



State of New Jersey
DEPARTMENT OF HEALTH
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Lt. Governor

www.nj.gov/health

JUDITH M. PERSICILLI, RN, BSN, MA
Commissioner

May 15, 2023

Nateasha Robinson-Burns, Laboratory Owner
Kimyetta M. Robinson, DO, Laboratory Director
Gentle Hands Mobile Phlebotomy
1999 Morris Avenue, Suite 1
Union, New Jersey 07083

Re: Notice of Penalty Assessment
Investigation Control # 2023-CLIS32GH-01

Dear Ms. Robinson-Burns and Dr. Robinson:

The New Jersey Department of Health (Department) is vested with the responsibility of carrying out the provisions of the New Jersey Clinical Laboratory Improvement Act (Act), N.J.S.A. 45:9-42.26 et seq., which was enacted in part to ensure that clinical laboratories in New Jersey are of the highest quality. To this end, the Act grants the Department the power to license clinical laboratories in this State and to prescribe standards for the operation of these laboratories. In furtherance of each of the aforementioned statutory objectives, the Department adopted rules that govern the licensure and inspection of clinical laboratories. The rules are set forth in their entirety at N.J.A.C. 8:44-2.1 et seq.

The Department is issuing this Notice of Penalty Assessment, pursuant to N.J.S.A. 45:9-42.43, after determining that Gentle Hands Mobile Phlebotomy (Gentle Hands) is in violation of N.J.S.A. 45:9-42.28 for operating as a clinical laboratory collection station without the requisite licensure from November 2, 2022 through April 28, 2023, as described in further detail below.

On November 3, 2022, three surveyors from the Department's Public Health and Environmental Laboratories, Clinical Laboratory Improvement Services (CLIS) conducted an unannounced complaint investigation of Gentle Hands. The investigation revealed serious deficiencies with Gentle Hands' compliance with clinical laboratory licensure, employee recordkeeping, occupational safety and health, and quality control requirements. Relevant here, the investigation revealed that Gentle Hands was collecting patient specimens and sending the specimens to clinical laboratories for testing, even though Gentle Hands did not have a CLIS collection station license authorizing it to collect, process and transmit specimens for clinical testing. Gentle Hands was operating

without a license, even though CLIS advised Gentle Hands in 2017 that it required a CLIS clinical laboratory license in order to operate as a collection station in New Jersey.

By letter dated November 29, 2022, Gentle Hands was notified of the results of the onsite complaint investigation and the violations found by the Department's surveyors, which included the failure of Gentle Hands to obtain a license to operate as a clinical laboratory. Subsequently, Gentle Hands submitted an incomplete application for licensure on December 15, 2022, as well as a plan of correction. CLIS notified Gentle Hands in writing on December 22, 2022, that it must cease and desist operations because it was not licensed, and that its plan of correction was not deemed sufficient.

CLIS again notified Gentle Hands by hand delivery on January 12, 2023 that it must cease and desist operations because it was not licensed. Despite being advised on multiple occasions that it could not operate unless and until it received a CLIS license and knowing that its clinical operations were not in conformance with CLIS's rules, Gentle Hands had not ceased operations and continued to operate without a license through the date of the most recent CLIS inspection on April 28, 2023, as confirmed by CLIS through multiple inspections and documents.

As defined by the Act, a clinical laboratory includes "any facility used for the collection, processing and transmission of specimens to another facility for the performance of clinical tests." N.J.S.A. 45:9-42.27. The Act further provides that "[n]o person shall conduct, maintain, or operate a clinical laboratory or solicit or accept specimens for laboratory examination unless a license therefor has been obtained from" the Department of Health. N.J.S.A. 45:9-42.28.

Gentle Hands falls squarely within the statutory definition of a clinical laboratory as it is collecting, processing and transmitting specimens to another facility for the performance of laboratory testing. Accordingly, Gentle Hands required a license from CLIS to conduct specimen collections. Yet, Gentle Hands operated without a license, despite that fact that CLIS advised Gentle Hands on several occasions, going back as far as 2017, that it required a clinical laboratory collection station license to operate. Gentle Hands' noncompliance and disregard of the orders of the Department as well as the law concerning licensure is unacceptable and placed laboratory patients at risk of harm.

Pursuant to N.J.S.A. 45:9-42.43, the Department may assess a monetary penalty against a clinical laboratory for violating any provision of the Act or any rule promulgated thereunder in an amount not less than \$100.00 nor more than \$1,000.00 for each violation. Based upon the foregoing, CLIS has determined that Gentle Hands is in violation of N.J.S.A. 45:9-42.28 for operating as a clinical laboratory collection station without the requisite licensure from November 2, 2022 through April 28, 2023. **As a result, you are hereby assessed a total monetary penalty of \$6,000 (\$1000 per month x 6 months of unlicensed operation) pursuant to N.J.S.A. 45:9-42.43.** Please note that this Notice of Penalty Assessment addresses only the licensure violation.

Payment of \$6,000.00 must be electronically submitted within 30 days from the date of this notice through the e-payment link on the CLIS website located at <https://www.nj.gov/health/phel/epayments.shtml>. Please select License - Clinical Laboratory/Collection Station following Assessment of Penalty link. Please include Control Number **2023-CLIS32GH-01**.

Pursuant to N.J.S.A. 52:14B-1 et seq., you may request a hearing before the Office of Administrative Law to contest this monetary penalty. Your request for a hearing on this matter must be submitted in writing and must be accompanied by a response to the charges contained herein. In the event that you request a hearing, the penalty shall be held in abeyance until such time as the hearing has been concluded and a final decision rendered. If you wish to request a hearing, please include the **Control Number 2023-CLIS32GH-01** on your correspondence, and forward your request to:

New Jersey Department of Health
Office of Legal & Regulatory Compliance
P.O. Box 360
Trenton, NJ 08625-0360

Email: olrc@doh.nj.gov

Finally, please note that failure to submit a request for a hearing within 30 days from the date of this Notice shall be interpreted as an acceptance of the Department's penalty, thereby negating any further appeal rights and converting the penalty as final and immediately due. In accordance with N.J.S.A. 45:9-42.43, failure to pay this penalty may result in the delinquent account being referred for collection, pursuant to N.J.S.A. 2A:58-10. If you have any questions concerning this matter, please contact Department of Health Clinical Laboratory Improvement Services at (609) 406-6830.

Sincerely,



Alan Rimmer, MD
Executive Director
Clinical Laboratory Improvement Services
New Jersey Department of Health

c: Thomas Kirn, Medical Director
Rosalind Finney, Division Director
Joan Mikita, CLIS Manager

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