ADOPTIONS SECTION

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF FAMILY HEALTH SERVICES

SPECIAL CHILD HEALTH SERVICES

NEWBORN SCREENING AND GENETIC SERVICES

DIVISION OF PUBLIC HEALTH AND ENVIRONMENTAL LABORATORIES

Notice of Readoption

Newborn Biochemical Screening

Readoption with Technical Changes: N.J.A.C. 8:18

Authority: N.J.S.A. 26:2-110, 26:2-110a, 26:2-111, 26:2-111.1, 26:2-111.2, 26:2-111.3, 26:2-111.4, 26:2-111.8, and 26:2-111.9.

Authorized By: Kaitlan Baston, MD, MSc, DFASAM, Commissioner, Department of Health.

Effective Dates: December 4, 2024, Readoption;

January 6, 2025, Technical Changes.

New Expiration Date: December 4, 2031.

Take notice that, pursuant to N.J.S.A. 52:14B-5.1, the rules at N.J.A.C. 8:18, Newborn Biochemical Screening, were scheduled to expire on February 6, 2025.

N.J.A.C. 8:18-1 establishes standards applicable to the Department of Health (Department), hospitals and birthing centers, physicians, midwives, home health agencies, public health officers, and parents of newborns attendant to the collection,

transmission, and testing of bloodspots taken from newborns for purposes of the mandated newborn screening, and related follow-up activities.

The Department is developing rulemaking to revise and update existing N.J.A.C. 8:18 and anticipates filing this rulemaking with the Office of Administrative Law for processing in the ordinary course. However, this rulemaking would not be concluded prior to the expiration of existing N.J.A.C. 8:18. Therefore, the Department is readopting the chapter with technical changes to maintain its effectiveness pending the completion of the rulemaking in development. The Department is making technical changes throughout the chapter to correct grammar, update references to program names, contact information, and website addresses, and correct references to the name of the Department pursuant to N.J.S.A. 26:1A-2 and 2.1.

The Commissioner has reviewed N.J.A.C. 8:18 and determined that, pending the finalization of the anticipated rulemaking described above, and subject to the technical changes described above, the existing chapter remains necessary, proper, reasonable, efficient, understandable, and responsive for the purposes for which it was originally promulgated and should be readopted. Therefore, pursuant to N.J.S.A. 52:14B-5.1.c(1), N.J.A.C. 8:18 is readopted and shall continue in effect for seven years.

Full text of the technical changes follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 1. NEWBORN BIOCHEMICAL SCREENING

8:18-1.2 Definitions

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

"Acknowledgment of Receipt of Notice of Availability of Supplemental Newborn Screening" or "Acknowledgment" means the [second page] **gray box** of the Notice.

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"Birth attendant" means [the] **a** physician, [nurse-midwife] **midwife**, or other person who attends a non-hospital birth and who is required to register the birth of a child [under] **pursuant to** N.J.S.A. 26:8-30 or 26:8-31.

. . .

"Department" means the New Jersey [State] Department of Health [and Senior Services].

"Follow-up Program" means **the** Newborn Screening and Genetic Services **Program**, Special Child Health [and Early Intervention] Services, Division of Family

Health Services, Public Health Services Branch, New Jersey Department of Health [and Senior Services], PO Box 364, Trenton, NJ 08625-0364.

. . .

"Home health agency" means a facility [which is licensed by] **that** the [New Jersey] Department [of Health and Senior Services] **licenses** to provide preventive, rehabilitative, and therapeutic services to [the] **a** patient[s] in the patient's home or place of residence.

. . .

"Notice of Availability of Supplemental Newborn Screening" or "Notice" means the document promulgated by the Department pursuant to N.J.S.A. 26:2-111.1b(1), that explains the availability of supplemental newborn screening.

1. The Notice and Acknowledgment are available on the website of the

Follow-up Program at [http://nj.gov/health/fhs/prenatal/screening.shtml]

https://www.nj.gov/health/fhs/nbs/bloodspot
and the Department's forms page
at http://nj.gov/health/forms, form numbers SCH-7 for the English version and SCH-7A for the Spanish version, as amended and supplemented.

2. (No change.)

. .

"Specimen collection form" means the current specimen collection form [as] provided by the Department [of Health and Senior Services].

. . .

"Testing laboratory" means the [Inborn Errors of Metabolism] **Newborn Screening** Laboratory, Division of Public Health and Environmental Laboratories, New Jersey Department of Health [and Senior Services], PO Box 371, Trenton, NJ 08625-0371.

8:18-1.13 Confidentiality of reports

(a) The reports made pursuant to this subchapter are to be used only by the Department [of Health and Senior Services] and other agencies that may be designated by the Commissioner and shall not otherwise be divulged or made public, so as to disclose the identity of any person and shall be deemed "information relating to medical history, diagnosis, treatment or evaluation" within the meaning of Executive Order No. 26, § 4b1 ([McGreevey, August 13,] 2002), and, therefore, not "government records" subject to public access or inspection within the meaning of N.J.S.A. 47:1A-1 et seq., particularly 47:1A-1.1.

(b) (No change.)