

**Newborn Screening Advisory Committee
Meeting Minutes
October 14, 2016
10:00 a.m. – 4:00 p.m.**

**Moreton Building, Conference Room M-653
1100 W. 49th Street, Austin, TX 78756**

Table 1: Newborn Screening Advisory Committee member attendance at the Friday, October 14, 2016 meeting.

MEMBER NAME	YES	NO	MEMBER NAME	YES	NO
Dr. Nancy Beck	X		Dr. Scott McLean	X	
Dr. Alice Gong	X		Dr. Michael Speer		X
Ms. Aida Gonzalez	X		Dr. Elizabeth "Kaili" Stehel	P	
Dr. Charleta Guillory	X		Ms. Benna Timperlake	X	
Ms. Tiffany House	P		Dr. Thomas Zellers	P	

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

Table 2: Newborn Screening Advisory Committee staff attendance at the Friday, October 14, 2016 meeting.

HHS STAFF NAME	YES	NO	HHS STAFF NAME	YES	NO
David Martinez	X		Beth Rider	X	
Dr. Debra Freedenberg	X		Susan Tanksley	X	
Felipe Rocha	X		Dr. Rachel Lee	X	
Patti Lanfranco	X		Karen Hess	X	
Lori Fitzgerald	X		Lynette Borgfeld	X	
Patricia Hunt	X		Brendan Reilly	X	
Olivia Walker	X				

Table 3: Newborn Screening Advisory Committee guest attendance at the Friday, October 14, 2016 meeting.

GUEST NAME/ORG.	YES	NO	GUEST NAME/ORG.	YES	NO
Shannon Lucas, March of Dimes	X		Opal Cushing, Baylor S&W	X	
Brandy Lee, OZ Systems	X		Kerry Ryder, Baylor S&W	X	
Mark Vane, Gardere Law Firm	X		Gwendolyn Quintana, TMA	X	
Raven Steward, Baylor S&W	X		John Sepehri, Gardere Law	X	
Clayton Travis, TX Pedi Society	X				

Agenda Item 1: Welcome and Introductions

Mr. David Martinez greeted everyone and turned the floor over to Dr. Charleta Guillory. Dr. Guillory requested the Committee introduce themselves. Ms. Stephanie Gutierrez reviewed logistics with the Committee.

Agenda Item 2: Review and Approval of Minutes for June 17, 2016

MOTION: Dr. Alice Gong

SECOND: Ms. Benna Timperlake

Dr. Guillory requested a motion to approve the minutes. Dr. Gong motioned with Ms. Timperlake seconding. The motion carries to accept the June 17, 2016 minutes as approved by unanimous vote.

Agenda Item 3: Proposed Revision to Bylaws

Dr. Guillory requested discussion on the proposed revisions of the bylaws. The Committee discussed duration of terms for members as well as reappointment.

MOTION: Ms. Benna Timperlake

SECOND: Dr. Alice Gong

Ms. Timperlake makes a motion that the Committee adopt the changes to the bylaws as printed. Dr. Gong seconded the motion. The motion carries to accept the revisions of the proposed advisory committee bylaws by unanimous vote.

Agenda Item 4: Newborn Screening Consultant Survey Results

Dr. Debra Freedenberg gave background information to the Committee and relayed the concern reported from providers that the clinical portion of the newborn screening program is not reimbursed adequately. Dr. Freedenberg also shared general findings of the survey that can be found in the PowerPoint, Newborn Screening Consultant Survey Summary. Dr. Freedenberg provided graphs of participant answers to the survey questions for the Committee.

The Committee had a thorough discussion regarding the survey and specifically Medicaid billing, preauthorization, documenting and billing, billing tracking systems, clinical hotlines, and ideas of what reimbursement would ideally look like from Medicaid. Other topics of discussion from the Committee were online web-based systems to collect data, follow-up

programs, specialists' salaries, workforce requirements, funding available through other programs or sources, and second screenings.

Agenda Item 5: Lunch

Agenda Item 6: Newborn Screening Video/Texas NewSTEPS 360 Hospital Quality Improvement Project

Ms. Codie Prinz presented to the Committee the Timeliness Improvement Project. Ms. Prinz referred to the PowerPoint, Newborn Screening Timeliness Improvement Project available in the packets for each Committee member.

Ms. Prinz shared the Newborn Screening Provider Self-Assessment tool that was created to capture data, the Newborn Screening Best Practice Tips that was created for hospitals and providers, and the Newborn Screening Site Visit Feedback Form created as a resource for the facility and completed by the Department of State Health Services (DSHS).

Ms. Prinz mentioned the Newborn Screening Video Concept. This project consists of six short videos for providers. The video is available on the DSHS YouTube channel and will be sent out to all providers on the Listserv.

Agenda Item 7: Newborn Screening Fee Increase Update

Dr. Rachel Lee presented to the Committee the PowerPoint, Newborn Screening Fee Increase Updates available in all Committee member packets.

Dr. Lee turned the floor over to Dr. Susan Tanksley to answer a question from the Chair. Dr. Tanksley stated that Medicaid pays for the newborn screening kits by voucher based on the number of Medicaid eligible screens in the previous quarter. DSHS receives this funding, in part as designated by the legislature. Stakeholder meetings were held as part of the public comment period of the rulemaking process prior to the fee increase. DSHS has been proactive in ensuring providers are aware of the increase so they could renegotiate their contracts with private insurance companies to adjust the reimbursement rates accordingly.

A subsequent increase in Medicaid reimbursement for the increased cost of newborn screening is also being sought.

Agenda Item 8: Laboratory Continuous Quality Improvement Projects

Dr. Lee provided updates on DSHS Newborn Screening Laboratory quality improvement projects to the Committee.

Dr. Lee shared with the Committee an update on residual specimen retention, which requires parental consent via a Parent Decision Form. If signed parental consent is obtained, the laboratory is allowed to keep the specimen for up to 25 years for potential public health research use. If the laboratory does not receive a form or the parent says no, the laboratory must destroy the specimen within two years of receipt. The laboratory has initiated efforts to review return rates for the Parent Decision form and identify means for increasing returned forms. The Committee discussed whether a means for documenting the parent decision using an electronic means would be possible. Additionally, the committee discussed the possibility of including the return rates on the Newborn Screening "Report Card."

The Committee had further discussion regarding whether it would be possible to develop electronic means for improving provider access to ACT and FACT sheets, allow diagnostic case data entry, and allow for the documentation of activities for billing purposes.

Dr. Lee separately shared information on efforts to determine the percentage of eligible newborns in Texas that successfully receive a newborn screen as legislatively mandated. There is currently no means for the program to track Parent Refusals of Newborn Screening specimen collection based on an established religious belief. As such, there is currently no means for the program to determine whether the 1.6% of eligible newborns who did not receive a screen was due to parental refusal or for other deficiencies in the newborn screening system. Dr. Lee proposed the question of what additional steps the committee would recommend to better determine the percentage of newborns for which the newborn screen is refused.

Mr. Brendan Reilly updated the Committee on a recently completed project to improve laboratory turnaround times. The project resulted in significant improvements to adherence to the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's recommendations for timeliness in newborn screening.

Agenda Item 9: X-ALD, Pompe, and MPS1 Screening Panel Update

Mr. Martinez passed out a letter drafted by Dr. Guillory on behalf of the Newborn Screening Advisory Committee. The letter was addressed to DSHS Commissioner Dr. John Hellerstedt regarding the Newborn Screening for X-ALD.

Regarding Pompe and MPS1, Dr. Tanksley informed the committee members of the method used for screening and reported that budget costs for the screen and the clinical coordination are unknown at this time. Perkin Elmer

has submitted a plan to the institutional review board for a prospective blind study in the DSHS lab and the data would be submitted to Federal Drug Administrative (FDA) in an effort to seek FDA approval of the kit to identify lysosomal storage disorders. The lysosomal disorder kit is estimated to be approved by the FDA in late 2018. The DSHS laboratory would need to acquire six to seven new tandem mass spectrometers.

The Committee resumed discussion about how states are currently screening for X-Linked Adrenoleukodystrophy (X-ALD), the start-up cost, and overall cost analysis. Dr. Guillory requested the Committee review the letter for edits. Dr. Guillory requested a motion to accept the letter with the proposed revisions.

MOTION: Ms. Benna Timperlake

SECOND: Dr. Alice Gong

The motion to send the letter with typographical errors corrected and removing the first sentence in the last paragraph was made by Ms. Timperlake. Dr. Gong seconded. The motion carries by unanimous vote.

Agenda Item 10: Public Comment

No public comment.

Agenda Item 11: Future Agenda Items/ Confirm Next Meeting Date

1. Second screen for physicians with small practices
2. Medicaid representative at the meeting to discuss specialists' workforce coverage
3. Hearing screening data collection and parent permission requirement
4. Pompe and MPS1, specifically cost savings
5. Newborn Screening fee increase update
6. Lab Continuous Quality Improvement (CQI) Plan Update – include capturing data on parental refusal and next steps

The next meeting will be via conference call. Ms. Beth Rider will send out a poll of dates.

Agenda Item 12: Adjourn

Dr. Guillory adjourned the meeting at 3:53 p.m.