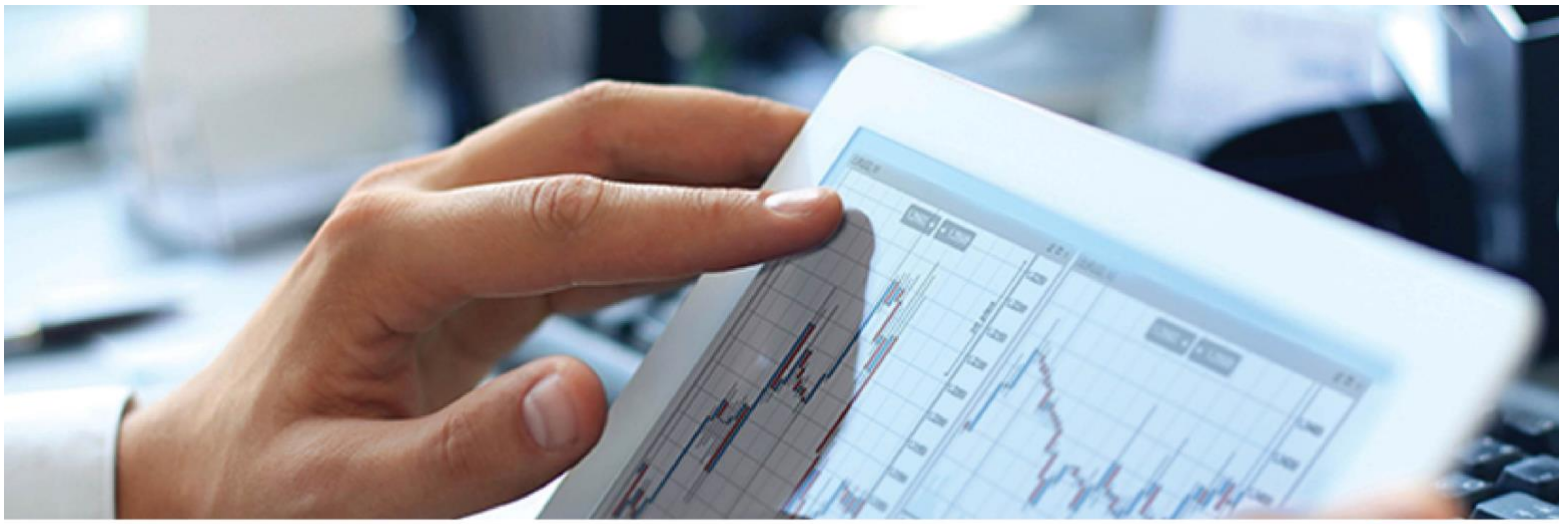
Health and Human Services

Sickle Cell Task Force

December 11, 2025

This summary contains supplemental information from reliable sources where that information provides clarity to the issues being discussed. Power Point tables used in the presentations may also be used in this summary. Names of individuals may be misspelled but every attempt has been made to ensure accuracy. Tables and Text have been used from executive and legislative agencies and departments' presentations and publications.



Sickle Cell Task Force raises public awareness of sickle cell disease and sickle cell trait. Texas Health and Safety Code, Chapter 52, directs the Texas Health and Human Services (HHSC) Executive Commissioner to establish and maintain a task force to raise awareness of sickle cell disease and sickle cell trait. The purpose of the Sickle Cell Task Force is to study and advise the department on implementing the recommendations made in the 2018 Sickle Cell Advisory Committee Report published by the Sickle Cell Advisory Committee or any other report the executive commissioner determines is appropriate. Members:

Presiding Chair Titilope Fasipe, M.D., Ph.D.	Houston	Representative of a health-related institution	2023	6/5
Melissa Frei-Jones, M.D., M.S.C.I.	San Antonio	Physician specializing in hematology	2024	8
André Harris, M.S.W.	Houston	Member of the public who has sickle cell disease (SCD) or is a parent of a person with SCD or sickle cell trait (SCT)	2025	6/5
Justin Luong, Pharm.D.	Austin	Representative of Health and Human Services Commission	TBD	00
Alecia Nero, M.D., M.S.C.S.	Dallas	Physician specializing in hematology	2024	2/3
Presiding Vice-Chair Marqué Reed-Shackelford	Houston	Member of the public who has SCD or is a parent of a person with SCD or SCT	2023	6/5
Linda Wade	Austin	Member from a community-based organization with experience addressing the needs of individuals with SCD	2024	7
Vacant		Member from a community-based organization with experience addressing the needs of individuals with SCD		
Vacant		Member of the public who has SCD or is a parent of a person with SCD or SCT		
Vacant		Texas Education Agency representative		
Vacant		Texas Health and Human Services Commission representative		
Vacant		Physician with experience addressing the needs of individuals with SCD or SCT		
Vacant		Researcher from a public health-related or academic institution with experience addressing SCD or SCT		
Vacant		Health care professional with experience addressing the needs of individuals with SCD or SCT		

1. Call to order, roll call, and welcoming remarks. The meeting was convened by Marque Reed-Shakelford. A quorum was present.

2. Consideration of June 26, 2025, and August 19, 2025, draft meeting minutes. Both minutes were approved.

3. 2025 SCTF annual report status and recommendations discussion.

In Summary. Members were reminded of the annual report recommendations, including:

- Updating definitions in Medicaid contracts to explicitly include sickle cell disease.
- Evaluating Medicaid/CHIP eligibility extension to age 26 for sickle cell patients.
- Studying and potentially funding comprehensive care models and care centers for sickle cell.
- Pursuing sickle cell-specific quality metrics in state programs.
- Developing sickle cell quality care plans for both Medicaid and private payers.
- Updating provider education modules and periodicity schedules to include sickle cell content and counseling.
- Studying feasibility of state-level care quality rating for sickle cell.
- Improving data collection and awareness campaigns, and expanding support for data programs.

Minor edits from the Department of State Health Services were acknowledged, with consensus on the direction and language of recommendations.

Selected Sections of the 2025 Annual Report.

Texas Health and Safety Code, Section 52.0007, requires the Sickle Cell Task Force (Task Force) to report on their work and recommend actions or policy changes, including recommendations on improving sickle cell disease (SCD) education for health care providers. The report is due to the Governor and Texas Legislature annually by December 1.

The purpose of the Task Force is to raise awareness of SCD and sickle cell trait (SCT). The Task Force also advises the Texas Department of State Health Services (DSHS) on implementing recommendations made in the 2018 Sickle Cell Advisory Committee Report or any other report the Texas Health and Human Services Commission (HHSC) Executive Commissioner determines appropriate.
This report provides updates on the Task Force's work with DSHS to implement 2018 recommendations. The Task Force also proposes the following recommended actions for 2025:

- Update Managed Care Organization (MCO) contract definition of Members with Special Health Care Needs (MSHCN) to specifically include SCD as an inclusion criterion.
- Evaluate options to increase Medicaid and Children's Health Insurance program (CHIP) eligibility for individuals diagnosed with SCD until age 26 years.
- Use available resources to study the development of comprehensive medical home models and ways to create and fund comprehensive sickle cell care centers as a quality improvement project.
- Partner with Medicaid and CHIP Services to pursue SCD-specific quality metrics through one or more of Texas Medicaid's quality improvement programs.
- Develop sickle cell quality care plans for Medicaid and private payors.
- Update Texas Health Steps Online Provider Education module on SCD so it is more comprehensive and is eligible for continuing education (CE) credit.
- Update the Texas Health Steps Periodicity Schedule to include SCT counseling for teenagers who were diagnosed with SCT at birth or have unknown status.
- Study the feasibility of a state-level sickle cell quality rating system for health care facilities.
- Collaborate with HHSC to incorporate a reporting process for sickle cell care provided by health care facilities into an existing statewide system.
- Develop partnerships with Texas colleges and universities to create sickle cell awareness campaigns and identify funding for statewide awareness activities.
- Continue to support the efforts of the Texas Sickle Cell Data Collection (SCDC) Program to expand current data collection activities.

Recommended Actions.

Update Medicaid MCO contract definition of Members with Special Health Care Needs to specifically include SCD as an inclusion criterion.
Under Texas's Medicaid-managed care program, contracted MCOs must identify and provide service coordination to members with special health care needs (MSHCN). An MSHCN is a member who
1. Is in one or more of the following groups: pregnant women identified as high

risk, members with behavioral health conditions, or members with serious ongoing illness or a chronic complex condition that is anticipated to last for a significant period and requires ongoing therapeutic intervention and evaluation; or

2. Has been identified as MSHCN.

SCD has progressive complications such as pain crises, acute chest syndrome, stroke, and a constant red blood cell shortage. Given that SCD is a chronic illness, the Task Force recommends the state update the MCO contract definition of MSHCN to specifically list SCD as an inclusion criterion. Doing so will ensure that Medicaid recipients with SCD receive the additional services they need to manage the disease, mitigate complications, and prevent additional serious health outcomes.

Evaluate options to increase Medicaid and CHIP eligibility for individuals diagnosed with SCD until age 26 years.

The Task Force recommends HHSC evaluate options to increase Medicaid and CHIP services for any individual with SCD. During early adulthood, individuals with SCD have a higher chance of experiencing an increase in SCD-related complications, such as progressive organ damage and early death. Early adulthood is also a time when individuals with SCD may face a gap in health care coverage if they age out of Medicaid. Many individuals over 18 years old are only eligible for Medicaid if they have a disability and meet income requirements. Having a SCD diagnosis alone is not enough for an individual to be considered disabled. These individuals may not have access to a parent's health insurance plan either, which would provide continuous health care coverage until age 26 years.

Use available resources to study the development of comprehensive medical home models and ways to create and fund comprehensive sickle cell care centers as a quality improvement project.

Currently, no standards exist for providing care to patients with SCD. Establishing standards by creating sickle cell care models and comprehensive sickle cell care centers may improve care for patients with SCD. Given multiple barriers people face receiving high-quality sickle cell care, the Task Force recommends studying the development of comprehensive sickle cell medical home models for both urban and rural Texas communities as a quality improvement project. These models can be based off existing state models for patients with complex care needs and on the American Society of Hematology sickle cell expert recommendations. ASH Pocket Guides - Hematology.org

Partner with Medicaid and CHIP Services to pursue SCD-specific quality metrics through one or more of Texas Medicaid's quality improvement programs.

The Task Force recommends partnering with Medicaid and CHIP Services to pursue SCD-specific quality metrics. Metrics would include rates of stroke screening, hydroxyurea prescriptions, penicillin prescriptions, etc., through one or more Texas Medicaid quality improvement programs, e.g., External Quality Review Organization. Monitoring these metrics would allow the state to better understand the sickle cell landscape, the treatments provided to sickle cell patients, and any potential gaps in care. See the 2024 External Quality Review of Medicaid and CHIP Managed Care Annual Technical Report as an example. External Quality Review of Texas Medicaid and CHIP Managed Care Annual Technical Report for SFY 2024

Develop sickle cell quality care plans for Medicaid and private payors.

To support initiatives to assist managed care plans in promoting timely, evidence informed health care plan services to plan enrollees, the Task Force continues to recommend DSHS collaborate with HHSC to create quality care plans for individuals with SCD to guide Medicaid and private payors in prioritizing and reinforcing access to preventive care based on national, evidence-based guidelines from the American Society of Hematology and the National Heart, Lung, and Blood Institute at National Institutes of Health. The Task Force continues to work with HHSC Medicaid and CHIP Services and HHSC to explore plan complexities and encourage payors to implement quality care plans as part of their covered benefits and services.

Update Texas Health Steps Online Provider Education module on sickle cell disease so it is more comprehensive and is eligible for continuing education (CE) credit.

The Task Force recommends updating the Texas Health Steps Online Provider Education module on SCD to reflect most current SCD guidelines and resources. The current module is outdated. A newly revised module could help medical professionals understand sickling disorders and treatment options better. Additionally, it will support health care worker competency and engagement needed for effective treatment and disorder management for affected patients. Adding CE credit would also promote awareness efforts.

Update the Texas Health Steps Periodicity Schedule to include SCT counseling for teenagers who were diagnosed with SCT at birth or have unknown status.

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While the Texas newborn screening panel includes testing for SCT, parents may not remember to share the results with their children as they age. The Task Force recommends Health and Human Services update the Texas Health Steps Medical Checkup Periodicity Schedule for Infants, Children, and Adolescents to direct physicians and other medical professionals to provide SCT counseling to teenage patients who screened positive for SCT at birth or have unknown SCT status during a routine adolescent health care visit. Counseling should include SCT education and additional testing, if needed. Education and improved individual awareness of the trait could help adolescents understand potential risks and prepare them prior to family planning decisions. The Task Force recommends state agencies promote this practice through provider education efforts.

Study the feasibility of a state-level sickle cell quality rating system for health care facilities.

The Task Force recommends studying the feasibility of a state-level sickle cell quality rating system to set SCD standards for quality care. To allow for consumer comparison of health care institutions that provide care to individuals with SCD, a statewide reporting system can collect data to show low-performing and high performing facilities and general compliance history to include allegations and surveyed substantiations. DSHS may use this data for quality improvement efforts at facilities with higher incidence and reporting rates. Publishing facility history and data reports may aid individuals with SCD in selecting an appropriate provider.

Collaborate with HHSC to incorporate a reporting process for sickle cell care provided by health care facilities into an existing statewide system.

The Task Force recommends DSHS collaborate with HHSC to incorporate a reporting process for health care facilities providing sickle cell care into an existing complaint and incident intake system. Patients may report issues with facility care received including hospital emergency departments. Facilities may also self-report. The program area that processes these reports could determine if a regional surveyor should investigate and recommend appropriate corrective actions, if necessary.

Develop partnerships with Texas colleges and universities to create sickle cell awareness campaigns and identify funding for statewide awareness activities.

The Task Force recommends DSHS coordinate with sickle cell community-based organizations to partner with Texas colleges and universities, including medical schools, to create and launch impactful and relevant public awareness campaigns and press releases. The goal should be to launch at least two statewide campaigns per year with an emphasis on September, Sickle Cell Awareness Month, and June 19,

World Sickle Cell Day. Potential topics to spotlight include state-specific SCD data, newborn screening, trait or carrier status awareness, and National Collegiate Athletic Association requirements. Sickle Cell Trait - NCAA.org

To promote statewide awareness activities, the Task Force could work with DSHS to establish a sickle cell awareness calendar to post on the DSHS website and share on relevant email distribution lists to stakeholders. Community organizations and health care institutions could submit their activities to DSHS. DSHS could consider adding these activities to the calendar along with state-run activities.

Additionally, the Task Force recommends the identification of dedicated, ongoing funding for statewide SCD and SCT awareness activities, including:

- Providing community SCD and SCT education;
- Improving detection of individuals with SCD and SCT;
- Coordinating service delivery for people with SCD; and
- Providing training for health professionals regarding SCD and SCT.

Continue to support the efforts of the Texas SCDC Program to expand current data collection activities.

Significant progress has been made in bolstering the state's capacity to conduct sickle cell surveillance. The Task Force supports the activities of the Texas SCDC Program to meet the goals of the CDC grant and recommends continued support towards the realization of a SCD registry.

Discussion.

The 2025 report recommendations were presented and an opportunity to ask questions was provided.

The recommendations were reviewed by the DSHS and HHSC staff and nonsubstantive changes may have been made. To the approved draft.

4. Member reports (Clinical partner activities, Community-based organization activities, Sickle cell warrior activities) This is a new agenda item and is an opportunity to provide relevant updates from the Sickle Cell community.

- Andre Harris shared upcoming holiday activities and conference participation (including ASH and SCDA), with further updates planned for future meetings.

- Dr. Alicia Nero reported on a successful September sickle cell health expo and blood drive in Dallas, with plans for a repeat event in 2026 and the development of a continuing education event in the spring focused on adult sickle cell care competency.
- Dr. Frei-Jones highlighted the publication of national pediatric sickle cell consensus guidelines and their relevance for Medicaid and quality measures discussions.
- Spring workshop for caregivers in Houston was announced, with details to follow.

5. DSHS Newborn Screening Program updates and announcements

Summary. Recent additions (August 2025) to the newborn screening panel include Pompe, MPS1, MPS2, and Krabbe disease; implementation of GAMT is expected in 2026. A contact list for clinical care coordination was distributed; a 24-hour helpline is available for urgent newborn screen result questions. (Both appearing below)
Survey results were presented from the 2024 on provider knowledge and showed gaps in specimen collection timing, follow-up understanding, and awareness of program elements (TEDDI). Recommendations include increased provider/staff education, awareness campaigns, better ACT sheet utilization, and ongoing educational events such as the Newborn Screening Summit (summer 2025).

Newborn Screening Updates and Notices.

December 17, 2025:

Update on Newborn Screening For Duchenne Muscular Dystrophy
The 89th Texas Legislature passed a bill which authorizes the Texas Newborn Screening Program to test for Duchenne Muscular Dystrophy (DMD), including follow-up services. We cannot begin DMD testing at this time because the current Texas Department of State Health Services (DSHS) Laboratory does not have space for the required equipment.

The Legislature approved funding (capital authority) for DSHS to use federal funds to build the additional laboratory space. The project to build the additional laboratory space began this year and will take about five years to complete. Once the additional

space is complete, DSHS will validate and implement DMD testing and follow-up services.

We will share updates as progress continues. Thank you for supporting Texas newborns.

For Questions Please Contact:
Newborn Screening Laboratory
Phone: 512-776-7585
Fax: 512-776-7157

Email: newbornscreeninglab@dshs.texas.gov
Laboratory Newborn Screening URL:
https://www.dshs.texas.gov/lab/newbornscreening.shtm

This service is provided to you at no charge by the Texas Department of State Health Services.

December 15, 2025:

DSHS Newborn Screening Laboratory Holiday Closure
Christmas Closure: Wednesday, December 24, 2025, clinical care coordination registered nurses will report time critical disorder results to providers. Routine newborn screening (NBS) testing will not occur this day.
Thursday, December 25, 2025, the Texas Department of State Health Services (DSHS) NBS Laboratory will not be open, and no testing will occur.
Friday, December 26, 2025, the NBS Laboratory will resume all testing.

New Year's Day Closure: Thursday, January 1, 2026, the NBS Laboratory will not be open, and no testing will occur.

DO NOT Delay Collection or Shipment

- Ship dried NBS specimens within 24 hours of collection. If mail or courier services are unavailable, ship as soon as possible.
- DSHS recommends shipping NBS specimens using an overnight or trackable service like USPS Priority Mail, FedEx, or UPS.
- If you use one of these services, plan accordingly for your site to ensure specimens are not delayed due to shipping.

Newborn Screening Supply Order Requests

- Standard orders received before noon Tuesday, 12/23/2025, will get processed and shipped via FedEx Ground.

- Priority overnight orders received by noon on Tuesday, 12/23/2025, will get processed and shipped via FedEx Priority Overnight.
- Orders received after noon Tuesday, 12/23/2025, through Friday, 12/26/2025, will get processed Monday, 12/29/2025.
- Orders received on Thursday, 1/1/2026, will get processed on Friday, 1/2/2026.

Need help?
Contact DSHS Newborn Screening Laboratory:
Phone: 512-776-7585
Email Newborn Screening: NewbornScreeningLab@dshs.texas.gov
Order Questions: ContainerPrepGroup@dshs.texas.gov

Presentation Leslie.McKenzie@dshs.texas.gov ; Jessica.BrownObiora@dshs.texas.gov

New Disorder Implementation: Lysosomal Diseases

Lysosomal Diseases (LDs)

- Pompe disease
- Mucopolysaccharidosis type I (MPS I)
- Mucopolysaccharidosis type II (MPS II)
- Infantile Krabbe disease

Screening implemented on August 18, 2025

Guanidinoacetate Methyltransferase Deficiency (GAMT)--•GAMT screening implementation expected late Winter/Spring 2026.

24-hour phone line: 512-776-7318 This is to be utilized when infant's screen result isn't readily available and needs care outside normal business hours.

Provider Survey Summary --In fiscal year 2024, the Texas Department of State Health Services (DSHS) Newborn Screening (NBS) Program developed a survey to examine providers' understanding of NBS and identify gaps in knowledge. The survey was administered online from July to December 2024. The survey had 177 responses from various providers including physicians, nurse practitioners, midwives, clinic administrative staff, clinical coordinators, and social workers.

Provider Survey Summary Blood Spot --Based on survey responses, respondents' knowledge of the age NBS specimens are collected varies. Only 46% of respondents

selected 24- 48 hours and 65% selected 7-14 days of the age. 41% of clinicians reported ever caring for an infant with an abnormal screening result

- 24% of providers reported not receiving instructions for next steps of care (ACT sheet)
- 64% of providers reported the ACT sheets were "easy to understand" and 30% reported they were "somewhat easy to understand"

Provider Survey Summary Hearing and CCHD --61% of respondents surveyed indicated Critical Congenital Heart Disease (CCHD) as a part of NBS and 57% of respondents indicated hearing loss. Of the clinicians who completed the survey, only 41% are familiar with the Texas Early Hearing Detection and Intervention (TEHDI) program.

Provider Survey Summary Follow Up-- 77% of providers indicated they could not provide the care the instructions recommended. This survey question is more tailored to the primary care providers' experience. The reasons for not being able to provide the needed care included:

- Lack of insurance;
- Provider could not access screening results;
- Inadequate number of specialists throughout Texas; • Lack of access in rural areas; and
- No transportation.

Providers surveyed indicated they are interested in additional NBS education. Providers are interested in webinars and a dedicated NBS conference.

Provider Survey Summary Recommendations --Based on survey results, these are recommendations to improve provider knowledge and experience with NBS.

- Increase education to providers on hearing loss and CCHD screening as part of comprehensive NBS;
- Expand NBS educational efforts to non-patient facing staff in hospitals and clinics (social workers, clinic coordinators, Texas Health Steps administrators);
- Create awareness campaign promoting Texas is a two-screen state and the age NBS is collected;
- Increase providers access to NBS blood spot conditions resources for abnormal screening results and referrals;
- Collaborate with providers to improve impact and utilization of ACT sheets;
- Increase provider education on hearing loss screening: 1-3-6 Plan, TEHDI Management Information System (MIS), and types of intervention services.

Texas Newborn Screening Summit

- Over 70 in-person attendees
- Almost 300 virtual attendees
- Over 200 continuing education certificates distributed, including for Midwifery
- Excellent feedback on sessions and information presented

Feedback from surveys

- "I will utilize the educators more often when PCPs have more questions."
- "The clinical director & I recognized a few flaws in our workflow that we are working to correct to ensure our NBS workflow is better"
- "Thank you parents for showing us how important it was to get newborn screening and how to respect a parents opinions and ideas on their child's care!"
- "As an out-of-hospital practice, I will ensure I have the appropriate equipment to perform the CCHD, as well as performing it at the correct time."
- "Loved how actual parents and their experiences were shared. This made it personal and real as to how getting screenings done and getting proper diagnosis and treatments can make a world of difference. Great conference!"
- "The team did an excellent job putting together this seminar - Very professional and highly informative"

Discussion There was no discussion

6. Potential future of hemoglobinopathy newborn screening

In Summary. Omar Ordonez (DSHS lab manager) presented on current and future hemoglobinopathy screening methods. The current process is manual (IEF primary, HPLC secondary), labor-intensive, and reliant on aging equipment. Future options were presented including: automated HPLC (primary or in combination), capillary electrophoresis (Scibia), each with tradeoffs in accuracy, specificity, and cost.
Both new methods would reduce staff time but may have challenges in detecting certain variants, emphasizing the need for two screening methods. There was group discussion that was very technical and focused on clinical implications of missing rare variants, reporting non-significant variants, and balancing efficiency with diagnostic accuracy. Follow-up presentations and cost analysis were requested.

Presentation.

Current Hemoglobinopathy Screening Lab: **Workload**

- Perform testing 6 days a week (Mon-Sat).
- Screen approximately 2,500 specimens per day.
- Initial testing is by isoelectric focusing (IEF).

- Retest all abnormal results by IEF. NOTE: Approximately 100 specimens per day.
- Retest certain abnormal results by high-performance liquid chromatography (HPLC).
- Monthly: Identify an average of 40 clinically significant results. NOTE: Includes SS, SC, S-beta thalassemia, Hemoglobin H disease, all beta thalassemia and diseases.
- DNA test for confirmation of most clinically significant results

IEF is a very manual, but specific, testing method and the Revvity Resolve IEF kit is Federal Drug Administration (FDA) cleared for the detection for a wide range of Hemoglobinopathies including: Hb A, F, S, C, and Hb Barts. Texas also uses external controls to be able to identify G and D variants, and uses a second method (HPLC) to detect O- Arab and E.

IEF Testing: Gels are set up on electrophoresis units and run for 75 minutes. When the run is complete, gels are fixed and stained. The staining process uses O-dianisidine, a potential carcinogen. Qualitative, looking at abnormal bands and relative intensities of the bands.

IEF Retest Gel Abnormal specimens are re-punched using a larger blood spot (4.7mm) and additional controls are added. (NOTE: On IEF, it is possible that different hemoglobinopathy variants can run in the same or near the same location on the gel. This is why a second method is needed to identify them).

Current HPLC Testing Current High Performance Liquid Chromatography (HPLC) Testing Criteria:

- Clinically significant results such as SS, SC, CC and EE.
- All specimens with S or E trait
- Bad Measures.

Volume: Approximately 50 specimens a day; HPLC testing is a limited secondary method currently.

Potential Future of Hemoglobinopathy Screening: Overview As technology advances, there are options to automate the hemoglobinopathy testing. Texas is investigating a few different options:

- (HPLC) screening.
- Capillary electrophoresis screening.

Texas would continue to use a secondary testing method to ensure accurate results.

HPLC: Primary Method Many other Newborn Screening (NBS) state labs are using HPLC as their primary, and IEF secondary, or HPLC only for hemoglobinopathy reporting. Texas is already familiar with HPLC and already has experience with interpreting the chromatography. The method provides autonomy and throughput – 3 plates per run – 20 samples/hour. It is estimated that 15 instruments would be needed for daily processing if HPLC was first tier. FDA cleared to identify, F, A, D, S, E, and C.

HPLC: Missed Variants. HPLC has less sensitivity and specificity compared to IEF. For example:

- Light variants may be missed.
- Transfused specimen with Hb variants may not appear on HPLC. EXAMPLE: Sample will be HPLC=A,F; IEF=A,F,S.
- G and D variants run in the same retention window on HPLC. All G would be reported out a D if only use HPLC. Secondary method is needed to be able to report out G.

Some specimens on IEF are F,A but HPLC picks up degradation that resulted as F, A, Other. NOTE: This represents a small number of abnormal results that would have been read as normal with IEF and not HPLC.

HPLC: Benefits

- All clinically significant variants and diseases on the Recommended Uniform Screening Panel (RUSP) will still be captured.
- Electronic traceability of reagents.
- Less hands-on time for staff.
- Centers for Disease Control and Prevention (CDC) presented a poster of the various methods that state NBS labs use, and it highlighted the need for a second method to ensure all clinically significant variants are captured.

HPLC: With Two Methods

With a secondary method, Texas would not miss any variants. NOTE: If HPLC is primary and IEF is secondary, then:

- Hb D would reflex to IEF to differentiate from Hb G.
- Hb E would reflex to IEF to r/o G-Galveston.

There would be the possibility to miss some variants where HPLC is normal so there would not be secondary IEF. We have seen specimens with some “other unknown” bands on IEF that look normal on HPLC. F, A, Barts would be impacted the most.

- Texas would need to develop a numerical value (percentage of peak on HPLC).
- The instrument will assign “b” flag for a peak area >10%. However, degradation products can exaggerate the peak area.

Capillary Electrophoresis (CE) is a new technology from Sebia.

- Automated.
- Removes the manual process of sampling gels.
- FDA cleared instrument with variants F, A, S, C, E, D, and Barts.
- Claims to have narrower peaks and better resolution than HPLC.
- High autonomy and throughput – 8 plates per run – 70 samples/hour.

Regarding CE Variants

- All clinically significant variants and diseases on the RUSP will still be captured.
- Capillary system has less sensitivity and specificity compared to IEF.
- For example, would not be able to identify G traits, O-Arab, or fast band that are reported out as F, A, Other.
- Note: The zones in which G-Philadelphia and O-Arab migrate to are known but are not FDA cleared. Texas would need to do in-house validation to report these.

Regarding CE: Barts-- The Hb Barts zone may not be specific.

- No correlation of Hb Barts peak's height and it's severity.
- Different patterns all lead to one conclusion/result.

A comparison was done between HPLC and Sebia's CE for Barts and false positives were identified on the Sebia. There will have to be more testing done for Barts by the vendor.

In summary, either new technology would reduce staff hands-on time. Neither method has the specificity or sensitivity that current (IEF and HPLC) method has.

- Neither system can identify G without in-house validation.
- Neither system can be specific with Barts. (HPLC has a percentage that can be used for H disease).

Next Steps There is currently a cost analysis in progress to assess the cost of current testing compared with the cost of any future testing. Texas is considering visiting a lab that has the capillary system to learn more about the benefits and challenges of this system's workflow and reporting variants. They are requesting feedback from Hematology colleagues.

Questions by and to the group

- Are there concerns if hemoglobinopathies other than those listed on the Recommended Uniform Screening Panel are not reported? (SS, SC, S-beta thalassemia).
- Are there concerns if non-clinically significant hemoglobinopathies are not reported? (O-Arab, G-trait, false positives for Barts, or missed variants for transfused newborns).
- What other concerns does the group have about these possible changes?

Contact information.
Omar Ordonez Email: omar.ordonez@dshs.texas.gov
Phone: 512-776-3843
Newborn Screening Educators Phone: 512-776-7585
Newborn Screening Laboratory | Texas DSHS

Discussion.

The discussion was highly technical

There was a low turnout at the last hemopathy meeting. When you have a compound heterozygote they will be reported as sickle cell trait. We currently do IEF and a backup that is labor intensive for staff. There are only three options. DSHS stated HPLC only is not a viable option, so only two options are available. Please circle back after there is a cost analysis.

What items are reported but will not be reported in the future? DSHS stated that Hemoglobin H would still be reported. O-Arab would not go away with IEF HPLC.

The gels will be run twice under the present method, would there be a reason to do the Gel first then the HPLC? I would want all the data reported. DSHS stated that they understand the question to be to screen with IEF and then skip to HPLC. DSHS stated that there are some things that do not need reconfirmation and as such the proposal statement would send more for an HPLC screen unnecessarily.

7. Sickle Cell Data Collection and House Bill 107, 89th Texas Legislature, Regular Session, 2025 update. 89(R) HB 107 - Enrolled version

In Summary. The update given by Dr. Heidi Boies (DSHS). House Bill 107 mandates an opt-in sickle cell registry; an assessment and environmental scan are underway to guide implementation.

Regarding continued grant activity for the sickle cell disease data collection program, the program is now in its third year, with data acquisition from newborn screening and hospital records occurring.

Collaborative projects for awareness materials and data analysis have begun with UT Health and UT Austin. They are using the RC KMS system for real-time reporting. Stakeholder engagement will inform next steps, and feedback is welcomed.

Bill Summary. House Bill 107 amends the Health and Safety Code to require the Department of State Health Services (DSHS) to establish and maintain a sickle cell disease registry consisting of records of sickle cell disease cases that occur in Texas and any other information concerning such cases that the executive commissioner of the Health and Human Services Commission considers necessary and appropriate to assist with the cure or treatment of the disease. The bill provides for the manner by which DSHS may receive, record, and analyze data from health care facilities concerning sickle cell disease cases and may compile and publish statistical and other studies derived from that data, and the bill further provides for the confidentiality of information obtained for the registry.

Fiscal Analysis. The bill would authorize the Department of State Health Services (DSHS) to establish and maintain a registry of cases of sickle cell disease in the state. Health care facilities would provide data regarding individuals who have been diagnosed with sickle cell disease to DSHS. The Health and Human Services Commission (HHSC) shall adopt rules related to implementation of the registry including ensuring confidentiality and informed consent related to information obtained on individuals for the registry. The bill would require DSHS to submit an annual report on information in the registry to the legislature, and DSHS would be authorized to publish other reports in cooperation with other sickle cell disease reporting organizations and research institutions.

The analysis assumes DSHS would require 5.0 additional full-time-equivalent positions (FTEs) to establish and maintain the registry. This includes 2.0 FTE Epidemiologist III positions to calculate appropriate statistics, to analyze data quality, and to create reports; a 1.0 FTE Information Specialist IV position to oversee the dissemination of data and reports from the Sickle Cell Registry and to conduct trainings and education for registry users; a 1.0 FTE Program Specialist V position to oversee the Sickle Cell Registry Program and serve as the subject matter expert; and a 1.0 FTE Systems Analyst V position for programming, quality assurance testing, managing system specifications and requirements, and security and updates on the new Sickle Cell Disease Registry system.

Salaries, benefits, and other related costs for the new FTEs total $531,242 in fiscal year 2026 and $746,854 in fiscal year 2027, all from the General Revenue Fund. The lower cost in fiscal year 2026 is attributable to a later start date for the new positions assumed in the first fiscal year and because the Systems Analyst V position would begin as a 0.5 FTE in fiscal year 2026.

DSHS would build a standalone registry system modeled off an existing system to receive lab and provider reports for sickle cell disease. The agency will utilize HHSC information technology (IT) staff augmentation to build the system estimated to total $1,151,652 in fiscal year 2026 and $287,623 in fiscal year 2027, all from the General Revenue Fund.

Other IT costs related to new requirements and components of the new registry include new hardware costs of $350,000 in fiscal year 2026; software licenses costs of $300,000 in fiscal year 2026 and $100,000 in fiscal year 2027; Identity Account Management development and integration costs of $350,000 in fiscal year 2026; Independent Validation and Verification requirement for new IT projects costs of $350,000 in fiscal year 2026; and State Health Analytics and Reporting Platform (SHARP) integration and report development costs of $314,000 in each fiscal year, all from the General Revenue Fund.

Discussion.

A registry assessment will first be performed with an environmental scan and will engage stakeholders. They will provide an outline for a registry and appropriate IT solutions.

The collection grant activities. This is the third year of grant activities. A core data set of people with sickle cell will be established and data collected and analyzed. They had an IRB approval and data has started to be gathered. The Texas Department of State Health Services (DSHS) received funding from the Centers for Disease Control and Prevention (CDC) to establish a state sickle cell data collection system. This initiative aims to inform sickle cell practices and policies in Texas and is one of 16 states funded by the CDC. The SCDC program serves as a foundation for measuring sickle cell burden in Texas by assessing long-term trends in sickle cell disease diagnosis, treatment, and healthcare access. The goal is to collect, maintain, and disseminate high-quality sickle cell data to improve diagnoses, treatments, survival, and quality of life for individuals with sickle cell disease in Texas.

Sickle Cell Data Collection (SCDC) Program. In 2023, the Texas Department of State Health Services (DSHS) applied for and received funding from the Centers for Disease Control and Prevention (CDC) to establish a state sickle cell data collection system that informs sickle cell practices and policies in Texas. Texas SCDC is one of 16 states funded by the CDC.

Texas SCDC is a one-time state data collection effort and is not a state sickle cell disease registry. Texas SCDC serves as the foundation for measuring sickle cell burden in Texas by assessing long-term trends in sickle cell disease diagnosis, treatment, and healthcare access. In the absence of population-based surveillance, Texas SCDC provides information on all individuals with sickle cell disease in Texas, regardless of age, insurance status, or geography.

The goal of Texas SCDC is to collect, maintain, and disseminate high quality sickle cell data that will contribute to improving diagnoses, treatments, survival, and quality of life for all individuals with sickle cell disease in Texas.

Sickle Cell Disease Education | Texas DSHS

Regarding the Opt-In model, are there any barriers or issues that would prevent people from opting in? DSHS stated that this data gap will be addressed in the IT assessment.

RCKMS rckms.org is being used as part of the data gathering.

The Reportable Conditions Knowledge Management System (RCKMS) is an authoritative, real-time portal to improve disease surveillance. RCKMS stores comprehensive information on public health reporting requirements and acts as a decision support service (DSS) to determine if a potential case is reportable and to which jurisdiction(s). RCKMS consists of 3 parts: the authoring interface, knowledge repository and decision support service.

Accurate, timely and complete coverage of reportable conditions depends on healthcare reporters having correct and current information regarding reporting criteria. Currently, reporting criteria are difficult for human users to locate, as there is no single place where information can be accessed. Reporting criteria are complex and differ across state and local jurisdictions. Information is generally human-readable but not in a format suitable for machine-processing.

RCKMS strengthens disease surveillance in the US by providing a single authoritative portal for public health to efficiently author, manage and update reporting specifications as they change over time. It provides a mechanism to communicate updates to reporters and improves the completeness of case reports sent to public health by reporters.

RCKMS can decrease the time and effort needed by healthcare professionals to comply with reporting requirements by providing a centralized location to view, query and download information on public health reporting criteria. It provides a centralized decision support service that can determine whether a case is reportable and to which jurisdiction(s), and eventually a mechanism to receive updates for when public health reporting requirements are changed.

The **authoring interface** is a web portal for public health agencies to input, edit and manage their jurisdictional reporting criteria. The authoring interface is pre-populated with default reporting criteria as defined by CSTE position statements. Users can choose to adopt and use the default as is or adjust the criteria to meet jurisdictional needs. The authoring interface also includes commonly requested optional reporting criteria that jurisdictions can select from.

The **knowledge repository** is a database containing default and jurisdictional reporting specifications. After being entered by users, reporting specifications are stored in the knowledge repository and deployed to the decision support service.

The **decision support service** is invoked by an automated call from an EHR system, either directly or through an intermediary service, to determine if a potential case is reportable and to which jurisdiction(s).

8. Newborn Screening Benefits Program presentation

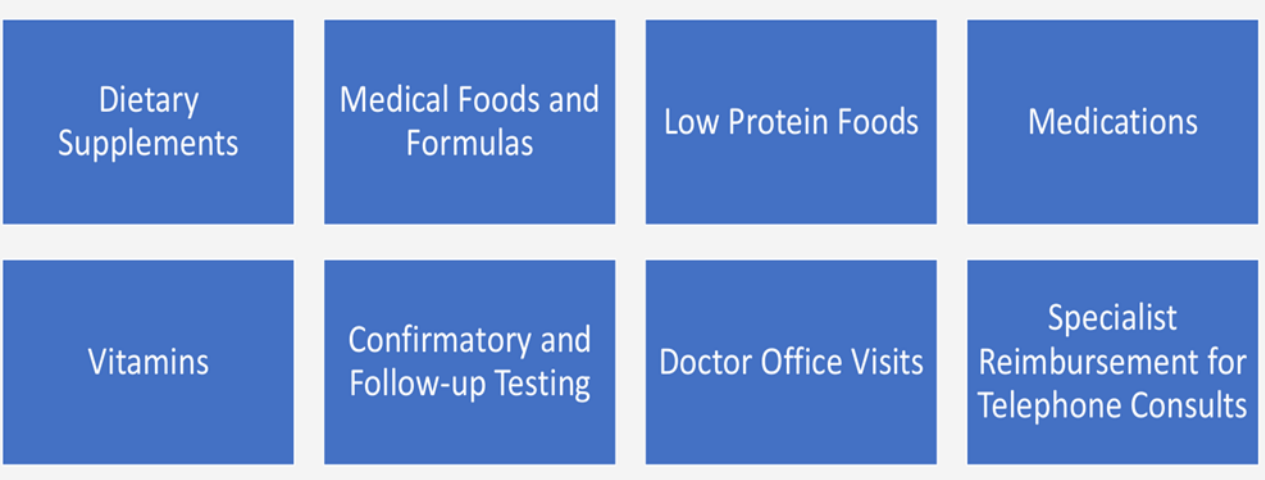
In Summary. Robin Damon described the Newborn Screening Benefits Program that provides reimbursement for dietary supplements, medications, and labs for eligible children with a diagnosed disorder from the screening panel. Currently, no sickle cell patients or clinical vendors are enrolled. This program is the payer of last resort and eligibility requires application and the meeting of income criteria, while prioritizing younger age groups, pregnant women, and those without other coverage. The program is seeking new healthcare partners with open enrollment ongoing. The program covers medications (penicillin, hydroxyurea, etc.), but not stem cell transplants/gene therapy. Dr. Brown emphasized that this program does not cover general care (e.g., well visits, ER, hospital) and called for more vendors, especially to support adolescents and young adults.

Presentation

Newborn Screening

2005 NBS panel expanded to 27 disorders.
2007 NBS Benefits Program established, Texas Health and Safety Code, Chapter 33.
2021 NBS panel expanded to 55 disorders.
2025 NBS panel expanded to 59 disorders.

Benefits NBS Benefits offers reimbursement to contracted entities for the provision of benefits and services. This includes:



The Department of State Health Services (DSHS) contracts with several entities which provide benefits or services. These entities include:

- Hospitals and Providers;
- Laboratories;
- Pharmacies; and
- Low Protein Food Providers.

Definitions:

- Dietary Supplement – A product intended to supplement the diet that includes one or more of the following ingredients: vitamins, minerals, herbs or other botanicals, or amino acids ingested through oral, parenteral, or injectable routes.
- Medical Foods and Formulas – A food source or substance which is formulated to be consumed or by enteral administration under the supervision of a physician and which is intended for the specific dietary management of a disease or condition.
- Low Protein Foods – Modified foods which are low in protein.

- Medications – A substance or preparation used in treating disease. Medications can be used for maintenance of health and the prevention, alleviation, or cure of disease.
- Vitamins – An inorganic compound and a vital nutrient that a person requires in limited amounts and is usually available in a typical person's diet.

For Patients with Sickling Hemoglobinopathies:

Medications and Treatments

- Penicillin
- Antibiotics
- Analgesics
- Hydroxyurea
- Desferrin
- Oxygen
- IV Fluids

Laboratory Services

- Complete Blood Count (CBC)
- Hemoglobin electrophoresis
- Iron
- CBC with differential
- Serum iron, total iron binding capacity (TIBC) •Reticulocyte count
- Alanine aminotransferase (ALT), Aspartate aminotransferase (AST), Gamma-Glutamyl Transferase (GGT) (specific Liver Function Tests)
- Serum total and direct bilirubin
- Prothrombin Time (PT), Partial Thromboplastin Time (PTT), and International Normalized Ratio (INR) (for transfusions)
- Blood type and Rhesus factor (Rh)

The NBS Benefits Program serves approximately 200 individuals each year.

Newborn Screening Benefits Lifecycle

- The DSHS Public Health Laboratory reports abnormal results to NBS Clinical Care Coordination staff.
- NBS Clinical Care Coordination staff notify hospital staff, physicians, or families of abnormal results for follow-up care and diagnosis confirmation.
- If the infant is diagnosed with a screened disorder, the diagnosing physician or a designee will assist families with gathering required documentation and completing the NBS Benefits application.
- NBS Benefits Program staff review and determine eligibility, notify contracted parties of eligibility, and submit requests for reimbursement

To be eligible, applicants:

- Must be a State of Texas resident.

- Family income must be at or below 350% of the federal poverty income level.
- Must be diagnosed with (or pending confirmation of) a DSHS NBS disorder.
- All NBS Benefits cases are subject to annual review.

An applicant is not eligible to receive the benefits described in Texas Administrative Code, Section 37.60 if the individual or the parent, managing conservator, or legal guardian is eligible for some other benefit, such as Medicaid, CSHCN Services Program, CHIP, or private insurance, that would pay for all or part of the services in question. As a payor of last resort, applicants must first apply for other programs and be denied before applying for the NBS Benefits Program. This includes:

- Children With Special Health Care Needs (CSHCN) Specialty Program;
- Medicaid; Children's Health Insurance Program (CHIP); and
- Children's Health Insurance Program – Perinatal (CHIP-P).

NBS Benefits program prioritizes eligible individuals based on the following order:

- 0-2 years;
- 3-5 years;
- 6-21 years;
- Pregnant women;
- Women of childbearing age; and
- Other adults.

Presumptive Eligibility and Standard Application Processes

Presumptive Eligibility:

- Must have an immediate medical need;
- Declare eligibility while awaiting formal verification;
- Covers 60 days of eligibility; and
- Must reapply via the standard application process before the eligibility period ends.

Standard Application:

- There is no immediate medical need;
- Applicant must first apply for other programs such as Medicaid and CHIP;
- Submit application packet and all required verification; and
- Reapply after a 12-month eligibility period

Fiscal Year (FY) 2025 Open Enrollment

- On April 9, 2024, the FY 2025 Open Enrollment period for NBS Benefits Contractors opened.
- On August 31, 2030, the Open Enrollment period closes.

Open Enrollment Contractor Requirements

Hospitals and Providers--Board certified physicians:

- Medical Biochemical Genetics
- Adult/Pediatric Endocrinologists
- Adult/Pediatric Hematologists
- Adult/Pediatric Pulmonologists

Pharmacies must have ability to provide prescribed:

- Medications
- Vitamins
- Dietary supplements
- Formulas

Laboratories

- Must be Clinical Laboratory Improvement Amendments (CLIA) certified.
- Must have capacity to conduct confirmatory and follow-up testing.

Low Protein Food Providers must provide and manufacture low protein foods.

- Foods needed for clients with inborn errors of metabolism to prevent a metabolic crisis

Open Enrollment Resources

Email for questions regarding Open Enrollment Inquiries/Application Submissions: NBSOE@dshs.texas.gov

DSHS Open Enrollment Resources: https://resources.hhs.texas.gov/open-enrollments

Newborn Screening Benefits Program Contact Information

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Discussion.

This differs from traditional insurance and does not cover well exams and other services. It is designed for the specialty interaction. There are very few vendors able to provide this care however.

9. SCTF subcommittee updates

No subcommittees had met.

Medicaid Subcommittee—No update

Public Awareness Campaigns Subcommittee—No update

Legislatively Mandated Report Subcommittee—No update

Education Subcommittee—No update

~~10. Sickle cell trait testing discussion~~. TABLED

11. 2026 report development discussion. There was no discussion

12. Public comment. There was no public comment

13. Action items and future agenda items.

Future Meetings. February 2, 2026, May 15, 2026, August 21, 2026

Future Agenda items.

- Update on Screening item (Hemoglobinopathy) .
- Standing items, including the updates item
- Call and Gene therapy access model update
- Tabled Agenda Item Ten, Trait Testing

14. Adjournment. There being no further business, the meeting was adjourned.