

**Newborn Screening Advisory Committee  
Meeting Minutes  
October 27, 2017  
11:00 a.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 27, 2017 meeting.

MEMBER NAME	YES	NO	MEMBER NAME	YES	NO
Nancy Beck, M.D.	P		Joseph Schneider, M.D.	X	
Alice Gong, M.D.	X		Michael Speer, M.D.	X	
Charleta Guillory, M.D.	X		Elizabeth "Kaili" Stehel, M.D.	X	
Tiffany House, J.D.		X	Benna Timperlake, R.N.	X	
Tiffany McKee-Garrett, M.D.	X		Linda Zediana, RN	X	
Scott McLean, M.D.	X				

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

Table 2: Newborn Screening Unit and other HHS staff attendance at the Friday, October 27, 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	
Lara Anton	X		Karen Hess	X	
Kelly McDonald	X		Lynette Borgfeld	X	
Katlyn Le	X		Brendan Reilly	X	
Patricia Hunt	X		D'Andra Luna	X	
Beth Rider	X		Yan Chen	X	
Rhonda Stokley	X		Karen Nail	X	
Jennifer Soria	X		Amanda Flores	X	
Dawn Ferriter	X		Michelle Shaffer	X	
Nicole Williams	X		Mary Dingrando	X	
Lucretia Jones	X				

Table 3: Newborn Screening Advisory Committee guest attendance at the Friday, October 27, 2017 meeting.

GUEST NAME/ORG.	YES	NO	GUEST NAME/ORG.	YES	NO
Cesar Lopez, Texas Hospital Association	X		Mike McBrierty, Biogen	X	
Kellie Dees, Texas Pediatric Society	X		Matthew Choi, Texas Tribune	X	
Clayton Travis, Texas Pediatric Society	X		Elizabeth Moore, Cure SMA	X	
Khrystal Davis, FAST	X		Tiffany Britton, Caddo Associates	X	
Shannon Lucas, March of Dimes	X		Steffi Lee, KXAN/Nexstar	X	
Ashley Tsuo, KXAN	X		Rustin Dudley, Legislative Budget Board	X	

**Agenda Item 1: Welcome and Introductions**

Dr. Charleta Guillory, Neonatologist and Chair of the Newborn Screening Advisory Committee, greeted everyone and requested the members introduce themselves as well as members of the public.

**Agenda Item 2: Committee Business Logistics**

Dr. Guillory turned the floor over to Ms. Stephanie Gutierrez, Stakeholder Relations, HHSC. Ms. Gutierrez reviewed logistics, called roll, and noted quorum.

**Agenda Item 3: Review and Approval of Minutes for August 11, 2017**

Dr. Guillory announced the need to approve the August 11, 2017 minutes and turned the floor over to Ms. Gutierrez. Ms. Gutierrez requested a motion to approve the August 11, 2017 minutes. Dr. Michael Speer motioned with Dr. Alice Gong seconding. A roll call vote was taken. The motion carried to accept the August 11, 2017 minutes as approved by unanimous vote.

**Agenda Item 4: Newborn Screening Overview**

Dr. Guillory introduced Dr. Debra Freedenberg, Medical Director of the Newborn Screening Genetics program and Dr. Rachel Lee, Biochemical and Genetics branch manager in the lab.

Dr. Lee referenced the PowerPoint and handout titled, *Newborn Screening Overview in Texas*. The Committee discussed ways in which the information can ultimately be captured electronically as opposed to paper. Dr. Lee mentioned DSHS Laboratory is working on upgrading the lab system for reporting. The Committee also discussed ways in which the fee can be adjusted and the process of inputting demographic information can be

modified to be most efficient and helpful overall. Dr. Lee stated the process is being reviewed and in regards to the fee, funding is always an issue. The Committee requested Dr. Lee walk through the steps where funding is not in place for a new screen and cannot be collected until the screen is implemented. Dr. Lee stated that payment for private pay and insurance kits is generally received three to four months from the date of testing, and reimbursements from Medicaid process longer at approximately four to eight months.

Dr. Freedenberg referenced the PowerPoint and handout titled, *Newborn Screening Overview in Texas*. Dr. Freedenberg explained to the Committee that Clinical Care Coordination (CCC) links a child to care and ensures that the child receives the benefit of newborn screening once they are informed of an abnormal or out of range screening. The CCC staff work diligently to find the baby's medical provider. Urgent results are faxed to the medical provider to follow up with the baby, along with the ACT/FACT sheets as education. Out-of-range results are provided to the parent(s) along with brochures as education. To assist with the long-term follow-up, the Committee discussed the issue of locating young females with hyperphenylalanemia at risk of difficult pregnancies and informing parent(s) of the clinical diagnosis. The Committee also discussed quality measures to continue to improve on and assess the work. Dr. Freedenberg stated that national quality measures are being discussed to incorporate into the system. The Committee discussed aging out of the newborn screening benefits program. Dr. Freedenberg stated there is no aging out but, if necessary, the younger babies would get priority. Regarding the hearing screening follow-up, there is concern that babies failing the hearing screens do not get appropriate intervention with audiology services. There is funding for the Blue Ribbon Program, in part by the Centers for Disease Control and Prevention (CDC), which includes interns who participate with the Newborn Screening (NBS) hearing screening (TEHDI) program.

### **Agenda Item 5: Break**

### **Agenda Item 6: WORKING LUNCH: Future Planning: Conditions not currently screened in Texas**

Dr. Guillory introduced Dr. Susan Tanksley, Laboratory Operations Unit Manager; Dr. Rachel Lee, Biochemistry & Genetics Branch, Laboratory; and Mr. David Martinez, Newborn Screening Unit Manager. Dr. Guillory stated that Pompe, X-Linked Adrenoleukodystrophy (X-ALD), and Mucopolysaccharidosis, Type 1 (MPS-1) have been approved and added to the national Recommended Uniform Screening Panel (RUSP). SMA will be up

for discussion. The Committee discussed how to move forward in adding the three conditions to the Texas screening panel and improving the processes and systems currently in place for newborn screening. Dr. Guillory asked the Committee how to be proactive in their thinking when having to add a new screen to the Texas panel. The Committee discussed the practice of implementing a first screen only versus a second screen. Dr. Tanksley stated there was a retrospective Center for Disease Control (CDC) cost study as a comparison between one-screen and two-screen states. Two of the states involved were Texas and California. The concentration was on endocrine disorders. Dr. Tanksley stated that the results were favorable to indicate continuing the second screen; however, she also agreed that a prospective cost study might be in order to determine the cost effectiveness. Dr. Tanksley explained different scenarios where the data between states could not be accurately compared due to differences in follow-up processes. The Committee continued to discuss the need to improve the system and look at new technology for the addition of new conditions to make sure all babies are screened for all conditions on the RUSP.

Dr. Gong suggested the full Committee be involved with the appropriations requests. Dr. Schneider made a motion for the full Committee to write a strong letter to Dr. Hellerstedt recommending the State establish a mechanism for funding to stay up to date with the RUSP recommendations both now and in the future. Dr. Gong seconded the motion. A roll call vote was taken. The motion carried.

### **Agenda Item 7: Newborn Hearing Screening in NICU**

Dr. Guillory informed the Committee that this Agenda Item will be moved to the next meeting.

### **Agenda Item 8: Fee Increase Data Impact to Provider Practices**

Dr. Guillory introduced Mr. Brendan Reilly, Laboratory, DSHS. Mr. Reilly updated the Committee regarding questions the Committee had from the last meeting. Mr. Reilly referred to the handout and PowerPoint titled, *Impact of NBS Fee Increase as Required by DSHS Newborn Screening Advisory Committee*.

Dr. Guillory requested that this agenda topic remain on the agenda going forward.

The Committee discussed Rider 37 which requires studying the most effective way to bill private insurance for Texas newborn screening kits and

report the findings. By August 2018 a report will have to be written. The Rider 37 report is currently being worked on.

Dr. Stehel made a motion that the Newborn Screening Advisory Committee creates a letter to Dr. Hellerstedt recommending Committee involvement in the response created as required by Rider 37. The motion was seconded by Dr. McKee-Garrett. A voice vote was taken. The motion carried.

### **Agenda Item 9: Spinal Muscular Atrophy (SMA)**

Dr. Guillory introduced Dr. Freedenberg, Dr. Tanksley, and Dr. Lee. Dr. Freedenberg and Dr. Lee presented to the Committee and referenced the PowerPoint and handout titled, *Newborn Screening for Spinal Muscular Atrophy (SMA)*. Dr. Lee notified the Committee of current pilot studies located in New York and Taiwan. Massachusetts and Missouri have legislation to add SMA in January 2019, and Massachusetts will have a pilot study. Dr. Lee mentioned that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) is in the evidence review process with a recommendation expected in February. Dr. Lee also notified the Committee of how the State is helping with the review process by completing a public health impact analysis survey to determine how ready Texas is for SMA screening and how will SMA screening impact our system. The Committee discussed how many babies could be expected as diagnosed using the SMA screening, treatment for SMA, and the elderly with SMA. Dr. Lee informed the Committee that the State is looking into how to move forward with SMA screening.

### **Agenda Item 10: Possible Action: Parental Refusal Form: DSHS Lab Update and Subcommittee Reporting**

Dr. Guillory introduced Dr. Elizabeth Stehel, Pediatrician and Subcommittee Chair, and turned the floor over. Dr. Stehel informed the Committee that the goal is that every infant will be screened twice. Currently, there are approximately 1.6% of newborns who aren't screened, resulting in about 6,600 babies per year who are not screened. Right now legislation requires that a parent sign they have refused newborn screening. Dr. Stehel presented two forms to the Committee. She stated that the form is below fifth grade level.

The Committee discussed whether there was a process for facilities notifying the infant's doctor that the parent refused screening in addition to the form being taken to the physician by the parent. The Committee discussed creating this process for Texas and bringing this discussion back to the next meeting.

Dr. Schneider made a motion to approve the refusal form combining version on page 33 with a single modification to be determined for readability. Dr. Speer seconded the motion. A voice vote was taken. The motion carried.

### **Agenda Item 11: Future Agenda Items/Next Meeting Date**

Dr. Guillory stated the Committee will continue with the consent forms. Dr. Guillory informed the Committee the next meeting will be at the end of January 2018. The Committee discussed they want to have Mr. Reilly update the Committee regarding technology. Dr. Guillory requested the Committee look at cost efficiencies. Ms. Beth Rider, Advisory Committee Support Specialist, read to the Committee their charge and notified them of their options in terms of having additional subcommittees.

Agenda items for next meeting:

1. Newborn Hearing Screening for NICU, deferred from previous meeting
2. Fee Increase Data Impact to Provider Practices
3. Technology and Systems Updates regarding newborn screening
4. Further discuss the formation of a subcommittee to advise the agency on strategic planning for newborn screening
5. Refusal Form and Process
6. CCHD follow-up: pulse oximetry screening and reporting
7. Report out from two subcommittees

### **Agenda Item 12: Possible Action: Critical Congenital Heart Disease (CCHD) Education**

Dr. Guillory introduced Dr. Elena Ocampo, FAAP, FACC Texas Children's Hospital. Dr. Ocampo referenced the PowerPoint and handout titled, *Screening Compliance for Critical Congenital Heart Disease in Texas Newborns*.

**ACTION ITEM:** The State will get Dr. Ocampo and the Committee the number of babies with congenital heart disease.

The Committee used the data from Dr. Ocampo's presentation and discussed the percentage of patients found by screening versus the percentage of patients not picked up by screening. The Committee also discussed what can be done to ensure all patients are screened and information is reported.

The Committee discussed recommending a standard electronic reporting approach for Texas. The Committee also discussed the possible need to receive consent from parents before all screening data could reported to the State or request de-identified data. The Committee recognizes that the law for reporting includes only diagnosed cases.

Dr. Scott McLean made a motion to create a subcommittee of the Newborn Screening Advisory Committee to evaluate methods for improving the quality of the CCHD screening program in Texas. Ms. Benna Timperlake seconded the motion. A voice vote was taken. The motion carried.

Ms. Rider read the bylaws of the full Committee regarding the functionality of a subcommittee.

Dr. Guillory requested volunteers for the subcommittee. Members of the subcommittee are:

1. Dr. Scott McLean - Chair
2. Dr. Joseph Schneider
3. Dr. Tiffany McKee- Garrett
4. Ms. Linda Zediana
5. Ms. Benna Timperlake

### **Agenda Item 13: Public Comment**

Dr. Guillory turned the floor over to Ms. Gutierrez. Ms. Gutierrez read Public Announcement Logistics to the Committee. Ms. Gutierrez called Ms. Khrystal Davis to the podium to address the Committee.

**Public Comment:** Ms. Khrystal Davis introduced her son, Hunter Davis, and informed the Committee of the number of friends her son has lost due to SMA. Ms. Davis also informed the Committee of Hunter's medical history and their experience regarding SMA and what doctors have told her about the life span of her son. Ms. Davis also discussed the treatment Biogen's Spinraza for SMA. Ms. Davis spoke about the importance of SMA being placed on the Newborn Screening panel.

Ms. Gutierrez read a letter of public comment to the Committee from Ms. Carriston Hendricks, FNP-C.

Dr. Guillory asked of the staff how parents can participate on the subcommittee. The staff informed Dr. Guillory that parents can be Subject Matter Experts.

### **Agenda Item 14: Adjourn**

Dr. Guillory adjourned the meeting at 4:13 p.m.