

GENETICS AND NEWBORN SCREENING ADVISORY COUNCIL MEETING

The Genetics and Newborn Screening Advisory Council (GNSAC) meeting was held Friday, February 15, 2019, at the Florida Department of Health Bureau of Public Laboratories, 1217 North Pearl Street, Jacksonville, Florida.

Call to Order:

The meeting was called to order at 9:12 am, EST, by Paul Pitel, MD, Council Chairperson. Roll was taken and introductions were made.

Members Present:

Paul Pitel, MD, Chairman, Hematologist
Robert Fifer, PhD, Audiologist
Dorothy Shulman, MD, University of South Florida (USF)
Roberto Zori, MD, University of Florida (UF)
Jeffrey Brosco, MD, Children's Medical Services (CMS) Deputy Secretary
Carina Blackmore, MS Vet Med, PhD, Department of Health, Delegate for the Surgeon General
Heather Smith, Parent Consumer
Brian Kirk, Newborn Screening/March of Dimes Representative
Barry Byrne, MD, Practicing Pediatrician
Gary Kleiner, MD, University of Miami
Mark Weatherly, MD, Practicing Pediatrician

Guests:

Jeanne Brunger, PerkinElmer, Inc.
Larry Vroegindewey, PerkinElmer, Inc.
Angela Darnell, PerkinElmer
Donna O'Steen, USF
Max Salfinger, USF
Thomas Suter
Mark McBrierty, Biogen
Joy Sherrick, Biogen
Scott Shone, RTI
Lindsay Kahn
Richard Finkel, SMA
Alissa Swota
Kyle Myers, SMA parent advocate
Katherine Myers, SMA parent advocate
Hannah Williford, SMA parent advocate
Audra Butler, Cure SMA
Madeline Dale
Jeremy Camp
Ann Lucas, Sanofi Genzyme
Amy Van Meter, UF Genetics
Kristin Mantay, UF Genetics
Jessica Abernathy
Gerold Schiebler, MD, CMS Consultant

DOH Personnel Present:

Cassandra G. Pasley, JD, BSN, Tallahassee – CMS
Marcy R. Hajdukiewicz, MS, Tallahassee – CMS

Dusty Edwards, BSN, RN, Tallahassee – CMS
Jessica Meyer, Tallahassee – CMS
Emily Reeves, BSN, RN, Tallahassee – CMS
Caitlin Roberts, Tallahassee – CMS
Ken McCain, Tallahassee – CMS
Erik Kirk, Tallahassee – CMS
Patty Lewandowski, Bureau of Public Health Laboratories, Tallahassee
Bonnie Taffe, PhD, MPH, Bureau of Public Health Laboratories, Jacksonville
Patti Ryland, MT, BS, Bureau of Public Health Laboratories, Jacksonville
Sajani Mamallapalli, Bureau of Public Health Laboratories, Jacksonville
Lori Bair, Bureau of Public Health Laboratories, Jacksonville
Melissa Rodriguez, Bureau of Public Health Laboratories, Jacksonville
Elliott Bailey, Bureau of Public Health Laboratories, Jacksonville
Rey Abrea, Bureau of Public Health Laboratories, Jacksonville

Attended Via Conference Call:

George Fox, Parent Consumer (Member of GNSAC)
Lori Gephart, APD Representative (Member of GNSAC)
Cyril Blavo, DO, Nova Southeastern (Member of GNSAC)
Sarah Gilbert, Everylife Foundation
Kristin Spence, USF Genetics
Stephanie Hacker, UM Genetics
Willa Thorson, MD, UM Genetics

Office of CMS Managed Care Plan & Specialty Programs Overview

Dr. Jeffrey Brosco gave an overview of the CMS Managed Care Plan and Specialty Programs.

- As of February 1, 2019, the CMS Managed Care Plan transitioned to WellCare.
- An overview of the new setup, how to navigate the plan to ensure coverage, what is provided under WellCare, and differences under WellCare was requested by those in attendance.

Newborn Screening Laboratory Update

Dr. Bonnie Taffe provided the Newborn Screening Laboratory update. Information regarding planned upcoming renovations was provided, which will be done during two phases.

X-ALD testing was discussed.

An update regarding the laboratory readiness for testing new disorders, Pompe, and Mucopolysaccharidosis Type I (MPS I), was provided.

Ethics Issues in Newborn Screening Presentation

Dr. Alissa Swota led a discussion on the ethical issues that exist in newborn screening.

- The ethics concerning identifying and informing patients/families about late-onset conditions were discussed.

Dr. Byrne moved to create a group that would look more deeply into the issue of when to inform families about late onset conditions, and how to help move Newborn Screening forward in a safe manner. Findings from the group should be discussed at the next meeting. Dr. Shulman seconded the motion at 10:42 am.

Medical Foods

Dr. Zori would like to raise concern over a report from AHCA that low protein food will not be covered and recommends that information regarding this matter be sent out in order to properly inform affected patients/families.

Spinal Muscular Atrophy (SMA) Disorder Review

Dr. Scott Shone gave a presentation on Spinal Muscular Atrophy (SMA) that reviewed the different types, estimated caseloads, and current available treatment.

Public Comment (11:32 am) – Below is a list of parents/advocates that provided public comment in support for adding SMA:

- Audra Butler
- Katherine Myers
- Hannah Williford
- Joy Sherrick
- Richard Finkel

Committee votes on SMA – Dr. Pitel made a motion to add SMA to Florida’s screening panel at 1:00 pm. Dorothy Shulman seconded the motion. The motion passed unanimously.

CMS Division Update

Mrs. Cassandra G. Pasley gave an update for the Division of Children’s Medical Services.

CMS will work to fulfill the following requests made by the council:

1. Provide current procedures for how to refer children to CMS now that the transition to WellCare has occurred as requested by Drs. Shulman and Zori.
2. Provide clarification on the scope of services being provided by WellCare, specifically pertaining to the traditional Network, Clinics, Specialty/University Contracts.
 - a. Provide a summary of changes specified in the following three categories as requested by Dr. Zori:
 - i. Eliminated services
 - ii. Continued services
 - iii. New services
3. Request to include other specialists in the conversations with the Pediatric Chairs as these specialists might have discipline specific information/concerns as noted by Drs. Pitel and Zori; as specifically mentioned by Dr. Brosco, conversations have been ongoing with Pediatric Chairs and the Florida Chapter of the American Academy of Pediatrics.
4. Provide geographic breakdown of former CMS providers who are now WellCare providers with the intended goal to identify any gaps as requested by Brian Kirk.
5. Provide communication to address the misinformation that “CMS no longer exists” as requested by Brian Kirk and Dr. Zori.
6. Provide information on why some children who were on CMS were transferred to other plans, such as Sunshine, during the transition to WellCare, as requested by Dr. Shulman.
7. Provide a copy of Dr. Brosco’s presentation, as well as the opportunity to assist with communicating CMS’ messages as requested by Drs. Byrne and Zori.
8. Provide more details and assistance on how this transition can be operationalized at the family and provider level as requested by Dr. Zori.

9. Address concerns raised regarding the reduction of specialty contract funds (some used the term university contracts) as requested by Dr. Pitel.
 - a. Further information on the details and explanations needed regarding R-NAQs and S-NAQs.
 - b. Address concerns regarding the impact of contract reductions.
10. Provide more details regarding respite care as requested by Drs. Shulman and Zori.
11. Provide instructions for obtaining low protein foods (not formula) using CMS Safety Net funds as requested by Dr. Zori.
12. Provide clarification on the difference between AHCA (Medicaid) and DOH as it relates to paying for Low Protein Foods - CMS Plan vs. CMS Safety Net (general comments).
13. Guidance needed on how to obtain low protein foods for Maternal (pregnant women) and Adults as requested by Dr. Zori and general comments.

Newborn Hearing Screening Follow-Up Program Update

Mrs. Jessica Meyer provided the Newborn Hearing Screening Program update. Information regarding staffing was provided.

- An update was provided regarding the Early Hearing Detection and Intervention Advisory Committee. The next committee meeting is being held February 20, 2019.
- The National EHDI Conference is in March 2019, in Chicago; Newborn Hearing Screening Program will be presenting at this meeting.

Dr. Fifer suggests that a goal for EHDI should be long-term follow up of Early Intervention data for children identified with a hearing loss/impairment at twelve, eighteen, and twenty-four months of age in order to see how many are still enrolled for services at each stage.

Newborn Screening Follow-Up Program Update

Ms. Dusty Edwards provided an update to the Council.

- The NBS statistics were reviewed with the Council including an increase in the statewide Unsatisfactory Rate and number of MSMS referrals.
- Updates to the specimen card were reviewed.
- The newly updated/revised Newborn Screening brochure was displayed.

Mrs. Emily Reeves provided an update regarding X-ALD follow-up.

Approval of Minutes from Previous Meeting

Dr. Pitel moved for the minutes to be accepted from the August meeting. Dr. Shulman seconded his motion at 1:43 pm.

The meeting adjourned at 1:50 pm.