

Newborn Screening Advisory Committee (NBSAC)
APPROVED Meeting Minutes
Monday, October 24, 2022
12:00 p.m.

Hybrid Meeting:

Microsoft Teams Virtual Meeting

Robert D. Moreton Building, Public Hearing Room M-100
 1100 West 49th Street, Austin, Texas 78756

Agenda Item 1: Welcome, introductions, and logistical announcements

Dr. Michael Speer, Newborn Screening Advisory Committee (NBSAC) Chair, called the meeting to order at 12:01 pm. He welcomed committee members, staff and members of the public.

Ms. Jacqueline Thompson, Facilitator, Advisory Committee Coordination Office (ACCO), Office of Policy and Rules, Texas Health and Human Services Commission (HHSC) announced the meeting was being conducted in accordance with the Texas Open Meetings Act, conducted roll call, and noted that a quorum was present for the meeting.

Table 1. Newborn Screening Advisory Committee member attendance at the October 24, 2022, meeting.

Member Name	In Attendance
Dr. Kaashif Ahmad	Yes
Ms. Beryl (Pam) Andrews	Yes
Ms. Khrystal Davis, JD	Yes
Dr. Titilope Fasipe	No
Dr. Melissa Frei-Jones, Vice-Chair	Yes
Dr. Alice Gong	Yes
Dr. Charleta Guillory, MPH	Yes
Dr. Tiffany McKee-Garrett	Yes
Dr. Barbra Novak, CCC-A	No
Dr. Fernando Scaglia	No
Dr. Joseph Schneider	Yes
Dr. Michael Speer, Chair	Yes
Dr. Elizabeth (Kaili) Stehel	Yes

Yes: Indicates member attended the meeting

No: Indicates member did not attend the meeting

Dr. Michael Speer recognized Texas Department of State Health Services (DSHS) staff and requested they introduce themselves. Dr. Debra Freedenberg, Dr. Susan Tanksley, Ms. Karen Hess, Ms. Aimee Millangue, and Ms. Laura Arellano provided introductions.

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

Dr. Speer announced the July 8, 2022, draft meeting minutes would be tabled for consideration at the next NBSAC meeting.

Agenda Item 3: DSHS Newborn Screening Laboratory renovation update

Dr. Speer introduced Dr. Susan Tanksley, Deputy Director, DSHS Laboratory, to provide a Newborn Screening Laboratory renovation update.

Highlights of the presentation included:

- Construction starts Friday, October 28.
- A lot of work is going on in and around the lab to prepare for the renovation.
- This phase (Friday, October 28-Sunday, October 30) involves work on air handlers and exhaust units that affect building airflow. New testing will not be conducted during that time; samples will be held until Monday when operations resume.
- The specimen acquisition area and functions are being relocated until the phase of the renovation finishes, which they anticipate for late November.
- The laboratory will maintain continuity of operations, especially during exhaust and electricity shut downs.
 - They relocated data entry and lab reporting areas on campus.
 - Starting November 5, they will send specimens to a back-up laboratory.
 - They worked on logistics with the back-up laboratory and will be able to use HL7 electronic reporting.
 - The back up laboratory will send out different lab reports.
 - This will allow the lab to maintain testing with the reasonable turnaround time.
 - Health care providers will still send samples to Austin, and the DSHS Laboratory will coordinate whether they test the specimens in Austin or send them to the back-up laboratory.

- The DSHS Laboratory staff anticipate resuming newborn screening testing operations on November 14 due to building modifications and temporary air handler installation.
- If all goes well, they expect the laboratory to be turned back over to staff and fully functional by November 24.

Members discussed:

- If the back-up laboratory can handle the volume of testing and has been stress tested.
- Contingency plan for the back-up laboratory.
- Turnaround time and logistics for samples received on the days the laboratory will not perform testing.
- How the laboratory will make sure reports go out to the providers from the back-up laboratory and whether the reports are standardized to collect the appropriate results.
- The Clinical Care Coordination group will continue to follow up and will communicate changes with providers while testing is outsourced.

Agenda Item 4: Screened conditions status updates

Dr. Speer introduced Dr. Debra Freedenberg, Medical Director, DSHS Newborn Screening (NBS) Unit, and Ms. Karen Hess, Unit Director, DSHS NBS Unit to provide screened conditions updates.

Highlights of the presentation included:

- X-linked adrenoleukodystrophy (X-ALD) diagnosed cases August 2019-September 2022
 - 42 males hemizygous affected
 - 25 female heterozygotes
 - Have not added a lot to other conditions detected, such as contiguous gene deletion.
 - 11 cases of Zellweger syndrome, 1 carrier
 - 7 cases of peroxisome disorders (1 peroxisomal biogenesis disorder, 2 D-bifunctional protein deficiency, 1 PEX6, 1 TREX1, 11 Aicardi Gouiterres syndrome, and 1 NAXE leukoencephalopathy)

- In discussion with other states, Texas may have a few more Zellweger cases than other states are identifying, but that is based on the population.
- 34 Spinal muscular atrophy (SMA) cases confirmed with clinical and molecular diagnosis
 - 2 - 1 copy of SMN2 (most severe form)
 - 12 - 2 copies of SMN2
 - 13 - 3 copies of SMN2
 - 7 - 4 copies of SMN2
- Regarding lab randomization on SMA, they will not be getting immediate results for SMN2, and they're preparing communications and education for clinicians, part of the newborn screening programs, and part of the system.
- Ms. Hess can send a chart of diagnosed cases, but it looks like they had a high year in 2018, went down in 2019, went down a little more in 2020, and looking to pick up in 2021.
- They will potentially have a few 100 more cases in 2021 than previous few years.

Dr. Tanksley requested to provide an update on the Association of Public Health Laboratories Symposium they attended the previous week.

- Brendan Reilly presented the congenital hypothyroidism algorithm project.
- John Levitt presented a poster on second-tier confirmatory testing Hemoglobinopathies in Texas.
- Derek Seidel presented a poster on Newborn Screening for Severe Combined Immunodeficiency (SCID) in Texas.
- Rebecca Tangelos presented a poster on the utility of A5 spot punch in Hemoglobinopathy and SCID testing.
- Brendan Reilly accepted the first ever award for achievements in public health informatics, which honors a person working in any aspect of newborn screening worldwide and has made significant contributions in one or more areas.

Members discussed:

- What information they have on treatment and payment for treatment.

- Funding for genetic services, especially as it relates to the number of Go Fund Me campaigns around the country for paying for therapies and Medicaid coverage.
- Congratulating Brendan Reilly on his award.

Agenda Item 5: Future condition implementation updates

Dr. Speer introduced Dr. Tanksley and Dr. Freedenberg to provide an update on the implementation of conditions.

Highlights of the presentation included:

- Implementation status of Pompe, mucopolysaccharidosis type I (MPS I), and mucopolysaccharidosis type II (MPS II)
 - DSHS submitted an updated budget estimate and are working toward the implementation date of May 2024.
 - DSHS received a Centers for Disease Control and Prevention grant that will assist with implementation cost, covering the cost to bring up second-tier and third-tier tests.
 - They hope to obtain funding for the rest of implementation through funds in the Newborn Screening Preservation Account.
 - Laboratory renovations will allow them to receive and install testing equipment.
 - Conditions will be screened using tandem mass spectrometry, and they will implement MPS 2 testing using liquid chromatography tandem spectrometry, which will necessitate hiring additional staff.
- Other conditions under consideration
 - Guanidinoacetate methyltransferase deficiency – waiting to hear back from the Federal Health and Human Services Secretary on its acceptance to be added to the Recommended Uniform Screening Panel.
 - Krabbe – will be presented at meetings and go through reviews before being voted on in February, and it now has second-tier testing.
 - Duchenne muscular dystrophy – has been submitted for prescreening, but it needs second and third-tier screening.
 - Congenital cytomegalovirus (CMV) – initial reviewers felt condition was not ready for review, so it is pending resubmission.

Members discussed:

- The delay on CMV screening.
- Contents and recipients of the CMV decision letter.

ACTION ITEM: Dr. Freedenberg will provide the CMV decision letter to share with members.

Agenda Item 6: Sickle Cell Subcommittee reporting

Dr. Speer turned the floor over to Dr. Frei-Jones, Sickle Cell Subcommittee Co-Chair. Dr. Frei-Jones referenced the handout, *Sickle Cell Subcommittee meeting minutes*.

Highlights of the presentation included:

- Met October 12 with Dr. Frei-Jones, Dr. Titilope Fasipe, and DSHS staff.
- Subcommittee has taken on a couple of things to validate list of Texas providers who care for children with abnormal newborn screens for hemoglobinopathy and do the same thing for adult providers.
- Worked on a survey to find out if providers have a transition process and to whom they send transitioned patients to create a list of adult providers.
 - Program staff sent out survey and have only received four responses and two names.
 - Brainstormed how to find additional individuals to send survey to and decided to send the survey out a couple more times and potentially send the survey to community-based organizations.
- Tabled discussion to assess long-term follow up form.
- In the past year, they reviewed and updated the ACT (Action) and Fact sheets, which they plan to review again in January.
- Continue to try to develop an adult consultants list that can be available for patients.

Members discussed:

- Also reaching out to moms and obstetrician-gynecologists when transitioning patients from pediatrics.

Agenda Item 7: Rare Diseases Subcommittee reporting

Dr. Speer introduced Ms. Pam Andrews, subcommittee member, to provide the Rare Diseases Subcommittee report.

Highlights of the presentation included:

- The report from the last subcommittee meeting will be available at the next NBSAC meeting.

Agenda Item 8: Consideration of bylaws amendment - TABLED

Dr. Speer announced that the bylaws amendment would be tabled for consideration at the next NBSAC meeting.

Due to presenter availability, the NBSAC proceeded to agenda item 10.

Agenda Item 10: Public Comment

Ms. Thompson read public comment logistical announcements and called on Ms. Alice McConnell, parent advocate, who pre-registered online to provide oral comment.

Oral Comment was received from:

- Ms. Alice McConnell, Parent Advocate, SSADH (Succinic semialdehyde dehydrogenase deficiency) Association. Ms. McConnell described how the current newborn screening system created harm and extended the diagnostic odyssey of her child and requested that this be addressed through educating physicians and parents and providing something simple as an information sheet to explain newborn screening is not comprehensive for all disorders. She also requested that this topic be on the agenda for the next meeting.

ACTION ITEMS:

- The topic of newborn screening education and improving the diagnosis process is assigned to the Rare Diseases Subcommittee to also include exploring the messaging on the lab results report to providers.
- The Newborn Screening Laboratory staff will bring this issue back to their staff educators, and they will share messages with their list serv, the Texas Medical Association, Texas Pediatric Society, and Texas Hospital Association.

No one registered onsite for public comment.

The NBSAC returned to agenda item 9.

Agenda Item 9: Newborn Screening Preservation Account

Dr. Speer introduced Ms. Donna Sheppard, Chief Financial Officer, DSHS to present on the Newborn Screening Preservation Account.

Highlights of the presentation included:

- Sharing what DSHS staff know about the financial side of the fund.

- Created by Senate Bill 747, 86th Legislative Session to implement new panels or tests to the Texas Newborn Screening Program; having a fund would allow the process of implementing panels or tests by bypassing the need to wait to for an upcoming legislative session to request funding for that purpose.
- November 2019 was the earliest funds could have been deposited after the bill passed, but they are estimating to have the first deposit in November 2022.
- They estimate the deposit will transfer \$28.4 million or \$12 million into the account, the difference being some interpretations with the Comptroller.
- Texas Health Safety Code, Section 33.052, and the General Appropriations Act, Article 2, Section 14, have fund guidance.
 - Texas Health Safety Code, Section 33.052:
 - Establishes and designates the fund be dedicated for this purpose specifically;
 - Allows DSHS to transfer annual deposits of any unexpended or unencumbered Medicaid funds into the account, which DSHS collects through Medicaid program billing for newborn screening client services;
 - Allows private gift donations and collection of interest; and
 - Restricts private billings from being considered for the account and the use for only DSHS newborn screening purposes.
- General Appropriations Act Rider:
 - Appropriates program funding to the DSHS Laboratory for operating costs, the HHSC Medicaid program and state psychiatric hospitals; funds remaining after all programs are funded can be for Preservation Account use.
 - Restricts access to no more than \$12 million in any biennium without Legislative Budget Board and Office of the Governor approval.
 - Requires the Comptroller to certify funds are indeed available and not obligated for other purposes.
- Currently speaking with Comptroller to find out how to interpret the rider to determine if they are transferring \$12 million or larger amount that that they may begin to open the account and start internal use.
- They are creating budgets to determine how far the funds will go and timelines for implementation and the order of operations for different screening tests to add.

Members discussed:

- Concerns about clarity and transparency.
- Clarified that the money that goes into the account is from Medicaid newborn screening kit payments.
- Clarified that account funds may be used to set up new tests that would be on the panel for all patients, not just Medicaid patients.

ACTION ITEM: A Newborn Screening Preservation Account update will be included on the next meeting agenda.

Agenda Item 11: Future agenda items, next meeting date, and adjournment

Dr. Speer opened the floor for discussion of agenda topics for the next meeting and introduced Ms. Aimee Millangue, Advisory Committee Coordinator and Ombudsman, DSHS Newborn Screening Unit, to provide a recap.

Members discussed:

- Legislative riders and bills that impact the Texas Newborn Screening Program
- Bill filing deadline and when the Legislature convenes
- Laboratory renovations update
- Bylaws and addressing membership term rules before getting new members on the committee.

Recap included:

- Consideration of draft meeting minutes from the July 8, 2022, and October 24, 2022, meetings
- Sickle Cell Subcommittee update
- Rare Diseases Subcommittee update
 - Reporting on August and next meeting
 - Looking into provider education on rare diseases
- Standing items:
 - Laboratory continuity of operations
 - Updated funding request for meeting timeliness goals and estimated cost of a seven-day working lab to include follow up care costs if babies are not screened

- New member solicitation announcement will be posted soon
- Newborn Screening Preservation Account update

Dr. Speer announced the next meeting for January 26, 2023, and thanked everyone.

Dr. Speer adjourned the meeting at 1:34 p.m.

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Below is the link to the archived video of the October 24, 2022, 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](#)