Indiana Department of Health
410 IAC 3-3 Newborn Screening
LSA Document #23-798

Readoption Review

I. Continued Need for the Rule

There is a continued need for the rule because the newborn screening program is both federally and state mandated. The purpose of newborn screening is to identify critical and significant medical conditions at birth in order to provide the necessary interventions as early as possible. Newborn screening consists of three parts: the dried blood spot screen, hearing screen, and critical congenital heart disease screen. Successful newborn screening programs consist of six components: education, screening, short-term follow-up, diagnostic information, management (long-term follow-up) and evaluation/continuous quality improvement. The rule minimizes the expenses to regulated entities that are required to comply with the rule; persons who pay taxes or pay fees for government services affected by the rule; and consumers of products and services of regulated entities affected by the rule. The regulated entities that are required to comply with the rule include delivering hospital staff, midwives, health care providers, and the designated newborn screening laboratory. Expenses are minimized to maintain the required screening of conditions on the current panel. The rule minimizes expenses to persons who pay taxes or pay fees for government services affected by the rule. Families of infants born in Indiana will be subject to the newborn screening fee which funds the program's expenses. The hospital or healthcare provider bills the patient's insurance for the newborn screen.

The regulations are necessary and based on evidence-based practice to improve the outcomes of all children identified with conditions included in the newborn screening conditions. Although the newborn hearing screening is included in the regulation, the Indiana Early Hearing Detection and Intervention Program (EHDI) manages the newborn hearing screening process. The EHDI program is required to submit Indiana data and outcomes of deaf and hard of hearing children to both the CDC (Centers for Disease Control) and HRSA (Health Resources and Services Administration). The EHDI program collects all newborn hearing screening results and provides robust follow up procedures on newborns who do not pass the hearing screening until they receive confirmatory diagnosis or one year. The policies and regulations for EHDI include evidence based best practice for improving the outcomes of congenitally deaf and hard of hearing children. State and national data has continued to support the need for newborn hearing screenings as part of the newborn screening program.

The rule achieves the regulatory goal in the least restrictive manner. The responsible health care provider must perform the appropriate screenings or collect the appropriate sample for screening shortly after birth and the laboratory must screen the sample appropriately to ensure the goals of timely diagnosis, intervention, and treatment are met. This ultimately prevents

morbidity and mortality. There is no duplication of standards found in state or federal laws. Each state has oversight of their respective newborn screening program. The rule is written for ease of comprehension to ensure all regulated entities perform newborn screening consistently. The rule has practicable enforcement through state mandate to conduct newborn screening.

II. Analysis of fees, fines, and civil penalties under IC 4-22-2-19.6

The rule includes the newborn screening fee which covers the current costs for the dried blood spot program as well as the documentation and data collection for pulse oximetry and hearing screening results. Costs for the dried blood spot program include but are not limited to personnel, laboratory equipment and maintenance, laboratory assays, laboratory software, supplies, operational expenses, metabolic formula, care coordination services for infants identified at risk for a condition. The fee was last assessed and increased in 2021 based on the expenses of the dried blood spot program and the addition of adrenoleukodystrophy to the list of conditions required for screening. The fee is assessed as part of a standard process for evaluation of adding conditions. The EHDI program (except for the director position) is funded separately by federal CDC and HRSA funding. An increase in the fee is based on the increase in current expenses to maintain a successful newborn screening program in comparison to estimated revenue generated from the fee.

III. Complaints and Comments

The program has received comments from some hospitals stating confusion in the way the rule is written, specifically for blood spot rescreening of infants born premature or low birth weight, infants who will need a transfusion, and infants admitted to the neonatal intensive care unit. The program is currently working with the Office of Legal Affairs to amend the rules to resolve this confusion. No additional complaints nor comments have been received regarding this rule. The rule has consistently improved the outcomes for children identified by these conditions.

IV. Difficulties Encountered

There are no difficulties in the agency administering the rule, however, there have been challenges with regulated parties complying with the rule. As mentioned above, the agency received comments from hospitals stating confusion in following the rescreen protocols because of the way they are currently written. The agency has performed substantial education to hospitals to rectify the current confusion and plans to submit a request to change the rules to prevent this difficulty in hospitals complying with the rule in the future. There are additional challenges with midwives in complying with the rule. As the responsible health care provider, they are responsible for performing the hearing screen, the critical congenital heart disease screen, and collecting dried blood spot samples. Midwives often ask for hearing equipment or pulse oximeters to comply with the mandate, however, the newborn screening fee does not cover the cost for the state health department to supply this equipment. Newborn screening is state mandated and a successful public health program to prevent morbidity and mortality and ensure the best health outcomes for Indiana children. Therefore, all infants should be screened

regardless of whether the woman decides to give birth at a hospital, licensed birth center, or at home.

V. Changes in Technology, Economic Conditions, or Other Factors

Advancements in technology have created improved medical treatments for conditions identified by newborn screening. There are more effective gene therapies and other treatments that make newborn screening for rare diseases more effective at preventing morbidity and mortality. Technology in cochlear implants has only confirmed the necessity and importance of newborn hearing screening in order to diagnose deaf and hard of hearing children as early as possible. This is the only way to maximize the benefit of cochlear implants, language, health and overall development of Indiana's deaf and hard of hearing children. Advancements in surgical treatments of complex congenital heart defects have improved health outcomes for children and adults. Conditions will continue to be added to newborn screening as advancements in effective gene therapies and other treatments become available. The costs of all goods and services have increased which have impacted newborn screening. It is critical to sustain newborn screening to prevent associated morbidity, mortality and improved health for children. No additional factors have changed in newborn screening.

VI. Revised Regulatory Analysis

There are no changes to the cost benefit, economic impact, fiscal impact, or regulatory burden that affect the analysis of the rule.