

The following is a Summary of Public Comments for LSA#18-158

Comment #1 from Barb Lesko:

The Fatty Acid Oxidative Disorders should read “Glutaric Acidemia Type II”

ISDH Response to Comment #1:

We agree it needs to be updated and have made the change in the final version of the rule.

Comment #2 from Barb Lesko:

IRT and Biotinidase are not methods, they are analytes/enzymes measured using methods ‘D’ and ‘F’

ISDH Response to Comment #2:

We agree these are misplaced. The analytes and enzymes have been appropriately matched with the procedure and method in the final version of the rule.

This is the comment that initiated the changes made to the methods section, including the removal of “amino acids and acylcarnitine” and the Biotinidase mentioned here. To be inclusive of all analytes/enzymes, these were removed and the enzyme assays was changed to state “other enzymatic assay”.

Comment #3 from Barb Lesko:

(f) preterm collection is pretransfusion period, not just for total exchanges. Those are very rare and we really need to address any transfusion.

ISDH Response to Comment #3:

All special cases including prematurity and transfusions are defined and associated with the appropriate screening timeline within the final version of the rule. ISDH removed the phrase “total exchange” before the reference to transfusion.

Comment #4 from Barb Lesko:

For the NICU protocol, we recommend collection at 24 hours, 2 weeks, and monthly until discharge or until 3 months of age. National recommendation is 24 hours, 2 weeks, and 1 month. We have picked up some delayed hypos between 1 month and 3 months which is why we take it out longer per Endo’s request. Is there a reason the 2 week collection is being removed?

ISDH response:

ISDH added the 14 day repeat screen in agreement with this comment.

Comment #5 from Barb Lesko:

The fee section refers to the surcharge which was \$30. This is the amount we can agree to send at the close of the month. It appears that you are changing this to the cost of the screen. How do you anticipate this working? There has to be some separation of fees since we are the ones assuming the expense to transport, test, report, and collect.

ISDH response to Comment #5:

The newborn screening fee is being listed in full for transparency. The division between laboratory services and follow-up services will be identified in the contract process instead of the rule. This allows for flexibility on both sides to ensure laboratory needs are met (including transportation, analysis, reporting, etc.) as well as follow-up and wraparound service needs. Necessary adjustments can be made through the contract amendment process instead of being defined by the mandate.

Comment #6 from Dr. Rowena Grumbine

Dear Sir/Madam:

I am a pediatric hospitalist working at Hendricks Regional in Danville, IN.

The specimen collection for the newborns done at 48 hours had given the babies great blessings.

At 48 hours of life, babies generally are jaundiced; the pda (patent ductus arteriosus) closes at that time; and at that period of the babies's life, the babies' biochemical structure is deemed best for the detection of the metabolic disorder from the newborn screen via mass spectrometry regardless of feeding history or medical conditions.

If the specimen for the newborn screen is drawn too early (especially close to 24 hours of life) there can be a likely chance of getting false negative readings which can be devastating to the babies.

I am hoping that the upcoming change (Newborn screen specimen collection to be done between 24-48hours instead of the previous code of having it done at 48 hours of life) slated [on July 1, 2018](#) can be reconsidered.

Please reinstate the old rule in doing the specimen collection done at 48 hours or close to 48 hours since the current technology allows a rapid turnaround time of results.

When parents are told that the state of Indiana DOH requires that the screen to be done at 48 hours of life, nobody argues about it. The hospital staff, the hospital administration, and the parents accept it. The babies get the most benefits. They get to stay at the hospital for at least 48 hours. The babies are not home having possible heart issues, jaundiced issues, or having false negative results on the newborn screen, etc.

The hospital administration has to provide the extra 'three shifts' nursing staff and accept that the bed space is not available for another 24 hours. The mom would sacrifice sleeping at the hospital bed for another 24 hours for the benefit of the baby. The OB physician would have to make rounds on the mom on the 2nd day even if they believe that the mom could have been discharged the day prior.

The babies could not speak for themselves but we as pediatricians do speak for them.

With the previous state code of having the specimen collection for the newborn screen drawn at 48 hours, we did not have to argue with the above issues. The babies are not having those possible issues at home (being jaundiced, having heart issues, having false negative results on the newborn screen, etc).

Please re-consider having the previous state code back, that is, specimen collection for the newborn metabolic state screen at 48 hours of life or close to 48 hours instead of 24-48 hours of life.

Thank you kindly,

Rowena Grumbine MD

ISDH Response to Comment #6:

The timing of the newborn screening is not tied to discharge timing. The change to 24-48 hours for newborn screening improves the timeliness of detection and intervention of severe disease. The technology for screening has progressed so the tests are accurate taking the sample at 24 hours. By keeping newborn screening time and discharge time separate, it places discharge planning in the hands of healthcare providers and their individual patients. In the instances that mother and newborn may be discharged prior to 48 hours, this change in newborn screening timeliness allows for that, but doesn't dictate it. The need for patients to remain in the birthing facility for 48 hours or longer continues to be a decision based upon healthcare needs as determined between a patient and the healthcare provider. Additionally, the screening time has been changed in statute and ISDH must comply with that change.

Comment #7 from the Immune Deficiency Foundation

The Immune Deficiency Foundation wrote a letter in support of adding Severe Combined Immune Deficiency (SCID) to the disorders on Indiana newborn screening panel and representative spoke at the Executive Board meeting. The comment stated that screening for SCID would save an estimated 1 to 2 babies per year and approximately \$3 million in medical costs in the first year of life. This would translate to almost \$1 million in Indiana Medicaid funds. If a child is identified and treated for SCID with a bone marrow transplant costing \$75,000 to \$200,000, within the first four months of life, there is a 94% chance that the child will live a normally and healthy life. 45 states screen for SCID already.

ISDH Response to Comment #7:

ISDH agrees with the comment and has added SCID to the list Indiana newborn screening panel. No change to the proposed rule is needed as SCID was included in that version.