

**Newborn Screening Advisory Committee
Meeting Minutes
October 2, 2020
12:00 p.m.**

Location: Microsoft Teams Live Event

Table 1: Newborn Screening Advisory Committee attendance Friday, October 2, 2020.

MEMBER NAME	IN ATTENDANCE
Kaashif Ahmad, M.D., M.Sc.	Yes (Arrived at Item #4)
Beryl (Pam) Andrews	Yes
Nancy Beck, M.D.	Yes (Arrived at Item #4)
Khrystal Davis, J.D.	No
Titilope Fasipe, M.D., Ph.D.	Yes
Melissa Frei-Jones, M.D.	Yes
Alice Gong, M.D.	Yes
Charleta Guillory, M.D., M.P.H.	Yes
Tiffany McKee-Garrett, M.D.	Yes (Arrived at Item #4)
Barbra Novak, Ph.D., C.C.C.-A.	Yes
Scott McLean, M.D.	Yes
Joseph Schneider, M.D.	Yes
Michael Speer, M.D.	Yes
Elizabeth (Kaili) Stehel, M.D.	Yes

Table 2: Newborn Screening Advisory Committee attendance Friday, October 2, 2020.

GUEST NAME and ORGANIZATION	IN ATTENDANCE
Ms. Mahan Farman-Farmaian, Director, HHS Rules Coordination Office	Yes

Agenda Item 1: Welcome and Introductions

Dr. Alice Gong, Chair of the Newborn Screening (NBS) Advisory Committee, convened the meeting at 12:01 p.m. and welcomed everyone in attendance.

Agenda Item 2: Committee Business Logistics

Dr. Gong introduced, Ms. Sallie Allen, HHSC, Policy & Rules, Advisory Committee Coordination Office and she reviewed logistics announcements, called roll, and determined a quorum was present.

Dr. Gong acknowledged and welcomed new advisory committee members, Dr. Kaashif Ahmad and Dr. Barbra Novak.

Agenda Item 3: Review and Approve Meeting Minutes for July 30, 2020

Ms. Allen requested a motion to approve the July 30, 2020 meeting minutes.

MOTION: Dr. Joseph Schneider made a motion to approve the July 30, 2020 meeting minutes. Dr. Michael Speer seconded. Ms. Allen conducted a roll call vote, and the motion carried with no objections or abstentions. Dr. Kaashif Ahmad, Dr. Nancy Beck, and Dr. Tiffany McKee-Garrett were not present at the time of the roll call vote.

Agenda Item 4: Texas Administrative Code Rulemaking Process

Dr. Gong introduced, Ms. Mahan Farman-Farmaian, Director, HHS Rules Coordination Office. Ms. Farman-Farmaian referenced the PowerPoint/handout, *Rulemaking Process Overview*.

Highlights of the presentation:

- Law and Rules
 - Federal and state law, Agency rules, policy and procedures
- Texas Administration Code (TAC)
 - Administration Procedure Act – Establishes the procedures all agencies follow to propose, amend, or delete rules.
- Health and Human Services System (HHSC/DSHS)
 - Guides what the agency will do and how agency delivers services
- Rules Coordination Office (RCO)
 - Ensures standardized processes are implemented
 - Edits and formats rules drafted by the agency experts
 - Oversees all phases – from proposal to adoption
- Chief Policy Officer (CPO)
 - Rule Making Process
 - Steps that create a rule project are:
 - Program development, proposal and packet completion
 - Post review, adoption, post adoption

Members comments:

Dr. Alice Gong expressed concern that the Committee was not afforded an opportunity to do due diligence in reviewing and commenting on the proposed Newborn Hearing Rule.

Mr. David Martinez, Director, DSHS Newborn Screening Unit, responded there was a conflict of schedules between the Advisory Committee meetings due to COVID-19 and the schedule of the Rules Packet timelines. Informal comments by the Committee were taken into account while drafting the Rule, and it is believed to be a good Rule as a result. Due to policy, the Committee will have to wait until the Rule is adopted before the Committee can review the Rule.

Agenda Item 5: Spinal Muscular Atrophy (SMA) screening implementation update

Dr. Gong introduced, Dr. Susan Tanksley, Laboratory Operations Unit Manager, DSHS Laboratory.

Dr. Tanksley stated:

- Funding was approved by the Governor to add SMA to the newborn screening panel in August. Awarded \$3.415 million for Fiscal Year 2021. Expenses will include \$1.1 million in new equipment and 14 new positions.
- Instrument replacement has been delayed due to COVID-19. Molecular testing and supplies are in high demand and short supply.
- Due to COVID-19, the purchasing process and installation of equipment is delayed.
- Currently working on brochures and in planning stages with Specialists in the community for follow-up algorithms and clinical care coordination letters.
- DSHS is on target to go live in 2021.

Agenda Item 6: Future condition implementation updates

Dr. Gong introduced, Dr. Susan Tanksley, Laboratory Operations Unit Manager, DSHS Laboratory.

Dr. Tanksley stated:

- Space for future condition screening is being created in the lab.
- The Laboratory is in the process of converting Congenital Hypothyroidism testing to the new equipment (genetic screening processors). Then screening for cystic fibrosis will be switched to the Genetic Screening Processor as well.
- There are two options for screening for lysosomal storage disorders – tandem mass spectrometry and digital microfluidics platforms.
- The target to start implementation of Pompe and Mucopolysaccharidosis Type I is Fall 2022 with go-live estimated for Jan 2024.

Agenda Item 7: Newborn Screening Fee

Dr. Gong introduced, Dr. Susan Tanksley, DSHS, Laboratory Operations Unit Manager.

Dr. Tanksley stated:

- Plan is to update newborn screening fee at the same time that Medicaid rates change, which is January 1, and not more than once per year.
- Appropriated funding will cover expenses for SMA screening through Aug 2021.
- The fee increase for Private Pay is not expected to be more than \$3.00 and will be effective January 1, 2022.

Agenda Item 8: Screened condition status updates

Dr. Gong introduced, Dr. Debra Freedenberg, M.D., Ph.D., Medical Director, DSHS Newborn Screening Unit. Dr. Freedenberg, referenced the PowerPoint/handout, *2016-2019 Confirmed Conditions*.

Dr. Freedenberg stated:

- The chart outlines the various Recommended Uniform Screening Panel (RUSP) conditions for the period 2016 through 2019.

- The numbers presented in the chart fluctuate as diagnoses are added or change. The numbers could also be attributed to birth rates.

Agenda Item 9: X-linked Adrenoleukodystrophy (X-ALD) testing update

Dr. Gong introduced, Dr. Debra Freedenberg, M.D., Ph.D., Medical Director, DSHS Newborn Screening Unit. Dr. Freedenberg, referenced the PowerPoint/handout, *Texas NBS X-linked Adrenoleukodystrophy (X-ALD) Case Summary, August 2019-July 2020*.

Dr. Freedenberg provided case summary results by category:

- 8 males hemizygous affected
- 4 female heterozygotes
- 1 CADD
- 2 Zellweger Syndrome, 1 Zellweger carrier

Dr. Freedenberg notified the committee that the Centers for Disease Control grant was received. This will allow the program to evaluate an algorithm for screening for hypothyroidism. This screening has the highest number of false positives. The goal is to reduce false positives and improve time to detection.

Members discussed:

Discussion between Dr. Freedenberg and the Committee regarding the ability to evaluate the families of these patients. There are several barriers including insurance and Medicaid that will only pay for the patients and not the sequencing for family members. The State Funds do not have the capacity to cover the families.

Agenda Item 10: COVID-19 Newborn Screening Protocols

Dr. Gong introduced, Dr. Susan Tanksley, Ph.D., Laboratory Operations Unit Manager, DSHS Laboratory, and Dr. Debra Freedenberg, M.D., Ph.D., Medical Director, DSHS Newborn Screening Unit. They referenced the PowerPoint/handout, *COVID-19 Impact on Newborn Screening*.

Dr. Tanksley stated:

- There has been a slight increase of first screens collected at less than 24 hours of life (recommendation is to collect first screen at 24-48 hours of life).
- Experienced a decrease in second screens in March
- First screens (collected at less than 7 days of age) were decreased from April to September 2020 compared to 2019.
- Second screens (collected at 7 or more days of life) were also decreased in March and May to September 2020 in comparison to 2019.
- Evaluating if there are fewer births or fewer screens per birth and if number of screens in border counties declined.

Agenda Item 11: Critical Congenital Heart Disease (CCHD) Subcommittee Reporting

Dr. Gong announced Dr. Michael Speer replaced Dr. Scott McLean as the new CCHD Subcommittee Chair. Dr. Speer was not present thus no report was provided.

Dr. Gong added the Consultants' Fees Subcommittee business was completed with the letter to Dr. Hellerstedt sent.

Agenda Item 12: Newborn Hearing Screening in Neonatal Intensive Care Unit (NICU) Subcommittee Reporting

Dr. Gong introduced, Dr. Tiffany McKee-Garrett, Subcommittee Chair.

Dr. McKee-Garrett stated:

The Subcommittee is currently working on a draft letter to be sent to Dr. Hellerstedt. The letter addresses NICU screening protocols. It will be distributed to various State agencies, stakeholders, and the Committee.

Protocols include:

- Screening at 34-44 weeks post menstrual age
- Diagnostic testing by 1 month
- Intervention by 2 months

This letter will be finalized at the next subcommittee meeting.

It was recommended that the Subcommittee furnish the letter to the Advisory Committee to be signed by Dr. Gong, Dr. Speer, and Dr. McKee-Garrett before sending to Dr. Hellerstedt.

Agenda Item 13: Sickle Cell Subcommittee Reporting

Dr. Gong introduced, Dr. Titilope Fasipe, and Dr. Melissa Frei-Jones, Sickle Cell Subcommittee Co-Chairs.

Dr. Fasipe stated:

- Currently the Subcommittee is evaluating each of the sickle cell providers of care to the pediatric population to ensure they meet National Institutes of Health standards.
- Reviewing docs from the Newborn Screening Unit to determine if anything needs to be refreshed.
- Working on education, awareness, campaigns and tracking

Agenda Item 14: Health Information Technology Subcommittee Reporting

Dr. Gong introduced Dr. Joseph Schneider, Subcommittee Chair.

Dr. Schneider stated:

Acknowledged that the agency members have contributed to the subcommittee's work in a very positive way, covering:

- Link to Vital Records database
- Improving interoperability
- Chief Technology Officer staff meeting with other staff to assist in next steps going forward

New members expressed interest in subcommittee participation. Ms. Aimee Millangue, Advisory Committee Liaison, DSHS Newborn Screening Unit, advised

subcommittee membership will need to be reviewed to ensure a quorum of members is not present for subcommittees.

Agenda Item 15: Review of Bylaws

Dr. Alice Gong, introduced Ms. Sallie Allen, HHSC, Policy & Rules, Advisory Committee Coordination Office. Ms. Allen reviewed the draft of the bylaws with the members and noted the language revisions to "Section 7. Presiding Chair and Vice Chair." Ms. Allen requested a motion to approve the Newborn Screening Advisory Committee Bylaws as presented October 2, 2020.

MOTION:

Dr. Joseph Schneider made a motion to approve the Newborn Screening Advisory Committee Bylaws, presented October 2, 2020. Dr. Tiffany McKee-Garrett seconded. Ms. Allen conducted a roll call vote, and the motion carried with no objections or abstentions.

Members were reminded to sign the Statement by Members page of the bylaws and send to Ms. Aimee Millangue.

Agenda Item 17: Public Comment

Ms. Allen read the public comment logistical announcements and called on those registered for public comment.

Written public comment was received from:

- Heather Johnson from Wichita Falls, Texas. She is a supporter of newborn screening for SMA. She has a child with SMA and is thankful for the State's work in early screening to support the best long-term care.
- Caroline Grossman and Joel de Jesus with Mirepoix, LLC. Newborn sickle cell screening/antigen testing should be a covered benefit without preauthorization for the lifetime improvement in health outcomes and patience experience.
- Kenneth Hobby, President, Cure SMA. Expressed support and recognized the work of the advisory committee and the State to improve outcomes concerning SMA screenings.

Agenda Item 19: Future Agenda Items/ Next Meeting Date/ Adjournment

Dr. Gong stated the next meeting will be sometime in January 2021. Dr. Gong would like for the Sickle Cell Subcommittee to look into public comments received from Mirepoix, LLC.

Members discussed future agenda items:

- Impact of COVID-19 on the number of screens versus births
- Standing items – Subcommittee reporting, Future Conditions, Screened conditions
- Newborn Hearing Screening Rules – should be available by next meeting
- Legislative Update

- Action Item follow-up list:
 - Dr. Freedenberg followed up but was unable to get additional details to present on the involvement of specialists on a borderline X-ALD case for which a primary care provider requested DNA, and topic will not be pursued further.
 - Presentation in works for January on how Texas screening results can be included in ClinVar, a national genetic variants database.
 - Medicaid funding from newborn screening reimbursements distributed outside of the program – pending a presenter
 - Vital Statistics data linking – pending a presenter

Dr. Gong adjourned the meeting at 3:00 p.m.

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To listen to the webcast recording of the October 2, 2020 meeting go to:

<https://texashsc.swagit.com/play/10022020-709>