

**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: The proposal removed one definition, "other qualified individual", that is no longer utilized and expanded one definition, "risk factors" for clarity and to be in alignment with national terminology.

310:540-1-3: In an effort to align with the Governor's Executive Order, the proposal simplifies and clarifies language within the Guidelines section. Headings have been added for ease of use and clarity along with a screening refusal section with details and needed documentation. Paragraphs (g) and (h) were expanded to include detailed language regarding the responsibility of the hospital personnel, audiologist, or other health care provider regarding newborn hearing screening reporting to parents and the Oklahoma State Department of Health. Details were expanded to include instructions and form names.

AUTHORITY:

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

COMMENT PERIOD:

November 16, 2020, through December 16, 2020, interested persons may informally discuss the proposed rules with the contact person identified below; or may, through December 16, 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 December 16, 2020, via WebEx accessible from the site www.publichearings.health.ok.gov, from 9AM to noon. The alternate date and time in the event of extreme inclement weather is December 18, 2020, via WebEx accessible from the site www.publichearings.health.ok.gov, from 9AM to noon. Those wishing to present oral comments should be registered to speak by 9:15 a.m. Directions for comment registration will be provided on the website. The hearing will close at the conclusion of comments from those registered to speak. Interested persons may attend for the purpose of orally submitting data, views, or concerns 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 December 16, 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.health.ok.gov.

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.health.ok.gov.

CONTACT PERSON:

Audrey C. Talley, Agency 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:**

- Removed “other qualified individual” definition as no longer in current document
- Enhanced “risk factors” definition to include “delayed-onset or progressive” hearing loss
- Added headings to Guideline section for ease of use and clarity
- Added Refusal section with details and needed documentation
- Simplified language in Part 310:540-1-3 (b), (d), (e), (f)
- Revised Part 310:540-1-3 (g) and (h) to provide further guidance regarding the responsibility of the hospital personnel, audiologist, or other health care provider regarding newborn hearing screening reporting to parents and the Oklahoma State Department of Health.
- Provided detailed instructions on action steps for screening and reporting as well as form names and sections to be utilized
- Combined language from Hospital standards 667:19-2 (4) newborn hearing screening reporting to reduce duplicity

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 live 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 economic 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. Providers will be able to locate all newborn hearing guidance in one section due to this change as a portion of the information was formally located in Hospital standards 667:19-2 (4).

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

- None

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

- There will be no cost to the Department to implement the amendments.

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:**

- No additional impact will be placed on those birthing facilities (hospitals or midwives) that meet the definition of a small business.

8. **EFFORTS TO MINIMIZE COSTS OF RULE:**

- No less costly or non-regulatory 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:**

- There will be no impact detrimental effects if not adopted at this time.

11. **PREPARATION AND MODIFICATION DATES:**

This rule impact statement was prepared on October 2, 2020.

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

310:540-1-2. Definitions

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 a state licensure in the field 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 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 (JCIH 2000 Position Statement or later) which place a newborn at risk for delayed-onset or progressive 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

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

(b) **Screening Based on Birth Location.** Requirements for the Hearing Screening Procedure are as follows:

(1) Hospitals:

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

~~(A)(i)~~ All infants will receive a physiologic and risk factor screening ~~prior to~~ before discharge.

~~(B)(ii)~~ Infants transferred to another facility will be screened by ~~that the receiving institution facility~~ prior to ~~before~~ discharge.

~~(2)(B)~~ For facilities with a two-year average annual birth census of ~~fewer than 15~~ 14 or less:

~~(A)(i)~~ All infants will receive a physiologic and risk factor screening ~~prior to~~ before discharge if physiologic screening equipment is available.

~~(B)(ii)~~ Infants transferred to another facility will be screened by ~~that the receiving institution facility~~ prior to ~~before~~ discharge.

~~(C)(iii)~~ If physiologic screening equipment is not available, the infant will: ~~be screened for risk factors and;~~

(I) be screened for risk factors; and
(II) receive a physiologic screening referral. A parent is encouraged to have the infant's screening occur within the first month of life.

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

~~(3)(2) Out-of-Hospital Births: 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 other health care provider is responsible for completing the risk factor screening and for referring the infant to a health care facility with trained personnel and appropriate equipment for a physiologic screen or an audiologist.~~

~~(c) Hospital universal newborn hearing screening programs will be administered by an audiologist and/or health care facility.~~**Refusal.** A parent may refuse the newborn hearing screening on the grounds that such examination conflicts with their religious tenets and/or practices; refusal of hearing screening shall be indicated in writing utilizing the Newborn Screening Program Refusal Form provided by the Department. The Newborn Screening Program Refusal Form must be completed in its entirety.

~~(d) **Physiologic Screening.** A qualified and properly trained individual, as determined by the screening facility, will perform the Hearing Screening Procedure. 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); or~~
- ~~(3) Any new or improved techniques ~~deemed considered~~ 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 **Sharing Results.** the The hospital or midwife will ensure that hearing screening results provided will be made available to the 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.~~

~~(f) **Audiologist Referral.** Newborns A newborn may be referred to an audiologist for a diagnostic hearing evaluation for these reasons:~~

- ~~(1) They did not pass the hearing screening;~~
- ~~(2) They passed the initial or subsequent hearing screening but, based on risk factors, were is at risk for progressive or late onset hearing loss identified by the Joint Committee on Infant Hearing or did not pass the recommended six month follow up hearing screening.~~
- ~~(3) They did not pass the recommended six month follow hearing screening.~~

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

Parent Education. Before discharge, a newborn's parent will receive the following information and materials:

(1) results of the infant's hearing screening, which may include the following.

- (A) passed physiologic hearing screening
- (B) referred on physiologic hearing screening; or
- (C) considered as "at risk" for hearing loss

(2) a copy and in-person review of the Newborn Hearing Screening Parent/Guardian Information Sheet; and

(3) appropriate resource information to allow the newborn to receive the medical, audiologic, and other follow-up services as necessary.

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

Reporting of Results and Quality Assurance. It is a hospital's responsibility to ensure that the newborn screening filter paper is correctly completed and that results are forwarded to the Oklahoma State Department of Health via the newborn screening filter paper, fax, or secure email within one week of performing the hearing screen. Efforts to ensure compliance includes the following:

(1) adhere to instructions for completion of the hearing screening section located on the newborn screening filter paper kit

(2) ensure hospital personnel involved in screening and/or reporting are properly trained using national and state resources such as in-service trainings, web trainings, or consultation with the Newborn Hearing Screening Program

(3) designate a site coordinator to ensure:

(A) every infant is screened,

(B) each infant's filter paper has been fully completed for each infant; and

(C) the detachable medical record copy is a permanent part of each infant's record.

(i) **Screening Verification.** 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) **Reporting Follow-Up Evaluations.** Health care facilities, physicians, audiologists or other health care providers involved in completing follow-up hearing screens or diagnostic evaluations will forward results and recommendations to the Oklahoma State Department of Health via fax or secure email within one week of performing the hearing screen or diagnostic evaluation.

(k) **Reporting Standards.** 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) **Tracking System.** 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.

(m) **Data Reporting.** 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.