

Newborn Screening Advisory Committee (NBSAC)
FINAL APPROVED Meeting Minutes
Friday, March 24, 2023

1:00 p.m.

Virtual: Microsoft Teams Meeting Platform

In Person Meeting Site: Robert Bernstein Building, Room K-100
 1100 West 49th Street, Austin, Texas 78756

Table 1. Newborn Screening Advisory Committee member attendance at the March 24, 2023 meeting.

Member Name	In Attendance ^{1,2,3}
Kaashif Ahmad, M.D., M.B.B.S., M.S.C.	Yes
Beryl (Pam) Andrews	Yes*
Khrystal Davis, J.D.	Yes*
Titilope Fasipe, M.D., Ph.D.	Yes*
Melissa Frei-Jones, M.D., M.S.C.I., Vice-Chair	Yes
Alice Gong, M.D.	Yes
Charleta Guillory, M.D., M.P.H.	Yes
Tiffany McKee-Garrett, M.D.	Yes
Barbra Novak, Ph.D., C.C.C.-A.	No
Fernando Scaglia, M.D.	Yes
Joseph Schneider, M.D.	No
Michael Speer, M.D., Chair	Yes*
Elizabeth (Kaili) Stehel, M.D.	Yes

Agenda Item 1: Welcome, introductions, and logistical announcements

Dr. Melissa Frei-Jones, Newborn Screening Advisory Committee (NBSAC) Vice-Chair, called the meeting to order at 1:01 p.m. Dr. Frei-Jones welcomed committee members, staff, and members of the public. Dr. Frei-Jones announced Agenda Item 2: Consideration of July 8, 2022, and October 24, 2022, draft meeting minutes were tabled until the next NBSAC meeting.

Ms. Jacqueline Thompson, Facilitator, Advisory Committee Coordination Office (ACCO), Office of Policy and Rules, Texas Health and Human Services Commission (HHSC)

¹ Yes indicates member attended the meeting.

² No indicates member did not attend the meeting.

³ * indicates the member joined the meeting after roll call.

announced the meeting was being conducted in accordance with the Texas Open Meetings Act, provided logistical announcements, conducted roll call, and noted that a quorum was present for the meeting.

Dr. Frei-Jones turned the floor over to Ms. Karen Hess, Unit Director, Newborn Screening Unit, Texas Department of State Health Services (DSHS), to introduce herself and staff present. Ms. Hess called on DSHS staff to provide brief introductions then turned the floor over to Dr. Frei-Jones.

Agenda Item 2: Consideration of July 8, 2022, and October 24, 2022, draft meeting minutes – TABLED

Dr. Frei-Jones announced prior to start of meeting Agenda Item 2 would be tabled until the next NBSAC meeting.

Agenda Item 3: Membership update

Dr. Frei-Jones introduced Ms. Aimee Millangue, Advisory Committee Liaison and Ombudsman, Newborn Screening Unit, DSHS to provide a membership update.

Highlights of the presentation included:

- Due to a pending member bylaws amendment request, the solicitation is postponed for the three NBSAC members whose terms expired on August 31, 2022;
- The three members may continue to serve on the committee until the postponed solicitation process is completed;
- Solicitation will resume once recommended changes to committee Bylaws have been determined, approved, and adopted and will include the four members whose terms expire August 31, 2023;
- All current members are eligible to reapply for their positions, and members may send membership term questions offline;
- Members with terms ending in 2022 were notified;
- Aside from members approving changes to the bylaws later in the meeting, members have brought up looking into committee composition as conditions are added to the Texas Newborn Screening Panel; and
- Members may make look into membership composition and make a recommendation to add additional members to the committee.

Members discussed:

- Adding a metabolic specialist;
- Adding individuals with expertise as new conditions from the Recommended Uniform Screening Panel (RUSP) are added to the Texas panel;
- Whether legislation specifies committee member composition; and
- Neurology and endocrinology groups that meet to discuss completed screens.

- Submitting recommendations to the DSHS commissioner by letter.
- How to target individuals with certain areas of expertise to apply when the call for applications goes out.

ACTION ITEM: For next solicitation, program staff should send information out to subspecialists such as the endocrinology consultants, metabolic geneticists, and neurologists.

Agenda Item 4: Consideration of Bylaws Amendment

Dr. Frei-Jones reminded members they received the Bylaws amendments prior to the meeting for their review and turned the floor over to Ms. Millangue. Ms. Millangue referenced the handout, *Newborn Screening Advisory Committee Draft Bylaws Amendment*.

Highlights of the presentation included:

- Changes were requested at the July 2023 meeting;
- Received comments from Dr. Michael Speer, NBSAC Chair;
- Minor changes were made to language to be consistent with agency style guidelines and comply with the standard HHSC template throughout the document;
- A change was made to committee composition to include the DSHS commissioner add 3 additional members for a total of 13 members.
- Updated membership requirements;
- In order to comply with the standard template while addressing member concerns, language was added to apply the HHSC-required two term limit only to members appointed after August 2022;
- Member travel and in-person attendance requirements were updated to comply with the current hybrid meeting format and in compliance with the HHSC standard template and law;
- The Bylaws includes a list of all the revisions and their purpose;
- Additional updates were made to include requirements for revising bylaws and clarify member expectations and support staff responsibilities;
- The Statement by Members document was updated to include references to HHSC to and to spell out acronyms;
- Non-substantive edits such as spelling, grammar, and formatting were completed;
- Dr. Speer's questions on in-person attendance requirements needing to be in the Bylaws which program staff brought to the program's legal counsel, Ms. Natalie Adelaja;

- Ms. Adelaja added she would defer to ACCO on their recommendation for including attendance requirements in the bylaws, and that she has not seen that type of language included in other committee bylaws; and
- Mr. John Chacón, Associate Director, ACCO, Office of Policy and Rules, HHSC added that members may make motions to amend the bylaws, which would need to be vetted by the legal counsel tied to the NBSAC and clarified ACCO facilitates the template, but the template is not an ACCO template. It is a Texas Health and Human Services System (HHS) template that ACCO offers to all advisory committees within the HHS System.

Members discussed:

- Whether the new language on the number of committee members limits the committee to only 13 members, which is not what the committee previously discussed;
- Members may request adding members by recommendation letter to the DSHS commissioner;
- The DSHS commissioner must approve the addition of members, and the bylaws need to be amended to include the additional members;
- Clarifying the number of terms members appointed before July 2018 may serve.
- The reason the presiding member is required to attend the meeting in person and whether this needs to be stated in the bylaws;
- Whether the language about subcommittees and quorum needs to be clarified; and
- The Open Meetings Act and the Attorney General’s Office provide guidance on advisory committee meeting requirements, which are subject to change.

ACTION ITEM: Tabling further discussion on bylaws questions from Dr. Speer for a future meeting when he is available.

MOTION: Dr. Alice Gong moved to adopt the NBSAC Bylaws amendment as presented. The motion was seconded by Dr. Fernando Scaglia. Dr. Frei-Jones requested Ms. Thompson conduct a roll call vote. The motion carried by a vote of ten for, zero against, zero abstentions, and three absent (Dr. Barbra Novak, Dr. Joseph Schneider, and Dr. Michael Speer).

Agenda Item 5: Rare Disease Subcommittee reporting

Dr. Frei-Jones introduced Ms. Pam Andrews, subcommittee member. Ms. Andrews turned the floor back over Dr. Frei-Jones to review subcommittee meeting minutes, referencing handouts, *Rare Diseases Subcommittee Meeting Minutes, August 10, 2022*, and *Rare Diseases Subcommittee Meeting Minutes, January 6, 2023*.

Highlights of the presentation included:

- An August 10, 2022, meeting summary, and

- Members discussed the role of the subcommittee, funding challenges for implementing new conditions recommended on the Recommended Uniform Screening Panel (RUSP), and an update on Dr. Sanjiv Harpavat's biliary atresia screening pilot program currently underway in Houston;
- Dr. Debra Freedenberg, Medical Director, Newborn Screening Unit, DSHS provided updates on conditions reviews of guanidinoacetate methyltransferase deficiency (GAMT), cytomegalovirus (CMV), Duchenne muscular dystrophy (DMD), and Krabbe by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC);
- Program staff advised DSHS is working on implementing conditions on the RUSP that are not yet tested for in Texas;
- Current plans include implementing mucopolysaccharidosis type 1 (MPS I), mucopolysaccharidosis type II (MPS II), and Pompe in May 2024, contingent on funding;
- Subcommittee members also discussed Niemann-Pick, DMD, and the preservation account not having funding yet;
- Action items included inviting Dr. Harpavat to the next meeting to provide an update on his research, and Jennifer Taylor from the Newborn Screening Translational Research Network (NBSTRN) to discuss pilot programs for new conditions; and
- Determining next steps and ideas related to pilot programs and Noonan syndrome.
- A January 6, 2023, meeting summary.
 - Members reviewed action items from the last meeting;
 - Members discussed trying to identify parents to invite to meetings to make public comment that can be on the record;
 - The subcommittee has also been in communication with some family members to advocate for Noonan syndrome;
 - Discussion included the direction of the subcommittee and the original subcommittee purpose to give a voice to parents and other advocates to discuss conditions and implications of newer newborn screening technologies;
 - Members felt it was important for the subcommittee to continue to have family members and individuals affected by newborn screening conditions provide public input at meetings and to have the subcommittee be led by a parent representative on the committee, since that person is the most invested;
 - The subcommittee discussed that the NBSAC could recommend adding conditions not on the RUSP, but there is no current process in place for this;

- Future topics include Noonan syndrome discussion and subcommittee membership;
- Action items include requesting an annual presentation update from the NBSTRN and a presentation from Dr. Sue Berry; and
- The meeting was attended by only the physician members, so discussion included whether to explore if the subcommittee needs to be redesigned or redefined.

Members discussed:

- The subcommittee researching the bill introduced on CMV screening and how NBSAC members could support getting CMV screening added in Texas;
- Additional ACHDNC condition review updates;
- Other viruses screened for in Texas, and whether adding a virus screen would open a Pandora’s Box for screening for other viruses;
- Whether additional members could join the subcommittee;
- Screening babies in the neonatal intensive care unit for viruses and infections, and education legislation;
- Whether CMV discussions could involve infectious disease experts, ENTs (ear, nose and throat doctors), and audiologists; and
- Status of CMV screening nationally and by other states.

Agenda Item 6: Sickle Cell Subcommittee reporting

Dr. Frei-Jones, Subcommittee Co-chair, referenced the handout, *Sickle Cell Subcommittee Meeting Minutes, January 3, 2023.*

Highlights of the presentation included:

- The subcommittee has been trying to address the gaps in care for patients with sickle cell in Texas;
- While they have a well-defined list of pediatric facilities, they are looking at identifying adult providers who care for sickle cell patients across the state through a sickle cell provider survey;
- They have not received many responses to the survey, so the subcommittee reached out to the Texas Medical Association (TMA);
- While TMA is not able to share the survey with their membership because Dr. Frei-Jones and Dr. Fasipe, Subcommittee Co-chairs, are not TMA members, Dr. Gong suggested requesting a letter from the NBSAC to ask the TMA to provide the survey to their members;
- The subcommittee also discussed an update on the Sickle Cell Task Force, tabling discussion of the long-term follow up form while they continue to pursue the adult provider survey, and annual updates of the Hemoglobinopathy consultants lists and ACT (Action) and Fact sheets; and

- Dr. Frei-Jones announced that she and Dr. Fasipe sent a presentation to the Texas Pediatric Society, and they will present on sickle cell disease at the September meeting.

Members discussed:

- Logistics of writing and sending a letter to the TMA and why it would be a good idea;
- Why they would not be able to utilize NBSAC members who have TMA membership to contact the TMA; and
- Requesting TMA send out the survey to only the adult hematologists.

MOTION: Dr. Gong moved to have the NBSAC draft a letter to the TMA. Dr. Speer seconded the motion. Ms. Thompson conducted a roll call vote, and the motion carried.

Agenda Item 7: Sickle Cell Task Force update

Dr. Frei-Jones, Sickle Cell Task Force member, shared the floor with Dr. Fasipe, Sickle Cell Task Force Chair, to provide a Sickle Cell Task Force update.

Highlights of the presentation included:

- Dr. Fasipe expressing appreciation of NBSAC support, and with the letter, trying to optimize care for individuals with sickle cell disease;
- Describing how the Sickle Cell Task Force (SCTF) was created through legislative action in 2019 while sickle cell-related positions were added to the NBSAC;
- In the Sickle Cell Task Force Annual Report released in December 2022, the SCTF focused on three major themes of sickle cell disease awareness, Medicaid contracts, and sickle cell disease surveillance;
- The Sickle Cell Public Awareness Subcommittee looked for opportunities to make the state more aware of sickle cell disease;
- For Medicaid contracts, the SCTF has met with entities to try to understand how to optimize what is currently offered by Medicaid and areas for improvement in education of national guidelines concerning sickle cell disease;
- In the area of surveillance, the SCTF inquired how to estimate the number of individuals with sickle cell disease in Texas since Texas does not have current data on how many people have sickle cell disease;
- The SCTF is hoping to partner with the state to have Texas apply for the national Centers for Disease Control and Prevention surveillance program that currently includes 11 states;
- The SCTF includes 12 recommendations on the three major themes and maximizing SCTF expertise with membership, extending the membership, and extending the SCTF timeline;
- SCTF membership includes Dr. Fasipe as Chair and a parent of young adults with sickle cell disease as vice-chair;

- The SCTF has continued working on the items identified by the original Sickle Cell Advisory Committee with subcommittees for surveillance, Medicaid insurance, and public awareness;
- The Legislative Update agenda item will include some bills relating to sickle cell disease; and
- Dr. Frei-Jones and Dr. Fasipe met with some DSHS staff about an effort moving forward that will hopefully allow the state of Texas to participate in the national Sickle Cell Disease Data Collection Program.

Members discussed:

- Thanking the SCTF for the work that they are doing;
- How long the SCTF is supposed to last;
- The SCTF having hope to have their duration extended, as included as a recommendation in their report; and
- Thanking NBSAC members for their mentorship and championship.

Break/Roll Call:

At 2:45 p.m., Dr. Frei-Jones announced a ten-minute break and reconvened the meeting at 2:55 p.m. Ms. Thompson conducted a roll call and advised a quorum was present.

Agenda Item 8: Legislative update

Dr. Frei-Jones introduced Ms. Hess, and Dr. Susan Tanksley, Deputy Director, DSHS Laboratory, to provide a legislative update. Ms. Hess and Dr. Tanksley referenced the PowerPoint and handout, *Newborn Screening Related Legislative Updates*.

Highlights of the presentation included:

- Reviewing the list of house and senate bills, 88th Legislature, Regular Session, 2023, currently being monitored by DSHS and impacting newborn screening;
- H.B. 181 directs DSHS to create and maintain sickle cell disease registry and to publish an annual report to the legislature on sickle cell cases;
- H.B. 1481/H.B. 1488 and Companion Senate Bill (S.B.) 1757 affects agencies that include DSHS, HHS, Texas Education Agency, graduate medical education programs, and Texas Health Service Authority with requirements on health care services under managed care plans, Medicaid provider education, improving health outcomes of and establishing medical homes for recipients diagnosed with sickle cell disease, medical school curriculums, public school sickle cell disease and trait education, adding SCTF members, and sickle cell surveillance;
- Either H.B. 1481 or H.B. 1488 would provide DSHS the authority to collect data on sickle cell patients rather than going through the Institutional Review Board (IRB);

- S.B. 619 changes Texas Health and Safety Code, Chapter 47 on newborn hearing screening and impacts babies who are deaf or hard of hearing by removing some consent requirements, adding requirements on blanket consent, adding provider requirements for using the Management Information System, and directing DSHS to work with a specialist advisory board;
- S.B. 704 related to the capture and use of biometric identifiers and specimen disclosure, requirements for handling and destruction of genetic data and materials, and authorization of civil penalties, which does not impact newborn screening. However, the bill would change Texas Health and Safety Code, Chapter 33, to remove exemption language for opting out of newborn screening only based on religious tenants and practices, which may lead to families opting out of newborn screening altogether for any reason. This may have a huge impact on the number of newborn screening blood spot conditions missed;
- S.B. 1014 related to restrictions and use of genetic material that requires consent for genetic testing, which includes an exemption for newborn screening;
- S.B. 1667 adds Duchenne muscular dystrophy, which is not an approved RUSP condition, to Texas Health and Safety Code, Chapter 33; approved conditions have effective treatments and demonstrate a testing facility can perform an assay test for detection;
- S.B. 1285 and H.B. 4068 amend Texas Health and Safety Code, Chapter 47, on newborn hearing screening to include CMV as point-of-care (S.B. 1285) and newborn blood spot screening (H.B. 4068) and requirements;
- H.B. 2478 directs DSHS to develop a yearly report by September 1 for any condition on the RUSP but not on the Texas Newborn Screening Panel that will list any additional capacity or resources DSHS needs for implementing that test, summarize an implementation plan, and provide information on whether the condition can be implemented within 24 months;
- H.B. 3212 amends Texas Health and Safety Code, Chapter 33, to include birthing facility requirements on informing parents about the risks of discharging newborns prior to having newborn screening results and providing results within 24 hours and adds penalties;
- DSHS staff are tracking bill versions for significant changes, especially with H.B. 2478 and H.B. 3212 being scheduled for hearings in the House Public Health Committee;
- DSHS Laboratory staff discussed the impetus of H.B. 3212 with Representative Toth, for prompt screening and parent notification; and
- Representative Toth asked for costs for a seven-day work week and is trying to make changes to H.B. 3212 due to its impact on hospitals and birthing facilities. In addition, it cannot be implemented as currently written since reporting newborn screening results within 24 hours is impossible since specimens may not

have even reached the laboratory yet due to the impossibility of the 24-hour timeline for reporting newborn screening results.

Members discussed:

- The impossibility of implementing H.B. 3212 and whether there is a misunderstanding of newborn screening processes.
- The Texas Pediatric Society Fetus and Newborn Committee weighed in with their lobbyists to express their opposition to H.B. 3212 and another bill.
- If DSHS staff members know why there is such a penalty.
- If DSHS staff members were looking for feedback on legislation.
- For H.B. 2478, suggesting the annual report also include summaries of certain diseases and why they were denied being added to the RUSP.
- Circumstances behind the baby who passed away to understand the reasoning behind H.B. 3212.
- Issues with contacting parents after discharge and wanting to advise hospitals to update parent contact information when they come in.
- Receiving fines for not being able to contact parents would be illogical and unfair.
- While members may have concerns about H.B. 3212, it is encouraging a lawmaker has shown passion for newborn health and wants to improve their processes.
- The outcomes they hope come from the passing of some of the bills, such as funding for a seven-day work week.
- Proposed legislation cannot be evenly applied across the state.
- If parents receive standardized newborn screening information from the state when their children are born.
- Discussing the CMV bill with advocates educate them about the newborn screening process and how blood spot CMV testing should go under Texas Health and Safety Code, Chapter 33 instead of Texas Health and Safety Code, Chapter 47.

Agenda Item 9: February 2023 Winter Storm

Dr. Rachel Lee, Medical Screening Unit, DSHS Laboratory, and Dr. Debra Freedenberg, Medical Director, NBS Unit, DSHS, provided an update and referenced the PowerPoint and handout, *February 2023 Winter Storm Impact*.

Before Dr. Lee began her presentation, Dr. Frei-Jones announced Agenda Items 9 through 11 would be discussed simultaneously by Dr. Lee and Dr. Freedenberg.

Highlights of the presentation included:

- January 31 - February 2, 2023, laboratory staff were unable to travel to work due to ice storm;
- Many staff had no power at their place of residence;

- While many staff were able to work from home, when the DSHS building lost power, remote work ceased due to inability to connect to the network;
- Laboratory did not lose power;
- Because the agency was closed for three days, the laboratory was unable to receive samples;
- The courier service used by the lab was also unable to function due to weather; and
- Many samples received after the storm were too old for testing.

Agenda Item 10: Newborn Screening Laboratory Renovations update

Dr. Frei-Jones turned the floor over to Dr. Lee, Medical Screening Unit, DSHS Laboratory, and Dr. Freedenberg, Medical Director, DSHS NBS Unit. Dr. Lee and Dr. Freedenberg referenced the PowerPoint and handout, *DSHS Newborn Screening (NBS) Laboratory Renovation Updates*.

Highlights of the presentation included:

- Air Handling Units (AHU) and Laboratory Exhaust Units (LEU) were replaced during October 2022 through November 2022; and
- DSHS will send specimens for testing to back-up laboratories: PerkinElmer Genomics, and Washington NBS Lab.

Agenda Item 11: Future Condition Implementation Updates

Dr. Lee and Dr. Freedenberg referenced the PowerPoint and handout, *Future Condition implementation Updates*.

Highlights of the presentation included:

- Reviewing the implementation status of implementing Pompe, MPS I, MPS II, the core conditions on the RUSP not yet implemented in Texas;
- They received grant funding from the Centers for Disease Control and Preventions and Association of Public Health Laboratories;
- They received funding in the Newborn Screening Preservation Account;
- First steps include the laboratory retrofit and tandem mass spectrometry (MSMS) replacement installation;
- Implementation completion estimated for late 2024; and
- The status of Galactocerebrosidase deficiency (Krabbe Disease) and Duchenne muscular dystrophy, the other conditions nominated for addition to RUSP.

Members discussed the addition of Guanidinoacetate methyltransferase (GAMT) deficiency to the RUSP.

Agenda Item 12: Public Comment

No one pre-registered online or registered onsite for public comment.

Agenda Item 13: Future agenda items, next meeting date, and adjournment

Dr. Frei-Jones announced the next meeting is scheduled for Monday, May 8, 2023, and opened the floor for discussion of agenda topics for the next meeting.

Members discussed:

- Subcommittee reports from the Sickle Cell Subcommittee and Rare Diseases Subcommittee;
- Legislative update;
- The Rare Diseases Subcommittee discussing CMV;
- Update on the TMA being able to send out the adult provider survey from the Sickle Cell Subcommittee;
- Legislative session ends May 31, 2023;
- Membership update;
- Laboratory renovation update;
- Keeping implementation of new disorders update as an ongoing agenda item, since proposed legislation requires including disorders on the RUSP but not implemented in Texas be included in an annual report;
- Consideration of July 8, 2022, October 24, 2022, and March 24, 2023, draft meeting minutes;
- Newborn Screening Translational Research Network (NBSTRN) annual presentation to the Rare Diseases Subcommittee or full NBSAC;
- Topics and priorities for the Rare Diseases Subcommittee, since there is CMV and possible presentations on Noonan Syndrome and from NBSTRN;
- Cost-estimate for seven-day work week for the DSHS Newborn Screening Laboratory;
- Whole genomic sequencing;
- Medicaid coverage of rapid whole genome sequencing, depending on outcome of proposed legislation; and
- Texas Early Hearing Intervention and Detection Program update.

ACTION ITEM: Program staff will reach out to Dr. Guillory and Dr. Gong to get more information about CMV stakeholders.

Dr. Melissa Frei-Jones adjourned the meeting at 4:11 p.m.

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Below is the link to the archived video of the March 24, 2023, Newborn Screening Advisory Committee (NBSAC) that will be available for viewing approximately two years from date meeting posted on website and based on the HHSC records retention schedule.

[Newborn Screening Advisory Committee](#)