however, some hospitals get it from insurance providers before passing it into the state fund. Amount paid in is determined by previously mentioned algorithm. The algorithm/formula is written in statue to determine payments each year. This can only be amended by petitioning legislature. Midwives are not held to contributions as average birthrate is <10/year.



- Joe Orsini, New York Newborn Screening Program, presented on their program's funding model that does not charge providers or families. In NY, there is an Insurance Department Account that is paid into every year by insurance companies. The Department of Financial Services allots a portion for the newborn screening program (~14 million a year) and the program supplements with grant funding from CDC, APHL, HRSA, etc. Limitations include fairly flat funding for the last 10 years, very difficult to increase the allotment to meet increasing budget demands resulting from implementation of new screening. Grant funding is often needed and has time limits, so state support is needed for after the grant funding ends for continuation of services. Additionally, NY state mandates have precedence for new funding and this can impact the budget allotment for the program. Positive attributes include no birth hospital book-keeping, not dependent on new legislation to increase funding, can request increased budgets in response to program needs and mandates, and program flexibility with grant funding to enhance programs. Another limitation is that no carryover is allowed, so it's "use or lose" by end of fiscal year, which requires preemptive purchases at start of fiscal year.

Adjourn

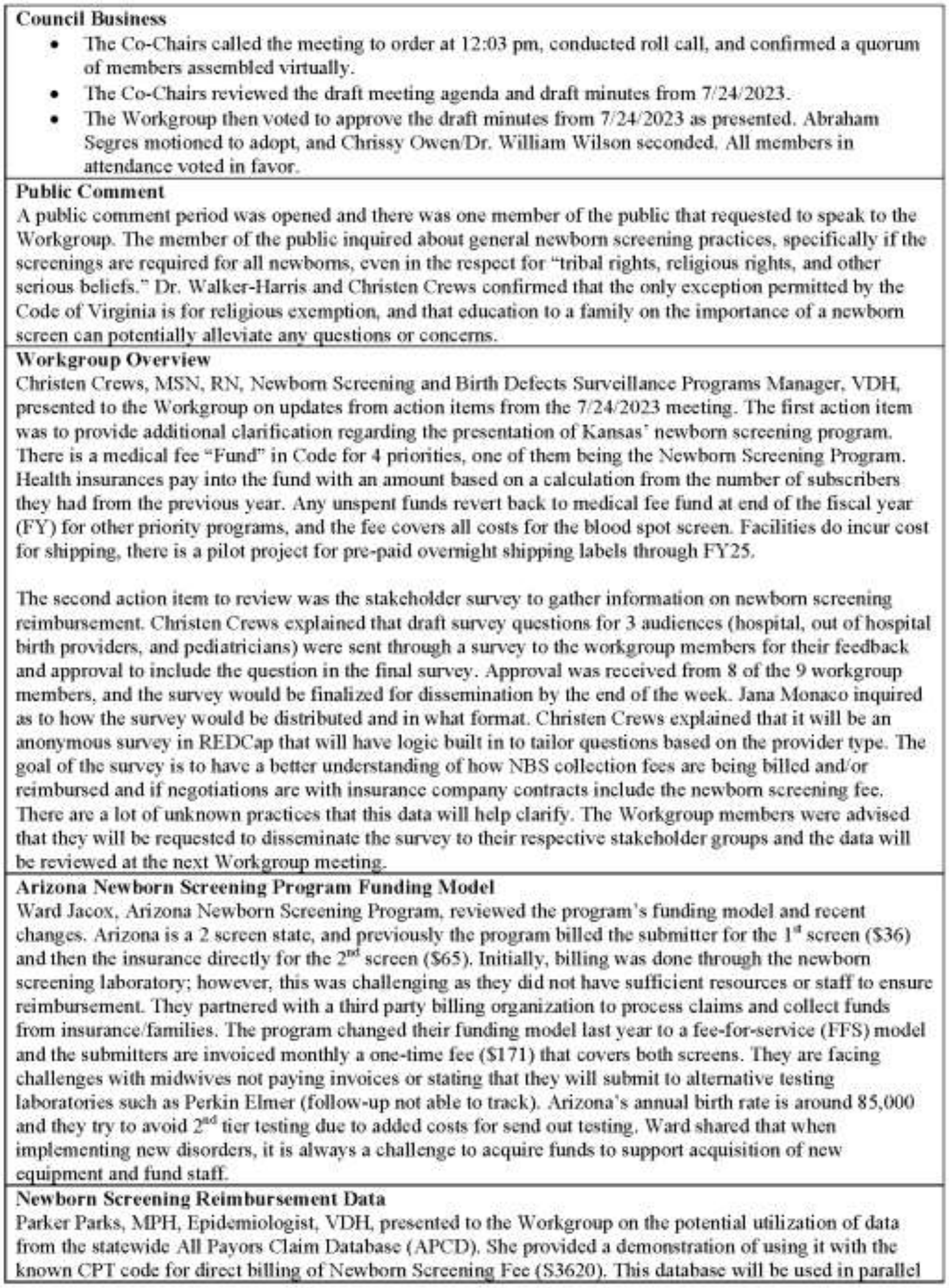
- The Workgroup summarized the following Action Items/Next Steps:
  - Contact VHI for birthing costs and billing
  - Provide additional information on how insurance is billed by hospitals
  - Reschedule Arizona NBS Program funding model presentation
- As the bylaws were adopted with an electronic meeting policy, the next meeting will be 100% virtual. The Workgroup Members will be polled for potential days.
- The Co-Chairs adjourned the meeting at 12:30 pm.



Newborn Screening Funding Model Workgroup Meeting
Wednesday August 16, 2023, 12:00 PM – 2:00 PM
Meeting Location:
Virtual (Zoom Webinar)
Registration: https://www.zoomgov.com/webinar/register/WN_4HPFhLDORDqPmmVNNmrSmA
Note: Workgroup Members have been pre-registered.

Meeting Minutes

Workgroup Member Attendance	**Representative Organization**	**Voting Record** Y=Yes, N=No, A=Abstain
Bold = Present * = Proxy (Name) *Italicized* = Absent		Approve 7/24/23 Minutes
	Voting Members	
Denise Toney, PhD	Division of Consolidated Laboratory Services/Department of General Services (DCLS/DGS)	Y
Vanessa Walker Harris, MD	Virginia Department of Health (VDH)	Y
Abraham Segres (Proxy: Rachel Becker)	Virginia Hospital and Healthcare Association (VHHA)	Y
Jana Monaco	Virginia Rare Disease Council (RDC)	Y
Chrissy Owen, CPM	Virginia Midwife Alliance (VMA)	Y
Lisa Stevens, MD* (Proxy: John Morgan, MD)	Department of Medical Assistance Services (DMAS)	Y
Julie Murphy	Parent Advocate	Y
William Wilson, MD	Newborn Bloodspot Screening Advisory Committee (NBS AC)	Y
Dr. Nayef Chahin, MD	Virginia Chapter of the American Academy of Pediatrics (VA AAP)	
	Support Staff	
Christen Crews	Virginia Department of Health (VDH)	
Mary Lowe	Virginia Department of Health (VDH)	
Parker Parks	Virginia Department of Health (VDH)	
Jennifer Macdonald	Virginia Department of Health (VDH)	
Emily Hopkins	Division of Consolidated Laboratory Services/ Department of General Services (DCLS/DGS)	
Keith Kellam	Division of Consolidated Laboratory Services/ Department of General Services (DCLS/DGS)	
Jessica Hendrickson	Division of Consolidated Laboratory Services/ Department of General Services (DCLS/DGS)	
Angela Fritzinger	Division of Consolidated Laboratory Services/ Department of General Services (DCLS/DGS)	
	Consultant	
Sikha Singh	Association of Public Health Laboratories (APHL)	



Council Business

- The Co-Chairs called the meeting to order at 12:03 pm, conducted roll call, and confirmed a quorum of members assembled virtually.
- The Co-Chairs reviewed the draft meeting agenda and draft minutes from 7/24/2023.
- The Workgroup then voted to approve the draft minutes from 7/24/2023 as presented. Abraham Segres motioned to adopt, and Chrissy Owen/Dr. William Wilson seconded. All members in attendance voted in favor.

Public Comment

A public comment period was opened and there was one member of the public that requested to speak to the Workgroup. The member of the public inquired about general newborn screening practices, specifically if the screenings are required for all newborns, even in the respect for "tribal rights, religious rights, and other serious beliefs." Dr. Walker-Harris and Christen Crews confirmed that the only exception permitted by the Code of Virginia is for religious exemption, and that education to a family on the importance of a newborn screen can potentially alleviate any questions or concerns.

Workgroup Overview

Christen Crews, MSN, RN, Newborn Screening and Birth Defects Surveillance Programs Manager, VDH, presented to the Workgroup on updates from action items from the 7/24/2023 meeting. The first action item was to provide additional clarification regarding the presentation of Kansas' newborn screening program. There is a medical fee "Fund" in Code for 4 priorities, one of them being the Newborn Screening Program. Health insurances pay into the fund with an amount based on a calculation from the number of subscribers they had from the previous year. Any unspent funds revert back to medical fee fund at end of the fiscal year (FY) for other priority programs, and the fee covers all costs for the blood spot screen. Facilities do incur cost for shipping, there is a pilot project for pre-paid overnight shipping labels through FY25.

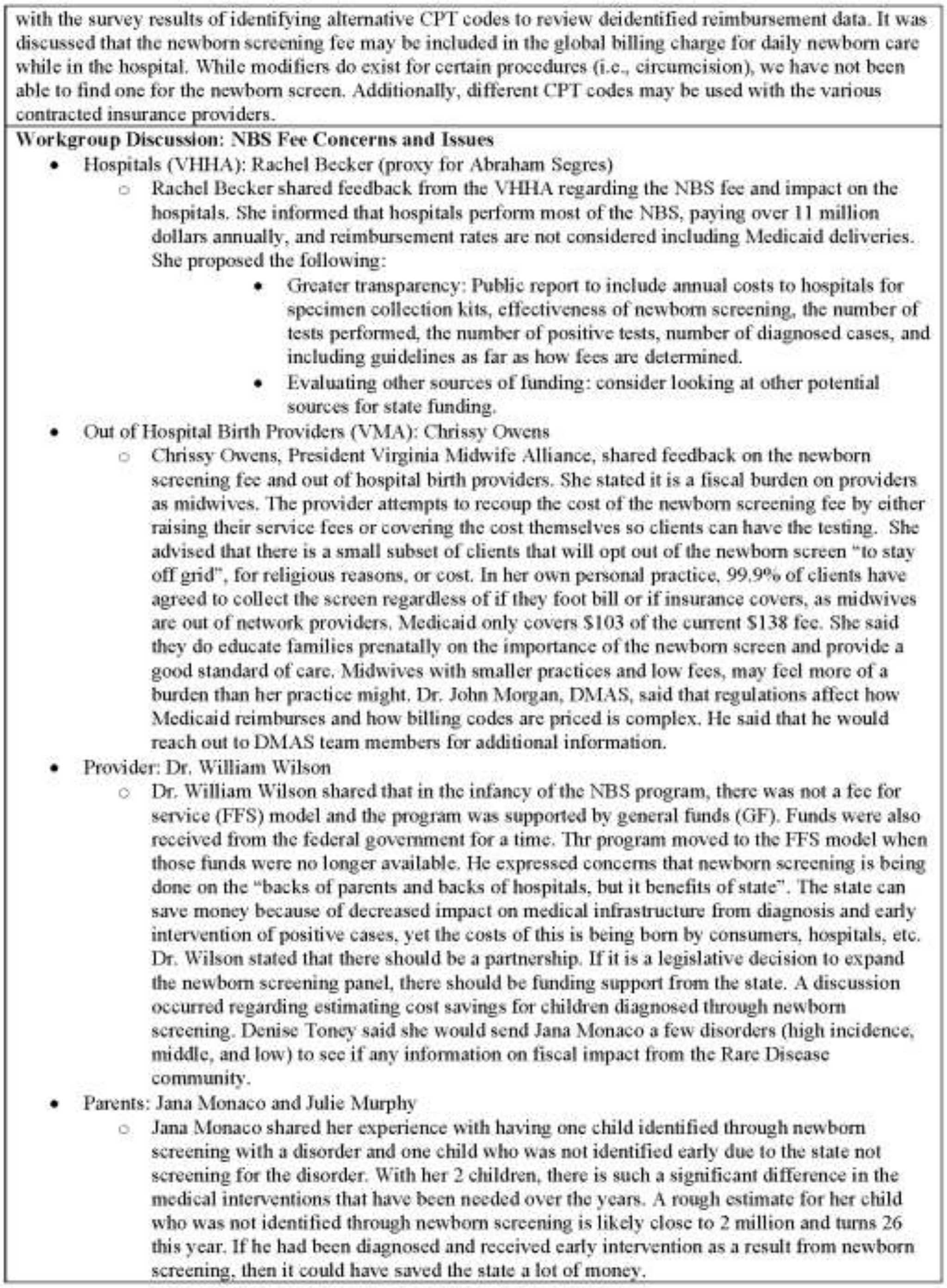
The second action item to review was the stakeholder survey to gather information on newborn screening reimbursement. Christen Crews explained that draft survey questions for 3 audiences (hospital, out of hospital birth providers, and pediatricians) were sent through a survey to the workgroup members for their feedback and approval to include the question in the final survey. Approval was received from 8 of the 9 workgroup members, and the survey would be finalized for dissemination by the end of the week. Jana Monaco inquired as to how the survey would be distributed and in what format. Christen Crews explained that it will be an anonymous survey in REDCap that will have logic built in to tailor questions based on the provider type. The goal of the survey is to have a better understanding of how NBS collection fees are being billed and/or reimbursed and if negotiations are with insurance company contracts include the newborn screening fee. There are a lot of unknown practices that this data will help clarify. The Workgroup members were advised that they will be requested to disseminate the survey to their respective stakeholder groups and the data will be reviewed at the next Workgroup meeting.

Arizona Newborn Screening Program Funding Model

Ward Jacox, Arizona Newborn Screening Program, reviewed the program's funding model and recent changes. Arizona is a 2 screen state, and previously the program billed the submitter for the 1st screen ($36) and then the insurance directly for the 2nd screen ($65). Initially, billing was done through the newborn screening laboratory; however, this was challenging as they did not have sufficient resources or staff to ensure reimbursement. They partnered with a third party billing organization to process claims and collect funds from insurance/families. The program changed their funding model last year to a fee-for-service (FFS) model and the submitters are invoiced monthly a one-time fee ($171) that covers both screens. They are facing challenges with midwives not paying invoices or stating that they will submit to alternative testing laboratories such as Perkin Elmer (follow-up not able to track). Arizona's annual birth rate is around 85,000 and they try to avoid 2nd tier testing due to added costs for send out testing. Ward shared that when implementing new disorders, it is always a challenge to acquire funds to support acquisition of new equipment and fund staff.

Newborn Screening Reimbursement Data

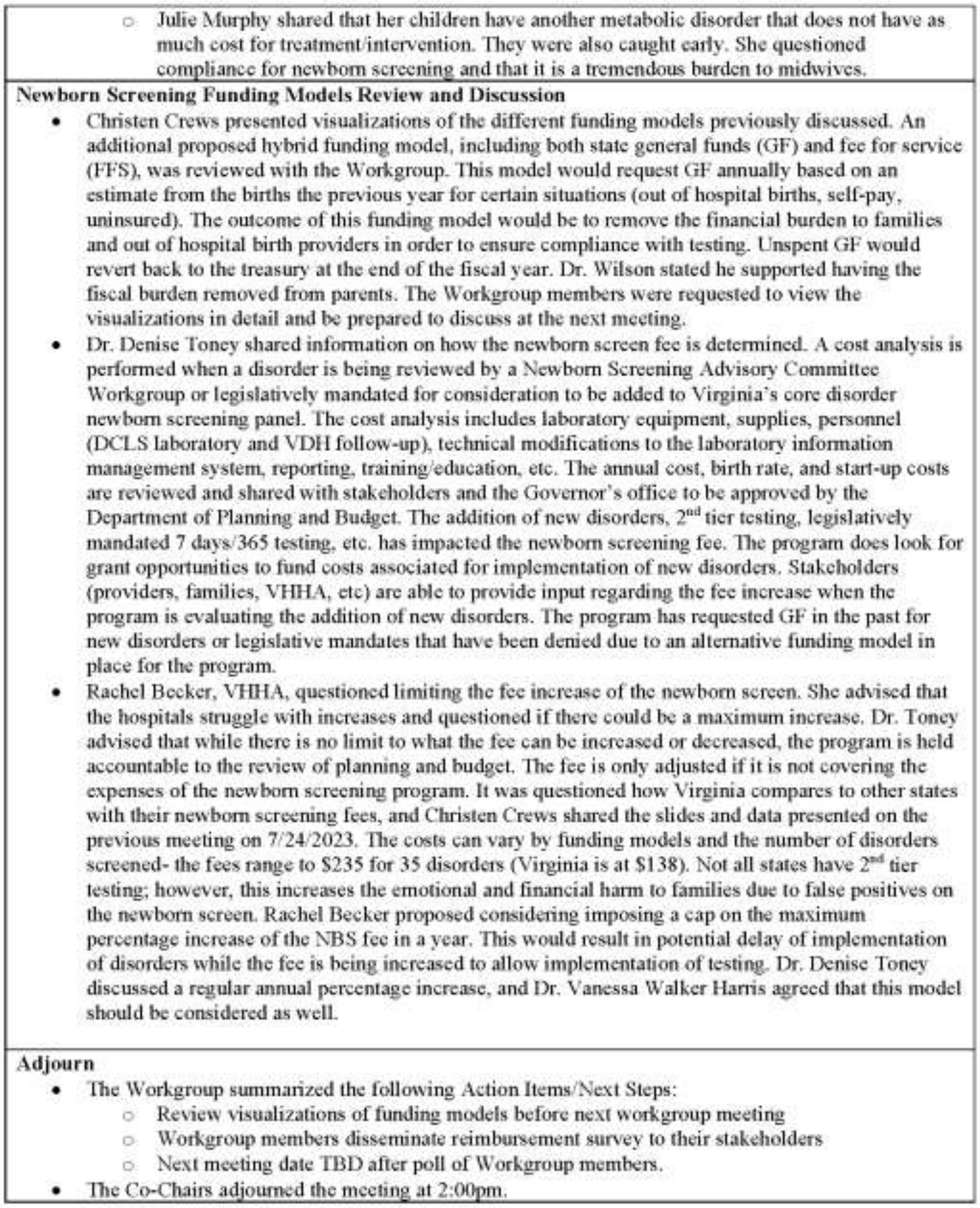
Parker Parks, MPH, Epidemiologist, VDH, presented to the Workgroup on the potential utilization of data from the statewide All Payors Claim Database (APCD). She provided a demonstration of using it with the known CPT code for direct billing of Newborn Screening Fee (S3620). This database will be used in parallel



with the survey results of identifying alternative CPT codes to review deidentified reimbursement data. It was discussed that the newborn screening fee may be included in the global billing charge for daily newborn care while in the hospital. While modifiers do exist for certain procedures (i.e., circumcision), we have not been able to find one for the newborn screen. Additionally, different CPT codes may be used with the various contracted insurance providers.

Workgroup Discussion: NBS Fee Concerns and Issues

- Hospitals (VHHA): Rachel Becker (proxy for Abraham Segres)
    - Rachel Becker shared feedback from the VHHA regarding the NBS fee and impact on the hospitals. She informed that hospitals perform most of the NBS, paying over 11 million dollars annually, and reimbursement rates are not considered including Medicaid deliveries. She proposed the following:
        - Greater transparency: Public report to include annual costs to hospitals for specimen collection kits, effectiveness of newborn screening, the number of tests performed, the number of positive tests, number of diagnosed cases, and including guidelines as far as how fees are determined.
        - Evaluating other sources of funding: consider looking at other potential sources for state funding.
- Out of Hospital Birth Providers (VMA): Chrissy Owens
    - Chrissy Owens, President Virginia Midwife Alliance, shared feedback on the newborn screening fee and out of hospital birth providers. She stated it is a fiscal burden on providers as midwives. The provider attempts to recoup the cost of the newborn screening fee by either raising their service fees or covering the cost themselves so clients can have the testing. She advised that there is a small subset of clients that will opt out of the newborn screen "to stay off grid", for religious reasons, or cost. In her own personal practice, 99.9% of clients have agreed to collect the screen regardless of if they foot bill or if insurance covers, as midwives are out of network providers. Medicaid only covers $103 of the current $138 fee. She said they do educate families prenatally on the importance of the newborn screen and provide a good standard of care. Midwives with smaller practices and low fees, may feel more of a burden than her practice might. Dr. John Morgan, DMAS, said that regulations affect how Medicaid reimburses and how billing codes are priced is complex. He said that he would reach out to DMAS team members for additional information.
- Provider: Dr. William Wilson
    - Dr. William Wilson shared that in the infancy of the NBS program, there was not a fee for service (FFS) model and the program was supported by general funds (GF). Funds were also received from the federal government for a time. Thr program moved to the FFS model when those funds were no longer available. He expressed concerns that newborn screening is being done on the "backs of parents and backs of hospitals, but it benefits of state". The state can save money because of decreased impact on medical infrastructure from diagnosis and early intervention of positive cases, yet the costs of this is being born by consumers, hospitals, etc. Dr. Wilson stated that there should be a partnership. If it is a legislative decision to expand the newborn screening panel, there should be funding support from the state. A discussion occurred regarding estimating cost savings for children diagnosed through newborn screening. Denise Toney said she would send Jana Monaco a few disorders (high incidence, middle, and low) to see if any information on fiscal impact from the Rare Disease community.
- Parents: Jana Monaco and Julie Murphy
    - Jana Monaco shared her experience with having one child identified through newborn screening with a disorder and one child who was not identified early due to the state not screening for the disorder. With her 2 children, there is such a significant difference in the medical interventions that have been needed over the years. A rough estimate for her child who was not identified through newborn screening is likely close to 2 million and turns 26 this year. If he had been diagnosed and received early intervention as a result from newborn screening, then it could have saved the state a lot of money.



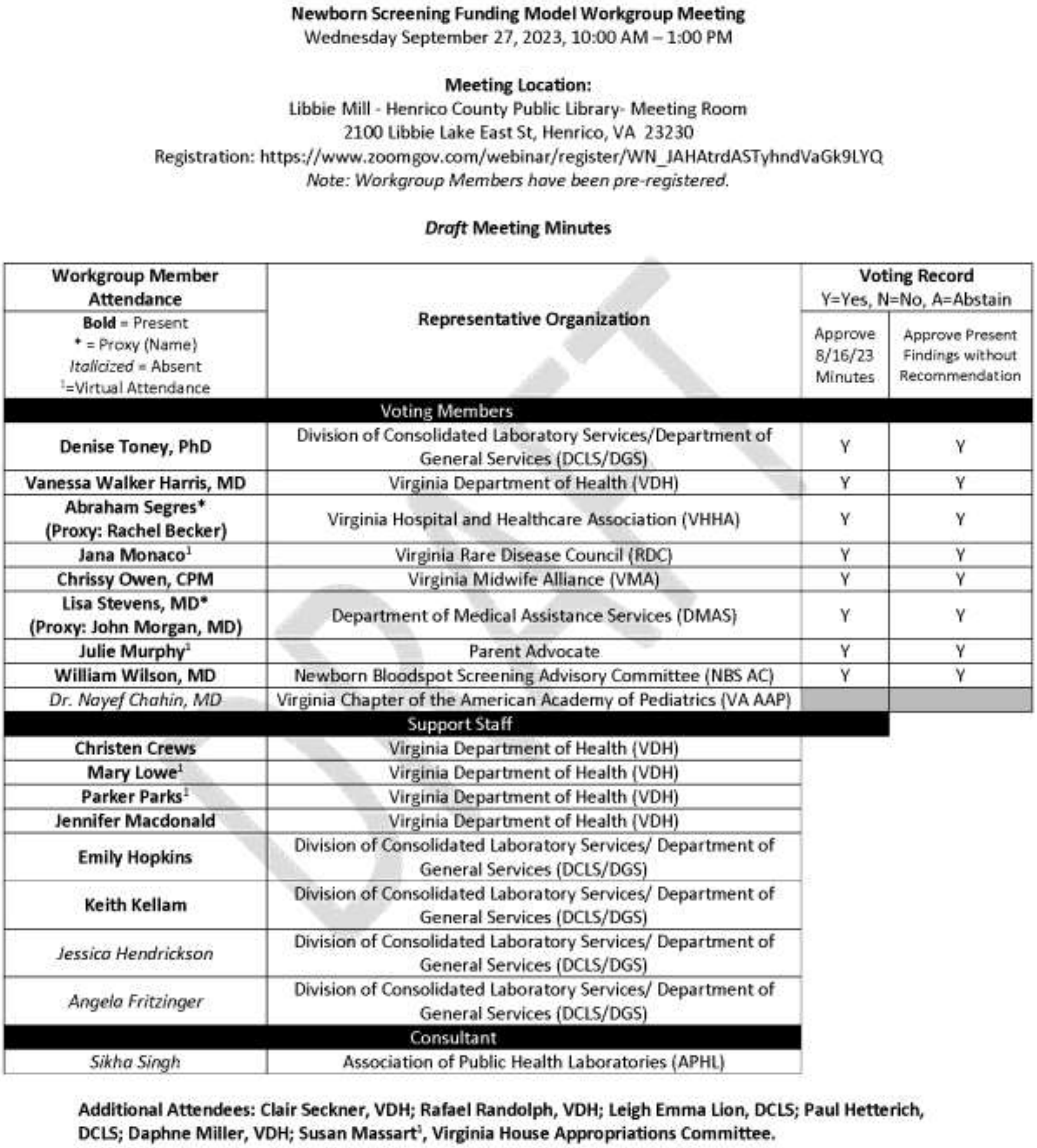
  - Julie Murphy shared that her children have another metabolic disorder that does not have as much cost for treatment/intervention. They were also caught early. She questioned compliance for newborn screening and that it is a tremendous burden to midwives.

Newborn Screening Funding Models Review and Discussion

- Christen Crews presented visualizations of the different funding models previously discussed. An additional proposed hybrid funding model, including both state general funds (GF) and fee for service (FFS), was reviewed with the Workgroup. This model would request GF annually based on an estimate from the births the previous year for certain situations (out of hospital births, self-pay, uninsured). The outcome of this funding model would be to remove the financial burden to families and out of hospital birth providers in order to ensure compliance with testing. Unspent GF would revert back to the treasury at the end of the fiscal year. Dr. Wilson stated he supported having the fiscal burden removed from parents. The Workgroup members were requested to view the visualizations in detail and be prepared to discuss at the next meeting.
- Dr. Denise Toney shared information on how the newborn screen fee is determined. A cost analysis is performed when a disorder is being reviewed by a Newborn Screening Advisory Committee Workgroup or legislatively mandated for consideration to be added to Virginia's core disorder newborn screening panel. The cost analysis includes laboratory equipment, supplies, personnel (DCLS laboratory and VDH follow-up), technical modifications to the laboratory information management system, reporting, training/education, etc. The annual cost, birth rate, and start-up costs are reviewed and shared with stakeholders and the Governor's office to be approved by the Department of Planning and Budget. The addition of new disorders, 2nd tier testing, legislatively mandated 7 days/365 testing, etc. has impacted the newborn screening fee. The program does look for grant opportunities to fund costs associated for implementation of new disorders. Stakeholders (providers, families, VHHA, etc) are able to provide input regarding the fee increase when the program is evaluating the addition of new disorders. The program has requested GF in the past for new disorders or legislative mandates that have been denied due to an alternative funding model in place for the program.
- Rachel Becker, VHHA, questioned limiting the fee increase of the newborn screen. She advised that the hospitals struggle with increases and questioned if there could be a maximum increase. Dr. Toney advised that while there is no limit to what the fee can be increased or decreased, the program is held accountable to the review of planning and budget. The fee is only adjusted if it is not covering the expenses of the newborn screening program. It was questioned how Virginia compares to other states with their newborn screening fees, and Christen Crews shared the slides and data presented on the previous meeting on 7/24/2023. The costs can vary by funding models and the number of disorders screened- the fees range to $235 for 35 disorders (Virginia is at $138). Not all states have 2nd tier testing; however, this increases the emotional and financial harm to families due to false positives on the newborn screen. Rachel Becker proposed considering imposing a cap on the maximum percentage increase of the NBS fee in a year. This would result in potential delay of implementation of disorders while the fee is being increased to allow implementation of testing. Dr. Denise Toney discussed a regular annual percentage increase, and Dr. Vanessa Walker Harris agreed that this model should be considered as well.

Adjourn

- The Workgroup summarized the following Action Items/Next Steps:
  - Review visualizations of funding models before next workgroup meeting
  - Workgroup members disseminate reimbursement survey to their stakeholders
  - Next meeting date TBD after poll of Workgroup members.
- The Co-Chairs adjourned the meeting at 2:00pm.



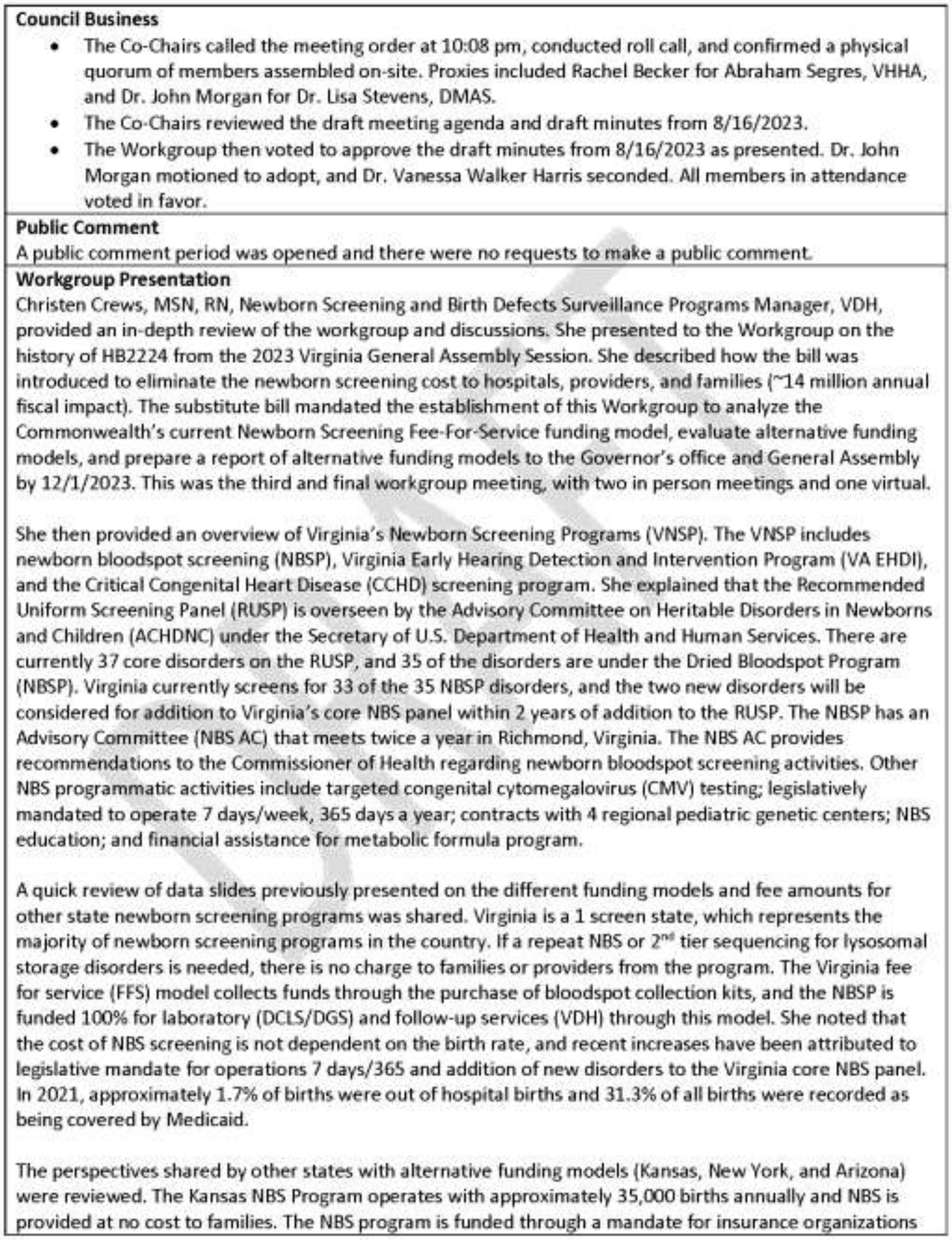
Newborn Screening Funding Model Workgroup Meeting
Wednesday September 27, 2023, 10:00 AM – 1:00 PM

Meeting Location:
Libbie Mill - Henrico County Public Library- Meeting Room
2100 Libbie Lake East St, Henrico, VA 23230
Registration: https://www.zoomgov.com/webinar/register/WN_JAHAtrdASTyhndVaGk9LYQ
Note: Workgroup Members have been pre-registered.

***Draft* Meeting Minutes**

Workgroup Member Attendance	**Representative Organization**	**Voting Record** Y=Yes, N=No, A=Abstain	
Bold = Present * = Proxy (Name) *Italicized* = Absent [1]=Virtual Attendance		Approve 8/16/23 Minutes	Approve Present Findings without Recommendation
	Voting Members		
Denise Toney, PhD	Division of Consolidated Laboratory Services/Department of General Services (DCLS/DGS)	Y	Y
Vanessa Walker Harris, MD	Virginia Department of Health (VDH)	Y	Y
Abraham Segres* (Proxy: Rachel Becker)	Virginia Hospital and Healthcare Association (VHHA)	Y	Y
Jana Monaco[1]	Virginia Rare Disease Council (RDC)	Y	Y
Chrissy Owen, CPM	Virginia Midwife Alliance (VMA)	Y	Y
Lisa Stevens, MD* (Proxy: John Morgan, MD)	Department of Medical Assistance Services (DMAS)	Y	Y
Julie Murphy[1]	Parent Advocate	Y	Y
William Wilson, MD	Newborn Bloodspot Screening Advisory Committee (NBS AC)	Y	Y
Dr. Nayef Chahin, MD	Virginia Chapter of the American Academy of Pediatrics (VA AAP)		
	Support Staff		
Christen Crews	Virginia Department of Health (VDH)		
Mary Lowe[1]	Virginia Department of Health (VDH)		
Parker Parks[1]	Virginia Department of Health (VDH)		
Jennifer Macdonald	Virginia Department of Health (VDH)		
Emily Hopkins	Division of Consolidated Laboratory Services/ Department of General Services (DCLS/DGS)		
Keith Kellam	Division of Consolidated Laboratory Services/ Department of General Services (DCLS/DGS)		
Jessica Hendrickson	Division of Consolidated Laboratory Services/ Department of General Services (DCLS/DGS)		
Angela Fritzinger	Division of Consolidated Laboratory Services/ Department of General Services (DCLS/DGS)		
	Consultant		
Sikha Singh	Association of Public Health Laboratories (APHL)		

Additional Attendees: Clair Seckner, VDH; Rafael Randolph, VDH; Leigh Emma Lion, DCLS; Paul Hetterich, DCLS; Daphne Miller, VDH; Susan Massart[1], Virginia House Appropriations Committee.



Council Business

- The Co-Chairs called the meeting order at 10:08 pm, conducted roll call, and confirmed a physical quorum of members assembled on-site. Proxies included Rachel Becker for Abraham Segres, VHHA, and Dr. John Morgan for Dr. Lisa Stevens, DMAS.
- The Co-Chairs reviewed the draft meeting agenda and draft minutes from 8/16/2023.
- The Workgroup then voted to approve the draft minutes from 8/16/2023 as presented. Dr. John Morgan motioned to adopt, and Dr. Vanessa Walker Harris seconded. All members in attendance voted in favor.

Public Comment

A public comment period was opened and there were no requests to make a public comment.

Workgroup Presentation

Christen Crews, MSN, RN, Newborn Screening and Birth Defects Surveillance Programs Manager, VDH, provided an in-depth review of the workgroup and discussions. She presented to the Workgroup on the history of HB2224 from the 2023 Virginia General Assembly Session. She described how the bill was introduced to eliminate the newborn screening cost to hospitals, providers, and families (~14 million annual fiscal impact). The substitute bill mandated the establishment of this Workgroup to analyze the Commonwealth's current Newborn Screening Fee-For-Service funding model, evaluate alternative funding models, and prepare a report of alternative funding models to the Governor's office and General Assembly by 12/1/2023. This was the third and final workgroup meeting, with two in person meetings and one virtual.

She then provided an overview of Virginia's Newborn Screening Programs (VNSP). The VNSP includes newborn bloodspot screening (NBSP), Virginia Early Hearing Detection and Intervention Program (VA EHDI), and the Critical Congenital Heart Disease (CCHD) screening program. She explained that the Recommended Uniform Screening Panel (RUSP) is overseen by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) under the Secretary of U.S. Department of Health and Human Services. There are currently 37 core disorders on the RUSP, and 35 of the disorders are under the Dried Bloodspot Program (NBSP). Virginia currently screens for 33 of the 35 NBSP disorders, and the two new disorders will be considered for addition to Virginia's core NBS panel within 2 years of addition to the RUSP. The NBSP has an Advisory Committee (NBS AC) that meets twice a year in Richmond, Virginia. The NBS AC provides recommendations to the Commissioner of Health regarding newborn bloodspot screening activities. Other NBS programmatic activities include targeted congenital cytomegalovirus (CMV) testing; legislatively mandated to operate 7 days/week, 365 days a year; contracts with 4 regional pediatric genetic centers; NBS education; and financial assistance for metabolic formula program.

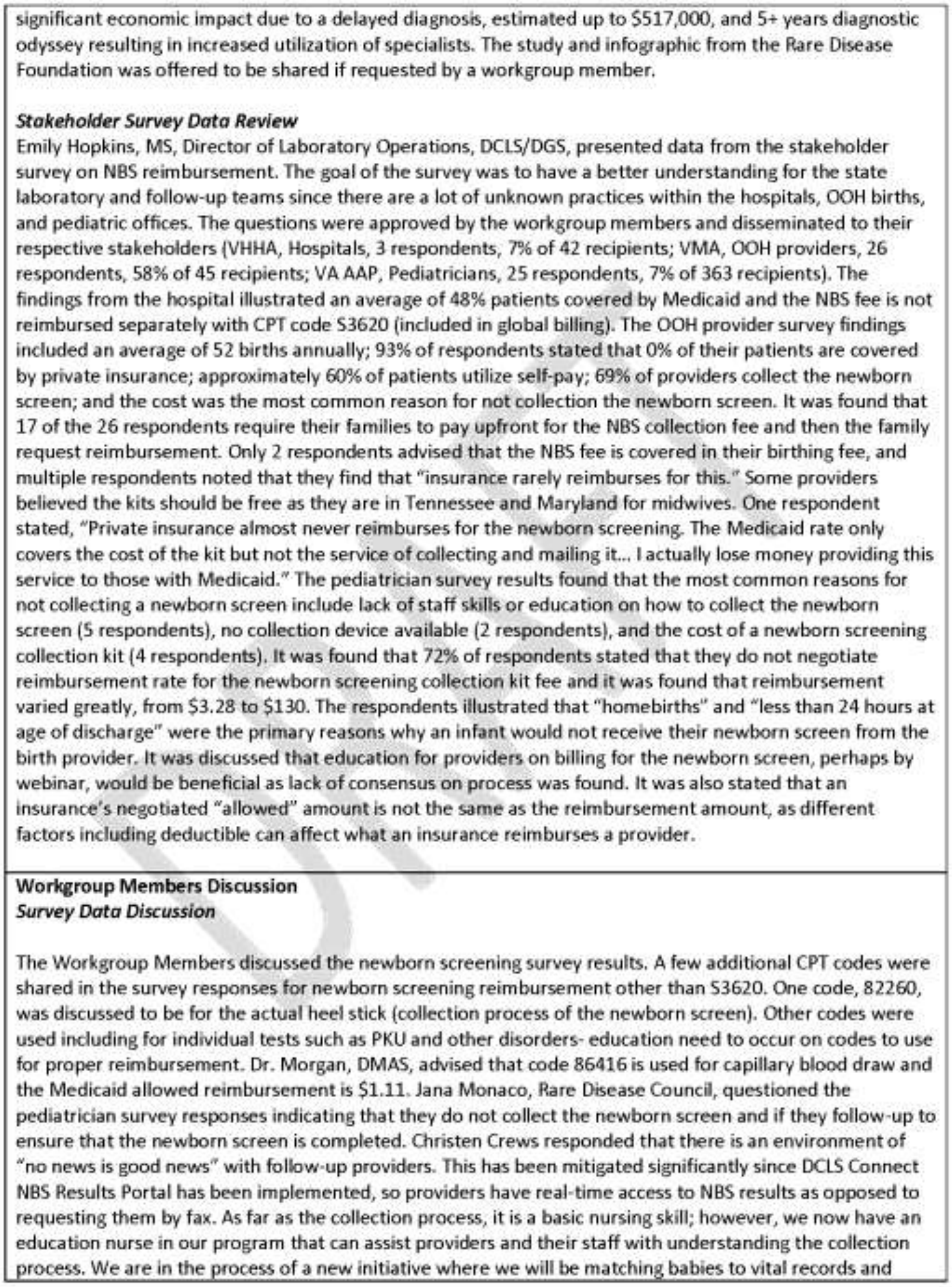
A quick review of data slides previously presented on the different funding models and fee amounts for other state newborn screening programs was shared. Virginia is a 1 screen state, which represents the majority of newborn screening programs in the country. If a repeat NBS or 2nd tier sequencing for lysosomal storage disorders is needed, there is no charge to families or providers from the program. The Virginia fee for service (FFS) model collects funds through the purchase of bloodspot collection kits, and the NBSP is funded 100% for laboratory (DCLS/DGS) and follow-up services (VDH) through this model. She noted that the cost of NBS screening is not dependent on the birth rate, and recent increases have been attributed to legislative mandate for operations 7 days/365 and addition of new disorders to the Virginia core NBS panel. In 2021, approximately 1.7% of births were out of hospital births and 31.3% of all births were recorded as being covered by Medicaid.

The perspectives shared by other states with alternative funding models (Kansas, New York, and Arizona) were reviewed. The Kansas NBS Program operates with approximately 35,000 births annually and NBS is provided at no cost to families. The NBS program is funded through a mandate for insurance organizations

operating within the state to pay into the medical fee fund, and the calculation is an algorithm in code based on the number of subscribers from the previous year. Midwives are not required to contribute due to the low birth rate. The New York NBS program has a similar funding model to Kansas; however, they have approximately 200,000 births a year. Limitations the program has experienced with this funding model is flat funding for the last 10 years, no carryover funds are allowed to help implement new disorders or improve program testing, and they must apply for grant funding in order to supplement budget for staffing. The Arizona NBS program operates with approximately 85,000 births annually and they are a two-screen state. Prior to 2022, the program had a different funding model where the 1st screen was billed to the submitter and the 2nd screen was billed directly to the insurance/family. The program stated that they did not have sufficient resources or staff to ensure reimbursement. The program changed its funding model to a FFS model in 2022 where the submitters are invoiced monthly for a fee that covers both screens. The program tries to avoid 2nd tier testing due to added costs for sending out testing and they are facing challenges with midwives not paying invoices.

A review of previous workgroup discussions included fiscal impact and viewpoints of NBS fee concerns and issues. Workgroup members had questioned if the fee was included in the global fee for insurance or charged separate to insurances/uninsured. It was discussed that it can vary by hospital and by insurance (or uninsured), and it may be different for smaller operations/hospitals. A survey on NBS reimbursement was planned and the results were shared later in the meeting. The hospital perspective (VHHA) viewpoint on NBS fee concerns and issues included that hospitals perform most of the NBS, paying over 11 million dollars annually, and reimbursement rates are not considered including Medicaid deliveries. VHHA proposed a public report to include annual costs to hospitals for specimen collection kits, effectiveness of newborn screening, the number of tests performed, the number of positive tests, number of diagnosed cases, and including guidelines as far as how fees are determined; and evaluating other sources of funding. VHHA also proposed limiting the maximum annual fee increase of the newborn screen. Another proposal included considering imposing a cap on the maximum percentage increase of the NBS fee in a year. This could result in potential delay of implementation of disorders while the fee is being increased to allow implementation of testing. A regular annual percentage increase was suggested as another potential funding model to consider. The Out of Hospital (OOH) provider perspective (VMA) shared that NBS is fiscal burden on providers as midwives. The provider attempts to recoup the cost of the newborn screening fee by either raising their service fees or covering the cost themselves so clients can have the testing. She advised that there is a small subset of clients that will opt out of the newborn screen "to stay off grid", for religious reasons, or cost. Medicaid only covers $103 of the current $138 fee. She said they do educate families prenatally on the importance of the newborn screen and provide a good standard of care. Midwives with smaller practices and low fees, may feel more of a burden than her practice might. Dr. John Morgan, DMAS, said that Medicaid should cover the entire $138 NBS fee, and that the provider should submit a claim for the S3620 CPT code. The provider perspective (NBS AC) shared that in the infancy of the NBS program, there was not a fee for service (FFS) model and the program was supported by general funds (GF). It was expressed that newborn screening is being done on the "backs of parents and backs of hospitals, but it benefits of state". The state can save money because of decreased impact on medical infrastructure from diagnosis and early intervention of positive cases, yet the costs of this is being born by consumers, hospitals, etc. The parent perspective shared having one child identified through newborn screening with a disorder and one child who was not identified early due to the state not screening for the disorder. There was a significant difference in the medical interventions that have been needed over the years between the two children (close to 2 million). The compliance for newborn screening was also questioned and they stated that it is a tremendous burden to midwives.

A discussion occurred regarding estimating cost savings for children diagnosed through newborn screening with a task to see if any information on fiscal impact from the Rare Disease community. To fulfill this need, an infographic was shared from an economic impact report on rare diseases. It was found that there is a

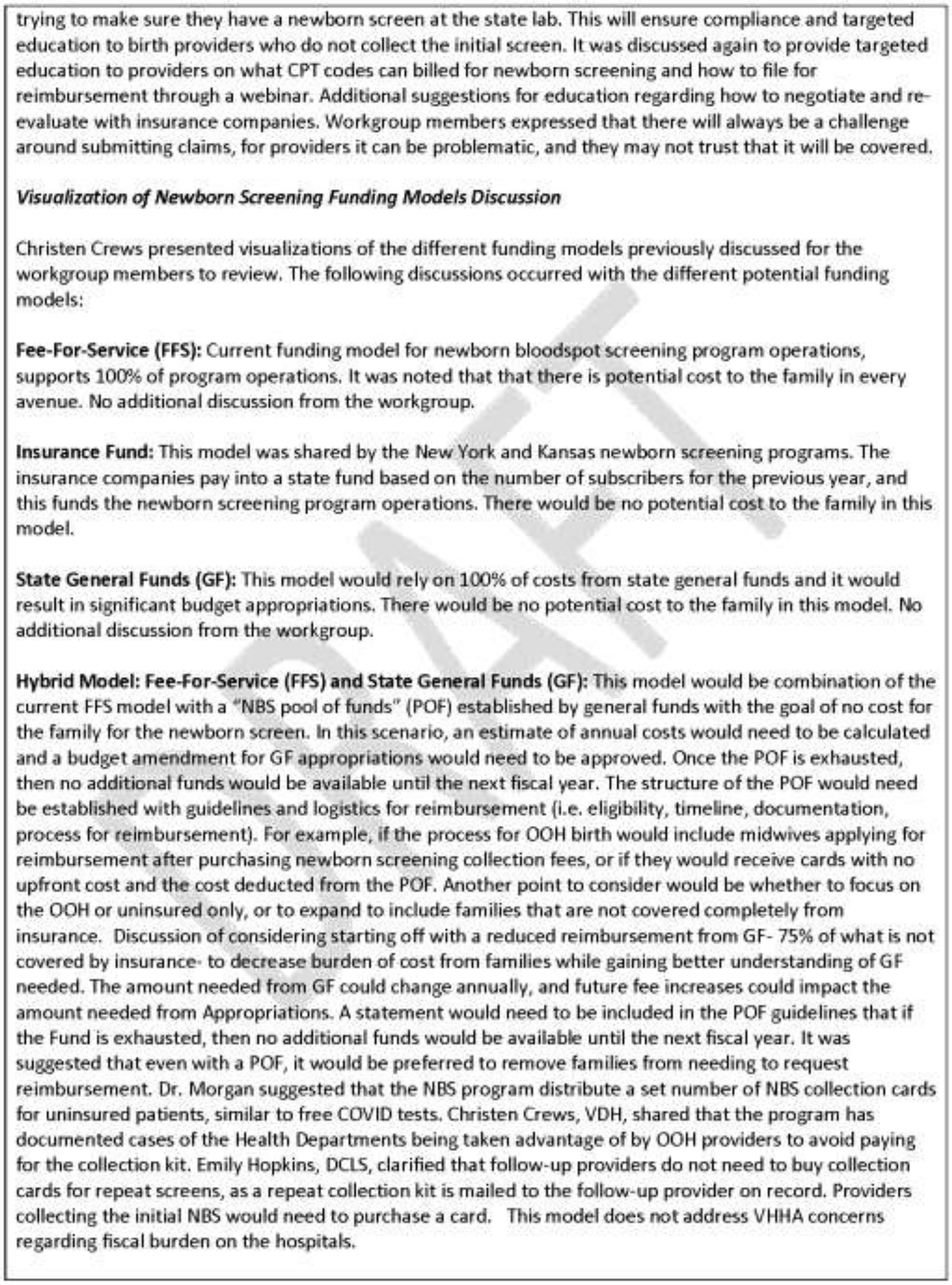


significant economic impact due to a delayed diagnosis, estimated up to $517,000, and 5+ years diagnostic odyssey resulting in increased utilization of specialists. The study and infographic from the Rare Disease Foundation was offered to be shared if requested by a workgroup member.

Stakeholder Survey Data Review
Emily Hopkins, MS, Director of Laboratory Operations, DCLS/DGS, presented data from the stakeholder survey on NBS reimbursement. The goal of the survey was to have a better understanding for the state laboratory and follow-up teams since there are a lot of unknown practices within the hospitals, OOH births, and pediatric offices. The questions were approved by the workgroup members and disseminated to their respective stakeholders (VHHA, Hospitals, 3 respondents, 7% of 42 recipients; VMA, OOH providers, 26 respondents, 58% of 45 recipients; VA AAP, Pediatricians, 25 respondents, 7% of 363 recipients). The findings from the hospital illustrated an average of 48% patients covered by Medicaid and the NBS fee is not reimbursed separately with CPT code S3620 (included in global billing). The OOH provider survey findings included an average of 52 births annually; 93% of respondents stated that 0% of their patients are covered by private insurance; approximately 60% of patients utilize self-pay; 69% of providers collect the newborn screen; and the cost was the most common reason for not collection the newborn screen. It was found that 17 of the 26 respondents require their families to pay upfront for the NBS collection fee and then the family request reimbursement. Only 2 respondents advised that the NBS fee is covered in their birthing fee, and multiple respondents noted that they find that "insurance rarely reimburses for this." Some providers believed the kits should be free as they are in Tennessee and Maryland for midwives. One respondent stated, "Private insurance almost never reimburses for the newborn screening. The Medicaid rate only covers the cost of the kit but not the service of collecting and mailing it... I actually lose money providing this service to those with Medicaid." The pediatrician survey results found that the most common reasons for not collecting a newborn screen include lack of staff skills or education on how to collect the newborn screen (5 respondents), no collection device available (2 respondents), and the cost of a newborn screening collection kit (4 respondents). It was found that 72% of respondents stated that they do not negotiate reimbursement rate for the newborn screening collection kit fee and it was found that reimbursement varied greatly, from $3.28 to $130. The respondents illustrated that "homebirths" and "less than 24 hours at age of discharge" were the primary reasons why an infant would not receive their newborn screen from the birth provider. It was discussed that education for providers on billing for the newborn screen, perhaps by webinar, would be beneficial as lack of consensus on process was found. It was also stated that an insurance's negotiated "allowed" amount is not the same as the reimbursement amount, as different factors including deductible can affect what an insurance reimburses a provider.

Workgroup Members Discussion
Survey Data Discussion

The Workgroup Members discussed the newborn screening survey results. A few additional CPT codes were shared in the survey responses for newborn screening reimbursement other than S3620. One code, 82260, was discussed to be for the actual heel stick (collection process of the newborn screen). Other codes were used including for individual tests such as PKU and other disorders- education need to occur on codes to use for proper reimbursement. Dr. Morgan, DMAS, advised that code 86416 is used for capillary blood draw and the Medicaid allowed reimbursement is $1.11. Jana Monaco, Rare Disease Council, questioned the pediatrician survey responses indicating that they do not collect the newborn screen and if they follow-up to ensure that the newborn screen is completed. Christen Crews responded that there is an environment of "no news is good news" with follow-up providers. This has been mitigated significantly since DCLS Connect NBS Results Portal has been implemented, so providers have real-time access to NBS results as opposed to requesting them by fax. As far as the collection process, it is a basic nursing skill; however, we now have an education nurse in our program that can assist providers and their staff with understanding the collection process. We are in the process of a new initiative where we will be matching babies to vital records and



trying to make sure they have a newborn screen at the state lab. This will ensure compliance and targeted education to birth providers who do not collect the initial screen. It was discussed again to provide targeted education to providers on what CPT codes can billed for newborn screening and how to file for reimbursement through a webinar. Additional suggestions for education regarding how to negotiate and re-evaluate with insurance companies. Workgroup members expressed that there will always be a challenge around submitting claims, for providers it can be problematic, and they may not trust that it will be covered.

Visualization of Newborn Screening Funding Models Discussion

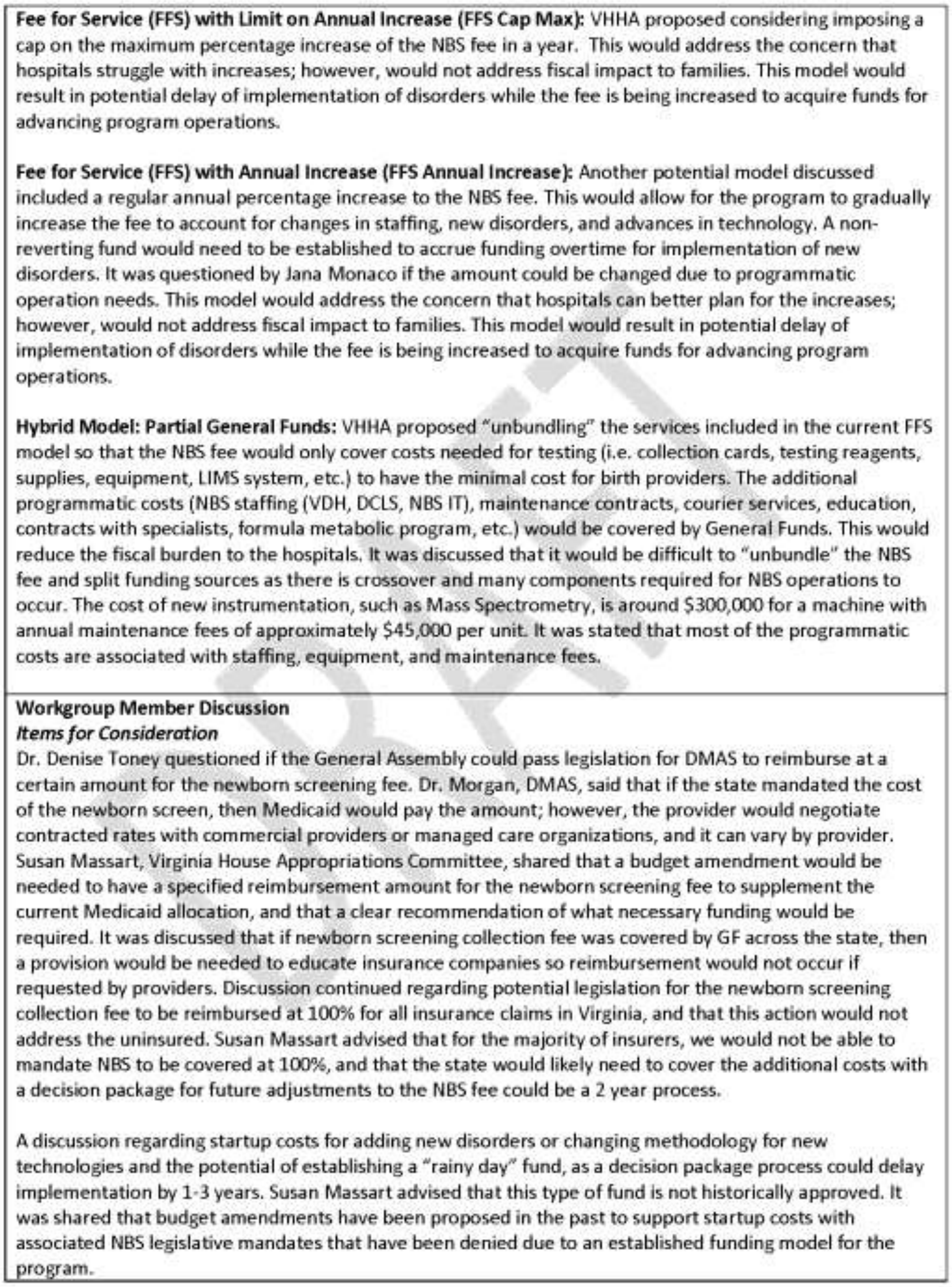
Christen Crews presented visualizations of the different funding models previously discussed for the workgroup members to review. The following discussions occurred with the different potential funding models:

Fee-For-Service (FFS): Current funding model for newborn bloodspot screening program operations, supports 100% of program operations. It was noted that that there is potential cost to the family in every avenue. No additional discussion from the workgroup.

Insurance Fund: This model was shared by the New York and Kansas newborn screening programs. The insurance companies pay into a state fund based on the number of subscribers for the previous year, and this funds the newborn screening program operations. There would be no potential cost to the family in this model.

State General Funds (GF): This model would rely on 100% of costs from state general funds and it would result in significant budget appropriations. There would be no potential cost to the family in this model. No additional discussion from the workgroup.

Hybrid Model: Fee-For-Service (FFS) and State General Funds (GF): This model would be combination of the current FFS model with a "NBS pool of funds" (POF) established by general funds with the goal of no cost for the family for the newborn screen. In this scenario, an estimate of annual costs would need to be calculated and a budget amendment for GF appropriations would need to be approved. Once the POF is exhausted, then no additional funds would be available until the next fiscal year. The structure of the POF would need be established with guidelines and logistics for reimbursement (i.e. eligibility, timeline, documentation, process for reimbursement). For example, if the process for OOH birth would include midwives applying for reimbursement after purchasing newborn screening collection fees, or if they would receive cards with no upfront cost and the cost deducted from the POF. Another point to consider would be whether to focus on the OOH or uninsured only, or to expand to include families that are not covered completely from insurance. Discussion of considering starting off with a reduced reimbursement from GF- 75% of what is not covered by insurance- to decrease burden of cost from families while gaining better understanding of GF needed. The amount needed from GF could change annually, and future fee increases could impact the amount needed from Appropriations. A statement would need to be included in the POF guidelines that if the Fund is exhausted, then no additional funds would be available until the next fiscal year. It was suggested that even with a POF, it would be preferred to remove families from needing to request reimbursement. Dr. Morgan suggested that the NBS program distribute a set number of NBS collection cards for uninsured patients, similar to free COVID tests. Christen Crews, VDH, shared that the program has documented cases of the Health Departments being taken advantage of by OOH providers to avoid paying for the collection kit. Emily Hopkins, DCLS, clarified that follow-up providers do not need to buy collection cards for repeat screens, as a repeat collection kit is mailed to the follow-up provider on record. Providers collecting the initial NBS would need to purchase a card. This model does not address VHHA concerns regarding fiscal burden on the hospitals.



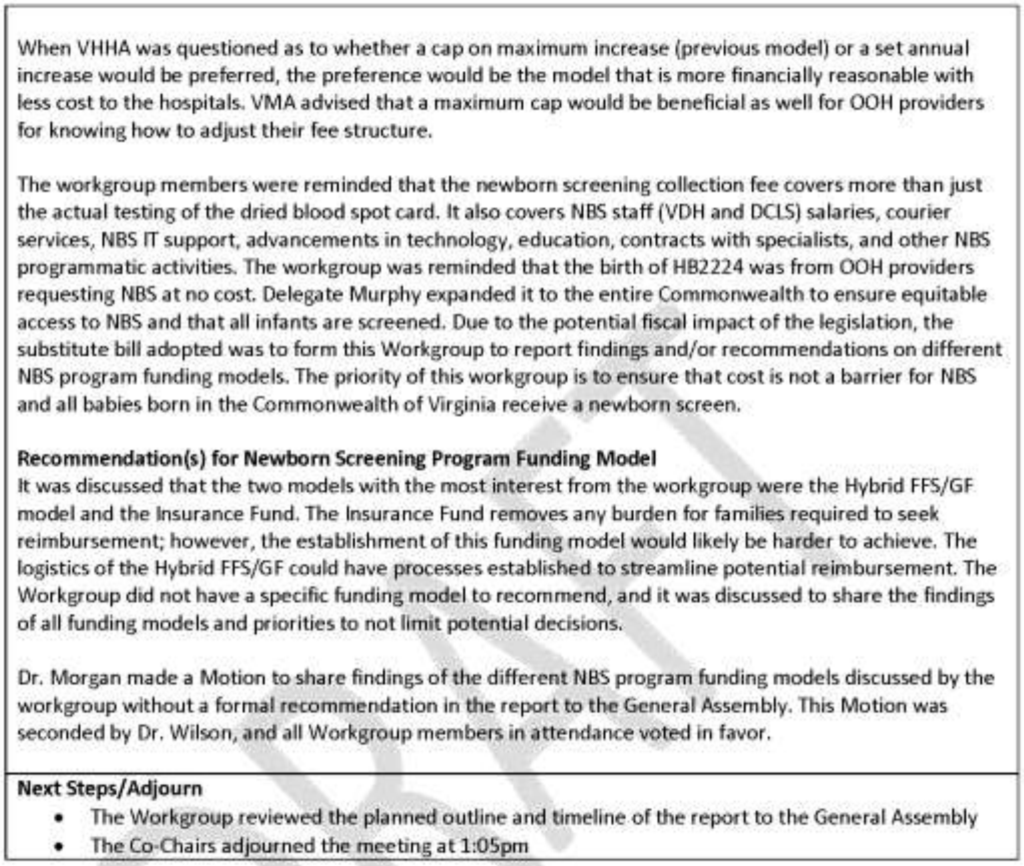
Fee for Service (FFS) with Limit on Annual Increase (FFS Cap Max): VHHA proposed considering imposing a cap on the maximum percentage increase of the NBS fee in a year. This would address the concern that hospitals struggle with increases; however, would not address fiscal impact to families. This model would result in potential delay of implementation of disorders while the fee is being increased to acquire funds for advancing program operations.

Fee for Service (FFS) with Annual Increase (FFS Annual Increase): Another potential model discussed included a regular annual percentage increase to the NBS fee. This would allow for the program to gradually increase the fee to account for changes in staffing, new disorders, and advances in technology. A non-reverting fund would need to be established to accrue funding overtime for implementation of new disorders. It was questioned by Jana Monaco if the amount could be changed due to programmatic operation needs. This model would address the concern that hospitals can better plan for the increases; however, would not address fiscal impact to families. This model would result in potential delay of implementation of disorders while the fee is being increased to acquire funds for advancing program operations.

Hybrid Model: Partial General Funds: VHHA proposed "unbundling" the services included in the current FFS model so that the NBS fee would only cover costs needed for testing (i.e. collection cards, testing reagents, supplies, equipment, LIMS system, etc.) to have the minimal cost for birth providers. The additional programmatic costs (NBS staffing (VDH, DCLS, NBS IT), maintenance contracts, courier services, education, contracts with specialists, formula metabolic program, etc.) would be covered by General Funds. This would reduce the fiscal burden to the hospitals. It was discussed that it would be difficult to "unbundle" the NBS fee and split funding sources as there is crossover and many components required for NBS operations to occur. The cost of new instrumentation, such as Mass Spectrometry, is around $300,000 for a machine with annual maintenance fees of approximately $45,000 per unit. It was stated that most of the programmatic costs are associated with staffing, equipment, and maintenance fees.

Workgroup Member Discussion
Items for Consideration
Dr. Denise Toney questioned if the General Assembly could pass legislation for DMAS to reimburse at a certain amount for the newborn screening fee. Dr. Morgan, DMAS, said that if the state mandated the cost of the newborn screen, then Medicaid would pay the amount; however, the provider would negotiate contracted rates with commercial providers or managed care organizations, and it can vary by provider. Susan Massart, Virginia House Appropriations Committee, shared that a budget amendment would be needed to have a specified reimbursement amount for the newborn screening fee to supplement the current Medicaid allocation, and that a clear recommendation of what necessary funding would be required. It was discussed that if newborn screening collection fee was covered by GF across the state, then a provision would be needed to educate insurance companies so reimbursement would not occur if requested by providers. Discussion continued regarding potential legislation for the newborn screening collection fee to be reimbursed at 100% for all insurance claims in Virginia, and that this action would not address the uninsured. Susan Massart advised that for the majority of insurers, we would not be able to mandate NBS to be covered at 100%, and that the state would likely need to cover the additional costs with a decision package for future adjustments to the NBS fee could be a 2 year process.

A discussion regarding startup costs for adding new disorders or changing methodology for new technologies and the potential of establishing a "rainy day" fund, as a decision package process could delay implementation by 1-3 years. Susan Massart advised that this type of fund is not historically approved. It was shared that budget amendments have been proposed in the past to support startup costs with associated NBS legislative mandates that have been denied due to an established funding model for the program.



When VHHA was questioned as to whether a cap on maximum increase (previous model) or a set annual increase would be preferred, the preference would be the model that is more financially reasonable with less cost to the hospitals. VMA advised that a maximum cap would be beneficial as well for OOH providers for knowing how to adjust their fee structure.

The workgroup members were reminded that the newborn screening collection fee covers more than just the actual testing of the dried blood spot card. It also covers NBS staff (VDH and DCLS) salaries, courier services, NBS IT support, advancements in technology, education, contracts with specialists, and other NBS programmatic activities. The workgroup was reminded that the birth of HB2224 was from OOH providers requesting NBS at no cost. Delegate Murphy expanded it to the entire Commonwealth to ensure equitable access to NBS and that all infants are screened. Due to the potential fiscal impact of the legislation, the substitute bill adopted was to form this Workgroup to report findings and/or recommendations on different NBS program funding models. The priority of this workgroup is to ensure that cost is not a barrier for NBS and all babies born in the Commonwealth of Virginia receive a newborn screen.

Recommendation(s) for Newborn Screening Program Funding Model
It was discussed that the two models with the most interest from the workgroup were the Hybrid FFS/GF model and the Insurance Fund. The Insurance Fund removes any burden for families required to seek reimbursement; however, the establishment of this funding model would likely be harder to achieve. The logistics of the Hybrid FFS/GF could have processes established to streamline potential reimbursement. The Workgroup did not have a specific funding model to recommend, and it was discussed to share the findings of all funding models and priorities to not limit potential decisions.

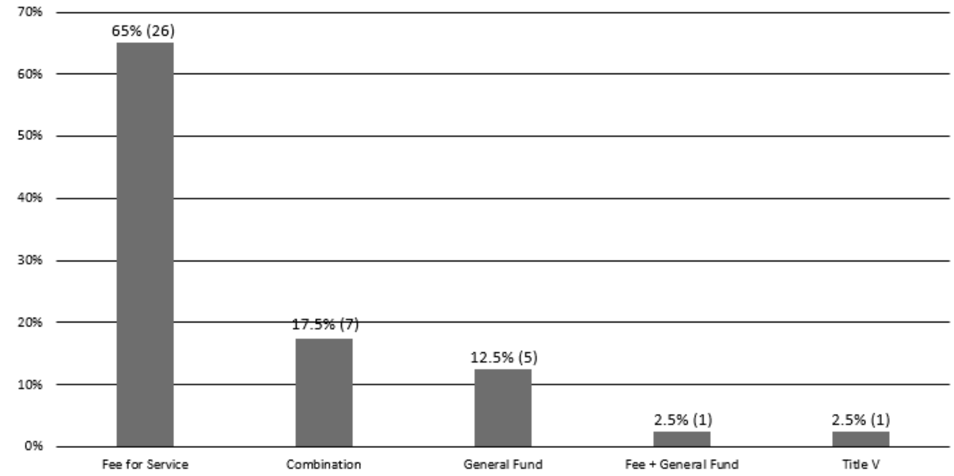
Dr. Morgan made a Motion to share findings of the different NBS program funding models discussed by the workgroup without a formal recommendation in the report to the General Assembly. This Motion was seconded by Dr. Wilson, and all Workgroup members in attendance voted in favor.

Next Steps/Adjourn

- The Workgroup reviewed the planned outline and timeline of the report to the General Assembly
- The Co-Chairs adjourned the meeting at 1:05pm

APPENDIX E – NEWBORN SCREENING PROGRAM DATA

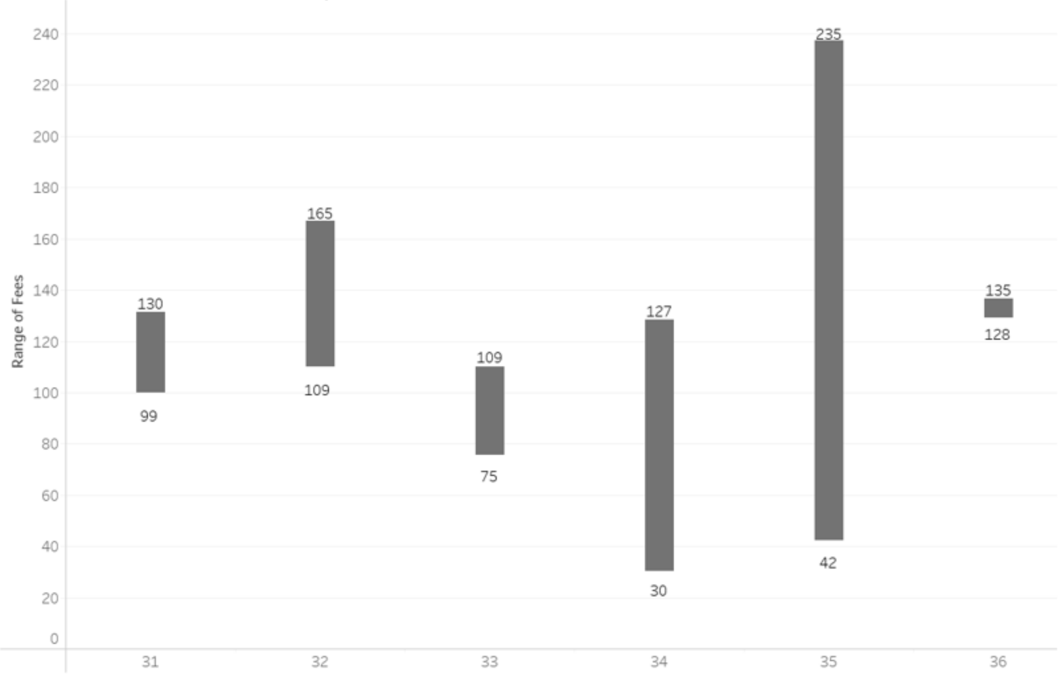
Current Funding Models, Single Screen States



Source: APHL, NewSTEPs Data Repository, as of June 9, 2023

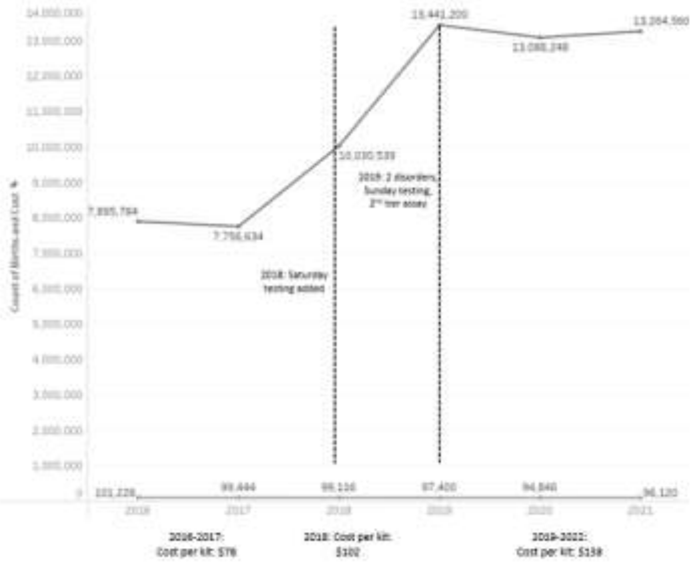
Fee Ranges by Number of Disorders Tested

One Screen States, 2021



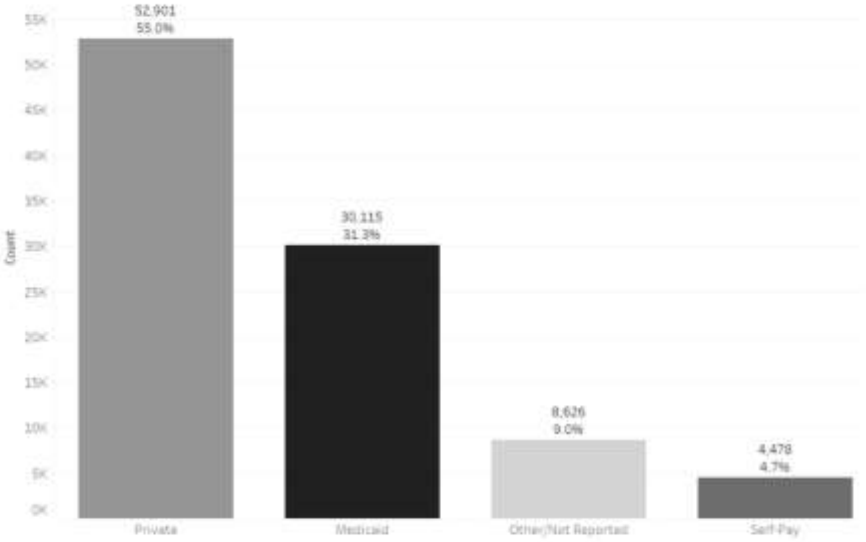
Source: APHL, NewSTEPs Data Repository, as of June 9, 2023

Birth Counts and Cost of Newborn Screening in Virginia, 2016-2021



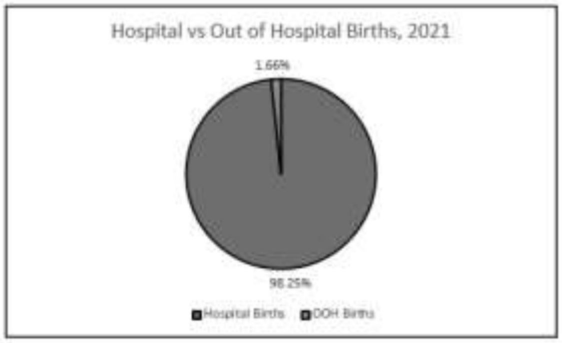
Source: Virginia Vital Statistics, DCLS

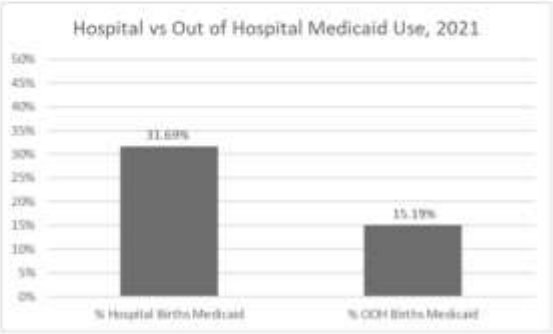
Number and Percent of Births by Insurance Provider Virginia, 2021



Source: CDC Wonder, Natality, 2021 as of June 15, 2023

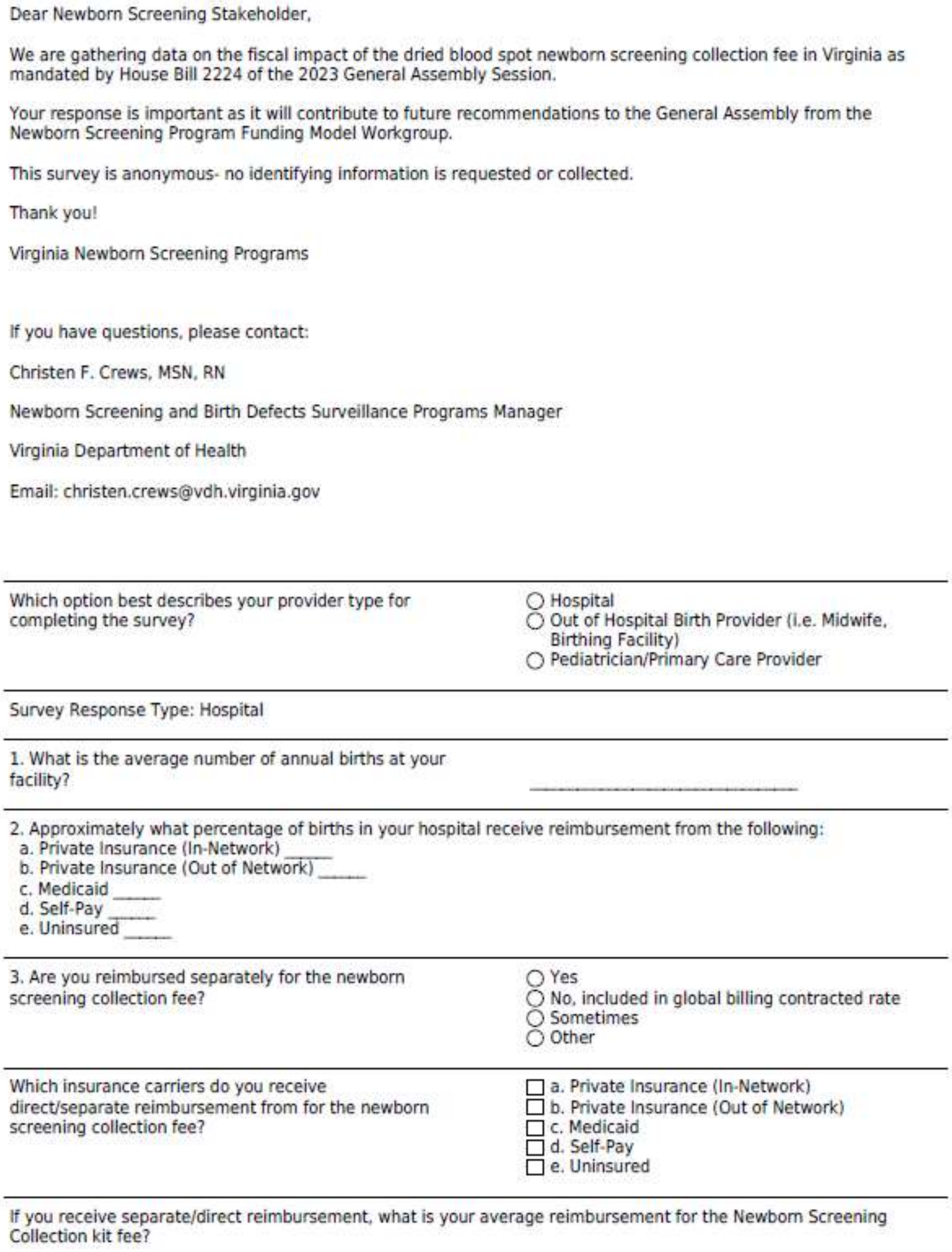
Hospital vs OOH births for 2021 (Virginia)
Hospital vs OOH Medicaid for 2021 (Virginia)





Source: CDC Wonder, Natality, 2021 as of June 15, 2023

APPENDIX F – STAKEHOLDER NBS REIMBURSEMENT SURVEY



Dear Newborn Screening Stakeholder,

We are gathering data on the fiscal impact of the dried blood spot newborn screening collection fee in Virginia as mandated by House Bill 2224 of the 2023 General Assembly Session.

Your response is important as it will contribute to future recommendations to the General Assembly from the Newborn Screening Program Funding Model Workgroup.

This survey is anonymous- no identifying information is requested or collected.

Thank you!

Virginia Newborn Screening Programs

If you have questions, please contact:

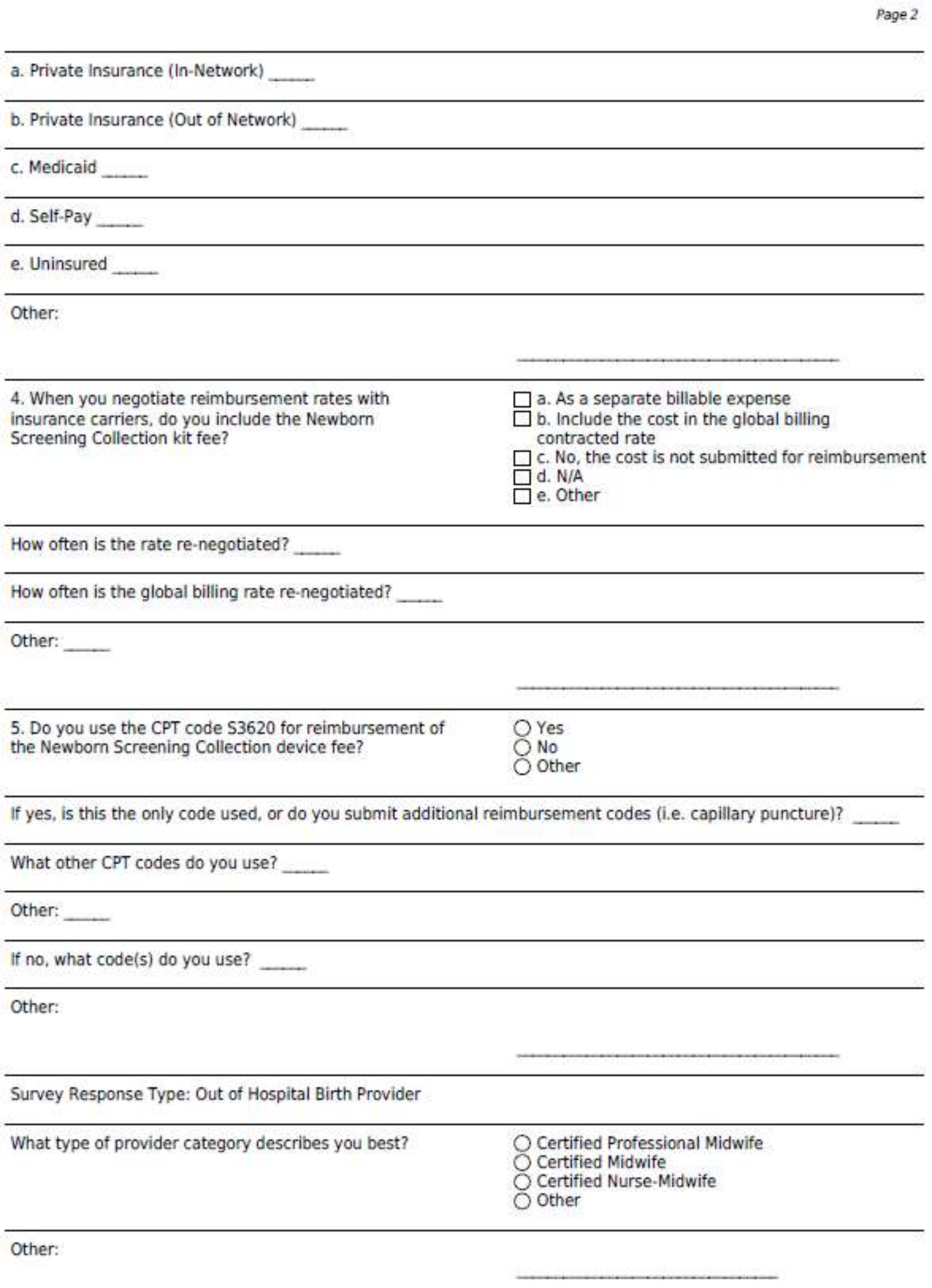
Christen F. Crews, MSN, RN

Newborn Screening and Birth Defects Surveillance Programs Manager

Virginia Department of Health

Email: christen.crews@vdh.virginia.gov

Which option best describes your provider type for completing the survey?	○ Hospital ○ Out of Hospital Birth Provider (i.e. Midwife, Birthing Facility) ○ Pediatrician/Primary Care Provider
Survey Response Type: Hospital	
1. What is the average number of annual births at your facility?	____________________
2. Approximately what percentage of births in your hospital receive reimbursement from the following: a. Private Insurance (In-Network) ______ b. Private Insurance (Out of Network) ______ c. Medicaid ______ d. Self-Pay ______ e. Uninsured ______	
3. Are you reimbursed separately for the newborn screening collection fee?	○ Yes ○ No, included in global billing contracted rate ○ Sometimes ○ Other
Which insurance carriers do you receive direct/separate reimbursement from for the newborn screening collection fee?	☐ a. Private Insurance (In-Network) ☐ b. Private Insurance (Out of Network) ☐ c. Medicaid ☐ d. Self-Pay ☐ e. Uninsured
If you receive separate/direct reimbursement, what is your average reimbursement for the Newborn Screening Collection kit fee?	



Page 2

a. Private Insurance (In-Network) ______

b. Private Insurance (Out of Network) ______

c. Medicaid ______

d. Self-Pay ______

e. Uninsured ______

Other: ______

4. When you negotiate reimbursement rates with insurance carriers, do you include the Newborn Screening Collection kit fee?	☐ a. As a separate billable expense ☐ b. Include the cost in the global billing contracted rate ☐ c. No, the cost is not submitted for reimbursement ☐ d. N/A ☐ e. Other

How often is the rate re-negotiated? ______

How often is the global billing rate re-negotiated? ______

Other: ______

5. Do you use the CPT code S3620 for reimbursement of the Newborn Screening Collection device fee?	○ Yes ○ No ○ Other

If yes, is this the only code used, or do you submit additional reimbursement codes (i.e. capillary puncture)? ______

What other CPT codes do you use? ______

Other: ______

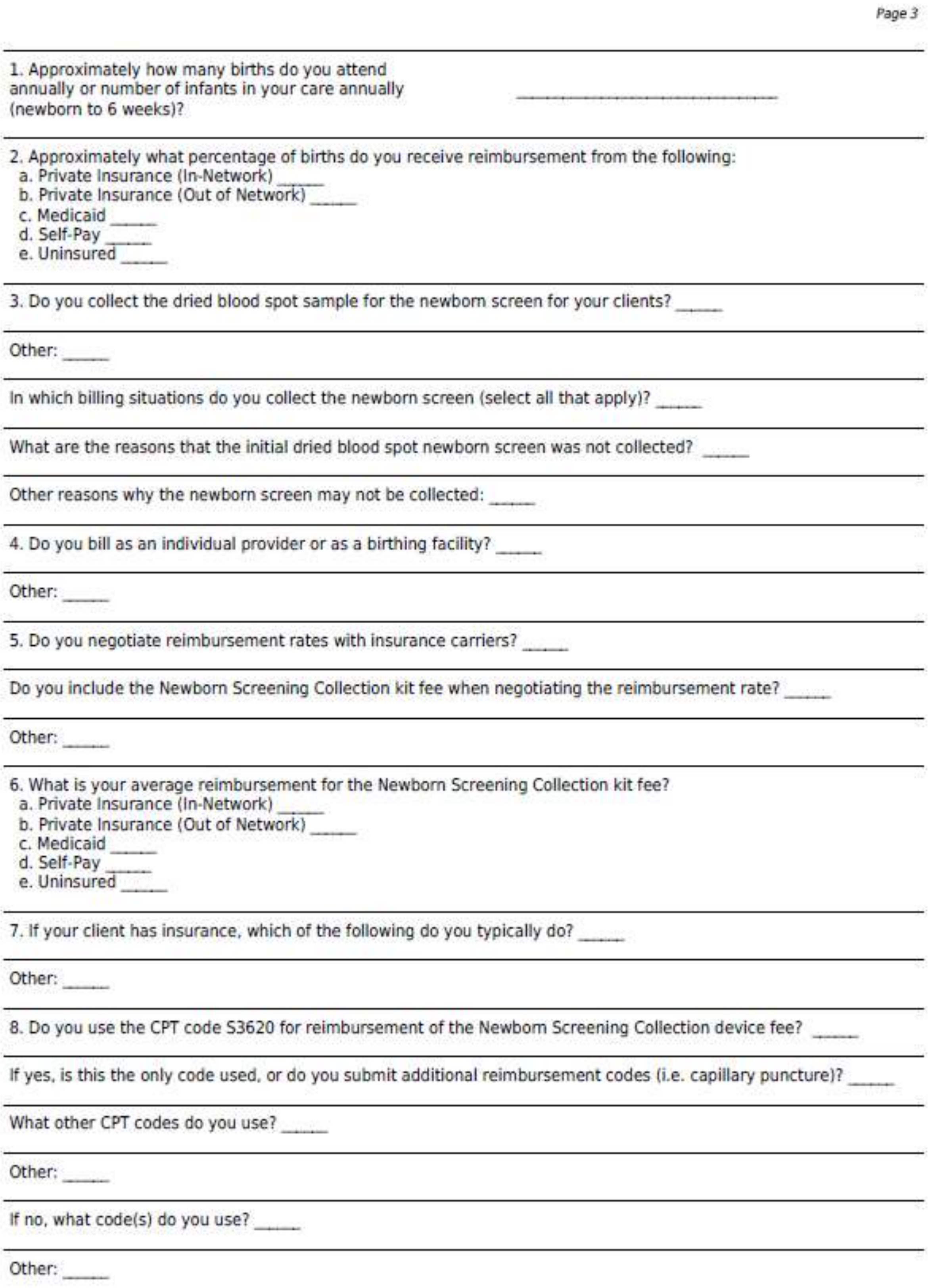
If no, what code(s) do you use? ______

Other: ______

Survey Response Type: Out of Hospital Birth Provider

What type of provider category describes you best?	○ Certified Professional Midwife ○ Certified Midwife ○ Certified Nurse-Midwife ○ Other

Other: ______



Page 3

1. Approximately how many births do you attend annually or number of infants in your care annually (newborn to 6 weeks)? ______________________

2. Approximately what percentage of births do you receive reimbursement from the following:
   - a. Private Insurance (In-Network) _____
   - b. Private Insurance (Out of Network) _____
   - c. Medicaid _____
   - d. Self-Pay _____
   - e. Uninsured _____

3. Do you collect the dried blood spot sample for the newborn screen for your clients? _____

Other: _____

In which billing situations do you collect the newborn screen (select all that apply)? _____

What are the reasons that the initial dried blood spot newborn screen was not collected? _____

Other reasons why the newborn screen may not be collected: _____

4. Do you bill as an individual provider or as a birthing facility? _____

Other: _____

5. Do you negotiate reimbursement rates with insurance carriers? _____

Do you include the Newborn Screening Collection kit fee when negotiating the reimbursement rate? _____

Other: _____

6. What is your average reimbursement for the Newborn Screening Collection kit fee?
   - a. Private Insurance (In-Network) _____
   - b. Private Insurance (Out of Network) _____
   - c. Medicaid _____
   - d. Self-Pay _____
   - e. Uninsured _____

7. If your client has insurance, which of the following do you typically do? _____

Other: _____

8. Do you use the CPT code S3620 for reimbursement of the Newborn Screening Collection device fee? _____

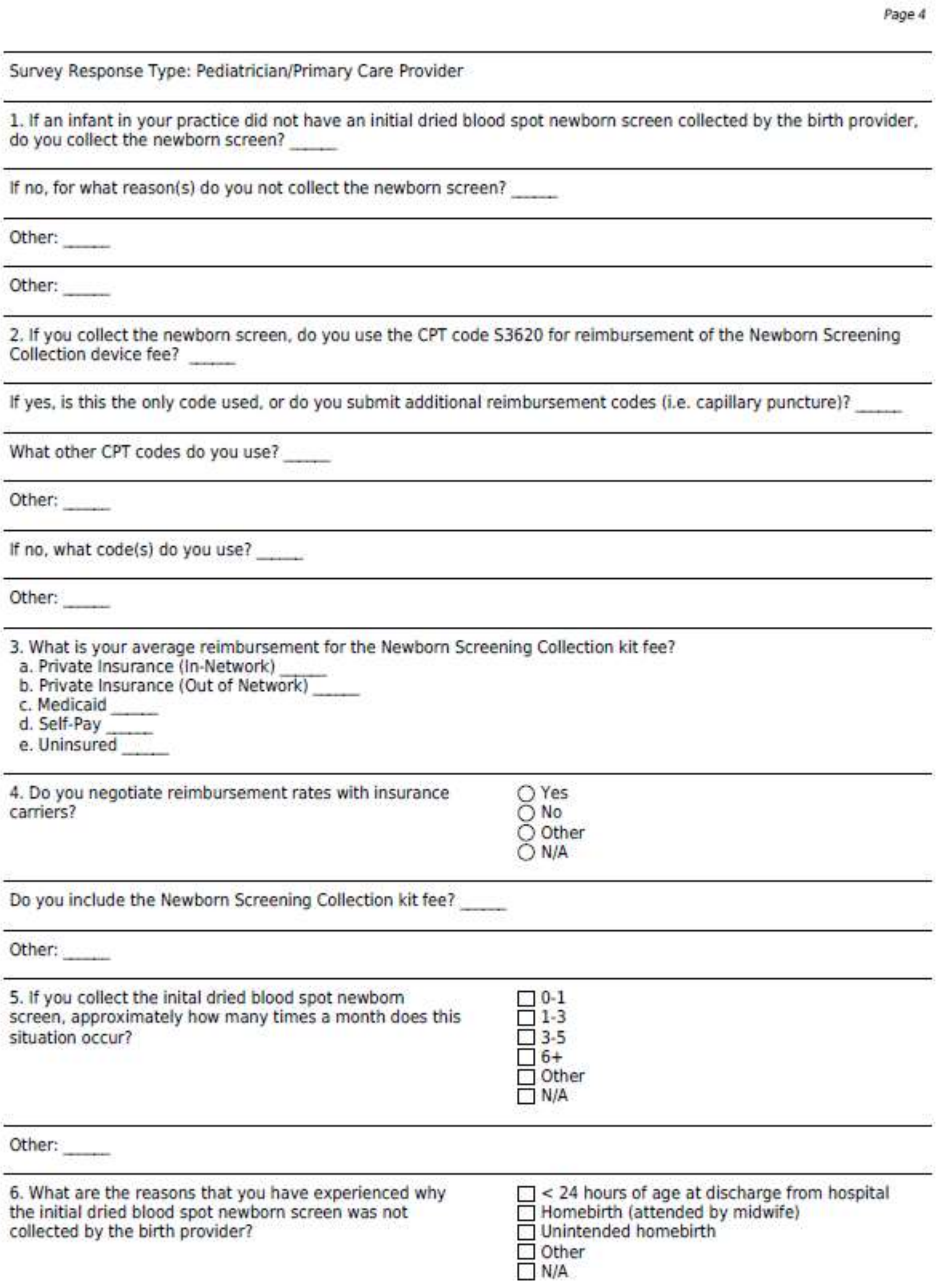
If yes, is this the only code used, or do you submit additional reimbursement codes (i.e. capillary puncture)? _____

What other CPT codes do you use? _____

Other: _____

If no, what code(s) do you use? _____

Other: _____



Survey Response Type: Pediatrician/Primary Care Provider

1. If an infant in your practice did not have an initial dried blood spot newborn screen collected by the birth provider, do you collect the newborn screen? ______

If no, for what reason(s) do you not collect the newborn screen? ______

Other: ______

Other: ______

2. If you collect the newborn screen, do you use the CPT code S3620 for reimbursement of the Newborn Screening Collection device fee? ______

If yes, is this the only code used, or do you submit additional reimbursement codes (i.e. capillary puncture)? ______

What other CPT codes do you use? ______

Other: ______

If no, what code(s) do you use? ______

Other: ______

3. What is your average reimbursement for the Newborn Screening Collection kit fee?
a. Private Insurance (In-Network) ______
b. Private Insurance (Out of Network) ______
c. Medicaid ______
d. Self-Pay ______
e. Uninsured ______

4. Do you negotiate reimbursement rates with insurance carriers?
○ Yes
○ No
○ Other
○ N/A

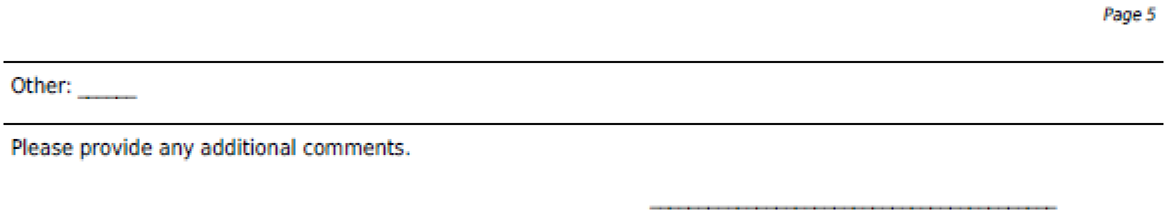
Do you include the Newborn Screening Collection kit fee? ______

Other: ______

5. If you collect the inital dried blood spot newborn screen, approximately how many times a month does this situation occur?
☐ 0-1
☐ 1-3
☐ 3-5
☐ 6+
☐ Other
☐ N/A

Other: ______

6. What are the reasons that you have experienced why the initial dried blood spot newborn screen was not collected by the birth provider?
☐ < 24 hours of age at discharge from hospital
☐ Homebirth (attended by midwife)
☐ Unintended homebirth
☐ Other
☐ N/A



Page 5

Other: ______

Please provide any additional comments.

____

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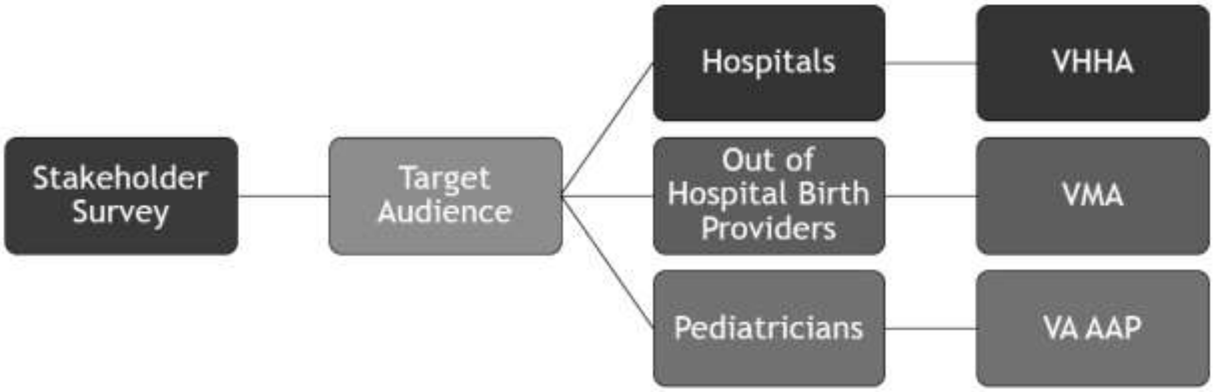
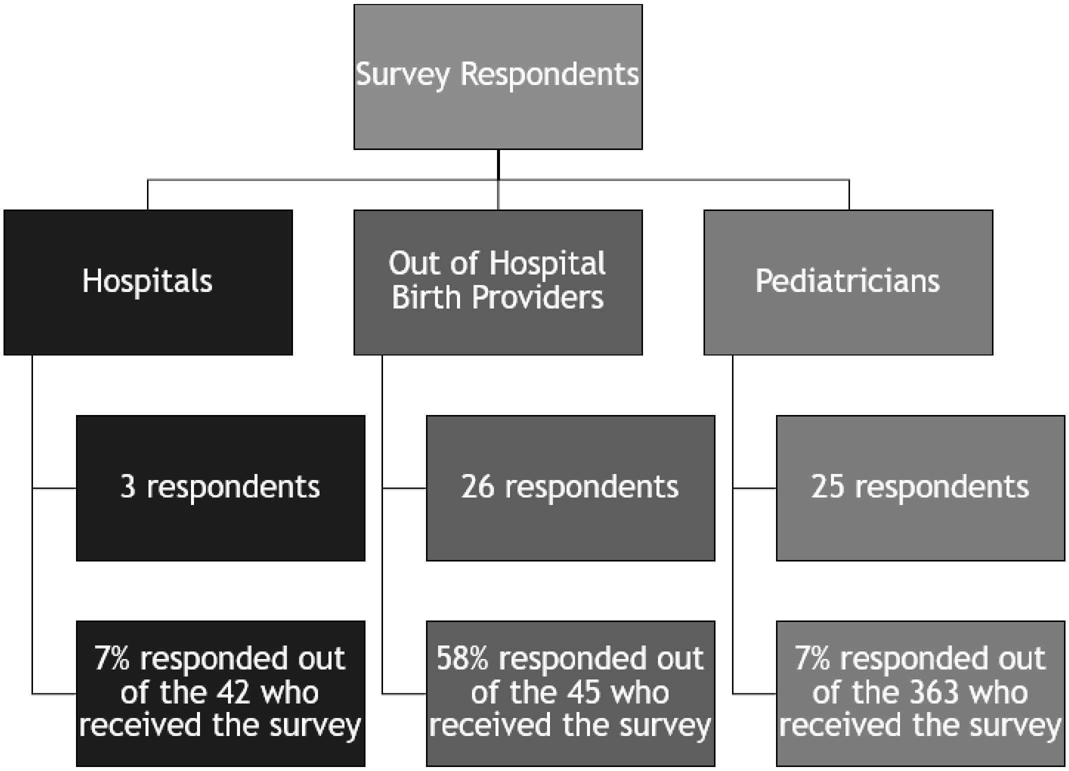
APPENDIX G – STAKEHOLDER SURVEY DATA FINDINGS





Hospital Findings

An average of **40%** of patients covered by private insurance at each hospital represented

Average of **48%** of patients covered by Medicaid at each hospital

Approximately 3,000 births annually

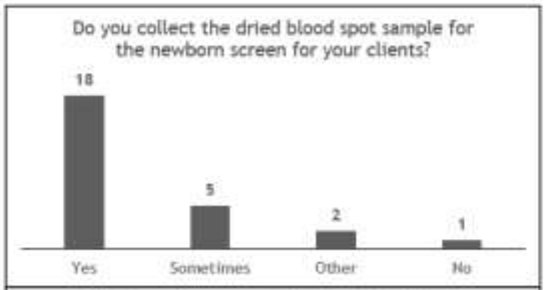
One hospital **does not include** NBS Collection Kit fee in **negotiations for reimbursement rates**

One includes the cost of the NBS Collection Kit **fee in the global billing contracted rate**

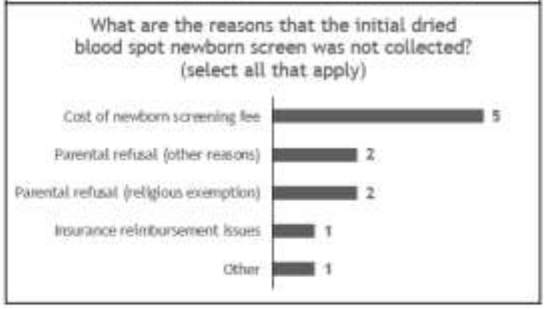
One hospital reported using CPT code 84030

None of the three hospital respondents reported using CPT Code S3620

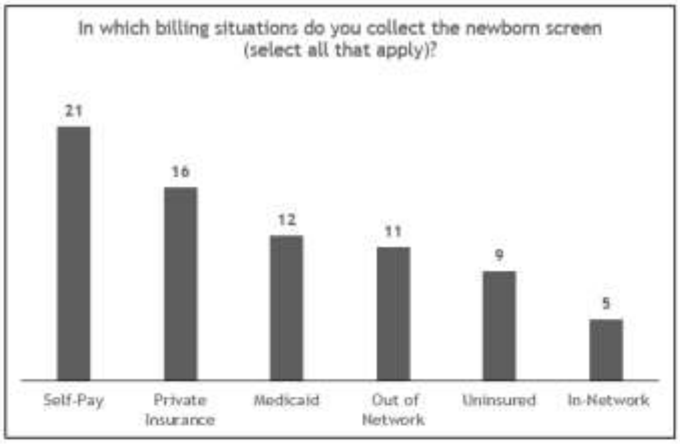
Out of Hospital Insight: Survey Responses



Do you collect the dried blood spot sample for the newborn screen for your clients?



What are the reasons that the initial dried blood spot newborn screen was not collected? (select all that apply)



In which billing situations do you collect the newborn screen (select all that apply)?

Out of Hospital Findings

Average of 52 births annually

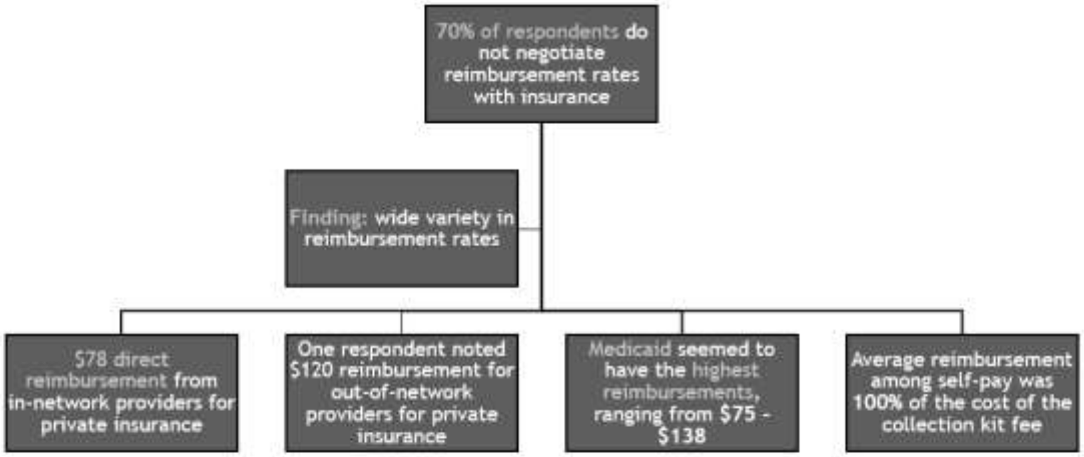
92.5% of respondents said 0% of their patients are covered by private insurance

Average of 60% of patients utilize self-pay

69% of respondents reported collecting the dried blood spot

Cost was the common reason for not collecting the dried blood spot

Out of Hospital Insight: Insurance and Reimbursement



70% of respondents do not negotiate reimbursement rates with insurance

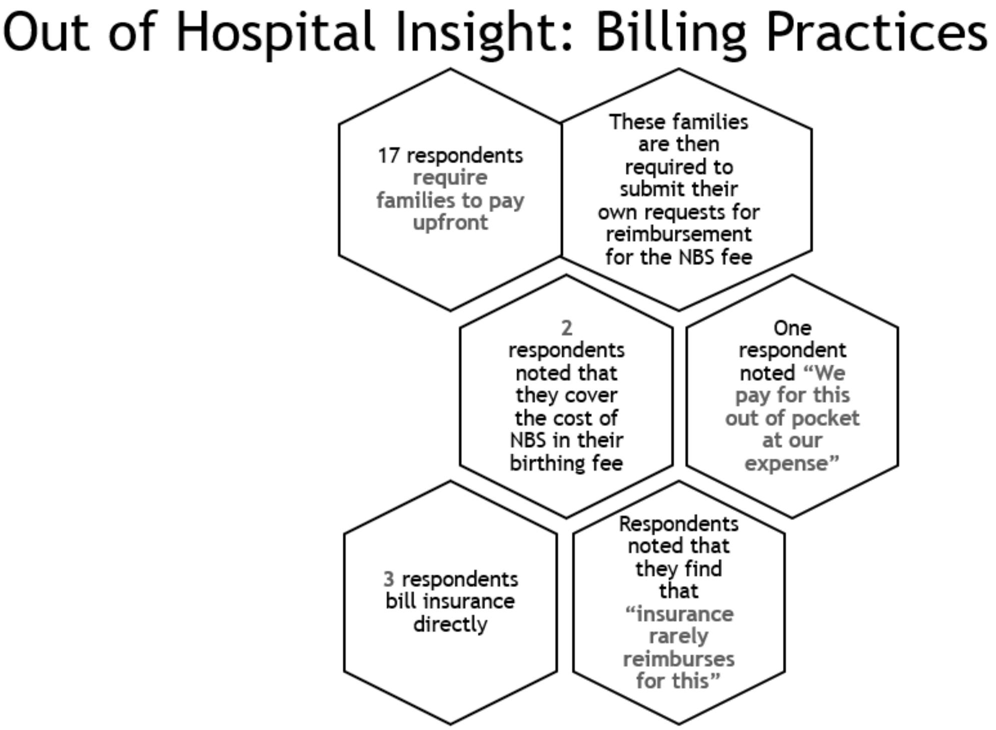
Finding: wide variety in reimbursement rates

$78 direct reimbursement from in-network providers for private insurance

One respondent noted $120 reimbursement for out-of-network providers for private insurance

Medicaid seemed to have the highest reimbursements, ranging from $75 - $138

Average reimbursement among self-pay was 100% of the cost of the collection kit fee



Out of Hospital Insight: Billing Practices

17 respondents require families to pay upfront

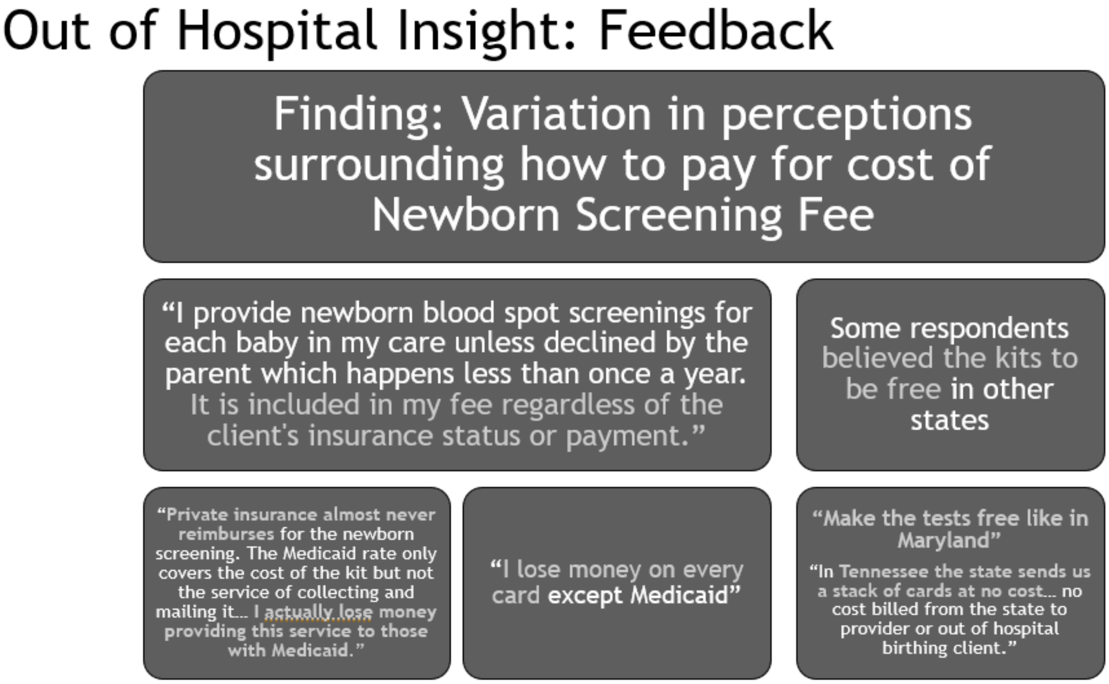
These families are then required to submit their own requests for reimbursement for the NBS fee

2 respondents noted that they cover the cost of NBS in their birthing fee

One respondent noted "We pay for this out of pocket at our expense"

3 respondents bill insurance directly

Respondents noted that they find that "insurance rarely reimburses for this"



Out of Hospital Insight: Feedback

Finding: Variation in perceptions surrounding how to pay for cost of Newborn Screening Fee

"I provide newborn blood spot screenings for each baby in my care unless declined by the parent which happens less than once a year. It is included in my fee regardless of the client's insurance status or payment."

Some respondents believed the kits to be free in other states

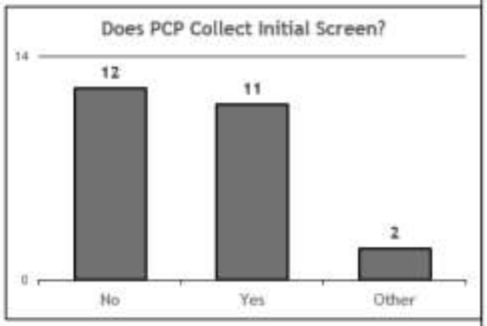
"Private insurance almost never reimburses for the newborn screening. The Medicaid rate only covers the cost of the kit but not the service of collecting and mailing it… I actually lose money providing this service to those with Medicaid."

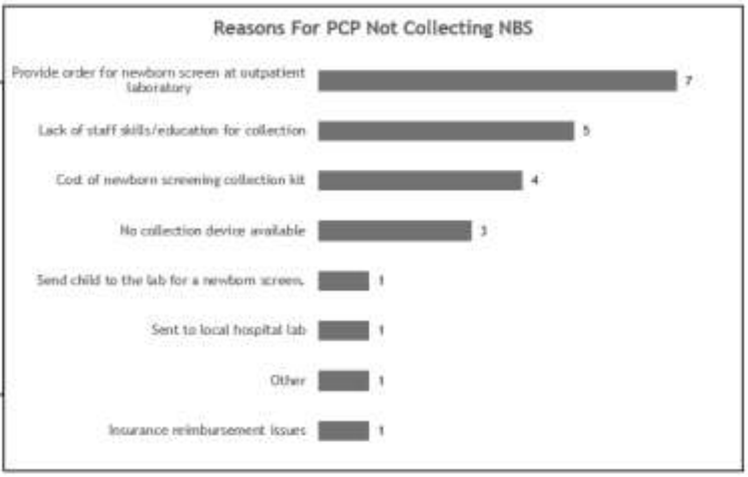
"I lose money on every card except Medicaid"

"Make the tests free like in Maryland"

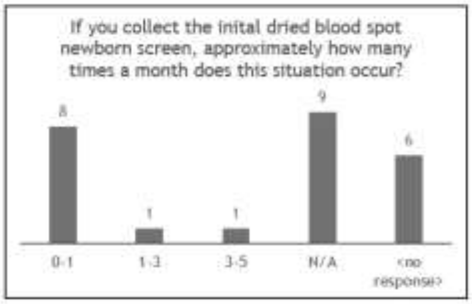
"In Tennessee the state sends us a stack of cards at no cost… no cost billed from the state to provider or out of hospital birthing client."

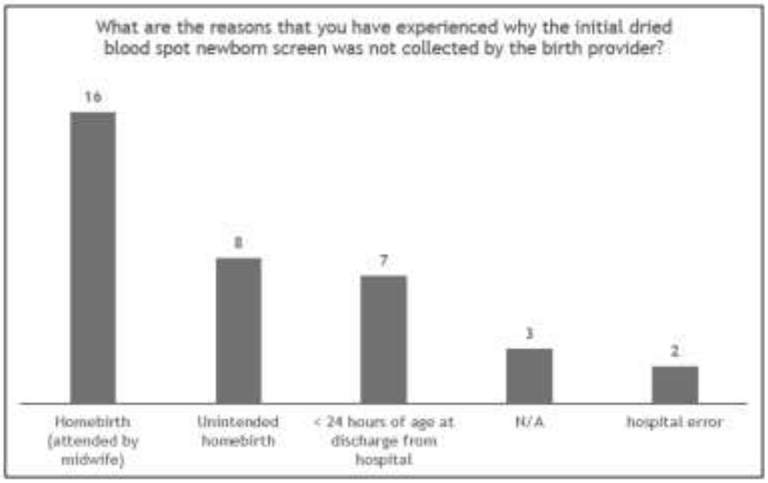
Pediatrician Insight: Survey Responses


Does PCP Collect Initial Screen?

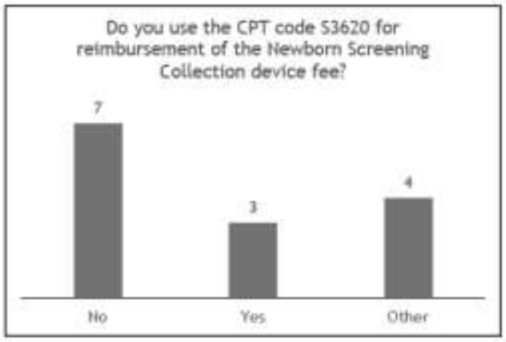

Reasons For PCP Not Collecting NBS

Pediatrician Insight: Survey Responses

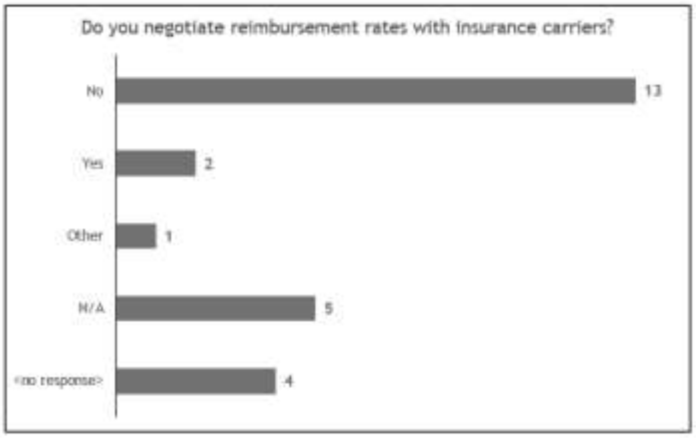

If you collect the inital dried blood spot newborn screen, approximately how many times a month does this situation occur?


What are the reasons that you have experienced why the initial dried blood spot newborn screen was not collected by the birth provider?

Pediatrician Insight: Survey Responses



One respondent also submits for capillary punction and handling fee.
One respondent also submits codes 99000, 36416.



Pediatrician Findings

"Do you collect the newborn screen if an infant in your practice did not have one initially by the birth provider?

- 12 said no
- 11 said yes
- 2 said they send patients to a lab for screening

Common reasons why pediatricians do not collect the newborn screen

- Lack of staff skills or education on how to collect (5 respondents)
- No collection device available (2 respondents)
- Cost of newborn screening collection kit (4 respondents)

Codes used for reimbursement

- 4 use S3620
- Other respondents noted "I wasn't aware there was a code that could be used" and "We send the screen at no charge to the patient
- One respondent stated: "Service is poorly reimbursed and the cost of the test card is exorbitant… we eat the cost but resent having to do so."

Pediatrician Insight: Insurance and Reimbursement

72% of respondents said they do not negotiate reimbursement rates with insurance or that this question is not applicable to them

The two respondents who do negotiate with insurance do not include the newborn screening collection kit fee

One respondent noted $130 reimbursement for NBS Collection kit fee for private, in-network insurance

Another respondent noted $3.28 reimbursement for patients in this same category

One respondent noted $10 reimbursement for out-of-network providers for private insurance

Medicaid seemed to have the highest reimbursements, at $60

Average reimbursement among self-pay was 100% of the cost of the collection kit fee

Pediatrician Insight: Feedback

Cost is a key reason for which pediatricians do not provide newborn screens

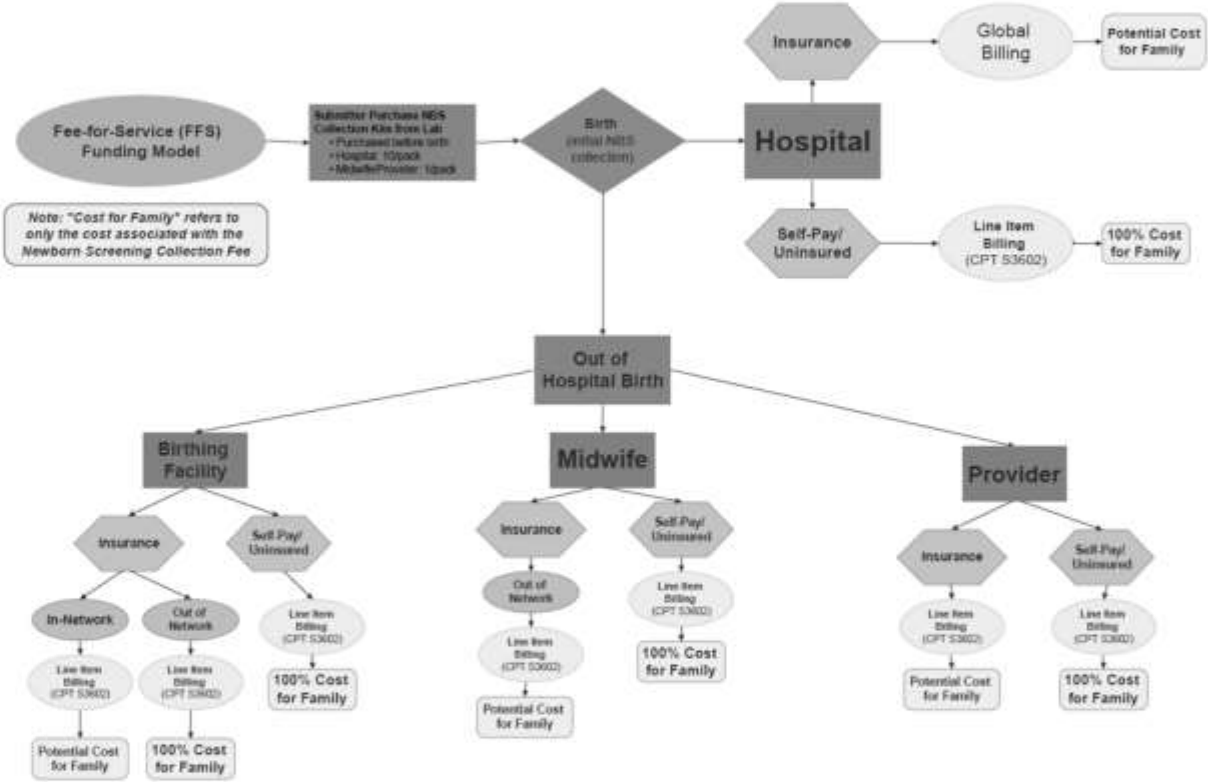
"Blood spot cards are extremely difficult to secure-my organization does not want to purchase them because of the cost"

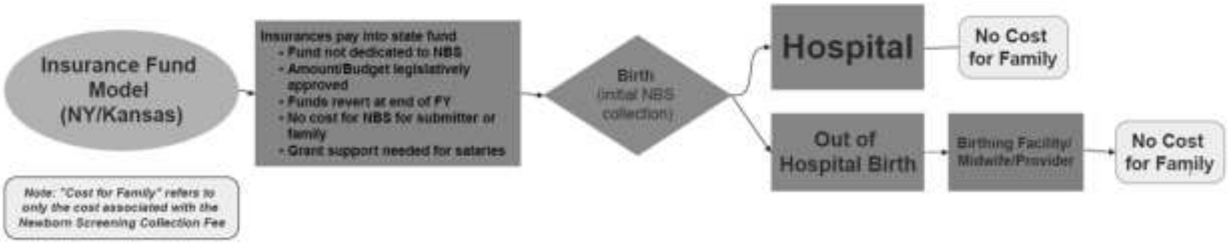
"The current system places the financial burden/risk for screening on the provider of the screen"

"Homebirths" and "<24 hours at age of discharge" were the primary reasons why an infant would not receive a screening at birth

"The cost of this program has been legislated to be cost neutral"

APPENDIX H – FUNDING MODEL VISUALIZATIONS






State General Funds (GF) Model
Note: "Cost for Family" refers to only the cost associated with the Newborn Screening Collection Fee
State General Funds Appropriated for NBS
• Amount/Budget legislatively approved
• Funds revert back to state treasury at end of FY
• No cost for NBS for submitter or family
Birth (initial NBS collection)
Hospital
No Cost for Family
Out of Hospital Birth
Birthing Facility/ Midwife/Provider
No Cost for Family


FFS/ Partial State GF Model
Note: "Cost for Family" refers to only the cost associated with the Newborn Screening Collection Fee
Use State GF to establish NBS "Pool of Funds" for Self-Pay/ Uninsured/ Out of Network (i.e. cost for family)
Submitter Purchase NBS Collection Kits from Lab
• Purchased before birth
• Hospital: [illegible]
No purchase cost for OOH births
Birth (initial NBS collection)
Hospital
Insurance
Global Billing
Potential Cost for Family
Self-Pay/ Uninsured
Apply to VDH for "Pool of Funds" for reimbursement
No Cost for Family
Out of Hospital Birth
Birthing Facility/ Midwife/Provider
NBS Program applies monthly to VDH for "Pool of Funds" for number of OOH births
No Cost for Family