TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

LSA #10-504

SUMMARY/RESPONSE TO COMMENTS FROM PUBLIC HEARING

The Indiana State Department of Health's (ISDH) Executive Board preliminarily adopted Rule 410 IAC 3-3, Newborn Screening Rule, on September 8, 2010. ISDH published the proposed rule on November 2, 2011 in the Indiana Register. A public hearing was held in Indianapolis on November 29, 2011, to solicit comments from the public on the proposed rule. The record of the hearing was held open for submission of written comments, until November 30, 2011. The following parties made comments during the public hearing or submitted written comments:

Spencer Grover, Vice President, Indiana Hospital Association

The following is a summary of the comments received and ISDH's responses thereto:

Comments received from Spencer Grover, Vice President, Indiana Hospital Association:

1. **New definitions.** Insert definitions for "health care provider," "midwife" and "physician" to clarify the individuals who will be responsible for actions within the rule. The definitions (in italics) were added.

   Sec. 1(8). "Health care provider" means the medical professional providing care after birth.

   Sec. 1(19). "Midwife" means an individual licensed under IC 25-23-1-13.1.

   Sec. 1(24). "Physician" means an individual licensed under IC 25-22.5-5.

   ISDH response: The agency agrees with this recommendation and has made the necessary changes.

2. **Correct typo in definition for "audiologist."** There needs to be an "and" between "Indiana's Best Practices Guidelines for Assessment" and "who administers short-term."

   Sec. 1(1). "Audiologist" means an audiologist licensed by the state of Indiana pursuant to the Indiana professional licensing agency board who meets the requirements outlines in Indiana's Best Practice Guidelines for Assessment and who administers short-term and long-term early hearing detection and intervention (EHDI) program follow-up.

   ISDH response: The agency agrees with this recommendation and has made the necessary changes.

3. **Clarification of Cost.** Insert a clause that states that the state designated laboratory will furnish the filter paper kits at no additional cost.

   Sec. 2.5(a) The state-contracted newborn screening laboratory will furnish filter paper kits, without additional cost, annually to hospitals, midwives, birthing centers, and other collections sources. Manufacturer and lot number for the filter paper must be included on the filter paper section of the kit in accordance with the Clinical Laboratory Standards

Institute (CLSI)-approved national standard. Sequential system control numbers for each collection kit must be printed on each information section of the collection card and on the filter paper section, if that section is detachable.

ISDH response: The agency agrees with this recommendation and has made the necessary changes.

4. **Correction of terms to match terms included in rule definitions.** Update all references to "birthing facility" to "birthing center" and some references of "physician" to "health care provider" in order to consistently match terms included in rule definitions.

   ISDH response: The agency agrees with this recommendation and has made the necessary changes.

5. **Clarification of responsibility as to who is responsible for providing written notice to parents.** Delete "administrator or a designated representative"

   Sec. 3-3-3(d). The hospital *~~administrator or a designated representative~~* or birthing center shall provide a written notice…

   ISDH response: The agency agrees with this recommendation and has made the necessary change.

6. **Clarify "hospital" to "collection source".** In order to ensure that midwiferies and other birthing centers are notified of missing newborn screening specimens, the following change (in italics) was made.

   Sec. 3-3-5(5). If the laboratory does not receive the repeat specimen within five (5) days, it shall send the *~~hospital~~ collection source…*

   ISDH response: The agency agrees with this recommendation and has made the necessary change.

7. **Clarification of "most current" version of Joint Committee on Infant Hearing (JCIH) Position Statement.** In order to cite the JCIH Position Statement referenced by medical professionals and the board, the following change (in italics) was made.

   Sec. 3-3-9(c). The department shall administer the EHDI program in a manner consistent with the *2007* joint committee on infant hearing (JCIH) position statement.

   ISDH response: The agency agrees with this recommendation and has made the necessary change.

8. **Clarification of "infants," "newborns," "babies" or "children".** Update all references to "infant(s)," "newborn(s)," "baby/babies" or "child(ren)" to consistently match the terms included in the rule definition.

   ISDH response: The agency agrees with this recommendation and has made the necessary change.

9. **Clarification of version of "Indiana's Best Practice Guidelines for Audiologic Assessment, Pediatric Amplification, and Intervention of the Infant.** Requested the date of the document be added which it has been in italics below.

Sec. 3-3-11(l)(2)(b). The facility: shall conduct the assessment in accordance with Indiana's Best Practice for Audiologic Assessment, Pediatric Amplification, and Intervention of the Infant *dated October 2010*.

ISDH response: The agency agrees with this recommendation and has made the necessary change.

10. **Clarification of responsible medical professional who provides home birth services.** In order to ensure that all physicians and midwives providing home birth services, regardless of whether or not these professionals work within a larger birthing center, are included in reporting responsibilities to ISDH, the following change (in italics) was made.

    Sec. 3-3-12(h)(3). Each *~~facility or midwife~~ midwife or physician* providing home birth services must complete an MSR by the fifteenth day of the following month.

    ISDH response: The agency agrees with this recommendation and has made the necessary change.

11. **Information provided to ISDH by all facilities that provide newborn hearing screening.** IHA suggested the following edits (in italics). He felt that information was not needed in the report.

    Sec. 3-3-12(j). Each screening facility shall make available the following items to the department's EHDI program in the reporting method and format specified by the department:
    (1) The name of the current person at the screening facility designated as the point of contact.
    (2) The type of hearing screening equipment utilized.
    (3) Equipment calibration records.
    (4) Whether the hearing screening program at that screening facility is conducted by screening facility personnel or is contracted to an outside entity.
    ~~(5) Name or names of person or persons providing staff training on equipment.~~
    ~~(6) Name or names of person or persons competent to perform hearing screenings at the screening facility.~~
    (7) Hearing screening protocols.
    (8) Test procedure or procedures used by the screening facility's universal newborn hearing screening program.
    (9) Pass criteria that minimally meet guidelines established by the department's EHDI program.
    (10) A description of the screening facility quality assurance/quality improvement program.

    ISDH response: The agency agrees with this recommendation and has made the necessary change.