Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MHL032-613	A. BUILDING: _____ B. WING _____	04/20/2023

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HOUSE OF CARE, INC	1118 KIMBALL DRIVE DURHAM, NC 27712

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
V 000	INITIAL COMMENTS An annual survey was completed on April 20, 2023. Deficiencies were cited. This facility is licensed for the following service category: 10A NCAC 27G. 5600C Supervised Living for Adults with Developmental Disabilities. This facility is licensed for six beds and currently has a census of five. The survey sample consisted of audits of 3 current clients.	V 000		
V 105	27G .0201 (A) (1-7) Governing Body Policies 10A NCAC 27G .0201 GOVERNING BODY POLICIES (a) The governing body responsible for each facility or service shall develop and implement written policies for the following: (1) delegation of management authority for the operation of the facility and services; (2) criteria for admission; (3) criteria for discharge; (4) admission assessments, including: (A) who will perform the assessment; and (B) time frames for completing assessment. (5) client record management, including: (A) persons authorized to document; (B) transporting records; (C) safeguard of records against loss, tampering, defacement or use by unauthorized persons; (D) assurance of record accessibility to authorized users at all times; and (E) assurance of confidentiality of records. (6) screenings, which shall include: (A) an assessment of the individual's presenting problem or need; (B) an assessment of whether or not the facility can provide services to address the individual's needs; and	V 105	See page 4 of 4 DHSR - Mental Health MAY 08 2023 Lic. & Cert. Section	

[redacted]

TITLE: Director

(X6) DATE: 5/4/2023

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V 105	Continued From page 1 (C) the disposition, including referrals and recommendations; (7) quality assurance and quality improvement activities, including: (A) composition and activities of a quality assurance and quality improvement committee; (B) written quality assurance and quality improvement plan; (C) methods for monitoring and evaluating the quality and appropriateness of client care, including delineation of client outcomes and utilization of services; (D) professional or clinical supervision, including a requirement that staff who are not qualified professionals and provide direct client services shall be supervised by a qualified professional in that area of service; (E) strategies for improving client care; (F) review of staff qualifications and a determination made to grant treatment/habilitation privileges: (G) review of all fatalities of active clients who were being served in area-operated or contracted residential programs at the time of death; (H) adoption of standards that assure operational and programmatic performance meeting applicable standards of practice. For this purpose, "applicable standards of practice" means a level of competence established with reference to the prevailing and accepted methods, and the degree of knowledge, skill and care exercised by other practitioners in the field;	V 105	See page 4 of 4	

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V 105	Continued From page 2 This Rule is not met as evidenced by: Based on record review and interviews, the facility failed to develop and implement an adoption of standards that ensured operational and programmatic performance meeting applicable standards of practice for the use of a glucometer and including the CLIA (Clinical Laboratory Improvement Amendments) waiver. The findings are: Review on 4/20/23 of the facility's record revealed: -There was no evidence of a CLIA waiver. Review on 4/20/23 of Client #2's record revealed: -Admission date of 12/5/13. -Diagnoses of Intellectual Developmental Disabilities- Moderate, Schizoaffective Disorder, Intermittent Explosive Disorder, Borderline Personality Disorder, Diabetes and Obesity. -Physician's order dated 1/10/23. True Metrix- Use once daily. Review on 4/20/23 of Client #2's Medication Administration record for the months of February 2023 through April 2023 revealed: -Client #2's sugar levels had been checked and recorded daily. Interview on 4/20/23 with Staff #1 revealed: -Staff checked Client #2's sugar levels daily. Interview on 4/20/23 with the Director revealed: -She was not aware that she needed a CLIA waiver. -She had developed a part of her policy that she thought addressed this situation.	V 105	See page 4 of 4	

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V 105	Continued From page 3 -She would complete the paperwork and submit to obtain the CLIA waiver. -She confirmed the facility failed to have a CLIA waiver in order to complete blood sugar levels.	V 105	House of Care, Inc.'s Director will complete the CLIA waiver application to obtain the certifictate from the State. House of Care, Inc. has developed a policy for the CLIA waiver.	On-going 5/4/2023

House of Care, Inc
CLIA Wavier Policy

A. Policy

House of Care, Inc will have a Certificate of Wavier for all group homes providing staff assisted blood glucose checks to perform blood glucose finger sticks in compliance with federal and state law.

Each employee who will perform finger sticks shall be aware of and be competent in the CLIA Wavier policy. This will be upon hire, or before the start of work, PRN, and must be updated annually.

B. Purpose

1. To ensure that HOC, Inc meets the requirement and guidelines of North Carolina Division of Health Service Regulation for CLIA Wavier.

2. HOC, Inc will abide by the federal and state laws in regard to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), stating that simple, low-risk tests can be waived and performed with no routine regulatory oversight in physicians' offices and various other locations.

   a. The CLIA program is administered by CMS and is implemented through three federal agencies—CDC, CMS and the Food and Drug Administration (FDA).
   b. Each service location that performs laboratory testing (waived or nonwaived) must have a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate as specified by the federal CLIA regulation (42 CFR 493.55 and 493.3) and applicable state laws.
   c. CLIA requires all entities that perform even one test, including waived test on…"materials derived from the human body for the purpose of providing impairment of, or the assessment of the health of, human beings" to meet certain Federal requirements. If an entity performs tests for purpose, it is considered under CLIA to be a laboratory and must register with the CLIA program.
   d. To receive a certificate of Wavier under CLIA, a lab must only perform tests like the glucose meter test, which the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have determined to be so simple that there is little risk of error. In addition, these are exempt from most CLIA requirements and the laboratories that perform them receive no routine inspections.

3. HOC, Inc will provide education and continued education to all employees that will be using glucose meters for blood sugar monitoring before the start of use PRN. This continuous education will include quality control of the glucometer according to the manufacturer's guidelines.

C. Procedure

1. HOC, Inc will follow the following CLIA requirements that apply to HOC, Inc testing site operating under a CLIA Wavier (CW) that perform blood glucose finger sticks that use glucometer:

a. HOC, Inc will enroll in the CLIA program.
b. HOC, Inc will renew the CW every 2 years.

c. HOC, Inc will perform only waived tests. Waived tests include test systems cleared by FDA for home use, and simple, low-risk tests categorized as waived under CLIA. Sometimes a test that can be performed using different specimens or procedures might be waived tests is constantly being revised as new test systems are added, the most current information about waived tests and appropriate specimens is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.

d. Hoc, Inc will follow the instructions in the most current manufacturer's product insert, without modification, when performing the test. Changes to the timing of the test or physical alteration of the test components (e.g. 'cutting test cards or strips to increase test are no longer waived tests and become subject to the more stringent CLIA requirements for nonwaived testing.

e. Permit announced or unannounced on-site inspections by CMS representatives.

2. HOC, Inc will follow the following safety requirements:

   a. HOC, Inc will follow the Occupational Safety and Health Administration (OSHA) and individual sate standards that require employees. Each HOC, Inc site that performs blood glucose finger sticks must comply with OSHA standards pertinent to workplace hazards.

3. HOC, Inc will follow the following physical requirements:

   a. HOC, Inc will perform tests in a separate designated area where there is adequate space to safely conduct testing and maintain patient privacy. In addition, work surfaces should be stable and level and be able to be adequately disinfected; work space should be adequately in size for patient confidentiality, ease of specimen collection, test performance, and storage of supplies and records.

4. HOC, Inc will perform Quality Control (QC) tests per manufacturers guidelines.

   a. HOC, Inc understands that performing QC testing procedures provides assurance that the test performs as expected and alerts the user when problems occur. QC testing is designed to detect problems that might arise because of operator error, instrument malfunction, or improper environmental conditions. Test procedures should describe the type of controls to be used, how to perform QC testing (including QC testing frequency), and actions to be taken when QC results are unacceptable.

   b. HOC, Inc will use the manufacturer's product manual to determine accurate QC measures, such as when a QC test should be performed for glucometer:

      - Before executing a blood glucose test with the meter for the first time.
      - When opening and using a new vial of test strips.
      - When the meter is dropped or splashed with liquids.
      - Whenever the test results are not consistent with symptoms.
      - Whenever Checking if the system is working properly.
      - Whenever practicing testing and checking correct procedure.

   c. Quality Control results/documentation will be reported quarterly to the Quality Improvement Council for review and analyzation.

5. Personnel

a. Laboratory Director

Laboratory Director (LD) is the title afforded by regulation.
given to an individual whose name appears on the Laboratory Director of record for Centers for Medicare and Medicaid Services (CMS) and Joint Commission purposes and they are responsible for all testing performed by the laboratory
service.

For waived testing, there are no federally defined qualifications for the licensure requirements for the Laboratory Director. HOC, Inc Laboratory Director is Ogo Emodi-Onwuka BA, QP.

b. Staff

Any staff working in the group home must be trained on the CLIA Wavier policy and procedure upon hire, PRN, and annually thereafter. All group home staff will be required to pass the Glucometer Competency Checklist (which includes diabetes training, how to use glucometer, and accurate quality control checks) conducted by the Laboratory. Director upon hire, PRN and annually thereafter.