**Section 661.610 Responsibilities of Medical Care Facilities**

a) All medical care facilities shall provide written information to all parents, legal guardians or caregivers before the newborn hearing screening is administered. The written information shall include:

1) Purpose and benefits of the hearing screening;

2) Description of typical auditory development;

3) Description of the procedures used for hearing screening;

4) Risk factors for hearing loss;

5) Factors that could result in a referral for further hearing screening; and

6) Importance of timely follow-up for hearing testing and intervention.

b) After completion of the newborn hearing screening, medical care facilities shall provide to parents, legal guardians, or caregivers, orally and in writing, the following information:

1) Time, date, screening technology and individual-ear screening results for the final screening session prior to discharge; and

2) Follow-up plan of care, including the coordination of follow-up screening or diagnostic appointments and service locations.

c) The medical care facility shall maintain written documentation of the newborn hearing screening in the newborn, infant or child's medical record, including the following information:

1) Time, date, screening technology and individual-ear screening results for the final screening session prior to discharge;

2) Individual administering each screening test;

3) Follow-up plan of care, including the coordination of follow-up screening or diagnostic appointments and service locations; and

4) Documentation of screening refusal, if applicable.

d) Newborn hearing screening shall be performed by an individual who is supervised by a licensed healthcare professional (recommended to be a licensed audiologist per 2019 Joint Committee on Infant Hearing Statement). The supervising healthcare professional and screener shall be trained in the following areas:

1) Anatomy and physiology of the ear;

2) Nature of responses being measured;

3) Patient and non-patient factors that influence responses;

4) Hearing screening procedures;

5) Documentation of results;

6) Type of screening equipment to be used;

7) Operation of the screening equipment;

8) Time frames for screening;

9) Provision of results to the parents, legal guardian or caregiver, the primary medical care provider, and the Department;

10) Confidentiality requirements;

11) Communicating accurate and appropriate information;

12) The plan of care if the newborn or infant passed the hearing screening; and

13) The plan of care if the newborn or infant did not pass the hearing screening.

e) A medical care facility shall identify a primary and secondary liaison to the EHDI Program at the Department.

f) A medical care facility shall identify, no later than January 1, 2023, the items listed below and shall report any changes thereafter, within 7 days, to the Department:

1) primary and/or secondary EHDI liaison;

2) hearing screening protocol; and/or

3) hearing screening equipment.

g) A medical care facility shall inform the Department no less than 30 days before any changes related to the outsourcing of newborn hearing screening services.

h) A medical care facility shall designate a manager or coordinator employed by the facility who is responsible for the oversight of newborn hearing screening services. The manager or coordinator shall be a licensed healthcare professional. The manager or coordinator shall be responsible for the following:

1) Documentation of medical care facility EHDI policy and protocols;

2) Maintenance, operation, and replacement of the hearing screening equipment within the equipment manufacturer's guidance;

3) Documentation of a hearing screening plan to ensure the continuation of hearing screening when the equipment is out of service for greater than 48 hours;

4) Training and supervision of newborn hearing screening personnel, including retraining and competency monitoring of newborn hearing screening personnel;

5) Monitoring reporting to the Department; and

6) Medical facility EHDI data management.

i) A medical care facility shall maintain newborn hearing screening equipment that is approved by the Food and Drug Administration for Newborn Hearing Screening and meets the following requirements:

1) Screening technology that measures a physiologic response; is implemented with objective response criteria; uses a procedure that measures the status of the peripheral auditory system and is highly correlated with auditory function; and is approved for newborn hearing screening; and

2) Screening methodology that detects, at a minimum, any unilateral or bilateral hearing losses equal to or greater than 35dB HL. The methodology used should have a false-positive rate and no less than 1% and no greater than 4%. For this purpose, false positive rate means the proportion of newborns or infants without hearing loss who are identified incorrectly by the screening process as having significant hearing loss.

j) Medical care facilities shall calibrate hearing screening equipment in the timeframe and manner recommended by the manufacturer. Calibration should occur annually or more frequently per manufacturer guidelines. Newborn hearing screening equipment per manufacturer guidance.

k) A medical care facility shall report to the Department when equipment is out of service for greater than 48 hours.