



Interagency Council for Genetic Services

Texas Department of State Health Services * Genetic Services Contractors
Texas Department of Aging and Disability Services * Texas Department of Insurance
University of Texas Health Science Centers * Consumer and Public Representatives

Meeting Minutes July 14, 2014

Members on Conference Call:

Lillian Lockhart, MD, UTHSC Rep
Cherry Sears, Consumer Rep
Carlos Bacino, MD
Alicia Dimmick Essary, DADS Rep
Patricia Brewer, TDI Rep

Members Present:

Debra Freedenberg, MD, DSHS Rep

Staff:

David R. Martinez, Department of State Health Services (DSHS) Newborn Screening Unit Manager
Eugenia Dunham, DSHS, Newborn Screening Manager
Monica Molina, DSHS, Ombudsman, Committee Support
Sam Cooper, DSHS, Specialized Health Services Section (SHSS), Section Director

WELCOME AND INTRODUCTIONS – Debra Freedenberg

The committee did not have an active chair, so Dr. Freedenberg moderated the meeting until an active chair could be elected. The meeting was called to order at approximately 1:05 pm and introductions were made.

ELECTION OF A NEW CHAIR FOR THE INTERAGENCY COUNCIL FOR GENETIC SERVICES (IACGS) – Debra Freedenberg

Dr. Freedenberg stated that Dr. Bacino has expressed an interest in being a candidate for the chair position. She asked the committee if there were any other nominations. All committee members supported Dr. Bacino as the new chair of the IACGS committee. He will assume his duties at the next meeting.

APPROVAL OF MINUTES – Debra Freedenberg

The March 7, 2014 meeting minutes were approved by the committee.

REPRESENTATIVE REPORTS

Department of Aging & Disability Services (DADS) – Alicia Dimmick Essary

Alicia Dimmick Essary had nothing major to report.

University of Texas Health Science Center (UTHSC) – Lillian Lockhart

Lillian Lockhart had nothing major to report.

Public and Private Entities that Contract with DSHS – Carlos Bacino

Dr. Bacino had nothing to report.

Newborn Screening Program and Laboratory Updates – Debra Freedenberg

Dr. Freedenberg gave the committee an update on the Newborn Screening Program.

- **Goals**
 - Two screening tests for each baby born in Texas
 - 24-48 hours of age
 - 1-2 weeks of age
 - Infants testing positive receive prompt and appropriate confirmatory testing
 - Diagnosed infants are maintained on appropriate medical therapy
- **Newborn Screening Panel**
 - Currently screen for 29 disorders by blood spot
 - Congenital Hypothyroidism
 - Congenital Adrenal Hyperplasia
 - 3 Hemoglobinopathies
 - Galactosemia
 - Biotinidase Deficiency
 - 6 Amino Acid Disorders
 - 5 Fatty Acid Oxidation Disorders
 - 9 Organic Acid Disorders
 - Cystic Fibrosis
 - SCID
- **Newborn Screening Workload**
 - In 2013, received ~753,000 specimens (~386,700 newborns)
 - Specimens assayed and reported - ~745,500
 - Test specimens Monday through Saturday
 - Average 2,450 specimens per day
 - ~ 7,400 unsatisfactory specimens (~0.98%)
 - In 2012, ~ 16,145 (~2%) specimens reported with presumptive positive results
 - ~ 800 cases diagnosed annually
 - Testing performed 6 days a week
- **Timeline of a specimen in the laboratory**
 - Critical results could be out as soon as day 3
 - Most results are out by day 5
 - Some of the second tier testing for Hemoglobinopathy and MCAD are performed in lengthy batches, so it may go slightly longer for the DNA
- **Quality Improvement Activities**
 - Revised submitter quality report cards-available only July, 2013
 - Expedited submitter fax notification on unsatisfactory specimens
 - Monthly submitter calls to consult providers with highest unsatisfactory rates
 - Complete redesign of NBS laboratory website
 - NBS transit time and courier services
 - Server OS and SQL and Lab LIMS upgrades
 - NBS Lean 6-Sigma projects
- **New Report Cards**
 - Produced monthly
 - Accessible to more users
 - Facility-specific data compared to state average
 - Available online since July 2013
 - Reports available for January 2013 forward

- Nationwide Attention-Transit Times
 - In 2009, baby with MCAD dies at 4 days of age in Colorado. Mother becomes active advocate
 - Media attention on transit times heightened-November, 2013
 - Milwaukee Journal Sentinel article “Deadly Delays”
 - Series of articles focused on timeliness in newborn screening
 - Primary criticisms
 - Hospitals-delays in transit to the laboratory
 - Laboratories-lack of weekend/holiday testing and lack of transparency (~ 20 states release data)
 - Texas noted as one of the poorest performers
 - Subsequent media
 - Minnesota Post, NPR, WOAI San Antonio, Houston Chronicle, Arizona Republic
- Specimen Collection Rules and Instructions
 - Texas Administrative Code (Rules)
 - Blood specimens must be mailed to the department within 24 hours after collection
 - Instructions
 - Must ship dried specimen WITHIN 24 HOURS
 - DO NOT hold specimens for bulk mailing. Send within 24 hours of collection
- Strategy for Improvement
 - Review and Revise Submitter Education
 - Expand Issue Awareness / Gather Information
 - Target Top 25 Sites
 - Identify Submitter Barriers and Issues
 - Implement New and Ongoing Outreach Initiatives
 - Pursue System Improvements
 - Enhance Monitoring
 - Expand Scope to Include Other Key Quality Measures
- Overall Status - > 96 hours
 - Overall status for specimens that were received > 96 hours
 - 2013 averaged 14.6%
 - April 2014 averaged 3.7%
- Electronic Data Transfer
 - Web-based demographic entry and reporting
 - Available to any healthcare provider, password protected
 - Users from 1,046 facilities submitting 75% of NBS specimens
 - ~2% of all demographics
 - ~12,000 result views per month
 - Monthly report cards available for all of 2013
- HL7 file transfer functions for LIMS
 - Direct transfer of demographics and results between computer systems
 - 3 large hospital systems fully implemented (~10% of all specimens)
 - Several facilities waiting to start implementation
 - New facilities on hold pending system reevaluation

- Second Tier Assay for CAH
 - Purpose is to dramatically cut false positive rate
 - Status
 - New LC/MS/MS installed
 - Method optimization is complete
 - Validation continues
 - 6 month pilot completed-analysis of results on-going
 - Preliminary finding
 - Reduce false positive rate by ~50%
- Second Tier Assay for VLCAD
 - Purpose is to provide additional information to metabolic specialists
 - Status
 - Control materials; e-mail sent out to metabolic specialists inquiring about genotypes for confirmed cases and already receiving information back
 - Validation plan proposal is almost complete and then will need appropriate approvals
 - Optimizing current primers before beginning validation testing
- Implementation of HB 411
 - HB 411 became law in June 2014 and made major changes to NBS specimen retention and residual use
 - Multiple internal processes, procedures and policies have been revised
 - Institutional Review Board policy has been revised
 - Opt-in for long term storage and possible research uses-effective June 1, 2012
 - Parent decision form and parent education form developed and distributed
 - ~49% of NBS have a parental decision form returned
 - 74% of those returned and valid give permission for public health research uses (36% of all newborns)
 - Survey of all submitters to identify challenges in returning parental decision forms
 - Worst performers tend to be large hospitals
 - Most common practice is to include Decision form in discharge packet with little or no explanation
 - Report Card
 - Destruction process started in April 2014
- NBS Hearing Grant Activities
 - CDC-5 year \$162,000 grant, in year 3
 - Tracking and date integration electronic health records
 - HL7 messaging
 - Enhanced interoperability of management information system
 - Educational materials and training on enhancements
 - HRSA-3 year \$300,000 grant, in year 3
 - Lost to follow-up
 - Multiple pilots on most effective follow-up procedures
 - Parent Support Group Projects utilizing quality improvement strategies
 - Early Childhood Hearing Outreach (ECHO) Project to better connect with Head Start

- Critical Congenital Heart Disease (CCHD)
 - US Health and Human Services (HHS) Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC)
 - In 2010, recommended that CCHD be added to the newborn Recommended Uniform Screening Panel (RUSP) to identify newborn with structural heart defects
 - 2011, endorsed by Secretary of HHS Kathleen Sibelius
 - 2013, Texas HB 740 added CCHD to core panel in 83(R) session
 - Implementation planned for Fall 2014 when rules are finalized
 - The seven defects classified as CCHD are:
 - Hypoplastic Left Heart Syndrome (HLHS)
 - Pulmonary Atresia with intact septum (PA/IVS)
 - Tetralogy of Fallot (TOF)
 - Total Anomalous Pulmonary Venous Return (TAPVR)
 - Transposition of the Great Arteries (TGA)
 - Tricuspid Atresia (TA)
 - Truncus Arteriosus Communis (TAC)
 - CCHD Activities
 - DSHS distributed survey to all birthing hospitals and birth facilities to determine current readiness to implement CCHD screening
 - Survey developed by D'Andra Morin, Debbie Freedenberg and Dorothy Mandel
 - 60/96 (62.5%) perform CCHD screening
 - 48/60 (80%) of those performing CCHD screening use recommended algorithm
 - CCHD Project
 - Education to medical professionals
 - PI-Dr. Alice Gong UTSAHSC
 - Joint project with TCH (Baylor) – Dr. Guillory, Dr. O'Campo
 - CCHD NBS Educational Tool Kits posted on DSHS and TPS websites
 - TxPOP2 funded focusing on NICUs and rural hospitals
- Newborn Screening Benefits Program
 - Designed to be payor of last resort
 - Eligibility
 - Presumptive positive screen or confirmed diagnosis of condition included in the Texas NBS panel
 - Be a bona fide resident of Texas
 - Family income < 350% of federal poverty income level (FPL)
 - Ineligible for Medicaid, CSHCN, CHIP, CHIPP, Title V or private insurance that would reimburse all or part of the services
 - Carve out
 - If patient's insurance does not provide coverage for a covered NBS benefit, and the family is otherwise eligible, NBS benefits may apply
 - Covered services
 - Clinical evaluations and follow-up care
 - Confirmatory and follow-up laboratory testing
 - Medications
 - Vitamins
 - Dietary supplements
 - Low protein foods

- NBS Education Efforts
 - NBS Grand Rounds 2013-2014
 - Dr. Elana O'Campo-CCHD
 - Dr. Priya Kishnani-Pompe Disease
 - Tales from the Crib
 - NBS Journal Club
 - Educational Outreach
 - Overview of NBS-available both as webinar and in person presentation
 - CF
 - SCID-in development
- Genetics Activities
 - Two Genetics Centers funded for Clinical Care (other facilities requested non-renewal)
 - Fee for Service
 - Teratogen Information Service contract awarded to UT Houston
 - Community based genetics seminars-Baylor Evening with Genetics
 - Three medical provider educational conferences, Tales from the Crib, Newborn Screening
 - Conference sites
 - San Antonio 7/26/2014
 - Dallas 8/2/2014
 - Austin 8/9/2014
- Genetics Projects
 - Funding of project to explore how changes in the health care system impact genetic services-UNT
 - Funding of project to update educational content of the DSHS Genetics website-UT Houston
 - Funding of 12 clinical genetics medical student summer 2014 internships
 - UT Southwestern/Dell Children's Hospital
 - Baylor/Children's Hospital San Antonio
 - UT Houston
 - UTMB
- Potential New Conditions
 - Pompe
 - The Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (DACHDNC) voted to add Pompe disease to the RUSP on May 17, 2013
 - HHS Secretary Sibelius requested the Interagency Coordination Council (ICC) to review with recommendation by July, 2014
 - Mucopolysaccharidosis Type 1 (MPS1)
 - DACHDNC sent to formal evidence review
 - X-Linked Adrenoleukodystrophy (X-ALD)

David R. Martinez informed the committee that Health and Human Services including DSHS is currently undergoing the Sunset Review process. The Sunset Commission has issued a report about DSHS and possible changes that could occur in the next couple of years and during the next legislative session. DSHS has prepared a response to the report and the committee can see our response at our website www.dshs.state.tx.us. You can also see the Sunset report on their website at www.sunset.tx.gov. There are several recommendations that have been made by the commission. The commission did hold a public hearing on June 24, 2014 where public testimony was accepted. The

commission will have a final meeting tentatively scheduled for August 13, 2014 where their report will be final.

Texas Department of Insurance (TDI) – Patricia Brewer

Patricia Brewer stated that she did not have anything new to report. She is still working on what she reported last time; however, she would like to change some of the language in the report she made to the committee at the March 7, 2014 meeting. She would like to change it to the following: *Patricia Brewer reported that she is working on the implementation of SB 1216 and SB 644, 83rd Legislature, Regular Session, which, respectively, require the commissioner to prescribe standard forms for requesting prior authorization of health care services and prescription drugs. Practically all state regulated plans in Texas will be required to accept and use the forms, including Medicaid and CHIP. Both bills require that the prior authorization forms be developed with input from advisory committees appointed by the commissioner.*

Consumer Reports – Cherry Sears

Cherry Sears had nothing to report.

Resource Allocation Plan – Dr. Freedenberg

Dr. Freedenberg asked the committee if there were any concerns or comments regarding the draft of the Resource Allocation Plan. Sam Cooper stated that he and David R. Martinez have talked about some anticipated work that we would look at for the next couple of years as we go through the council. Mr. Martinez mentioned the Memorandum of Understanding (MOU) that we might try to establish among the state agencies, so we can be very clear about our shared responsibilities. There may be some other opportunities for us to think about how this could play out to be a more structured process, and so not next year, but the year after when we are ready to submit our resource allocation plan for 2018-2019, everyone will have had a chance to really thoroughly anticipate what those needs might be and identify any concerns and questions up front, so that we have a lot of time to work through those together. Mr. Cooper thinks that is sort of the direction that the committee needs to hear we are taking at this point, and he thinks that unless anyone really does have a major concern or question about what has been submitted in this last draft, he thinks we are ready to move on and forward it to the directed parties that we are expected to do according to our statute. A roll call of all members voted to approve the Resource Allocation Plan.

PUBLIC COMMENT

No public comment.

AGENDA ITEMS

- Discuss accessibility and coordination of benefits for patients that are diagnosed with a genetic disease
- Update on Sunset Review
- Have Dr. Manda Hall from CSHCN discuss transition services for teens going from pediatric to adult care system

ADJOURNMENT

The next meeting is scheduled for **Friday, September 5, 2014**. There being no further business, the meeting was adjourned.