



Newborn Screening News

Fall 2015

The Michigan Department of Health and Human Services (MDHHS) Newborn Screening Follow-up Program works together with the State Newborn Screening Laboratory to find and treat infants who need early medical care.

Newborn Screening Card Fee Decrease

On October 1, 2015, the cost for the initial newborn screening card will decrease to \$122.35 (from \$125.36). The cost for repeat (pink) cards will be \$114.48 (from \$117.29). The fee supports the Newborn Screening Laboratory, Follow-up and Medical Management Coordinating Centers. The fee is adjusted annually to reflect changes in the Detroit Consumer Price Index and to cover the cost of adding new disorders to the newborn screening panel.

The Detroit Consumer Price Index decreased 2.4% this year. To reflect this change, MDHHS will apply a \$3.01 decrease to the cost of each initial (blue) newborn screening card, and a \$2.81 decrease to the cost of each retest (pink) card purchased. There is no fee increase this year for new disorders, and the panel will include 56 conditions when screening for Pompe disease begins in several months.

If you have questions regarding the fee, please contact the Newborn Screening Follow-up Program at (517) 335-4181.

CCHD Data Reporting Reminders



- CCHD screening data/files should be submitted at least on a **WEEKLY** basis.
- If you are using "ECHO" as a reason not screened, please state "ECHO NORMAL" if appropriate, to assist with follow-up.
- Receiving hospitals should be submitting CCHD screening data on ALL babies screened at their hospital (including transfers) and not just those BORN there.
- If you know the screen was missed, please report "MISSED" in the Pulse Ox Other field. Do not use "incomplete" or "unknown".
- If a single birth, leave the "Multiple birth order" field blank.
- If a CCHD is detected through screening please notify the newborn screening program.

If you have questions or comments, please contact Keri Urquhart, CCHD Nurse Educator at 517-335-8135 or urquhartk1@michigan.gov.

CCHD follow-up process

As part of ongoing quality improvement and assurance efforts the newborn screening program has been following up on all inconclusive CCHD Screening results including failed screens, ECHOs, transfers and rescreens. In the coming months we will be implementing a new follow-up procedure similar to that of the EHDl program. Birthing hospitals will receive a monthly report via fax that contains a list of those infants for whom CCHD screening data has not been submitted to the State. The missing data will need to be submitted to the program via a separate CCHD file upload or directly input into the eReports module. More information about accessing and using eReports is available on our website www.michigan.gov/cchd.

Please Note: Upcoming State Holidays

These are the holidays the State NBS Laboratory is closed:

- Wednesday, November 11, 2015
- Thursday, November 26, 2015
- Friday, December 25, 2015
- Friday, January 1, 2016



Lower Peninsula Hospitals: Quest will pick up your NBS specimens on November 11, Christmas Eve and New Year's Eve. Quest **will not** pick up your specimens on Thanksgiving Day, Christmas Day or New Year's Day.

Upper Peninsula Hospitals: UPS will pick up your NBS specimens on November 11 and Christmas Eve. UPS **will not** pick up your specimens on Thanksgiving Day, Christmas Day, New Year's Eve or New Year's Day.

NBS Follow-up Program Contact Information

Phone: 517-335-4181

Email: newbornscreening@michigan.gov

X-linked Adrenoleukodystrophy Recommended for the RUSP

On August 27, the Advisory Committee on Heritable Disorders in Newborns and Children voted to recommend the addition of X-linked Adrenoleukodystrophy (X-ALD) to the Recommended Uniform Screening Panel (RUSP). X-ALD is an X-linked peroxisomal disorder occurring in 1 in 17,000 births. It is caused by a defect in the adrenoleukodystrophy protein, resulting in the accumulation of very long chain fatty acids (VLCFA) in cells and demyelination in the nervous system and adrenal cortex. Approximately 35% of affected males are diagnosed with childhood cerebral ALD, an early onset form characterized by adrenal insufficiency, rapidly progressive cognitive and neurologic impairment, and death. Milder forms of X-ALD also exist, including adult onset adrenomyeloneuropathy and Addison's disease, a form limited to adrenal involvement. Treatments include adrenal hormone replacement therapy to address adrenal insufficiency and hematopoietic stem cell transplantation in childhood cerebral ALD, which recent studies suggest is most effective when implemented at the first signs of neurologic involvement.

Screening for X-ALD can be achieved by measuring levels of VLCFAs in newborn dried blood spots. Abnormal screens are followed up with confirmatory diagnostic testing consisting of repeat VLCFA levels and mutation analysis of the ABCD1 gene. This testing process allows for the identification of individuals affected with all forms of X-ALD as well as some females who carry the gene. In addition, abnormal screening results can lead to the diagnosis of other peroxisomal disorders associated with elevated VLCFAs.

Currently, New York is the only state that has already incorporated X-ALD into its newborn screening panel, although New Jersey, Connecticut, and California have passed legislative mandates and are in the process of preparing for implementation. Now that the ACHDNC has voted to recommend the addition of X-ALD to the RUSP, the next step is to forward its recommendation to the Secretary of the US Department of Health and Human Services for final approval. Once added to the list of conditions already included on the RUSP, it is anticipated that it will be easier for other states to gain local support and initiate efforts to add X-ALD to their own newborn screening programs, allowing for early identification of affected individuals at a time when treatment can be most effective.

BioTrust for Health Update

On December 18, 2014, President Obama signed into law the Newborn Screening Saves Lives Reauthorization Act of 2014. The law's provisions allow continued growth and optimal performance of newborn screening while an amendment, found in Section 12 of the law, creates challenges for using residual newborn screening blood spots in research. Section 12 stipulates that any research using residual newborn screening blood spots must be considered human subjects research and an Institutional Review Board (IRB) may not waive the requirement to obtain informed consent or approve a consent procedure which does not include or alters some or all of the elements of informed consent. These conditions apply to federally funded studies requesting blood spots collected after March 15, 2015.

The language in Section 12 leaves tremendous ambiguity in its interpretation and has left all state newborn screening programs grappling with how to be compliant. Official national guidance is expected this fall from the Office of Human Research Protections (OHRP).

Michigan's newborn screening program had the foresight and good fortune of hospital and home birth attendant support to implement a parental consent process in May 2010 for the research use of residual newborn screening blood spots. This has allowed us to be poised and ready to address the provisions of this law. MDHHS staff has worked directly with OHRP and our IRB to identify the necessary revisions to the consent material. This will allow the process to continue with no disruption for parents. A draft of the new proposed form is shown here. We anticipate the revised BioTrust consent brochure and form will be in circulation by January 2016. Carrie Langbo, our BioTrust Coordinator, will be contacting each NBS Coordinator this fall to further explain the law and BioTrust consent revisions. Michigan's pioneering work with the BioTrust and its accompanying consent process continues to be recognized as an exemplary model for other states to follow. We realize this accomplishment is not possible without your dedicated work and assistance. **Thank you!**

Before you sign this form please read, *Your Baby's Blood Spots*. It explains in more detail how your baby's blood spots may be used in health research through the Michigan BioTrust for Health. If you still have questions, please call the Michigan Department of Health and Human Services (MDHHS) toll free at 1-866-673-9939.

Yes, my baby's blood spots may be used for health research through the BioTrust.
By checking this box you understand:

- Unused blood spots are stored using a code and not your child's name. The spots are stored forever at a secure site (Biobank) unless you, or your grown child, change your mind.
- Stored blood spots may be used by the state lab to help ensure that newborn screening detects those at risk. Stored blood spots may also be used for research approved by MDHHS. Blood spots can only be used for studies to better understand disease or improve the public's health.
- Many types of laboratory methods are used to study biological factors like DNA or environmental factors like metals and toxins.
- The risk for using your baby's blood spots in research is that it could be identified. This risk is very low. Many steps are taken to protect privacy. Details that could identify your child or family are removed before your child's blood spots are given to a researcher.
- Most likely you or your child will not benefit from blood spot research.
- Participation is voluntary. You can call MDHHS at any time if you change your mind. There is no penalty or loss of benefits for saying no or changing your mind.

No, my baby's blood spots may not be used for health research.
By checking this box you understand:

- Blood spots will be stored forever but not used for research. These stored blood spots may still be used by the state lab to help ensure that newborn screening detects those at risk.
- You must contact MDHHS if you do not want blood spots stored for any reason after newborn screening.

Parent Signature _____ Date _____

Your choice applies to all blood spots collected for newborn screening. Please visit www.michigan.gov/biotrust for further information including research updates. For questions about your research rights or whom to contact in case of a research-related injury, please call the MDHHS IRB at 313-741-1528.

Spotlight on Unsatisfactory Specimens - Old Sample

Specimens that arrive more than 14 days after collection are marked unsatisfactory/old and a repeat specimen is requested. This past summer, two different hospitals sent first sample specimens to the State NBS Laboratory by US postal mail instead of by the NBS courier service. This was unusual since both hospitals involved consistently send specimens via the NBS courier that arrive by the appropriate day. Somehow an envelope intended for the courier was placed to be sent with other hospital mail, despite clear instructions to place the envelope in the designated area for courier pickup. This underscores the importance of reviewing the NBS courier service with all hospital staff that might be involved in the NBS process.

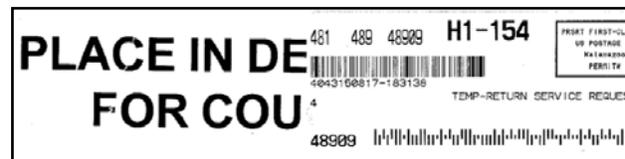
Points to remember to assure specimen receipt by appropriate day:

1. Allow a minimum of three hours for the specimen to dry
2. Schedule periodic 'sweeps' to make sure all dried specimens are packaged and ready for the courier
3. Know your Monday-Friday courier pick-up time and location
4. Know your Saturday (Upper Peninsula) or Sunday (Lower Peninsula) courier pick-up time and location
5. Educate all staff about the NBS process, including specimen transit
6. Keep a courier log that includes:
 - a. The baby's demographic information and medical record number
 - b. The NBS card ('kit') number
 - c. The barcode number of the envelope containing the NBS card (Lower Peninsula) or UPS tracking number (Upper Peninsula)
 - d. A line for the courier to sign and date that the envelope was picked up

Unsatisfactory specimens can result in:

- Delayed valid test results that could have a negative impact on the health of the baby
- Infant distress caused by the need for a repeat specimen collection
- Additional work for hospital and NBS staff
- Unnecessary burden on parents who have to bring their baby back for a repeat screen
- Increased cost to the hospital

The image to the right shows postage placed on top of the instructions to take the envelope to the designated courier pickup location.



NBS Quarterly Reports and Stellar Performance

During the second quarter of 2015, nine hospitals met all six of the NBS performance goals. We would like to congratulate the following hospitals on their impressive efforts!

- **Beaumont Hospital—Troy**
- **Dickinson County Healthcare System**
- **Lakeland of Niles**
- **McLaren Port Huron**
- **Mid-Michigan Medical Center—Midland**
- **Sparrow Hospital**
- **Spectrum Health Butterworth Campus**
- **Spectrum Health Gerber Memorial**
- **Spectrum Health Zeeland Hospital**

Performance Goals for NBS Quarterly Reports

1. <2% of screens are collected >36 hours after birth
2. >90% of screens arrive in the state laboratory by the appropriate day
3. <1% of screens are unsatisfactory
4. >95% of electronic birth certificates have the NBS card number recorded
5. >90% of specimens have a returned BioTrust for Health consent form that is completed appropriately
6. >90% of newborns with a dried blood spot have pulse oximetry screening results reported

We hope you will be able to use information in the quarterly reports to improve your part of the NBS system. If you have any questions, please call the NBS Follow-up Program at 1-517-335-4181.



Important Reminders!

Michigan Newborn Screening Online Card and Supply Orders

The NBS Online Ordering System (NBSO) is now available! Beginning October 1st, all NBS card orders must be placed through NBSO. NBSO can be accessed at <http://www.michigan.gov/nbsorders>. It is quick and easy to use. After you enter the site, click on NBSOnline Web Store – Order NOW! First-time users will need to register. Educational materials and NBS envelopes can be ordered without going through your purchasing department. Payment for NBS cards by eCheck or credit card is necessary at the time the order is placed. For more instruction on using NBSO, please refer to the *NBSO Registration and Order Guide*, available at www.michigan.gov/nbsorders.

Still have questions? Contact the NBSO Administrator at nbsorders@michigan.gov or call 517-335-8887.

In the past, the Michigan Newborn Screening Program has conducted a series of regional trainings every 2 years. The next round of trainings is tentatively scheduled for fall 2016. We are considering holding one central training in Lansing, as opposed to regional trainings, so we are asking for your feedback to help our planning efforts. Please copy and paste the following link to take the very brief survey: <https://www.surveymonkey.com/r/2MONRHR>

Celebrate 50 years of Newborn Screening!



Submitter Code: Please remember that staff members need to record the correct hospital submitter code on the newborn screening card. The last digit indicates the type of nursery: 0 means regular nursery, 1 means NICU, and 2 means SCN. The submitter code is used to make separate quarterly reports for each unit, so it's important that we can correctly identify which unit submitted each specimen.

Phone Number: Please remember only one phone number per provider should be used on the newborn screening card. Many requestors are using cell phone numbers or multiple different phone numbers for lines in provider offices and the laboratory is receiving new entries every day. Please have hospital staff clean up these lists and include one phone number per provider. Only include on the newborn screening card the doctor who is in charge of the baby's care when the baby leaves the hospital.

Birth Weight: Please remember to record birth weight in **grams** on the first sample newborn screening card. Enter the current weight in grams on the repeat sample card.

TECHNICAL ASSISTANCE

Lois Turbett, NBS nurse consultant, is available to work with staff in any hospital that requests help with specimen collection. She can be reached toll-free at (866) 673-9939 or by email at turbettl@michigan.gov to answer your questions. Keri Urquhart, CCHD nurse educator, is also available to work with hospitals on CCHD pulse oximetry screening and reporting, and can be reached at urquhartk1@michigan.gov. Together we can achieve our goal that all children diagnosed through newborn screening receive prompt and careful treatment in order to live the healthiest lives possible.

Please remember to share the quarterly newsletter with staff!

If you have questions please contact the NBS Follow-up Program at 517-335-4181 or newbornscreening@michigan.gov or visit our website at www.michigan.gov/newbornscreening