Newborn Screening Advisory Committee
Meeting Minutes
August 11, 2017
1:00 p.m.

Moreton Building, Public Hearing Room M-100
1100 W. 49th Street, Austin, TX 78756

Table 1: Newborn Screening Advisory Committee member attendance at the Friday, August 11, 2017 meeting.

MEMBER NAME	YES	NO	MEMBER NAME	YES	NO
Nancy Beck, MD	P		Joseph Schneider, MD	P	
Alice Gong, MD	P		Michael Speer, MD	P	
Charleta Guillory, MD	X		Elizabeth "Kaili" Stehel, MD	P	
Tiffany House, JD	P		Benna Timperlake, RN	P	
Tiffany McKee-Garrett, MD	P		Linda Zediana, RN	P	
Scott McLean, MD	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, August 11, 2017 meeting.

HHS STAFF NAME	YES	NO	HHS STAFF NAME	YES	NO
David Martinez	X		Dr. Susan Tanksley	X	
Dr. Debra Freedenberg	X		Dr. Rachel Lee	X	
Felipe Rocha	X		Karen Hess	X	
Patricia Lanfranco	X		Lynette Borgfeld	X	
Katlyn Le	X		Brendan Reilly	X	
Patricia Hunt	X		D'Andra Luna	X	
Beth Rider	X		Doug Dittfurth	X	

Table 3: Newborn Screening Advisory Committee guest attendance at the Friday, August 11, 2017 meeting.

GUEST NAME/ORG.	YES	NO	GUEST NAME/ORG.	YES	NO
Kurt Kampfschulte, ALD Connect	X		Mike McBrierty, Biogen	X	
Kellie Dees, Texas Pediatric Society	X		Victoria Ford, K&L Gates	X	
Candice Brannen, Baebies	X		Elizabeth Moore, Cure SMA	X	
Khrystal Davis, FAST	X		Tiffiny Britton, Caddo Associates	X	
Kristen Resendez, Cure SMA	X				

Agenda Item 1: Welcome and Introductions
Dr. Charleta Guillory greeted everyone, introduced the three new committee members, and requested the participants in the room introduce themselves.

Agenda Item 2: Committee Business Logistics
Dr. Guillory turned the floor over to Ms. Stephanie Gutierrez. Ms. Gutierrez reviewed logistics, called roll, and noted quorum.

Agenda Item 3: Review and Approval of Minutes for February 24, 2017
Dr. Guillory commented the topic of CCHD education was not included on this agenda but will be included on the next meeting agenda. Dr. Guillory requested a motion to approve the February 24, 2017 minutes. Dr. Gong motioned with Dr. Spears seconding. A roll call vote was taken. The motion carried to accept the February 24, 2017 minutes as approved by unanimous vote.

Agenda Item 4: Follow-Up: Hearing Aids for NICU Babies
Dr. Guillory introduced Mr. Doug Dittfurth, Texas Early Hearing Detection and Intervention (TEHDI) Coordinator. Mr. Dittfurth provided a follow up to the Committee regarding whether there is a policy against fitting and dispensing of hearing aids on Neonatal Intensive Care Unit (NICU) infants. Mr. Dittfurth stated there are currently no policies against fitting infants in the NICU. However, Mr. Dittfurth also stated there are sometimes medical contraindications for hearing aid fittings. The Committee discussed the possibility that intubation for NICU babies might be a medical contraindication. Dr. Guillory stated her concern that there may be babies in the NICU who are not receiving the hearing screen, for any reason, which could impact their need for hearing aids.

Agenda Item 5: Pompe and MPS-1 Cost Estimates
Dr. Guillory introduced Dr. Rachel Lee, Biochemistry and Genetics Branch Manager in the Laboratory. Dr. Lee informed the Committee of cost estimates for implementation of Pompe and MPS-1. The estimate for year one includes salary costs for the new full time employees (FTE's) that will be hired to perform testing, as well as a building and system retrofit, reagent and supplies of equipment, and indirect costs. The total cost estimates for laboratory only to implement Pompe and MPS-1 is $2.2 million for year one to implement the screening. For on-going testing after implementation is $2.75 million per year for laboratory only. These costs do not include clinical care coordination. The costs are based on New York incidence rates. The Committee members asked for information on estimated number of patients with presumptive positive screens for Pompe and MPS-1 needing clinical care coordination. The number of newborns with abnormal screens for Pompe is

approximately 70 and the number of newborns for MPS-1 is estimated to be 120 if considering first screens only. The cost to DSHS for clinical care coordination is estimated at $120,000 per year which includes two additional nurses.

The Committee discussed the potential and feasibility to ask for appropriating funding or possibly increasing the fee for screening which would require an amendment to the Texas Administrative Code (rule). Currently, the Health and Safety Code states that the fee cannot exceed the actual cost of testing. Therefore, projected costs cannot be included in the fee prior to DSHS incurring additional expense (e.g., implementation of a new test) in an effort to accumulate funds for future use. A change to the Health and Safety code would be required to allow more than actual cost to be charged for the screen.

Agenda Item 6: Plan for Implementation of X-ALD Screening

Dr. Guillory introduced Dr. Lee. Dr. Lee informed the Committee of the plan for implementation of X-ALD screening. Currently there are five states that have started screening. The DSHS laboratory plans for a two or three tier testing algorithm. DSHS received a new disorder grant from APHL to initiate some activities for X-ALD screening and send staff to training. Additionally, DSHS will host an X-ALD stakeholder meeting to be held on August 21-22, 2017 to discuss testing and follow up. The cost estimate provided to the Legislature was $1.5 million for the implementation year and $3.6 million a year for ongoing testing. The actual funding appropriated was $1.2 million for implementation. Funding is projected to start Fiscal Year 2018, and the plan is to begin the year-long process of changing the rule to increase the fee. Implementation is anticipated to be completed around March 2019. It is noted that additional funding has not been received to continue to screen beyond implementation.

In terms of the first tier of screening in the laboratory, small equipment will be purchased to complete a method evaluation study, evaluate an upgraded MSMS kit, and determine best potential markers and ratios to screen for X-ALD. The current tandem mass spectrometry equipment will also be used for the study. After evaluating the results from a study to determine what the presumptive positive rates from the first tier might be, it will be determined if a second tier is beneficial and validation studies for all methods will be performed in order to develop a final lab algorithm. Changes to the Laboratory Information Management System (LIMS), updates to the standard operating procedures, and training for existing staff will be determined. As for the DNA sequencing analysis, in Fiscal Year 2018, grant funds will be ready to use for the purchase of reagents to develop, optimize,

and validate the molecular method. Funds from the grant will also be used to retrofit the laboratory's dark room for the molecular method. A contract for the retrofit is pending from Texas Facilities Commission (TFC) for review and sign off. The laboratory will request changes in LIMS, purchase a new sequencer, and hire two staff for DNA sequencing and a research scientist to help with the implementation.

Agenda Item 7: Parental Refusal Form

Dr. Guillory introduced Dr. Lee. Dr. Lee reported that 1.6% of 400,000 newborns in Texas did not get screened in 2014. There is legal concern of establishing a database tracking parents who refuse screening. The concern stems from the possibility of open records requests. The Committee discussed the possibility of tracking the reasons for refusal with newborns de-identified. The potential problem with de-identified babies is that a refusal for two screens (same baby) would be counted twice, skewing the actual number.

Dr. Elizabeth Stehel delivered a presentation to the Committee. Dr. Stehel referenced the PowerPoint titled, "Documenting Newborn Screening Refusal".

The Committee discussed having a centralized repository on the DSHS website where the refusal forms are available and easily located so the refusals can be tracked and documented. The Committee also discussed opportunities for education, such as scripting that can be said to parents who initially decline the screening for their newborn. The Committee also discussed that medical records and forms, especially in hospitals, are electronically based and we might consider an electronic form.

Dr. Debra Freedenberg announced that state law requires if a child is diagnosed with a condition that was not detected by newborn screening it is required to report this to the Department of State Health Services. She also reminded the Committee that although there is not a cost to the hospitals and physician offices for the kits paid by Medicaid, there is a cost to the State.

Dr. Guillory recommended to the Committee that the subcommittee continue to work on the refusal form and the process for obtaining the refusals. The subcommittee will be inclusive in terms of getting comments from the full committee. Dr. Scott McLean made a motion to continue the Committee work of the proposed draft for the refusal form. Ms. Benna Timperlake seconded. A roll call vote was taken. The motion carried.

Ms. Beth Rider notified the new committee members to email her directly as opposed to the full committee for feedback on the proposed form as well as interest in participating on the subcommittee.

Agenda Item 8: Update: Fee Increase and Impact to Small Practices

Dr. Guillory introduced Mr. Brendan Reilly. Mr. Reilly referenced the PowerPoint titled, "Impact of NBS fee increase 3 Months and 9 months". Mr. Reilly updated the Committee regarding a follow up to the last meeting regarding collecting data on the impact of the fee increase to providers. Mr. Reilly stated that there was a slight increase in smaller provider offices submitting the screens. The number of second screens being referred to larger facilities dropped slightly. Data was recollected after 9 months from 3 months with data changing minimally.

Ms. Kellie Dees, Texas Pediatrics Society (TPS), presented to the Committee. Ms. Dees stated that TPS has a concern that inadequate and insufficient reimbursement for pediatricians is threatening the newborn screening program and is risking the health of babies in Texas. TPS has requested a meeting with and looks forward to working with DSHS to discuss a more comprehensive plan for adequate reimbursement to ensure every baby born in Texas can benefit from newborn screening. TPS also requests that this topic is added to the next meeting agenda. The Committee asked for information regarding the letter TPS is drafting following their identification of which insurance companies are not reimbursing at the cost of the kit. Ms. Dees stated that TPS will take this next step to submit the letter to certain Health Maintenance Organizations (HMOs) that have been identified as not reimbursing pediatric offices. The letter would explain the importance of newborn screening and the negative effects on those practices complying with the second screen submission. The Committee discussed the option of asking for a representative from the Texas Department of Insurance to address this issue with the members. Dr. Guillory also mentioned the Texas Medical Association (TMA) and the March of Dimes is involved in following this issue.

Agenda Item 9: Public Comment

Dr. Guillory turned the floor over to Ms. Gutierrez. Ms. Gutierrez read public comment logistical announcements. Ms. Gutierrez called Ms. Kristen Resendez to the floor. Ms. Resendez addressed the committee regarding Spinal Muscular Atrophy (SMA), optimal time of treatment, and adding SMA to the screening panel.

Ms. Gutierrez called Ms. Elizabeth Moore to the floor. Ms. Moore addressed the committee regarding SMA. Ms. Moore requested SMA be on the next meeting agenda so the Committee can discuss adding SMA to newborn screening.

Agenda Item 10: Future Agenda Items/Confirm Next Meeting Date
Dr. Guillory turned the floor over to Mr. David Martinez. Mr. Martinez announced to the Committee that reimbursement for travel for in-person meetings is no longer going to be funded for future advisory meetings.

The next in-person meeting is on Friday, October 27, 2017, from 11:00 a.m. to 4:00 p.m. in Austin, Texas.

The agenda items for the next Newborn Screening meeting are:

1. SMA
2. CCHD Education
3. Refusal Form
4. Voting new members onto Subcommittees
5. Fee increase
    a. Follow up from DSHS
    b. TPS information
6. Timeliness of hearing screening for babies in the NICU
7. Overview of Newborn Screening Program

Note: Laboratory Tour will be conducted prior to the meeting

Agenda Item 11: Adjourn
Dr. Guillory adjourned the meeting at 3:53 p.m.