



What's new with

**Newborn  
Screening**

ACT 36 HB 883

# OVERVIEW OF NEWBORN SCREENING LAW IN PA

# Newborn Screening

- Current PA Newborn Screening law and regulation
- PA Newborn Screening law after Act 36
- Federal Newborn Screening law

# Newborn Screening

- Newborn Child Testing Act (35 P.S. § 623) requires PA Department of Health (DOH) program for screening newborn children and follow-up services for children with an abnormal screening test result.
  - Phenylketonuria (PKU), Maple Syrup Urine Disease (MSUD) and Sickle Cell Disease (hemoglobinopathies).
  - Religious exception to screening.
  - Health care providers collect blood specimens.
    - Initial screening.
    - Repeat specimens.
  - Authority to promulgate regulations.

# Newborn Screening

- Newborn Screening and Follow-Up regulations (28 Pa. Code § 28.1, et. seq.):
  - Add three screened conditions: Congenital Adrenal Hyperplasia (CAH), Galactosemia (GAL), and Primary Congenital Hypothyroidism.
  - Confidentiality provision.
  - DOH newborn screening pamphlet.
  - Religious objection recorded in medical record and signed by parent.
  - Health care provider to designate newborn screening coordinator.
  - Timing & responsibilities for collection of initial & repeat blood specimen.
  - Reporting test results to health care provider.
  - Semi-annual data reporting requirement.

# Newborn Screening

- Laboratories
  - Enter Participating Laboratory Agreement with DOH. (71 P.S. § 531(b))
  - Report screening test results for six conditions to DOH. (28 Pa. Code § 27.22)
- Reporting: Health Care Practitioners and Health Care Facilities reporting case of disease (six conditions) to DOH. (28 Pa. Code § 27.21(a))

# ACT 36

- Effective July 1, 2009, Act 36 of 2008 amends the Newborn Child Testing Act:
  - Codifies existing newborn screening practice in PA.
  - Adds new requirements.
- Newborn Screening and Follow-Up Technical Advisory Board approves DOH's Newborn Screening Program.

# ACT 36



- Follow-up services:
  - 22 conditions added:
    - Total of 28 conditions for follow-up.
    - American College of Medical Genetics standard screening for 29 conditions (28 conditions and hearing screening).
  - Relating to case management, referrals, confirmatory testing, assessment and diagnosis.
  - For inconclusive, unacceptable and for abnormal screening test results.

# ACT 36

- Laboratories reporting results for 28 conditions to DOH for follow-up activities.
- Other Reporting to DOH:
  - Test results based upon screening tests for diseases listed in the Act for newborn children.
  - Diagnosis based upon screening tests for diseases listed in the Act for newborn children.

# ACT 36

- Changes to the list of screened or followed conditions:
  - Approval of the Newborn Screening and Follow-Up Technical Advisory Board.
  - DOH publication in the PA Bulletin.
- Confidentiality: Test results for conditions listed are subject to the confidentiality provisions of the Disease Prevention Control Law.

# Newborn Screening

## Federal Level

- Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children recommendations:
  - Adoption of ACMG recommended screening panel by every State.
  - Funding to study existing newborn screening educational materials and pre-natal education.
- “Newborn Screening Saves Lives Act” establishes grant programs for:
  - Education and outreach on newborn screening.
  - Coordinated follow-up care.
  - Implementation of Advisory Committee recommendations.

# QUESTIONS

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