

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 540. INFANT HEARING SCREENING**

RULEMAKING ACTION:

Notice of proposed PERMANENT rulemaking.

PROPOSED RULES:

310:540-1-2. Definitions [AMENDED]

310:540-1-3. Guidelines [AMENDED]

SUMMARY:

310:540-1-2. A few terms and definitions were added/revised for clarity and references. This includes “newborn screening filter paper”, “other health care provider”, “other qualified individual” and “subsequent hearing screening”. 310:540-1-3. The current rule references “regional sites” for follow-up screenings. However, regional sites no longer exist due to the expansion of screening capabilities at local county health departments and other health care provider locations. This proposal expands screening options for Oklahoma families to assist infants in receiving recommended follow-up. This proposal sets forth parameters to ensure national guidelines are met for screening by one month of life and hearing loss diagnosis by three months of life. The proposal establishes the manner and timeframe deemed appropriate by the Oklahoma State Department of Health to report hearing screening and diagnostic results as reporting results can guide individualized case management needs of infants through the early hearing detection and early intervention process. The proposal updates the current rule regarding when a newborn can be referred to audiologist for diagnostic hearing evaluation so that language reflects recommendations by the national Joint Committee on Infant Hearing.

AUTHORITY:

Oklahoma State Commissioner of Health, Title 63 O.S. Section 1-104; and Title 59 O.S. Section 1905(A)

COMMENT PERIOD:

February 3, 2020, through March 7, 2020. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through March 7, 2020, submit written comment to the contact person identified below, or may, at the hearing, ask to present written or oral views.

PUBLIC HEARING:

Pursuant to 75 O.S. § 303(A), the public hearing for the proposed rulemaking in this chapter shall be on March 6, 2020, at the Oklahoma State Department of Health, 1000 Northeast Tenth Street, Oklahoma City, OK 73117-1207, in room 1102 from 9AM to noon. The alternate date and time in the event of an office closure due to inclement weather is March 10, 2020, in room 1102, from to 9AM. Those wishing to present oral comments should be present at that time to register to speak. The hearing will close at the conclusion of those registering to speak. Interested persons may attend for the purpose of submitting data, views or concerns, orally or in writing, about the rule proposal described and summarized in this Notice.

REQUESTS FOR COMMENTS FROM BUSINESS ENTITIES:

Business entities affected by these proposed rules are requested to provide the agency with information, in dollar amounts if possible, on the increase in the level of direct costs such as fees, and indirect costs such as reporting, recordkeeping, equipment, construction, labor, professional services, revenue loss, or other costs expected to be incurred by a particular entity due to compliance with the proposed rule. Business entities may submit this information in writing through March 7, 2020, to the contact person identified below.

COPIES OF PROPOSED RULES:

The proposed rules may be obtained for review from the contact person identified below or via the agency website at www.ok.gov/health.

RULE IMPACT STATEMENT:

Pursuant to 75 O.S., Section 303(D), a rule impact statement is available through the contact person identified below or via the agency website at www.ok.gov/health.

CONTACT PERSONS:

Kim Bailey, General Counsel, Oklahoma State Department of Health, 1000 N. E. 10th Street, Oklahoma City, OK 73117-1207; phone (405) 271-6017, e-mail KimB@health.ok.gov or Audrey C. Talley, Rule Liaison, Oklahoma State Department of Health, 1000 N. E. 10th Street, Oklahoma City, OK 73117-1207, phone (405) 271-9444 ext.56535, e-mail AudreyT@health.ok.gov.

INITIAL RULE IMPACT STATEMENT

(This document may be revised based on comment received during the public comment period.)

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 540. INFANT HEARING SCREENING**

1. DESCRIPTION

Revised definitions for clarity and added a few addition definitions for further guidance.
Modified language to match current processes within the early hearing detection and intervention system.
Detailed the manner and timeframe deemed appropriate by the Oklahoma State Department of Health to report hearing screening and diagnostic results.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

Every baby born in Oklahoma is required to have a newborn hearing screening test performed prior to being discharged from the hospital or within one month of life if delivered outside of a hospital.
Hospitals are responsible for performing the hearing screening test and reporting the result to the Oklahoma State Department of Health (OSDH).
Physicians or other health care providers responsible for follow-up care after birth are responsible for verifying that screening was completed and follow-up measures have been undertaken if baby refers one or both ears or if the baby was not screened.
Hospitals, physicians and other health care providers refer to the rules for guidance regarding newborn hearing screening. It is important that the rules provide clear guidance and support to ensure children receive appropriate follow-up care when needed.

3. DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:

All children born in Oklahoma as well as their families will benefit. Early detection of hearing loss provides an opportunity for early treatment, lessening the severity of speech, language, cognitive, social and economical impact associated with late diagnosis. Early diagnosis also allows for the establishment of appropriate supportive services for families of affected individuals.
Hospitals and physicians will benefit from these proposed changes to the rules in that the updated rules will provide healthcare providers with the necessary resources reflecting the Newborn Hearing Screening Programs recommendation/requirements to ensure infant and families receive optimal services.

4. ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:

None

5. COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:

The cost to the Department to implement the amendments will be minimal. The proposed rules will be implemented and enforced by existing Department personnel and will have no anticipated effect on state revenues.

6. IMPACT ON POLITICAL SUBDIVISIONS:

There will be no impact on political subdivisions and it will not require their cooperation in implementing or enforcing the proposed amendment

7. ADVERSE EFFECT ON SMALL BUSINESS:

There will be an impact on those birthing facilities (hospitals or midwives) that meet the definition of a small business. However, the impact will be limited to the manner and timeframe for reporting hearing screening results.

8. EFFORTS TO MINIMIZE COSTS OF RULE:

No less costly or nonregulatory methods have been identified.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

Changes to the Newborn Hearing Screening rule will improve core public health services to children and families throughout Oklahoma. Early identification of infants with hearing loss can improve lifelong outcomes.

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:

Delayed reporting by hospitals other health care providers can lead to delayed early intervention placement. These delays can reduce a child's speech, language, cognitive and emotional development as a child hears up to one million words per month on average.

Outdated language will not accurately reflect current processes or recommendations by the program.

11. PREPARATION AND MODIFICATION DATES:

This rule impact statement was prepared on Thursday, December 12, 2019.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 540. INFANT HEARING SCREENING**

310:540-1-1. Purpose

The rules in this Chapter implement the Infant Hearing Screening Regulations, 63 O.S. 1991, Sections 1-543 through 1-545.

310:540-1-2. Definitions [AMENDED]

The following words or terms, when used in this Chapter, shall have the following meaning, ~~unless the context clearly indicates otherwise:~~

"Audiologist" means an individual holding certification in Audiology by the American Speech-Language-Hearing Association ~~and/or its equivalent~~ the American Academy of Audiology.

"Discharge" means the release of the newborn from care and custody of a perinatal licensed health facility to the parents or into the community.

"Hearing Screening Procedure" means the combination of physiologic hearing screening and risk factor tracking used to determine, from the total population of infants born, the infants at risk for hearing loss.

"Newborn Screening Filter Paper" means a newborn screening blood spot collection kit approved by the Oklahoma State Department of Health.

"Other Health Care Provider" means the health care provider who will be providing health care for the infant after birth including midwives, physician assistants, nurse practitioners, and hospital hearing screening vendors.

"Other qualified individual" means an individual working under the guidelines developed by the responsible ~~physician or audiologist~~ health care facility, physician, audiologist or other health care provider.

"Parent" means a natural parent, stepparent, adoptive parent, legal guardian, or other legal custodian of a child.

"Physician" means an M.D. or D.O. licensed in the State of Oklahoma to practice medicine.

"Physiologic Screening" means the use of a bilateral physiologic screening technique to determine, from the total population of infants born, the infants at risk for hearing loss.

"Risk Factors" mean conditions identified by the Joint Committee on Infant Hearing (JCHIH 2000 Position Statement or later) which place a newborn at risk for hearing loss.

"Subsequent hearing screening" means a hearing screening completed at minimum 72 hours after the initial hearing screening.

"Transfer" means release of the newborn from care and custody of one perinatal licensed health facility to another.

310:540-1-3. Guidelines [AMENDED]

(a) All newborns in Oklahoma ~~will~~shall have a Hearing Screening Procedure completed unless the parent or guardian refuses because of religious or personal objections.

(b) Requirements for the Hearing Screening Procedure are as follows:

(1) For facilities with a two-year average annual birth census of 15 or greater:

- (A) All infants will receive a physiologic and risk factor screening prior to discharge.
- (B) Infants transferred to another facility will be screened by that institution prior to discharge.

(2) For facilities with a two-year average annual birth census of fewer than 15:

- (A) All infants will receive a physiologic and risk factor screening prior to discharge if physiologic screening equipment is available.
- (B) Infants transferred to another facility will be screened by that institution prior to discharge.
- (C) If physiologic screening equipment is not available, the infant will be screened for risk factors and,

~~(D) The~~ The parents will be directed to a regional site providing referred for physiologic screening and encouraged to have the infant screened within the first month of life.

(3) Out-of-Hospital Births:

(A) All infants who are not born in a hospital will have their hearing screened within the first month of life. The infant's physician or ~~licensed or certified birth attendant~~ other health care provider is responsible for completing the risk factor screening and for referring the infant to a ~~regional hearing screening site~~ health care facility with trained personnel and appropriate equipment for a physiologic screen or an audiologist.

~~(B) Physicians, other health care providers, or local county health department staff who examine a child within the first three months of life who was not born in a hospital, or who was born out of state, will verify that the infant's hearing has been screened. Infants not screened will be referred to a regional hearing screening site.~~

(c) Hospital universal newborn hearing screening programs will be administered by an audiologist and/or ~~physician~~ health care facility.

(d) The physiologic screening will include the use of at least one of the following:

- (1) Auditory Brainstem Response Testing (ABR);
- (2) Otoacoustic Emissions Testing (OAE);
- (3) ~~any~~ Any new or improved techniques deemed appropriate for use in hearing screening procedures by the Commissioner of Health.

(e) The Hearing Screening Procedure will be performed by a qualified and properly trained individual, and the results provided to the ~~primary care~~ physician or other health care provider. Notification of the screening results to parents will be given prior to discharge or immediately following the Hearing Screening Procedure ~~if conducted through a regional site~~.

(f) Newborns ~~will~~ may be referred to an audiologist for a diagnostic hearing evaluation for these reasons:

- (1) They did not pass the hearing screening ~~prior to discharge~~;
- (2) ~~they~~ They passed the initial or subsequent hearing screening but were at risk for progressive or late onset hearing loss ~~because of a risk factor~~ identified by the Joint Committee on Infant Hearing or did not pass the recommended six month follow up hearing screening.

(g) The hospital personnel, audiologist, or ~~primary care physician~~ other health care provider involved in the screening of a newborn will provide the parents with appropriate resource information to allow ~~them~~ newborn to receive the medical, audiologic, and other follow-up services as necessary.

(h) The hospital personnel, audiologist, or ~~primary care physician~~ other health care provider involved in the initial Hearing Screening Procedure of a newborn will forward results to the Oklahoma State Department of Health ~~in a manner and time frame deemed appropriate by the Oklahoma State Department of Health~~ via newborn screening filter paper, fax, or secure email within one week of performing the hearing screen.

~~(i) Physicians, other health care providers, or local county health department staff who examine a child within the first three months of life will verify that the infant's hearing has been screened. Infants not screened will be referred to a health care facility with trained personnel and appropriate equipment for a physiologic screen or an audiologist.~~

~~(j) Audiologists or physicians~~ Health care facilities, physicians, audiologists or other health care providers involved in completing follow-up hearing screens or diagnostic evaluations will forward ~~test~~ results and recommendations to the Oklahoma State Department of Health ~~in a manner and time frame deemed appropriate by the Oklahoma State Department of Health~~ via fax or secure email within one week of performing the hearing screen or diagnostic evaluation.

~~(k)~~ (l) To facilitate the reporting of newborns and infants who have or are at risk for hearing loss, the reporting requirements will be designed to be as simple as possible and easily completed by nonprofessional and professional individuals involved in the program.

~~(l)~~ (1) The Oklahoma State Department of Health will utilize a tracking system to track infants identified at risk for hearing loss for a period up to one year in order to assure appropriate follow-up care.

~~(b)(7)(D)~~(m) The Oklahoma State Department of Health will compile and report data collected from hearing screening procedures at least annually and will share such information as directed by the Commissioner of Health.