

**Newborn Screening Advisory Committee  
Meeting Minutes  
October 19, 2018  
2:00 p.m.**

**Moreton Building, Public Hearing Room M-100  
1100 W. 49<sup>th</sup> Street, Austin, TX 78756**

Table 1: Newborn Screening Advisory Committee member attendance at the Friday, October 19, 2018 meeting.

MEMBER NAME	YES	NO	MEMBER NAME	YES	NO
Beryl (Pam) Andrews	X		Tiffany McKee-Garrett, M.D.	X	
Nancy Beck, M.D.	X		Scott McLean, M.D.	X	
Titilope Fasipe, M.D., Ph.D.	X		Joseph Schneider, M.D.	X	
Melissa Frei-Jones, M.D.	X		Michael Speer M.D.	X	
Alice Gong, M.D.	X		Elizabeth (Kaili) Stehel, M.D.		X
Charleta Guillory, M.D.	X		Linda Zediana, R.N.		X
Tiffany House, J.D.	P				

**Yes:** Indicates attended the meeting **No:** Indicates did not attend the meeting **P:** Indicates participated by phone

Table 2: Newborn Screening Advisory Committee guest attendance at the Friday, October 19, 2018 meeting.

GUEST NAME/ORG.	YES	NO	GUEST NAME/ORG.	YES	NO
Tiffany Britton, Caddo Associates	X		Orlando Jones, Texas Children's Hospital	X	
Kyle Dolliver, Founder, Ryan's Challenge	X		Brittani Bilse, Sarepta	X	
Stephanie Simpson, Sanofi, US	X		Terese Finitzo, OZ Systems	P	
Rosie Valadez-McStay, Texas Children's Hospital	X				

**Agenda Item 1: Welcome and Introductions**

Dr. Charleta Guillory, Chair of the Newborn Screening Advisory Committee, convened the meeting at 10:30 a.m. Dr. Guillory greeted everyone and requested Committee members and members of the public introduce themselves.

**Agenda Item 2: Committee Business Logistics**

Dr. Guillory turned the floor over to Ms. Stephanie Gutierrez, HHSC, Policy & Rules, Advisory Committee Coordination Office. Ms. Gutierrez reviewed logistics, called roll, and determined quorum.

### **Agenda Item 3: Review and Approve Meeting Minutes for July 16, 2018 & August 24, 2018**

Ms. Gutierrez requested a motion to approve both the July 16, 2018 and August 24, 2018 meeting minutes.

**MOTION:** Dr. Michael Speer made a motion to approve the July 16, 2018 & August 24, 2018 meeting minutes. Dr. Joseph Schneider seconded. A roll call vote was taken for members over the phone. A voice vote was taken for members in the room. The motion carried with no objections or abstentions.

### **Agenda Item 4: Review and Adopt the Newborn Screening Advisory Committee Bylaws**

Dr. Guillory introduced and turned the floor over to Mr. David Martinez, Manager, DSHS, Newborn Screening Unit.

Mr. Martinez briefed members of the initial vote of the bylaws with follow up regarding Section 14: Compensation and Travel Reimbursement. Mr. Martinez explained to members that for reimbursement to take place, the Newborn Screening Advisory Committee must be approved by legislature and identified in the General Appropriations Act. The Newborn Screening Advisory Committee is not identified for reimbursement without exception. Mr. Martinez stated Section 14: Compensation and Travel Reimbursement needs to be reinstated into the Bylaws.

Dr. Guillory opened the floor for discussion.

**MOTION:** Dr. Schneider made a motion to reinstate Section 14: Compensation and Travel Reimbursement back into the Bylaws. Dr. Speer seconded the motion. A roll call vote was taken for members over the phone. A voice vote was taken for members in the room. The motion carried with no objections or abstentions.

### **Agenda Item 5: X-ALD Screening Implementation**

Dr. Guillory introduced and turned the floor over to Dr. Susan Tanksley, Manager, DSHS, Laboratory Operations Unit.

Dr. Tanksley gave an update on:

1. Implementation of screening X- linked Adrenoleukodystrophy (X-ALD).
  - a. Dr. Tanksley stated DSHS was awarded a grant of \$135,000 in Fiscal Year (FY) 2017 which was used to:
    - i. Focused on establishing a third tier DNA sequencing assay
    - ii. Development of educational materials
    - iii. Development of a follow-up algorithm
  - b. DSHS was awarded \$1.2 million in the last legislative session for X-ALD implementation. DSHS has requested funding for on-going testing after implementation as part of the exceptional item request for FY 2020 and FY 2021
  - c. DSHS was awarded a two-year Centers for Disease Control and Prevention (CDC) new disorders grant for \$300,000 in September

- 2018 to purchase supplies for the first and second-tier screening as well as to provide training for laboratory staff and healthcare providers
- d. On November 26, 2018 there is an official project kick-off meeting to discuss the September 2019 implementation date
  - e. The Newborn Screening Kit received Federal Drug Administration (FDA) approval
  - f. The Clinical Care Coordination Team developed short-term process calls and protocols, ACT and FACT Sheets, an X-ALD educational brochure and a diagnosis form.

Members discussed:

1. The number of states that have implemented X-ALD screening
2. The total amount of money requested in the legislative appropriations
3. Effective interventions of screening and treatment
4. Tier sequencing
5. Involvement of genetic counselors
6. The need for a permanent funding mechanism to cover the screening for conditions added to the Recommended Uniform Screening Panel (RUSP) and for research and development costs not covered by grants
7. Abnormal screening follow through
8. Clarifying the methodology for linking follow up test results to previous test results

**ACTION ITEM:** The DSHS Laboratory to provide a cost comparison of two-tier versus three-tier screening.

#### **Agenda Item 6: Break**

Dr. Guillory announced a 10-minute break.

#### **Agenda Item 7: Proposed Laboratory Rule Change**

Dr. Guillory reconvened the meeting at 12:02 p.m. and turned the floor over to Dr. Tanksley.

Dr. Tanksley stated the DSHS laboratory proposed a rule change for the purpose of repealing the names of the test and associated fees being listed in the Texas Administrative Code. The DSHS laboratory will reference the fees on the DSHS website. The proposed rules are at HHSC for review and are on target to be reviewed during the December Executive Council meeting.

**MOTION:** Dr. Alice Gong made a motion for the Committee to formally support the change in laboratory rules as described by Dr. Tanksley. Dr. Speer seconded the motion. A roll call vote was taken for members over the phone. A voice vote was taken for members in the room. The motion carried with no objections or abstentions.

### **Agenda Item 8: Rider 37 Update**

Dr. Guillory turned the floor over to Dr. Tanksley. Dr. Tanksley gave a summary of the final outcome of Rider 37 to the Committee for the new members.

Members discussed:

1. The amount of money the State is reimbursed by Medicaid for each screen performed
2. Private Insurers
3. Other state screening models
4. Committee response to Rider 37
5. How the committee can make their voice heard during legislative session
  - a. Dr. Gong read the letter from Dr. Hellerstedt
  - b. Dr. Schneider suggested the Rider 37 subcommittee will draft a response letter to Dr. Hellerstedt.
6. Having a representative attend a meeting to discuss Medicaid payments

**MOTION:** Dr. Speer made a motion that the Committee supports the report conclusions of Rider 37 however the problem is not solved and the Committee recommends the conclusions be considered a work in progress with additional work to solve the problems pursued aggressively by the state. Dr. Scott McLean seconded the motion. A roll call vote was taken for members over the phone. A voice vote was taken for members in the room. The motion carried unanimously with no objections or abstentions.

#### **ACTION ITEMS:**

1. The Rider 37 Subcommittee will draft a letter of support of the Rider 37 Report's conclusion but make the recommendation that additional work needs to be done.
2. Members also requested for a funding SME to go over the logistics of the NBS funds received from Medicaid at a future meeting.

### **Agenda Item 9: Break**

Dr. Guillory announced a five-minute break.

### **Agenda Item 10: Critical Congenital Heart Disease**

Dr. Guillory reconvened the meeting at 1:49 p.m. Dr. Guillory turned the floor over to Dr. McLean. Dr. McLean referenced the PowerPoint and handout, *Report from the CCHD (Critical Congenital Heart Disease) Subcommittee*.

Members discussed:

1. The Texas Early Hearing Detection and Intervention (TEHDI) Management Information System (MIS) CCHD Reporting Module Pilot project
  - a. A law requirement
  - b. Planning for implementation
  - c. Funding
  - d. Inviting SMEs

**ACTION ITEM:** Members will identify champions for the pilot project. Subcommittee will also provide a status update on developing strategies to involve more hospitals and increase CCHD reporting to DSHS at the next meeting.

### **Agenda Item 11: Newborn Hearing Screening in Neonatal Intensive Care Unit (NICU) Subcommittee Reporting**

Dr. Guillory turned the floor over to Dr. Tiffany McKee-Garrett. Dr. McKee-Garrett referenced the handout and PowerPoint, *Development of best practices for hearing screening in the Texas NICU population a report from the Hearing Screening Subcommittee*.

Dr. Guillory called Mr. Doug Dittfurth, DSHS, Newborn Screening Unit, Texas Early Hearing Detection and Intervention (TEHDI), to the table to address members. Mr. Dittfurth asked the Committee to proceed carefully.

Members discussed:

1. Risk factor monitoring
2. Age at screening
3. Clarifying what the Joint Committee on Infant Hearing (JCIH) has stated

**ACTION ITEM:** Mr. Dittfurth will send a statement to the members of the Committee that will be included in their report.

### **Agenda Item 11: Public Comment**

No public comment was made.

### **Agenda Item 12: Future Agenda Items/ Next Meeting Date/Adjournment**

Dr. Guillory turned the floor over to Ms. Aimee Millangue, DSHS, Newborn Screening Unit. Ms. Millangue reviewed the action items of the meeting.

Members discussed:

1. Sickle Cell Advisory Committee 2018 Annual Report
2. Formation of a Sickle Cell Subcommittee
3. Adding legislative updates as a standing agenda item.
4. Adding implementation of new disorders to the Texas Newborn Screening Panel as a standing item.
5. Adding a "State of the Newborn Screening Program" update as an annual standing item with a status report on each screened condition in Texas.
6. The DSHS Laboratory's linking algorithm for matching 1<sup>st</sup> and 2<sup>nd</sup> screens
7. Status of updated Parental Consent Form
8. 2019 dates

Dr. Guillory adjourned the meeting at 3:50 p.m.

Webcast: <https://texashhsc.swagit.com/play/10192018-908>