Newborn Screening Advisory Committee Meeting
Tuesday, July 28, 2026, from 8:30 a.m. – 12:00 p.m.
Nebraska Children's Home Society – Omaha

Committee Members	Specialty	Present	Absent
Peter Abasolo, MD	Pathologist	X	
Jill Allen, RN	Nebraska Hospital Association Rep.	X	
Khalid Awad, MD	Chair, Neonatologist		X
Jill Beck, MD, MS	UNMC Pediatric Hematology/Oncology		X
Angela Brennan, MD	Family Physician	X	
Amy Brower, PhD	Adjunct Professor of Genetics at Creighton University and Med Center	X	
Ria Fyffe-Freil, PhD	Clinical Chemist in Pathology	X	
Zoe González-García, MD	Pediatric Endocrinologist	X	
Jessica Hansen, MSN, FNP-C	APRN	X	
Kathryn Heldt, RD	Dietitian/Metabolic Specialty	X	
Isabella Herman, MD	Pediatric Neurogenetics		X
Claire Jackson, MD	Hematology	X	
Alyssa Keller, MS, CGC	Certified Genetic Counselor	X	
Tiffany Moore, PhD, RN	Parent Advocate		X
Hana Niebur, MD	Vice-Chair, Pediatric Immunology	X	
Elizabeth Null, MD, FAAP, FACMG	Department of Pediatrics, Division of Inherited Metabolic Diseases, UNMC		X
Erin Pierce, MD	General Pediatrics		X
Robert Rauner	X-ALD Advocate	X	
William Rizzo, MD	Pediatric Genetic/Metabolic	X	
Jill Skrabal, PhD, RD	Dietitian/Metabolic	X	
Heather Thomas, MD	CF Clinic Director		X
Jennifer Wallin	Parent Advocate	X	
Emeritus Members			
James Harper, MD	Pediatric Hematologist	X	
Richard Lutz, MD	Pediatric Genetic/Endo/Metabolic	X	
Deborah Perry, MD	Pathologist	X	
Laboratory			
PJ Borandi	Operations Director Revvity Omics	X	
Meredith Patik	Revvity Omics NBS Lab	X	
Kristina Fura	Associate Director – Clinical Teams	X	
Staff	**Title**		
Erin Bryant, RN, BSN	Nurse Navigator, Hematology Sickle Cell Disease & Infant Hemoglobinopathies	X	
Jillian Chance, DNP, RN, APRN	NBS Program Manager		X
Michaela Howard, RD	NBS Inherited Diseases Clinical Specialist	X	
Yousif Ibrahim	NBS Inherited Diseases Clinical Specialist	X	
Kaylee Natho	NBS Intern	X	
Derek Ross	Birth Defects Registry Health Data Coordinator	X	

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Krizia Sanoy	Newborn Screen Systems & Metabolic Foods Coordinator	**X**	
Tim Tesmer, MD	Nebraska DHHS CMO	**X**	
Sarah Ward, MPH	NBS Inherited Diseases Clinical Specialist	**X**	
Guests & Speakers			
Jensin Cates	Nurse Navigator Children's Metabolic Clinic	**X**	
Catherine Harbert	Pediatric Genetic Counselor	**X**	
Jacinta Mwita	Parent Advocate	**X**	
Holly Sealer	Administrator Genetics	**X**	
Lois Starr, MD	Chief UNMC Division Genetics	**X**	
Jessica Rageth, MSN, RN	Nurse at Neurology Clinic – Children's	**X**	
Marisa Ruwe	Genetic Counselor	**X**	
Travis Schreier, MD	Genetics Fellow	**X**	
Rhonda Wright, MD	Pediatric Neurologist	**X**	

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Open Meeting Act Announcement

Robert Rauner, the chair, called the July 28, 2026, quarterly meeting for the Nebraska Newborn Screening Advisory Committee to order at 8:35 a.m. He announced that, under Nebraska Statute (Opening Meeting Act), a notice of this public meeting is posted on the State of Nebraska Public Meeting Calendar, and a copy of the Open Meeting Act and the agenda for the meeting are posted on the wall by the entrance of the meeting space.

Introduction

Rauner asked the guests, personnel, advisory committee members, and new advisory committee members to introduce themselves. Jensin Cates, BSN, RN, CPN (Nurse Navigator Children's Metabolic Clinic), Catherine Harbert, MS, CHG (Pediatric Genetic Counselor), Jacinta Mwita (Parent Advocate), Holly Sealer (Administrator Genetics), Lois Starr, MD (Chief UNMC Division Genetics), Jessica Rageth, MSN, RN (Neurology Nurse at Children's), Marisa Ruwe (Genetic Counselor), Travis Schreier, MD (Genetics Fellow), Rhonda Wright, MD (Pediatric Neurologist) all attended as guests.

Review/Approval of Minutes from the April 2026 Meeting

The approval for April 28, 2026, meeting minutes, was brought up by Robert Rauner. The motion to approve was made by Alyssa Keller, seconded by Dr. Angela Brennan, and passed unanimously by all committee members.

Laboratory Update

Revvity Omics presented an update on its continued investment in advancing newborn screening through implementation of the Genetic Screening Processor (GSP), an automated, high-throughput platform designed to improve laboratory efficiency while maintaining the accuracy and reliability of newborn screening testing. As part of this initiative, several newborn screening assays were successfully validated on the GSP in 2025, with implementation occurring in phases throughout the year. The presentation provided an overview of the technology, the validation process, assay-specific updates, anticipated implementation timeline, and future considerations for Nebraska's newborn screening program.

The GSP is an automated platform that utilizes DELFIA immunoassay and enzymatic technologies to analyze dried blood spot specimens collected on standard newborn screening cards. The system automates much of the laboratory workflow, including specimen processing, testing, result generation, and follow-up activities. By reducing manual handling, the GSP minimizes opportunities for human error while improving workflow efficiency, reliability, and consistency. The platform supports testing for biotinidase deficiency, congenital adrenal hyperplasia (CAH), congenital hypothyroidism (CH), cystic fibrosis (CF), galactosemia, and, following implementation, creatine kinase (CK-MM) screening for Duchenne muscular dystrophy (DMD).

Revvity explained that all assay validations followed established standard operating procedures and included evaluations of accuracy, precision, linearity, bias, and reference range establishment. Validation included more than 500 specimens consisting of confirmed normal and confirmed positive samples to ensure the new platform produced results equivalent to or better than the current testing methods.

Several assay-specific changes were discussed during the presentation. Biotinidase testing will transition from the Astoria Pacific colorimetric method to an immunoassay performed on the GSP while maintaining the same specimen punch size. Although the overall reporting process and clinical follow-up recommendations will remain unchanged, the reported values and measurement units will differ from the current assay. Revvity emphasized that providers should not compare historical values with new results because the assays use different methodologies. Updated reference ranges and interpretation guidelines will continue to be included on laboratory reports.

Galactosemia testing will also transition to the GSP. Total galactose testing will move from a fluorometric assay to an immunoassay while maintaining the same specimen punch size. Critical and inconclusive cutoff values will change to reflect the new methodology, and these updated values will be clearly displayed on laboratory reports. Galactose-1-phosphate uridyltransferase (GALT) testing will likewise transition to the GSP and will require a smaller specimen punch than the current assay. While the reported units and cutoff values will change, reflex DNA testing and follow-up recommendations for presumptive positive results will remain unchanged. The most significant changes involve congenital adrenal hyperplasia screening. Revvity explained that implementation of the GSP provided an opportunity to simplify birth weight categories used for interpreting total 17-hydroxyprogesterone (17-OHP) results, reducing the number of categories from seven to three. The extracted 17-OHP cutoff will remain unchanged for all birth weight groups. In addition to updating laboratory testing, Revvity and the Nebraska Newborn Screening Program reviewed current reporting and follow-up procedures to better align laboratory reporting with existing clinical practices. Proposed revisions include maintaining reflex testing for elevated total 17-OHP results, continuing preliminary presumptive positive notifications when additional testing is pending, classifying certain abnormal extracted 17-OHP results as urgent repeat specimens rather than routine repeats, and reporting specimens with elevated total 17-OHP but normal extracted 17-OHP as within normal limits with appropriate comments. These proposed changes are intended to simplify reporting while accurately reflecting current follow-up procedures.

Congenital hypothyroidism testing transitioned to the GSP in April 2025 without changes to methodology, specimen punch size, cutoffs, or reporting practices. Because the assay itself did not change, healthcare providers should not have noticed any differences in laboratory reports. However, the program is evaluating the possibility of introducing an inconclusive reporting category and increasing the presumptive positive thyroid-stimulating hormone (TSH) cutoff to greater than 50. Revvity emphasized that this proposal is independent of the GSP implementation and is being evaluated using historical program data to ensure that clinically significant cases would continue to be identified promptly.

Cystic fibrosis screening transitioned to the GSP on June 28, 2026, without changes to Nebraska's current screening algorithm. Elevated immunoreactive trypsinogen (IRT) results will continue to follow the existing reflex DNA testing process. Revvity also discussed future opportunities to expand cystic fibrosis DNA analysis, noting that several states have adopted larger mutation panels or sequencing approaches. Nebraska will continue evaluating these options in collaboration with clinical specialists while considering implementation costs and laboratory workflow.

Implementation of the remaining assays is anticipated during the fourth quarter of 2026. Prior to implementation, the Nebraska Department of Health will need to approve planned changes, and the Revvity will need to notify specimen submitters and coordinate with information technology staff to ensure that laboratory information systems and HL7 interfaces accurately reflect updated units, reference ranges, and reporting language.

Committee members asked several questions regarding the advantages of the automated platform. Revvity explained that the primary benefit of the GSP is workflow automation rather than dramatic reductions in turnaround time. Once specimen punches are loaded into the instrument, plate movement and processing occur automatically within the enclosed system, eliminating many manual handling steps. Although overall reporting times are already within one to two days and are not expected to improve substantially, automation reduces labor demands, decreases opportunities for human error, improves inventory management, and streamlines laboratory operations. Revvity indicated that approximately eight GSP instruments are expected to be in use once implementation is complete.

Additional discussion focused on whether Revvity plans to expand the GSP platform to include additional newborn screening disorders, such as hemoglobinopathies. Revvity clarified that the current project is limited to transferring existing assays onto the new platform rather than expanding the newborn screening panel. Committee members also asked whether future testing modifications would require changes to Nebraska regulations. The Nebraska Newborn Screening Program explained that testing methodologies are governed through the state's contract with Revvity, whereas the disorders included in newborn screening are established through Nebraska statutes and regulations. Therefore, changes in laboratory testing methods generally would not require legislative or regulatory revisions.

The committee also inquired whether the new platform would improve TSH turnaround times, which historically required overnight processing. Revvity responded that the GSP allows testing to begin earlier in the day, although the overall timing of result reporting to the state program is expected to remain essentially unchanged.

An emeritus committee member commended Revvity for implementing automation during a period of nationwide laboratory workforce shortages, particularly within the pre-analytical laboratory workforce. The member noted that technologies such as the GSP improve laboratory efficiency while maintaining validated testing quality and emphasized the importance of clinicians reviewing updated reference ranges rather than relying on familiarity with previous cutoff values, as both units and reference ranges will change for several assays.

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The Nebraska Newborn Screening Program concluded by discussing future opportunities to evaluate several of the proposed enhancements. Program staff indicated that modifications to biotinidase, galactosemia, and congenital adrenal hyperplasia appear straightforward and may improve clarity for healthcare providers. Additional review is ongoing regarding the proposed congenital hypothyroidism reporting changes to ensure that clinically significant cases are not missed. Expanded cystic fibrosis DNA testing will also continue to be evaluated in collaboration with clinical specialists and Revvity, with consideration given to implementation costs, laboratory workflow, and long-term benefits for Nebraska's newborn screening program.

Legislation, Regulation, and Policy

The Nebraska Newborn Screening Program provided an update on the status of several regulatory initiatives related to newborn screening. Public hearings were held on July 16, 2026, for proposed regulations to add Mucopolysaccharidosis Type II (MPS II) to Nebraska's dried blood spot newborn screening panel. On the same day, public hearings were also conducted for revisions to the Critical Congenital Heart Disease (CCHD) regulations.

Three public comments were submitted during the regulatory process, all of which expressed support for the proposed changes. Following the hearings, the regulations advanced to the next stage of the approval process and are awaiting review by the Nebraska Board of Health at its September meeting. If approved by the Board, the regulations will proceed to the Governor's Office for final approval and signature. Once the regulations go into effect, the Nebraska Newborn Screening Program will begin implementation of MPS II screening within the required implementation timeline.

The proposed revisions to the CCHD regulations primarily focus on strengthening statewide data collection by requiring birthing facilities to submit CCHD screening data to the Nebraska Newborn Screening Program. These reporting requirements are intended to improve statewide surveillance, enhance program evaluation, and support ongoing quality improvement efforts. The program also provided updates on additional disorders under consideration for expansion of the newborn screening panel. As of July 20, 2026, the proposal to add Guanidinoacetate Methyltransferase (GAMT) Deficiency remained under leadership review. Proposals for Metachromatic Leukodystrophy (MLD), Duchenne Muscular Dystrophy (DMD), and Infantile Krabbe Disease(IKD) had been submitted to leadership for review and approval as part of the program's ongoing evaluation of future newborn screening expansions.

Intern Presentation on Physician Manual Updates

The Nebraska Newborn Screening Program intern provided an update on projects completed during the summer, with a primary focus on updating the provider manual and expanding educational resources available to healthcare providers involved in the newborn screening process. The goal of this project was to improve accessibility, simplify navigation, and ensure provider education materials align with current national recommendations and best practices.

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As part of the provider manual update, research was conducted on how other state newborn programs present educational materials. Many programs have transitioned from large PDF-based manuals to more accessible web-based resources. Based on this review, the Nebraska Newborn Screening Program is developing a dedicated provider webpage that will allow healthcare professionals to quickly access important newborn screening information.

The updated provider webpage will include a streamlined summary of disorders screened in Nebraska, providing basic information about each condition in a more user-friendly format. The webpage will also include the updated practitioner manual in PDF format for providers who prefer a complete document, as well as direct links to additional resources such as the American College of Medical Genetics and Genomics (ACMG) ACT Sheets. These resources are intended to support providers in understanding screening results, recommended follow-up actions, and clinical management considerations.

Additional provider education materials are also being developed, including frequently asked questions (FAQ) resources designed to address common questions providers may receive from parents. These resources will provide guidance on topics such as the purpose of newborn screening, associated costs, timing of screening discussions during pregnancy, and general information families may need when navigating the newborn screening process.
The intern also discussed plans to develop an updated Health Practitioner's Guide for 2026. The previous newsletter was released in 2024, and the updated version will provide providers with current program information, education updates, and relevant newborn screening changes.

The proposed provider webpage will be organized into several sections, including provider quick links, education materials, screening requirements, ordering information, result interpretation, and follow-up recommendations. Parent education resources will also be included to help providers support discussions with families. These materials will highlight when newborn screening should be introduced during pregnancy, how screening is completed, and where families can access additional information.

A significant portion of the project has focused on improving provider guidance documents and workflows. One example is an updated guideline infographic addressing newborns discharged before 24 hours of age. This resource outlines provider responsibilities for completing required newborn screening components, including dried blood spot screening, hearing screening, and pulse oximetry screening. As early discharges become more common, the goal of this resource is to provide clear instructions to help ensure appropriate screening completion.

The intern has also been updating provider workflows to improve clarity regarding next steps after newborn screening results are received. These workflows are designed to guide providers through appropriate actions based on whether screening results are normal, require additional testing, or indicate the need for follow-up. Additional links will also direct providers to resources for ordering educational materials for families.

Additional updates to the provider manual include expanded information regarding newborn screening requirements, recommended screening timelines, and considerations for special

circumstances. Specific sections are being maintained for newborns transferred to the neonatal intensive care unit (NICU), including guidance on screening procedures and use of the appropriate transfer forms. These updates are intended to improve consistency and ensure providers understand the correct screening process for different clinical situations.

During discussion, a committee member asked how the updated provider resources align with national newborn screening standards and whether any differences exist between Nebraska practices and national recommendations. The committee member specifically referenced national organizations that provide newborn screening guidance, including the ACMG ACT Sheets and other evolving recommendations, and asked how these standards were being incorporated into the updated provider manual.

The intern explained that national recommendations were reviewed during the manual update process. The ACMG resources were used as a checklist to evaluate whether Nebraska's current provider manual aligns with recommended standards and to identify areas where updates may be needed. Any identified changes will be incorporated into the revised provider resources to ensure alignment with current recommendations.

The committee also discussed national classifications for time-critical and time-sensitive newborn screening conditions. A committee member asked whether Nebraska's clinical follow-up practices align with national guidance from organizations such as the Association of Public Health Laboratories (APHL) and the NewSTEPs program, particularly as disease knowledge and treatment recommendations continue to evolve.

The program's clinical follow-up specialist explained that Nebraska follows NewSTEPs definitions for time-critical and time-sensitive conditions and reports relevant data through APHL's NewSTEPs program. Nebraska's reporting processes align with national parameters, including distinctions between conditions requiring immediate intervention and those requiring timely follow-up.

The committee member noted that continued discussion with Nebraska clinicians may be beneficial to better understand how national classifications influence clinical care. As newborn screening evolves and additional information becomes available about specific disorders, classifications and recommendations may change. The committee member suggested future discussions to ensure clinicians are engaged in evaluating how national guidance impacts local practice.

The clinical follow-up specialist explained that the program has recently shared NewSTEPs data and resources with stakeholders, including information regarding time-to-treatment and time-to-intervention measures. However, a detailed comparison of Nebraska practices with evolving national recommendations has not yet been completed. The specialist noted that other states have reevaluated certain conditions, such as short-chain acyl-CoA dehydrogenase deficiency (SCAD), including whether conditions should remain on screening panels despite continued inclusion on the Recommended Uniform Screening Panel (RUSP). The program will continue monitoring

these discussions and consider future review of Nebraska's screening practices as additional information becomes available.

Program Updates

The Nebraska Newborn Screening Program provided an update regarding the implementation of its new data management system. The program reported that several challenges have been identified during the implementation process, resulting in delays to the planned system launch.

The original go-live date was scheduled for June; however, implementation has been postponed due to ongoing technical and operational barriers. The program is currently working closely with the vendor to address these challenges and has developed a process improvement plan intended to identify solutions and support a successful transition to the new system.

Due to continued implementation barriers, the program is also evaluating future options, including the possibility of exploring alternative vendors if necessary. The program will continue working toward resolving outstanding issues and will provide additional updates as more information becomes available.

Data

The Nebraska Newborn Screening Program provided an update on quality assurance (QA) metrics and trends related to specimen handling, information accuracy, shipping delays, and data entry performance. Overall, the data demonstrated significant improvements in several key quality indicators following implementation of targeted QA initiatives, while also identifying areas requiring continued monitoring and improvement.

Batching and/or Improper Specimen Handling Delays

Since implementation of QA measures addressing batching and improper specimen handling incidents that resulted in testing delays, there has been a 93.91% reduction in reported incidents. During the initial QA evaluation period in Q2 2023, a total of 230 incidents were identified. By Q2 2026, the number of incidents had decreased to 14, demonstrating substantial improvement in specimen handling practices, workflow compliance, and timely specimen processing.

Missing and/or Inaccurate Essential Information

Significant improvements have also been observed in incidents involving missing or inaccurate essential information. Since the implementation of QA monitoring, these incidents have decreased by 97.67%. In Q2 2023, the program identified 1,970 incidents related to incomplete or inaccurate information. By Q2 2026, this number had declined to 46 incidents, reflecting continued improvement in the accuracy and completeness of information submitted with newborn screening specimens.

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Unsatisfactory Specimens

During Q2 2026, a total of 20 unsatisfactory specimens were reported. Nineteen specimens were determined to be unsatisfactory due to collector-related errors, while one specimen was attributed to heat and humidity exposure. Continued education and monitoring of specimen collection practices remain important components of reducing preventable unsatisfactory specimens.

Shipping Delays

During Q2 2026, the program identified 27 avoidable shipping delays associated with issues such as missed pickups and lost shipments. In addition, 506 unavoidable shipping delays were reported due to external factors, including aircraft mechanical issues, delayed flights, severe weather events, and other circumstances outside the control of the shipping process. Continued monitoring of shipping trends will help distinguish opportunities for process improvement from delays caused by unavoidable circumstances.

Revvity Data Entry Errors

Since tracking began in Q1 2025, overall Revvity data entry errors have increased by 303.57%, rising from 28 errors in Q1 2025 to 113 errors in Q2 2026. Although the overall number of errors has increased, additional review of error categories provides insight into the primary contributors.

Of the 28 errors identified in Q1 2025, 14 errors involved information that was correctly recorded on the filter paper but was not entered into the portal, while 14 errors involved information that was recorded on the filter paper but entered incorrectly into the portal. No errors during this period were attributed to faded scans.

Of the 113 errors identified in Q2 2026, 104 errors involved information that was correctly recorded on the filter paper but was not entered into the portal, 9 errors involved information that was recorded on the filter paper but entered incorrectly into the portal, and 4 errors involved faded scans.

Faded scans continue to be tracked separately as a quality monitoring measure and are not included in the overall data entry error totals. The increase in data entry errors highlights an area requiring continued evaluation, particularly regarding processes that ensure information documented on filter paper is accurately transferred into the electronic portal.

Other Business

The next advisory committee will be held on October 27, 2026

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Adjourned

Robert Rauner adjourned the meeting at 09:40 a.m.

Respectfully Submitted:

Jillian Chance
Michaela Howard
Yousif Ibrahim
Kaylee Natho
Derek Ross
Krizia Sanoy
Sarah Ward