

**STATE OF NEW JERSEY**  
**DEPARTMENT OF HEALTH**  
**NOTICE OF RULE WAIVER/MODIFICATION/SUSPENSION**  
**PURSUANT TO EXECUTIVE ORDER NO. 103 (MURPHY)(MARCH 9, 2020)**  
**COVID-19 STATE OF EMERGENCY**

**Temporary Rule WAIVER/MODIFICATION OF N.J.A.C. 8:44-2.14 – Collection Stations and Patient Service Centers and N.J.A.C. 8:45-1.3 – Licensure Fee for Collection Stations adopted by THE COMMISSIONER OF THE DEPARTMENT OF HEALTH**

Date: June 5, 2020

Authority: N.J.S.A. App. A:9-45 & App. A:9-47; Executive Order No. 103 (Murphy)(“EO 103”)

Effective Date: June 5, 2020

Expiration Date: Forty-five (45) days after the Public Health Emergency has ended

This is an emergency adoption of a temporary rule waiver/modification of the licensing requirements for collection stations at N.J.A.C. 8:44-2.14 and the licensing fee for collection stations set out at N.J.A.C. 8:45-1.3. Section 6 of EO 103 issued in response to the COVID-19 pandemic, authorizes agency heads to waive/suspend/modify any existing rule, where the enforcement of the rule would be detrimental to the public welfare during the emergency, notwithstanding the provisions of the Administrative Procedure Act or any law to the contrary. Pursuant to that authority, and with the approval of the Governor and in consultation with the State Director of Emergency Management, the Commissioner of the Department of Health is waiving/modifying its rules as follows:

COVID-19 is a contagious, and at times fatal, respiratory disease that is responsible for the 2019 novel coronavirus outbreak. The Centers for Disease Control and Prevention (CDC) expects that additional cases of COVID-19 will be identified in the coming days, including more cases in the United States, and that person-to-person spread is likely to continue to occur. As of June 4, 2020, there were at least 162,530 positive cases of COVID-19 in New Jersey, with at least 11,970 of those cases having resulted in death. One of the primary methods to stem the outbreak is to increase the availability and accessibility of diagnostic testing, which will allow public health officials to identify and reduce the spread of COVID-19 in New Jersey.

Under N.J.A.C. 8:44-2.14, collection stations for laboratories must be licensed by the Department of Health’s Clinical Laboratory Improvement Services (CLIS). To obtain a license for a collection station, a laboratory must submit a completed CL-18 form to CLIS and pay the \$200 fee set out at N.J.A.C. 8:45-1.3(a). Each collection station must be separately licensed. Additionally, N.J.A.C. 8:44-2.14(b)(2)-(6) restricts the physical location and layout for collection stations.

The waiver of these requirements is necessary to ensure that licensed clinical laboratories have adequate temporary collection stations for COVID-19 related testing throughout the State. This will help provide greater access and convenience to New Jersey residents seeking COVID-19 testing as the testing capacity in New Jersey increases during this public health emergency.

Pursuant to this rule waiver/modification, New Jersey licensed clinical laboratories may open affiliated collection stations to collect specimens for COVID-19 testing without completing the collection station licensing process or paying the required fee. Additionally, the temporary collection stations do not need to comply with the location and layout requirements set out at N.J.A.C. 8:44-2.14(b)(2)-(6). This waiver is only applicable to laboratories that are properly licensed with the New Jersey Department of Health pursuant to N.J.A.C. 8:44. Collection stations for specimens unrelated to COVID-19 testing must continue to comply with the licensure and fee requirements set out at N.J.A.C. 8:44-2.14 and N.J.A.C. 8:45-1.3. Clinical laboratories that open a temporary COVID-19 specimen collection station must contact Patricia Jackman at the Department via e-mail at [Patricia.Jackman@doh.nj.gov](mailto:Patricia.Jackman@doh.nj.gov), and provide (1) the name of the parent clinical laboratory; (2) the address where the temporary collection station will be located; and (3) a contact phone number and e-mail for a representative from the parent laboratory.

This temporary waiver/modification is effective only during the period of Public Health Emergency declared by Governor Philip D. Murphy in Executive Order No. 103. This temporary rule waiver/modification shall expire forty-five (45) days after the Public Health Emergency has ended. Upon the expiration of this temporary rule waiver/modification, all collection stations will need to comply with the licensure and fee requirements set out at N.J.A.C. 8:44-2.14 and N.J.A.C. 8:45-1.3.

Full Text of the affected regulations follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

#### N.J.A.C. 8:44-2.14 Collection Stations and Patient Service Centers

(a) A clinical laboratory that operates a collection station in a physician's office, also known as in-office phlebotomy, shall be limited to collecting specimens from patients of the medical practice in which the collection station is located, and shall comply with the following provisions:

1. The collection station shall be licensed under this chapter and the license shall be prominently displayed in the collection station area;
2. No reimbursement, fees or any other type of direct or indirect payment shall be made to the physician including, but not limited to, payment of rent or other consideration for the space used for the collection station;
3. Laboratory staff in the collection station shall perform no services for the physician that are normally the responsibility of the physician's office staff, such as taking patient vital signs or other nursing functions, drawing specimens or performing testing for the physician office laboratory or performing clerical services;
4. Laboratory staff in the collection station shall not be shared with, jointly employed or retained as independent contractors by the physician or persons affiliated with the office where the collection station is located;

5. Except as necessary for the reporting of test results, the laboratory shall not provide office supplies, equipment, waste disposal services, test kits for the physician's own use, electronic medical records systems or other goods or services to the physician; and
6. A copy of the signed lease or agreement shall be made available to the Department upon request.

(b) A patient service center/collection station intended to serve the general public shall not be operated within a physician's office and shall be:

1. Open to, and serve the general public, and shall not be restricted to serving the patients of one or more of specific medical practices;
2. Located in a free standing building or occupy a space in a public access building;
3. Accessed directly through an exterior building entrance or from a public access foyer or hallway that clearly identifies the name of the laboratory and the days and hours of operation.
  - i. Access shall not be through a physician's office;
4. Identified to the public by clearly visible signage on the exterior of the building and listed in the building's on-site directory.
  - i. Advertisements and other public notices by the laboratory shall list the address and telephone number of the patient service center;
5. Self contained with regard to all aspects of the operations including the waiting room, reception area, phlebotomy rooms, restroom facilities and specimen and supply storage areas; except that the patient service center may share a common waiting area that is used by all the tenants of a building or a floor of the building, provided that two or more tenants renting separate office spaces are not referring physicians or healthcare providers; and
6. A copy of the signed written lease shall be made available to the Department upon request.

(c) The provisions of (a) and (b) above shall not be interpreted as prohibiting a laboratory from operating a patient service center in rented space in a professional building, which may be owned by a physician or group of physicians provided that the conditions of this section are met.

**(d) Notwithstanding the above provisions, during the period of the COVID-19 Public Health Emergency, clinical laboratories may open collection stations without applying for a collection station license under the following conditions:**

1. **The parent clinical laboratory for the collection station is licensed by the New Jersey Department of Health's Clinical Laboratory Improvement Services;**
2. **The temporary collection station is only used to collect specimens for COVID-19 testing; and**
3. **The clinical laboratory notifies the Department when it opens a temporary COVID-19 collection station by e-mailing Patricia Jackman at [Patricia.Jackman@doh.nj.gov](mailto:Patricia.Jackman@doh.nj.gov) and provides the following information:**
  - i. **The name of the parent clinical laboratory;**

- ii. The address where the temporary collection station is located; and
- iii. A contact phone number and e-mail for a representative from the parent clinical laboratory.

(e) Temporary collection stations meeting the requirements of paragraph (d) above, are exempt from complying with the requirements of subparagraph (b)(2)-(6) above.

(f) This temporary waiver/modification is effective only during the period of Public Health Emergency declared by Governor Philip D. Murphy in Executive Order No. 103. This temporary rule waiver/modification shall expire forty-five (45) days after the Public Health Emergency has ended. Upon the expiration of this temporary rule waiver/modification, all collection stations will need to comply with the licensure requirements set out at N.J.A.C. 8:44-2.14.

### N.J.A.C. 8:45-1.3 Licensure Fees

(a) Initial and annual renewal licensure fees shall be identical and are prescribed by the following table. Fees noted shall be payable per each specialty.

Specialty	Total Number of Employees of Entire Laboratory<1>				
	1-9	10-29	30-49	50-89	90 or more
Urinalysis	\$ 200.00	\$ 250.00	\$ 300.00	\$ 350.00	\$ 400.00
Mycobacteriology	\$ 200.00	\$ 250.00	\$ 300.00	\$ 350.00	\$ 400.00
Parasitology	\$ 200.00	\$ 250.00	\$ 300.00	\$ 350.00	\$ 400.00
Mycology	\$ 200.00	\$ 250.00	\$ 300.00	\$ 350.00	\$ 400.00
Bacteriology	\$ 200.00	\$ 250.00	\$ 300.00	\$ 350.00	\$ 400.00
Virology	\$ 200.00	\$ 250.00	\$ 300.00	\$ 350.00	\$ 400.00
Serology	\$ 200.00	\$ 250.00	\$ 300.00	\$ 350.00	\$ 400.00
Hematology	\$ 200.00	\$ 250.00	\$ 300.00	\$ 350.00	\$ 400.00
Immunohematology	\$ 200.00	\$ 250.00	\$ 300.00	\$ 350.00	\$ 400.00
Routine Chemistry	\$ 200.00	\$ 250.00	\$ 300.00	\$ 350.00	\$ 400.00
Endocrinology	\$ 200.00	\$ 250.00	\$ 300.00	\$ 350.00	\$ 400.00
Toxicology	\$ 200.00	\$ 250.00	\$ 300.00	\$ 350.00	\$ 400.00
Cytology	\$ 200.00	\$ 250.00	\$ 300.00	\$ 350.00	\$ 400.00
Cytogenetics and/or tissue typing	\$ 200.00	\$ 250.00	\$ 300.00	\$ 350.00	\$ 400.00
Collection Station only	\$ 200.00 per site				
Waived Tests only	\$ 200.00 per site				

<1> Exclusive of director, trainees in approved medical technology schools, clerical and maintenance employees. Part-time employees are to be included, prorated to full-time equivalents.

(b) Laboratories shall remit an additional fee of \$ 100.00 for renewal applications submitted after December 31 in order for the Department to process the renewal application.

(c) Laboratories shall pay a fee of \$ 100.00 for replacement of a license due to a change of address.

**(d) Notwithstanding the above provisions, during the period of the COVID-19 Public Health Emergency, clinical laboratories may open collection stations without paying the related licensure fees in paragraph (a) above if they meet the requirements of N.J.A.C. 8:44-2.14(d).**

**(e) This temporary waiver/modification is effective only during the period of Public Health Emergency declared by Governor Philip D. Murphy in Executive Order No. 103. This temporary rule waiver/modification shall expire forty-five (45) days after the Public Health Emergency has ended. Upon the expiration of this temporary rule waiver/modification, all collection stations will need to comply with the licensure and fee requirements set out at N.J.A.C. 8:44-2.14 and N.J.A.C. 8:45-1.3.**

I find that waiver/modification of the rules above is necessary because enforcement of the existing rules would be detrimental to the public welfare during this emergency.

**JUDITH M. PERSICILLI, RN, BSN, MA  
COMMISSIONER  
DEPARTMENT OF HEALTH**

June 5, 2020

**DATE**



**BY: Robert R. Rees, MHA, MT (ASCP)  
Acting Executive Director  
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