



State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 358
TRENTON, N.J. 08625-0358

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

www.nj.gov/health

JUDITH M. PERSICILLI, RN, BSN, MA
Commissioner

In Re Licensure Violation:	:	
	:	
THE BIRTH CENTER OF NEW JERSEY	:	DIRECTED PLAN OF
	:	CORRECTION
(NJ Facility ID# N25089)	:	
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TO: Nicola Pemberton, Executive Director
The Birth Center of New Jersey
1945 US 22 West
Union, New Jersey 07083
E-mail address: info@BirthCenterNJ.com and npemb1@yahoo.com

The Health Care Facilities Planning Act (N.J.S.A. 26:2H-1 et seq.) (the Act) provides a statutory scheme designed to ensure that all health care facilities are of the highest quality. Pursuant to the Act and N.J.A.C. 8:43E-1.1 et seq., General Licensure Procedures and Standards Applicable to All Licensed Facilities, the Commissioner of Health is authorized to inspect all health care facilities and to enforce the Standards for Licensing of Ambulatory Care Facilities set forth at N.J.A.C. 8:43A-1.1 et seq.

The Legislature has declared that “[n]ewborn screening is an essential public health activity that strives to screen every newborn infant for a variety of congenital disorders, which, if not detected and managed early, can result in significant morbidity, mortality, and disability.” N.J.S.A. 26:2-110. N.J.A.C. 8:18-1.5(a) provides that it is the responsibility of the birth attendant to:

1. Submit or cause to be submitted to the testing laboratory an initial blood specimen taken before the infant is 48 hours old from all infants born outside of, and not admitted to, a hospital;
2. Follow the specimen collection and submission procedures specified in N.J.A.C. 8:18-1.4(a)5 through 8 and 15 through 16;
3. Collect or cause to be collected a repeat specimen when requested by the testing laboratory, and shall submit or cause such repeat specimen to be submitted to the testing laboratory within 24 hours of collection; and

4. If a repeat specimen is not obtained, place on the infant's medical record written documentation of efforts made to secure or cause to be secured a repeat specimen within 14 days of receipt of the laboratory report.

"Birth attendant" means the physician, nurse-midwife or other person who attends a non-hospital birth and who is required to register the birth of a child under N.J.S.A. 26:8-30 or 26:8-31. N.J.A.C. 8:43A-28.7(d).

N.J.A.C. 8:18-1.4(a) provides that it is the responsibility of the chief executive officer to, among other things:

- Cause the development and implementation of written policies and procedures, to be reviewed by the Department and revised as required, for the early detection and treatment of biochemical disorders, pursuant to N.J.S.A. 26:2-110 and 111
- Designate a staff person to coordinate hospital or agency screening practices and function as a contact person with the Follow-up Program
- Assure that the infant's parent is informed of the purpose and need for newborn screening and given newborn screening educational materials provided by the Follow-up Program
- **Assure that specimens are taken before the infant is 48 hours old.** If an infant is transferred or discharged from a facility prior to 48 hours of life, a specimen shall be collected prior to discharge unless there are medical reasons to prevent specimen collection
- Assure that the parent shall be instructed directly and in writing of the need to collect a repeat specimen between the third and seventh day of life if the infant is less than 24 hours of age
- **Assure that all specimens are forwarded to the testing laboratory within 24 hours of collection** by next day delivery, or in the event service is unavailable with respect to Sundays and Federally designated holidays, then as soon thereafter as is practicable, using an account number the Department shall establish with an overnight package delivery service, which number the Department shall make available upon request

[N.J.A.C. 8:18-1.4(a)(emphasis supplied)].

Pursuant to N.J.A.C. 8:43A-28.7(d), "[t]he birth center shall have a written protocol to be followed in completing and reporting all newborn screening tests to the Department."

In the case of any infant whose parent or guardian object to testing on the grounds that it would conflict with his or her religious tenets or practices, the chief executive officer or responsible physician or birth attendant or home health agency shall assure that documentation of refusal to test becomes part of the infant's permanent medical record and that a copy of documentation of refusal is forwarded to the testing laboratory. N.J.A.C. 8:18-1.12.

Pursuant to N.J.A.C. 8:43A-3.2(a), "[t]he facility shall comply with applicable Federal, State, and local laws, rules, and regulations."

N.J.S.A. 26:2-111 establishes that the Department "shall provide laboratory services and a follow-up program on positive screen cases in order that measures may be taken to prevent death or intellectual or other permanent disabilities" and that the "[t]he program shall provide timely information and recommendations for referral to specialist treatment centers for newborn infants who screen positive for disorders." The section does not apply "if the parents of a newborn infant provide written notice to the hospital or birthing facility where the newborn infant was delivered, in a manner designated by the commissioner, that they object to the screening on the grounds that it would conflict with their religious tenets or practices."

LICENSURE VIOLATIONS

The Department of Health's Newborn Screening Laboratory (hereinafter "NSL") determined that The Birth Center of New Jersey (hereinafter "Birth Center"), has failed to comply with applicable licensing regulations by failing to pay for initial newborn screening kits and by utilizing "repeat" kits in place of initial screening kits even though they are missing critical information for testing, or, alternatively, sending the newborn to a birthing hospital. These methods delay the care of newborns and fail to comply with the law, which requires that newborn screening must be completed within 24 to 48 hours after birth.

As opposed to the initial kits, the repeat kits do not contain the following critical information:

- Gestational Age: Used for calculating results for Severe Combined Immunodeficiency (SCID) and Hemoglobinopathy (HGB) – 5 total disorders
- Time of Birth: Used for calculating results for Congenital Hypothyroidism (CH), Congenital Adrenal Hyperplasia (CAH) and Amino Acid Profile (AA) – 16 total disorders
- Mother's demographic information: Not used for testing/results but used for data analysis

A review of the Vital Events Registration and Information (VERI) Birth Record from January 1, 2022, to April 17, 2023, reveals a total of 151 infants identified as having Birth Center as their associated facility. The VERI Birth record reveals the following:

- 13 infants out of 151 did not receive a screen. Of the 13, the NSL only received documentation of refusal for one. The other 12 should either have had a screen or documentation of religious exemption, the only allowable refusal.
- The average age of collection was four days old (required within 24 to 48 hours) and average receipt in the laboratory was seven days (required 24 hours after collection)

In addition to the clinical violations, Birth Center has also failed to pay for the initial newborn screening kits required by N.J.S.A. 26:2-111. See also N.J.A.C. 8:45-2.1(c). Birth Center last paid for newborn screening kits in May 2022 and has placed three orders since then for initial kits but has not sent payment to complete the orders. The Department advanced 50-100% of these orders but due to nonpayment cannot send any more initial kits until payment is received. The facility has made no efforts to enter into payment arrangements with the Department. Instead, the facility has used the repeat kits or sent the newborn to a birthing hospital. The NLS has been in contact with the facility numerous times but the facility has either been nonresponsive or has replied that the "check is in the mail." On March 10, 2023, the Department sent the facility a 30-day notice with an invoice for \$10,500. The amount due for initial kits as of April 27, 2023, was \$10,950.

These violations pertain to the care of patients using the services at Birth Center.

DIRECTED PLAN OF CORRECTION

The Commissioner of the Department of Health hereby directs the following plan of correction. The facility shall submit to the Department daily reports, certified under penalty of law (see enclosure for signature template), with the following information:

- The name of each infant born within the last 48 hours
- Their parents' names and contact information and mother's demographic information
- The date and time of birth and gestational age
- The date and time specimens are taken

- The date and time specimens are forwarded to the testing laboratory (which must be within 24 hours)
- If a parent refuses testing, the refusal and the reason must be certified by both the attendant and Chief Executive Officer

The facility should send these daily progress reports by 4:00 p.m. to Julie.Trott@doh.nj.gov, Erin.Sembler@doh.nj.gov and Brielle.Easton@doh.nj.gov.

In addition, the facility is directed to maintain timely communication with the Department, as may be required.

Department staff will monitor facility compliance with this order to confirm compliance with this Directed Plan of Correction and to determine whether corrective measures are implemented by the facility in a timely fashion.

This Directed Plan of Correction shall remain in place until the facility is otherwise notified in writing by a representative of this Department.

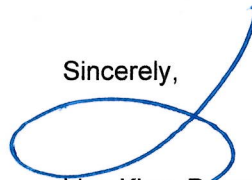
This enforcement action was taken in accordance with the provisions set forth at N.J.A.C. 8:43E-3.1 (Enforcement Remedies Available) in response to serious licensure violations identified by Department staff based on record review.

CURTAILMENT OF ADMISSIONS AND OTHER REMEDIES

At this time, the Department is not imposing a curtailment of admissions. The Department may, however, impose a curtailment of admissions if Birth Center fails to comply with the Directed Plan of Correction or fails to timely correct the violations. See N.J.A.C. 8:43E-3.6 (Curtailment of Admissions). In addition, failure to comply with the newborn screening program and pay the outstanding invoices may jeopardize renewal of the facility's license. Finally, failure to comply with these and any other applicable requirements, as set forth in pertinent rules and regulations, may result in the imposition of penalties.

Thank you for your attention to this important matter and for your anticipated cooperation. If you have any questions concerning the Directed Plan of Correction, please contact Lisa King, Office of Program Compliance, at Lisa.King@doh.nj.gov.

Sincerely,



Lisa King, Program Manager
Office of Program Compliance
Division of Certificate of Need and Licensing

DATED: May 11, 2023
E-MAIL
Control #AX23009
Enclosure

- C. Nursing Home Administrators Licensing Board
Frank Skrajewski, Health Facilities Evaluation And Licensing
Pamela Lebak, Health Facility Survey and Field Operations
Kimberly Hansen, Health Facility Survey and Field Operations
Julie Trott, Health Facility Survey and Field Operations

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Erin Sembler, Health Facility Survey and Field Operations
Brielle Easton, Newborn Screening Laboratory

Certification

I certify that the foregoing statement and/or information is true and correct.

Date: _____

Warning: It is an offense for any person to offer for filing with a governmental agency any written instrument knowing that the instrument contains a false statement or false information, punishable by a fine and or imprisonment (N.J.S.A. 2C:28-3)

