

# Insights

## ISDH Issues Proposed Rule Amending the Newborn Screening Program

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On May 9, 2018, the Indiana State Department of Health issued a proposed rule to amend certain regulations governing the Newborn Screening Program in 410 Indiana Administrative Code 3-3 (the "Proposed Rule"). The Proposed Rule amends the list of disorders newborns must be screened for and the time period for collecting specimens for such screenings, adds a new pulse oximetry screening requirement, and increases the Newborn Screening Program fee.

Specifically, the Proposed Rule amends 410 Indiana Administrative Code 3-3-3 and expands the mandatory screening list of disorders for all infants and newborns. The Proposed Rule also shortens the time period in which a specimen must be collected to no earlier than 24 hours after birth and no later than 48 hours after birth. Additionally, the time period for collecting the specimen for screening low birth weight or preterm newborns is similarly shortened to no earlier than 24 hours after birth and no later than 48 hours after birth, with a requirement that a repeat specimen collection be taken no earlier than 14 days and no later than 30 days after birth or discharge (whichever occurs first).

The Proposed Rule also adds 410 Indiana Administrative Code 3-3-3.5 to require every newborn to be given a pulse oximetry screening examination no earlier than 24 hours after birth and no later than 48 hours after birth. Finally, the Proposed Rule increases the Newborn Screening Fee collected from hospitals, birthing centers, public health nurses, physicians, and midwives who submit newborn screening specimens from \$30 to \$100.

A public hearing regarding the Proposed Rule has been scheduled for June 15, 2018. Should you have any questions about this Proposed Rule or related matters, please contact Thomas N. Hutchinson at [thutchinson@kdlegal.com](mailto:thutchinson@kdlegal.com).