NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

FEBRUARY 16, 2018
10:00 a.m. Central Time
Nebraska State Office Building – Lower Level B
301 Centennial Mall South, Lincoln, Nebraska

The purpose of this hearing is to receive comments on proposed changes to Title 181, Chapter 2 of the Nebraska Administrative Code (NAC)—*Screening of Infants for Metabolic Diseases*. The proposed changes to these regulations update the language referencing *metabolic diseases* to *inherited or congenital infant- or childhood-onset diseases*, add three new diseases to the newborn screening panel, and allow the Department of Health and Human Services (DHHS) to increase the per-infant-screened fee to $20.00 per infant. These proposed changes will bring the regulations into compliance with the passage of Legislative Bill 91 (2017).

Authority for these regulations is found in Neb. Rev. Stat. § 81-3117(7).

Interested persons may attend the hearing and provide verbal or written comments or mail, fax or email written comments, no later than the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 or dhhs.regulations@nebraska.gov, respectively.

A copy of the proposed changes is available online at http://www.sos.ne.gov, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8223. The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, Room 1305, State Capitol, Lincoln, NE, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8223. Individuals with hearing impairments may call DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

PROPOSED REGULATION
POLICY PRE-REVIEW CHECKLIST

Agency: DHHS – Division of Public Health
Title, Chapter of Regulation: Title 181, NAC 2
Subject: Screening of Infants for Metabolic Diseases
Suggest title change to: Screening of Infants for Congenital and Inherited Infant and Childhood Onset Diseases
Prepared by: Julie Luedtke, Program Manager Newborn Screening Program
Telephone: 402 471-6733

A. Policy Changes and Impacts

1. What does the regulation do and whom does it impact? Provide a brief description of the proposed rule or regulation and its impacts on state agencies, political subdivisions, and regulated persons or entities.

   These regulations implement the law governing screening of infants for inherited or congenital infant- or childhood-onset diseases. They define terms, state the requirements for screening, specify the diseases for which tests are required, and specify the time periods for performance and reporting of results of the tests by physicians, hospitals, laboratories, and births not attended by a physician.

   LB 91 passed in the 2017 Legislative session requires the addition of three new diseases to the newborn screening panel, and allows the Department of Health and Human Services to increase the per-infant-screened fee to $20 per infant. It also updated language referencing "metabolic diseases" to "inherited or congenital infant- or childhood-onset diseases. Currently the newborn screening laboratory that is awarded the competitively bid contract, bills the specimen submitters (Hospitals) for the screening and the hospitals bill insurance and ultimately families for unrecovered costs. Physicians and hospital personnel will also be affected relative to the education they are required to provide to new parents. The Department provides the "Parent's Guide to Your Baby's Newborn Screening" to hospitals and physicians to aid in this parent education.

2. Describe changes being proposed to current policy and briefly provide rationale.

   The main changes proposed for these regulations are to incorporate the new definitions of targeted diseases, the three conditions and adjust the fee collected by the laboratory and submitted to DHHS as specified in LB 91 Neb.Rev.Stat.§71-519 through 71-524.

Two additional changes are to update a reference about how the filter paper may be obtained and about the electronic database. The Department no longer distributes these, and requires the contracted newborn screening laboratory to manage the ordering and distribution of the filter paper dried blood spot collection kits. The department no longer maintains the database and requires the laboratory to provide it (via contract), and requires we have access to it 24/7.

And finally the three appendices are being deleted. Appendix A because the blood collection guidelines are updated every 3-5 years so referencing them eliminates the need for future reg revisions for the updates. The other forms will be posted on the web site and readily available for use by the contracted screening laboratory and hospitals.

In addition to deleting the two forms and guidelines in the appendices, other sections are being suggested for deletion following review through the lens of Executive Order 2017-04. These sections can be implemented with high voluntary compliance using professional guidelines (specifically section on confirmatory testing), or are testing laboratory requirements that can be implemented with specifications in the newborn screening laboratory testing services RFP and contract.

B. <u>Why is the rule necessary? Explain and provide an identification of authorizing statute(s) or legislative bill(s).</u>

1. Update of regulation (repeal of obsolete statutes, reflect current policy, editing or technical language changes, etc.)

   LB 91 revised Neb. Rev. Stat. § 71-519 through 71-524 in the 2017 legislature, requiring implementation by July 1, 2018. The increase in the per-infant screened fee is needed to help support the increased costs to the program to implement the statutory requirements of additional disease screening and mandatory provision of metabolic formula and foods. The update regarding distribution of filter paper and access to the electronic database is needed to reflect who is responsible for these two functions as mentioned above.

2. Annual changes – cost of living, hunting season schedules, etc. No

3. Law was changed – federal ___ or state __x_. LB 91, Neb. Rev. Stat. §§ 71-519 through 71-524 revised in the 2017 Legislative Session

4. Extension of established policy or program, new initiatives or changes in policy (within statutory authority). No

5. Constituent initiated Yes, originally w/ the Senator who introduced LB 91.

6. Financial needs – increases/decreases in fees : Yes

7. Litigation requires changes in rules: No

8. Addresses legal or constitutional concerns of Attorney General's office: No

9. Implements federal or court mandate: No

10. Other (explain)

C. <u>What happens if these rules are not adopted?</u>

We will be out of compliance with the statutory requirements to add the three new conditions, as will physicians attending births, hospitals, and for infants born outside of a hospital the person registering the birth would also be non-compliant with the law. In addition infants born with the three new mandated conditions who do not benefit from the screening will likely experience serious morbidity and mortality. Subsequent lawsuits to sue for damages would be a likely result.

D. <u>Policy Checklist</u>

1. Is this an update or editorial change reflecting essentially no change in policy? No

2. Does the policy in the proposed regulation reflect legislative intent? Yes

3. Is the policy proposed in the regulation a state mandate on local government? No Is it funded? The Fee increase would help fund the program's follow-up, administration and metabolic formula and foods program, but the newborn screening testing itself is not funded by the state.

4. Is the policy proposed in the regulation a federal mandate on local government? No Is it funded? N/A

E. <u>Fiscal Impact. In addition to completing the required Fiscal Impact Statement (a copy must be attached to this document), the agency must address the following:</u>

1. Will the proposed regulation reduce, increase, or have no change in resources – funds, personnel or FTE? There will be no increase in personnel but increased funds to help support the administration of the program and support the mandated metabolic foods and formula program also administered by the program.

2. Have initial contacts been made with citizens or organizations that may be impacted by the proposed regulation? Yes but more outreach to hospitals and physicians beyond the NBS Advisory Committee and mention of potential new disease screening at Pediatric Grand Rounds presentations is advisable. Announcements through the NHA, NMA, Ne AAP, Ne AFP, and NE AWHONN should be made.

3. Does the proposed regulation impact another agency? No. Explain the impact? N/A

4. Will the proposed regulation reduce, increase, or have no change on reporting requirements of businesses? For the approximately 25% births represented by hospitals without an electronic interface with the newborn screening laboratory, it will be an increase in reporting (3 more diseases' test results). For the approximately 75% births represented by hospitals with the interface there will be no change to their reporting (but updates to their interfaces will have to be completed first).

5. What is the agency's best estimate of the additional or reduced spending? If there is none, please note. If receipt of federal funds is contingent upon approval of the proposed regulation, then indicate the amount and nature of the federal funds affected, and enclose laws or correspondence from federal officials substantiating the information.

   At this time the estimated increase in costs to hospitals (insurers) for the additional tests plus the increase in the administrative fee will be $34.75 per infant screened. Until the competitive lab RFP is processed and a new contract in place (Due 7/1/18) we won't know for sure what the increased cost will be.

6. Include a description of the impact that the proposed regulation will have on the number of state employees and how the agency intends to address proposed increases or decreases in FTE. No impact. The position needed to be able to implement this change has already been repurposed for the program's follow-up and quality assurance.

F. <u>Unique problems or issues and recommendations.</u> Nothing foreseeable.

G. <u>Who is expected to be affected, or to oppose or support the proposed regulation? Explain what initial informal contacts have been made with organizations or citizens who may be affected by the regulation prior to the public hearing.</u> Representatives of the NBS Advisory Committee would be expected to support the regulation revisions. These representatives come

from NMA, NHA, March of Dimes, UNMC, Private hospitals, clinical practice, parents, and Medicaid.

It is possible hospital representatives may be opposed if they believe they will not be fairly compensated for their costs by insurers.

It is possible the insurance industry could be opposed if they believe they should not be billed for the administrative fee. Although this has never come up before in implementation of the administrative fee since 1997.

H. Are these proposed rules a likely candidate for negotiated rulemaking? Explain. Has the process been completed? No. **If so, explain how the issues were addressed.**

DHHS Division Director's Verification of Review

I have reviewed these proposals and verify that, at this stage of the regulation's development, these questions have been accurately addressed.

Thomas L. Williams, MD
Chief Medical Officer
Director, Division of Public Health
Department of Health and Human Services

10-5-17
Date

FISCAL IMPACT STATEMENT

Agency: **Department of Health and Human Services**	
Title: 181	Prepared by: Julie Luedtke
Chapter: 2	Date prepared:
Subject: Newborn Screening (Screening of Infants for Metabolic Diseases to change to: Screening of Infants for congenital and inherited infant and childhood onset diseases.	Telephone: 1-6733

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(☐)	(☒)	(☐)
Increased Costs	(☒)	(☐)	(☒)
Decreased Costs	(☐)	(☐)	(☐)
Increased Revenue	(☒)	(☐)	(☐)
Decreased Revenue	(☐)	(☐)	(☐)
Indeterminable	(☐)	(☐)	(☐)

Provide an Estimated Cost & Description of Impact:

State Agency: The per-infant-screened fees for newborn screening testing are “estimated” by the current newborn screening laboratory to be $10.50 for Pompe, $1.50 for MPS-I and $11.75 for X-ALD. In addition the administrative fee increase of $10 per infant screened is included, to cover the already approved repurposed FTE, and increased costs of providing the metabolic formula and foods. These increased fees are passed along to third party payers, so eventually as reimbursement rates are renegotiated, Medicaid will be impacted.

Political Subdivision: N/A

Regulated Public: Same as above for the third party payers.

If indeterminable, explain why:

NEBRASKA

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DEPT. OF HEALTH AND HUMAN SERVICES

Pete Ricketts, Governor

TO: Executive Board
Room 2108 State Capitol
Legislative Council

FROM: Brad Gianakos, Agency Counsel
Department of Health and Human Services (DHHS)

DATE: January 3, 2018

RE: Notice of Rulemaking under Neb. Rev. Stat. § 84-907.06

The Department of Health and Human Services (DHHS) will be holding a public hearing on proposed amendments to the following regulations:

TITLE: 181 Special Health Programs
CHAPTER: 2 Screening of Infants for Metabolic Diseases

These regulations are scheduled for public hearing on February 16, 2018.

The purpose of this hearing is to receive comments on proposed changes to Title 181, Chapter 2 of the Nebraska Administrative Code (NAC)—*Screening of Infants for Metabolic Diseases*. The proposed changes to these regulations update the language referencing *metabolic diseases* to *inherited or congenital infant- or childhood-onset diseases*, add three new diseases to the newborn screening panel, and allow the Department of Health and Human Services (DHHS) to increase the per-infant-screened fee to $20.00 per infant. These proposed changes will bring the regulations into compliance with the passage of **Legislative Bill 91 (2017).**

The following items are enclosed for your referral to the chair of the relevant standing committee of the Legislature:

1. A copy of the notice of public hearing;
2. A copy of the proposed regulations;
3. A copy of the Policy Pre-Review Checklist; and
4. The estimated fiscal impact of this rulemaking action on state agencies, political subdivisions or persons being regulated.