

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	
Bold = Present * = Proxy (Name) <i>Italicized</i> = Absent ¹ =Virtual Attendance		Y=Yes, N=No, A=Abstain	
		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 Monaco¹	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 Murphy¹	Parent Advocate	Y	Y
William Wilson, MD	Newborn Bloodspot Screening Advisory Committee (NBS AC)	Y	Y
<i>Dr. Nayef Chahin, MD</i>	Virginia Chapter of the American Academy of Pediatrics (VA AAP)		
Support Staff			
Christen Crews	Virginia Department of Health (VDH)		
Mary Lowe¹	Virginia Department of Health (VDH)		
Parker Parks¹	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)		
<i>Jessica Hendrickson</i>	Division of Consolidated Laboratory Services/ Department of General Services (DCLS/DGS)		
<i>Angela Fritzingler</i>	Division of Consolidated Laboratory Services/ Department of General Services (DCLS/DGS)		
Consultant			
<i>Sikha Singh</i>	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 Massart¹, 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 be 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 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 a 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 to 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