

**CHAPTER 28. SCREENING AND FOLLOW-UP FOR DISEASES OF
THE NEWBORN****GENERAL PROVISIONS**

- Sec.
28.1. Definitions.
28.2. Newborn diseases listed.
28.3. [Reserved].
28.4. [Reserved].
28.5. Confidentiality.

PURPOSE ADMINISTRATION OF TESTS

- 28.11. Informing the parent or guardian.
28.12. Religious objections.

SPECIMEN COLLECTION AND FOLLOW-UP

- 28.21. Responsibility for collecting and testing initial and repeat specimens.
28.22. Timing of initial specimen collection and handling in health care facilities.
28.23. Timing of initial specimen collection by health care practitioners.
28.24. Normal test results.
28.25. Circumstances require repeat specimens.
28.26. Timing of repeat specimen collection.
28.27. Abnormal screening test results.
28.28. Followup of symptoms consistent with newborn diseases.
28.29—28.31. [Reserved].

RECORDS

- 28.41. Recordkeeping requirements.

Authority

The provisions of this Chapter 28 issued under the Disease Prevention and Control Law of 1955 (35 P. S. §§ 521.1—521.21); and the Newborn Child Testing Act (35 P. S. § 621), unless otherwise noted.

Source

The provisions of this Chapter 28 adopted March 28, 1980, effective March 29, 1980, 10 Pa.B. 1387, unless otherwise noted.

Cross References

This chapter cited in 28 Pa. Code § 27.30 (relating to reporting cases of certain diseases in the newborn child); and 28 Pa. Code § 501.49 (relating to newborn infant care policies and procedures).

GENERAL PROVISIONS**§ 28.1. Definitions.**

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Abnormal confirmatory test result—A test result obtained from a specimen of blood, serum or plasma which is diagnostic of the newborn disease under investigation.

Abnormal screening test result—A test result obtained from a specimen collected on a specimen collection form which is outside the parameters for a normal test result according to testing criteria applicable to the screening test result.

Admission—The formal acceptance of custody or care by a birth center or hospital of a newborn child who is provided with bassinet or incubator, nutrition and continuous nursing service.

Birth center—As defined in section 802a of the Health Care Facilities Act (35 P. S. § 448.802a).

Days of age—The measurement of age of the newborn child in 24-hour periods so that a newborn child is one day of age 24 hours after the hour of birth.

Department—The Department of Health of the Commonwealth.

Discharge—The release of the newborn child from care and custody within and by birth center or hospital to the care and custody of the parent or guardian.

Health care practitioner—A licensed physician or a practitioner licensed to deliver and care for pregnant women and newborn children.

Health care provider—A birth center, hospital or health care practitioner.

Hemoglobin diseases—Sickle cell (SS, SC, S + other variant, S β Thalassemia, S O Arab) disease or trait or other clinically significant hemoglobin (CC, EE, F, H) disease or trait.

Hospital—As defined in section 802a of the Health Care Facilities Act.

Inconclusive screening test result—A test result obtained from a specimen collected on a specimen collection form that is equivocal according to criteria applicable to the screening test result and which indicates the need for a repeat specimen and repeat testing.

Initial specimen—The first sample of blood collected from the newborn child and submitted for testing purposes on a specimen collection form.

Newborn child—An infant less than 28 days of age.

Newborn screening program—The association of the Department, the testing laboratory and the health care provider to ensure that every newborn child born

in this Commonwealth has a blood specimen collected and screened for the newborn diseases in § 28.2 (relating to newborn diseases listed).

Presumptive abnormal test result—An abnormal screening test result which is sufficiently abnormal to indicate the probable presence of a newborn disease listed in § 28.2.

Repeat specimen—A specimen collected from a newborn child on a specimen collection form after the initial specimen.

Repeat test—The laboratory testing performed on a repeat specimen.

Specimen collection form—The official newborn screening program specimen form that includes both a multipart section for providing required information about the newborn child and a filter paper tab for application of blood.

Testing laboratory—The licensed clinical laboratory under contract with the Department to perform testing for the newborn diseases listed in § 28.2.

Transfer—The release of the newborn child from care and custody within and by a birth center or hospital and subsequent admission to another hospital.

Treatment center—A center under contract with the Department to provide expert consultation, diagnosis and treatment for children with a presumptive abnormal test result.

Unacceptable specimen—A blood specimen collected from a newborn child on a specimen collection form which is found to be unsuitable for testing in accordance with accepted laboratory testing standards as determined by the Department.

Authority

The provisions of this § 28.1 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

Source

The provisions of this § 28.1 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial pages (287186) and (240177).

§ 28.2. Newborn diseases listed.

A newborn child born in this Commonwealth shall be screened for the following diseases which may cause mental retardation, physical defects or death if not detected and treated soon after birth:

- (1) Congenital adrenal hyperplasia (CAH).
- (2) Galactosemia.
- (3) Hemoglobin diseases.
- (4) Maple syrup urine disease (MSUD).
- (5) Phenylketonuria (PKU).
- (6) Primary congenital hypothyroidism.

Authority

The provisions of this § 28.2 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

Source

The provisions of this § 28.2 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial page (240177).

Cross References

This section cited in 28 Pa. Code § 28.1 (relating to definitions); 28 Pa. Code § 28.11 (relating to informing the parent or guardian); 28 Pa. Code § 28.21 (relating to responsibility for collecting and testing initial and repeat specimens); 28 Pa. Code § 28.22 (relating to timing of initial specimen collection by birth centers or hospitals); and 28 Pa. Code § 28.28 (relating to follow-up of symptoms consistent with newborn diseases).

§ 28.3. [Reserved].**Source**

The provisions of this § 28.3 reserved May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial pages (240177) to (240178).

§ 28.4. [Reserved].**Source**

The provisions of this § 28.4 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial page (240178).

§ 28.5. Confidentiality.

(a) A health care provider, testing laboratory, the Department or any other entity involved in the newborn screening program may not release any identifying information relating to any newborn child screened in the newborn screening program to anyone other than a parent or guardian of the newborn child or the health care provider for the newborn child designated by a parent or the guardian except as follows:

- (1) As may be necessary to provide services to the newborn child.
- (2) With the consent of the newborn child's parent or guardian.
- (3) With the child's consent when the child is 18 years of age or older, has graduated from high school, has married or has been pregnant.

(b) Only the Department will have the authority to release or authorize the release of nonidentifying information concerning the newborn screening program.

Authority

The provisions of this § 28.5 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

Source

The provisions of this § 28.5 adopted May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435.

PURPOSE AND ADMINISTRATION OF TESTS**§ 28.11. Informing the parent or guardian.**

Prior to specimen collection, the health care provider shall provide the pregnant woman, prior to the infant's birth, or the mother or guardian, after the infant's birth, with a pamphlet supplied by the Department to explain the nature of the newborn screening blood tests for the diseases in § 28.2 (relating to newborn diseases listed).

Authority

The provisions of this § 28.11 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

Source

The provisions of this § 28.11 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial page (240178).

§ 28.12. Religious objections.

(a) A health care provider may not collect or cause to be collected, a specimen from a newborn child if the parent or guardian of the newborn child objects on the ground that the specimen collection conflicts with religious beliefs or practices held by the parent or guardian.

(b) If the parent or guardian of the newborn child objects to the collection of the specimen for screening on the ground that the specimen collection conflicts with religious beliefs or practices held by the parent or guardian, the health care provider shall ensure that the recorded objection of the parent or guardian is entered into the medical record of the newborn child. The entry shall include a written statement of the objection signed by the parent or guardian.

Authority

The provisions of this § 28.12 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

Source

The provisions of this § 28.12 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial page (240179).

SPECIMEN COLLECTION AND FOLLOW-UP**§ 28.21. Responsibility for collecting and testing initial and repeat specimens.**

(a) A birth center or hospital shall collect or cause to be collected from each newborn child delivered in that birth center or hospital, in accordance with instructions for newborn screening specimen collection in subsection (d), the initial and repeat specimens necessary to conduct the tests necessary for the detection of the newborn diseases specified in § 28.2 (relating to newborn diseases listed).

(b) When a newborn child is delivered other than in a birth center or hospital, the health care practitioner who delivered the newborn child shall collect or cause to be collected from the newborn child, in accordance with instructions for newborn screening specimen collection in subsection (d), the initial and repeat specimens necessary to conduct the tests necessary for the detection of the newborn diseases specified in § 28.2.

(c) The health care provider shall designate a newborn screening coordinator to do the following:

(1) Ensure that a specimen collection form contains correct and complete information.

(2) Ensure that the individual who collected the specimen records that act in the newborn child's medical record.

(3) Send all specimens collected by first class mail to the testing laboratory within 24 hours of collection.

(4) Record the laboratory screening results in the newborn child's medical records.

(5) Check each newborn child's record prior to discharge or release to ensure that a specimen has been collected.

(6) Ensure, in the event of transfer of the newborn child prior to 48 hours of age, that the receiving health care provider has been notified that it has the responsibility to collect the initial specimen.

(7) Assist the Department in follow-up of an abnormal or presumptive abnormal test result.

(8) Follow-up inconclusive test results.

(9) Receive notification from the testing laboratory or from the Department of the need for a repeat specimen.

(d) The health care provider shall ensure that the individual responsible for specimen collection shall collect the specimen necessary to conduct tests in accordance with consensus standards developed by the National Committee for

Clinical Laboratory Standards (NCCLS) and accepted by the Department. The Department will publish these standards, and any revisions thereto, in a notice in the *Pennsylvania Bulletin*.

Authority

The provisions of this § 28.21 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

Source

The provisions of this § 28.21 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial page (240179).

Cross References

This section cited in 28 Pa. Code § 501.49 (relating to newborn infant care policies and procedures).

§ 28.22. Timing of initial specimen collection by birth centers or hospitals.

(a) A birth center or hospital shall collect the initial specimen from each newborn child regardless of feeding history or medical condition, as close to 48 hours of age as possible but not later than 72 hours of age unless the newborn child falls into one of the following categories:

(1) *Transfer*. If the newborn child is transferred to another hospital for continuing care prior to 48 hours of age, the hospital to which the newborn child has been transferred shall collect a specimen from the newborn child, regardless of feeding history or medical condition, as close to 48 hours of age as possible but not later than 72 hours of age.

(2) *Exchange transfusion*. If the newborn child is to undergo an exchange transfusion, the birth center or hospital shall collect the initial specimen for testing immediately prior to the exchange transfusion.

(3) *Early discharge*. If the newborn child is discharged from the birth center or hospital before 24 hours of age, the birth center or hospital shall collect the initial specimen from the newborn child as close to the time of discharge as is practicable, regardless of feeding history or medical condition. The birth center or hospital shall give the parent or guardian in whose care and custody the newborn child is discharged written notification of the need for a repeat specimen and shall also provide instructions to the parent or guardian for obtaining a repeat specimen from the newborn child as described in § 28.26 (relating to timing of repeat specimen collection).

(b) When a newborn child, who was delivered other than in a birth center or hospital, is admitted to a hospital within the first 27 days of age and the hospital has received no record of results of an approved screening test for the newborn diseases in § 28.2 (relating to newborn diseases listed), the hospital to which the

newborn child is admitted shall collect the initial specimen within 48 hours of admission to the hospital and shall send the specimen to the testing laboratory specified by the Department within 24 hours of collection.

Authority

The provisions of this § 28.22 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

Source

The provisions of this § 28.22 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial pages (240179) to (240180).

Cross References

This section cited in 28 Pa. Code § 501.49 (relating to newborn infant care policies and procedures).

§ 28.23. Timing of initial specimen collection by health care practitioners.

A health care practitioner who delivers a newborn child other than in a birth center or hospital shall collect or cause to be collected the initial specimen from the newborn child, regardless of feeding history or medical condition, as close to 48 hours as possible but not later than 72 hours of age.

Authority

The provisions of this § 28.23 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

Source

The provisions of this § 28.23 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial page (240180).

Cross References

This section cited in 28 Pa. Code § 501.49 (relating to newborn infant care policies and procedures).

§ 28.24. Normal test results.

(a) Within 7-calendar days following the day when the testing laboratory obtains the normal test results, the testing laboratory shall send those results to the health care provider that collected the specimen from the newborn child.

(b) The health care provider to whom the normal test results are reported shall record the test results in the medical record of the newborn child.

Authority

The provisions of this § 28.24 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

Source

The provisions of this § 28.24 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial page (240180).

Cross References

This section cited in 28 Pa. Code § 501.49 (relating to newborn infant care policies and procedures).

§ 28.25. Circumstances requiring repeat specimens.

(a) The health care provider responsible for collecting the initial specimen shall collect or cause to be collected and submit for testing a repeat specimen if the initial specimen collected is either of the following:

- (1) Unacceptable for testing.
- (2) Yields an inconclusive screening test result.

(b) If a birth center or hospital collects the initial specimen from a newborn child prior to 24 hours of age because the newborn child is discharged from the birth center or hospital prior to 24 hours of age, the birth center or hospital shall collect or cause to be collected a repeat specimen.

(c) If the initial specimen collected yields an abnormal screening test result, the Department may require the health care provider responsible for collecting the initial specimen to collect a repeat specimen.

Authority

The provisions of this § 28.25 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

Source

The provisions of this § 28.25 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial page (240180).

Cross References

This section cited in 28 Pa. Code § 501.49 (relating to newborn infant care policies and procedures).

§ 28.26. Timing of repeat specimen collection.

(a) When the newborn child has been discharged from a birth center or hospital before 24 hours of age, the birth center or hospital shall collect or cause to

be collected a repeat specimen from the newborn child, regardless of feeding history or medical condition, as close to 48 hours of age as possible but not later than 72 hours of age.

(b) When the initial specimen is unacceptable or when the initial specimen yields an inconclusive screening test result, the Department or testing laboratory will notify the health care provider that collected the initial specimen. Within 72 hours of receipt of notice from the Department or testing laboratory, the health care provider that collected the initial specimen shall collect or cause to be collected from the newborn child a repeat specimen.

(c) If the health care provider cannot locate a parent or guardian of the newborn child within 4 days of notification of need for a repeat specimen, the health care provider shall contact the Department for consultation regarding additional means for locating a parent or guardian.

Authority

The provisions of this § 28.26 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

Source

The provisions of this § 28.26 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial pages (240180) to (240181).

Cross References

This section cited in 28 Pa. Code § 28.22 (relating to timing of initial specimen collection and handling in health care facilities); and 28 Pa. Code § 501.49 (relating to newborn infant care policies and procedures).

§ 28.27. Abnormal screening test results.

(a) When testing of the initial or repeat specimen yields an abnormal screening test result, the Department will notify the health care provider that collected the specimen. The health care provider shall promptly notify a parent or guardian of the newborn child.

(b) If the health care provider cannot locate the newborn child's parent or guardian within 48 hours of receiving notice from the Department, the health care provider shall contact the Department for consultation regarding additional means for locating a parent or guardian.

(c) The Department will assist the health care provider with and make available confirmatory testing.

(d) If the result of the confirmatory test is abnormal, the Department will assist with referral for diagnosis, treatment, and other follow-up services for the newborn child through designated treatment centers or clinical specialists.

Authority

The provisions of this § 28.27 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

Source

The provisions of this § 28.27 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial page (240181).

Cross References

This section cited in 28 Pa. Code § 501.49 (relating to newborn infant care policies and procedures).

§ 28.28. Follow-up of symptoms consistent with newborn diseases.

When a sick child exhibits symptoms suggestive of a newborn disease listed in § 28.2 (relating to newborn diseases listed) and has not already been determined to have one of those newborn diseases, the health care provider to whom care of the sick child has been entrusted by the parent or guardian shall collect and submit a blood specimen for newborn disease testing in accordance with standard diagnostic procedures.

Authority

The provisions of this § 28.28 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

Source

The provisions of this § 28.28 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial page (240181).

Cross References

This section cited in 28 Pa. Code § 501.49 (relating to newborn infant care policies and procedures).

§§ 28.29—28.31. [Reserved].**Source**

The provisions of these § 28.29—28.31 reserved May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial pages (240181) to (240182).

RECORDS**§ 28.41. Recordkeeping requirements.**

A health care provider offering maternity and newborn services shall collect and forward data semiannually to the Department on the number of patients for

whom specimens for newborn disease testing have been collected and the number of patients for whom the specimens have not been collected, together with the reason in each instance for the failure to collect.

Authority

The provisions of this § 28.41 amended under section 16(a) of the Disease Control and Prevention Act of 1955 (35 P. S. § 521.16(a)); sections 2102(g) and 2111(b) of The Administrative Code of 1929 (71 P. S. §§ 532(g) and 541(b)); and sections 3 and 5 of the Newborn Child Testing Act (35 P. S. §§ 623 and 625).

Source

The provisions of this § 28.41 amended May 17, 2002, effective May 18, 2002, 32 Pa.B. 2435. Immediately preceding text appears at serial pages (240182) to (240183).

Cross References

This section cited in 28 Pa. Code § 501.3 (relating to reports/contact person).

[Next page is 29-1.]