

BEFORE THE INDIANA STATE DEPARTMENT OF HEALTH

**AN ADMINISTRATIVE RULES HEARING
LSA DOCUMENT #18-158**

HEARING OFFICER REPORT

This matter came before the duly appointed Hearing Officer, Kelly MacKinnon, on the 15th day of June, 2018, at 10:00 a.m., at the Indiana State Department of Health (ISDH), 2 North Meridian Street, Indianapolis, Indiana.

Notice of time and place of the hearing was given as provided by law by publishing on May 9, 2018, in the *Indianapolis Star* and by publishing in the *Indiana Register* dated May 9, 2018. Proof of publication of this notice has been received by the ISDH and the notice and proof are hereby incorporated into the record of this cause by reference and placed in the official files of the ISDH.

No one appeared to testify at the public hearing and no written comments were received. The record was left open until June 22, 2018. No comments were submitted during that time period.

ISDH received comments outside of the public hearing.

ISDH received comments from Barb Lesko who works for IU Labs, the laboratory contracted to perform the newborn screening for ISDH. Her comments are:

1. The Fatty Acid Oxidative Disorders should read "Glutaric Acidemia Type II".
2. 410 IAC 3-3-3(a)(6) - IRT and Biotinidase are not methods. They are the analytes/enzymes measured used the methods in D and E.
3. 410 IAC 3-3-3(f) Preterm collection is pretransfusion period, not just for total exchanges. Those are very rare and we really need to address any transfusion.
4. For the NICU protocol, we recommend collection at 24 hours, 2 weeks, and monthly until discharge or until 3 months of age. Nation 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 endocrinologist request. Is there a reason the 2 week collection is being removed?
5. The fee section refers to the surcharge which was \$30. This the amount we can agree to send at the close of the month. It appears that you are changing 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.

Her comments are attached and incorporated into this report as Exhibit 1.

ISDH also received comments from Rowena Grumbine, MD, a hospitalist working at Hendricks Regional in Danville, IN. She requested that the change from 48 hours collection to 24 hours be reconsidered. She stated that babies' biochemical structure was best for detection of metabolic disorders at 48 hours. She is concerned that if the specimen is drawn earlier, such as the new 24 hour requirement, that there can be a chance of getting false negatives. She stated that nobody argued when the screen was required to be done at 48 hours (hospital staff, hospital administration, and parents). She states that babies get the most benefit because they get to stay at the hospital for at least 48 hours. They are not sent home with possible heart issues, jaundiced issues, or having false negatives on the newborn screen. She also stated that "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." Her email is attached and incorporated into this report as Exhibit 2.

The final comment for this rule is 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. The Immune Deficiency Foundation comment is attached and incorporated into this report as Exhibit 3.

Dated at Indianapolis, Indiana this 6th day of July, 2018.



Kelly MacKinnon
Hearing Officer



From: Lesko, Barbara G [<mailto:bglesko@iupui.edu>]

Sent: Monday, May 14, 2018 3:11 PM

To: Griffie, Megan L <MGriffie@isdh.IN.gov>

Subject: RE: NBS Rule

****** This is an EXTERNAL email. Exercise caution. DO NOT open attachments or click links from unknown senders or unexpected email. ******

Hey Megan,

I read through the rule changes and I have a couple things.

1. The FAO vi. should say Glutaric Acidemia Type II
2. 6) G (IRT) and H (Biotinidase) are not methods. They are analytes/enzymes measured using methods D and F

amendments instead of being restricted by the mandate.

This time in the process and the public hearing is for exactly these things – catch the hiccups we missed, voice concerns if any, offer support if desired, etc. I really appreciate your eye on this, please let me know if you see anything else or have any more questions.

Best,

MEGAN GRIFFIE, PhD, MS
Director, Genomics and Newborn Screening

Maternal and Child Health
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From: Lesko, Barbara G [<mailto:bglesko@iupui.edu>]

Sent: Monday, May 14, 2018 3:11 PM

To: Griffie, Megan L <MGriffie@isdh.IN.gov>

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MacKinnon, Kelly

From: ISDHNBS
Sent: Tuesday, June 26, 2018 1:02 PM
To: Griffie, Megan L
Subject: FW: Nb screen at 48 hours old



Thank you,

HANNA PITTS
Special Projects Coordinator

*Maternal and Child Health
Indiana State Department of Health
P: 317.232.2978
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E: HPitts@isdh.IN.gov
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From: John Grumbine [mailto:nozirev3@verizon.net]
Sent: Tuesday, June 26, 2018 9:18 AM
To: ISDHNBS <ISDHNBS@isdh.IN.gov>
Subject: Nb screen at 48 hours old

****** This is an EXTERNAL email. Exercise caution. DO NOT open attachments or click links from unknown senders or unexpected email. ******

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 (i.e. <48 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 especially with the current 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 code back, that is, specimen collection for the newborn metabolic state screen at 48 hours of life instead of 24-48 hours of life.

Thank you kindly,

Rowena Grumbine MD
(814)934-0255- cell
(317)718-4740- work

Sent from my iPhone

Sent from my iPhone

The National Patient Organization Dedicated to Advocacy, Education and Research for Primary Immunodeficiency Diseases

November 8, 2017

Commissioner Kristina Box
State Health Commissioner
Indiana State Department of Health
2 North Meridian Street
Indianapolis, IN 46204

Re: Amendments to Rule 410 IAC 3-3 Newborn Screening to Add Severe Combined Immune Deficiency

Dear Commissioner Box,

The Immune Deficiency Foundation (IDF) is the national patient organization dedicated to improving the diagnosis, treatment and quality of life of persons with primary immunodeficiency diseases, including Severe Combined Immune Deficiency (SCID), through advocacy, education and research. Primary immunodeficiency diseases (PI) are a group of more than 300 rare, chronic disorders in which part of the body's immune system is missing or functions improperly. While not contagious, these diseases are caused by hereditary or genetic defects, and, although some disorders present at birth or in early childhood, the disorders can affect anyone, regardless of age, gender or ethnicity. SCID, one of the rarest and most devastating of these diseases, does present at birth.

Since 2008, IDF has been working to ensure that all states include screening for SCID as part of their newborn screening panels. There are now 45 states that screen for SCID, accounting for 92% of all newborns in the U.S., and we look forward to adding Indiana to the list.

As you are aware, screening for SCID will not only save the lives of Indiana babies, but it will likely save the state millions of dollars should a baby on Medicaid be diagnosed with SCID. The prevalence of infants born with SCID in Indiana is estimated to be 1 to 2 per year, based on the rate of occurrence of SCID and the number of Indiana live births per year. We know from experience in Indiana that an undiagnosed Medicaid infant with SCID can expend up to \$3 million in medical costs in the first year of life. This translates to almost \$1 million in Indiana Medicaid funds. If a baby should survive, the healthcare costs will continue to be quite large. However, 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 normal and healthy life.

We urge you to amend Rule 410 IAC 3-3 to add SCID to the Indiana newborn screening panel, to allow for statewide SCID screening in Indiana in 2018.

Thank you for your consideration. Should you have any questions, please contact me: 443-470-6466 or jsexton@primaryimmune.org.

Regards,



Jamie Sexton
Government Relations Specialist

Cc: Members of the Indiana State Department of Health Executive Board

