HINMAN STRAUB PC
ATTORNEYS AT LAW

MEMORANDUM

TO: ESAAL

FROM: Hinman Straub P.C.

RE: Limited Service Laboratory Registration Requirements for Adult Care Facilities in New York

DATE: November 15, 2016

On October 27, 2016, the Director of the New York State Department of Health's Clinical Laboratory Evaluation Program ("CLEP"), issued a "Dear Adult Care Facility Administrator" letter advising adult care facilities regarding federal and state requirements implicated when a facility seeks to perform "laboratory tests on materials obtained from the human body for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment," such as **fingerstick glucose, urine dipstick, occult blood, and influenza testing**.

Upon review of federal and state law, this memorandum confirms that adult care facilities performing "laboratory testing," including those tests identified above, are required to register with the Department of Health in order to obtain authorization to perform testing. In most cases, the type of testing performed by adult care facilities in New York will be considered "waived" testing, requiring registration of the facility as a "Limited Services Laboratory" rather than a more highly regulated "Clinical Laboratory". Registration as a "Limited Services Laboratory" allows the facility to obtain a registration certificate from the New York State Department of Health as well as a federal Clinical Laboratory Improvement Amendments Program ("CLIA") identification number authorizing the facility to provide certain, identified, CLIA "waived" tests in compliance with state and federal law.

This memorandum:

- **Provides background regarding the Federal and State Laws requiring registration as a Limited Service Laboratory in New York.** While requirements for state and federal registration have been in place for a number of years, it is our understanding that the Department of Health has recently identified adult care facilities as a population of providers that may not be in compliance with these requirements.

- **Explains that registration as a Limited Services Laboratory in New York and enrollment in the CLIA program is required only for adult care facilities that "perform laboratory tests".** For example, registration is required where adult care facility employees perform glucose testing (e.g., the employee obtains the specimen

(pricks the finger), performs the test (puts the blood on the test strip), and reads and records the glucose result. However, we have discussed with the the Department whether registration is required where the resident care aide is merely helping or assisting the resident to read or record the result The Department may issue additional guidance in this regard. , Registration is not required in instances where laboratory testing is performed off-site (for example, where facility staff collects a sample and forwards it off-site to a laboratory that performs the testing).

- **Provides an overview of the requirements applicable to Limited Service Laboratories.** This includes: (1) Completing an Initial Limited Services Laboratory Registration Application identifying the specific waived tests that will be performed (with a $200 application fee and biennial registration fee), (2) designating a laboratory director to oversee testing and establish policies and a quality assurance program, (3) authorizing on-site inspections by the Department, (4) maintaining proper records; and (5) where required, ensuring test results are properly reported.

- **Clarifies the required qualifications of the Laboratory Director of a Limited Services Laboratory**. In New York, all Limited Service Laboratories must have a laboratory director responsible for all testing performed. **The qualifications for the laboratory directors of Limited Services Laboratories are less restrictive than those required for the laboratory director of a Clinical Laboratory**. Specifically, New York State licensed medical doctors, doctors of osteopathy, dentists, nurse practitioners, certified nurse midwives or physician assistants may serve as a laboratory director at laboratories performing waived (i.e. Limited Services Laboratories) or provider-performed microscopy procedures (PPMP). ***In such instances, a Certificate of Qualification, is not required***. Ph.D.s and individuals holding a Doctor of Science ***that also hold a Certificate of Qualification*** may act as director at laboratories conducting waived testing only**.**

I. Federal Law

All facilities in the United States that test human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being are regulated under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). 42 USC 263a PL100-578 (1988).

This law sets forth a certification requirement for "laboratories" and "clinical laboratories," as defined below.

> **(a) "Laboratory" or "clinical laboratory" defined**
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> As used in this section, the term "laboratory" or "clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the

> diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.
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> **(b) Certificate requirement**
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> No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

The law applies to a broad category of "facilities," resulting in application of CLIA to an expansive scope of entities/providers, including those other than health care providers, such as assisted living facilities, prisons, and schools.[1] CLIA applies even if only one or a few basic tests are performed, and even if a facility is not charging for testing. However, the law does not apply where the facility does not perform laboratory testing on-site.

Notwithstanding the broad applicability of CLIA, there are three categories of testing that dictate the level of regulatory oversight. These include tests that fall into the following three categories: waived, moderate complexity, and high complexity.[2]

CLIA defines a "waived" test as tests that:

> (1) Are cleared by FDA for home use;
> (2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
> (3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.[3]

A list of waived tests are set forth in federal regulation (at 42 CFR 493.15(c)) and can be found at:https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/waivetbl.pdf. For adult care facilities, the most common "waived" test is likely glucose testing.

While "waived" tests are not exempt from CLIA, federal law requires facilities performing only those tests categorized as waived to apply for a CLIA Certificate of Waiver ("CW"). Under federal law, facilities performing only waived tests have no routine oversight, no personnel requirements and are required only to obtain a CW, pay biennial certificate fees, and follow manufactures' test instructions. As further described below, New York has imposed additional requirements upon facilities providing "waived" testing in New York.

II. New York State Law

States and local jurisdictions vary as to the extent to which they regulate laboratory testing. In New York, clinical laboratories and laboratories conducting clinical or forensic testing on specimens originating in New York State, regardless of location, must hold a New York State

[1] See CLIA Application for Certification, p.2, Section III, Type of Laboratory, available at: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf
[2] See 42 C.F.R. § 493.5.
[3] 42 CFR 493.15(b).

Department of Health clinical laboratory permit pursuant to Title V, Section 574 of the New York State Public Health Law. In New York, the Clinical Laboratory Reference System ("CLRS"), administered by the New York State Department of Health's public health laboratory, the Wadsworth Center, assists clinical laboratories and blood banks in applying for licensure with the New York State Department of Health. In recognition of the fact that the Clinical Laboratory Reference System has requirements that are equal to or more stringent than CLIA, the program was granted exempt status by the federal Centers for Medicare and Medicaid Services ("CMS") in 1995. As a result, laboratories located in New York State meet CLIA accreditation requirements, as documented by a valid New York Stat permit, which includes a CLIA number.

In New York, facilities that perform only tests classified under CLIA as "waived" or provider-performed microscopy procedures (PPMP) (i.e., tests that require use of a microscope and are performed by physicians, dentists, or midlevel practitioners during a patient's visit) are required to register as "Limited Services Laboratory." Amendments to the New York State Public Health Law effective August 8, 2008 authorized the Department of Health's processes for oversight and registration of "Limited Service Laboratories".[4] These amendments except facilities registered as "Limited Services Laboratories" from New York's larger regulatory framework for Clinical Laboratories so long as a facility:

(i) Holds a valid certificate of registration issued by the department authorizing the performance of one or more waived tests or provider-performed microscopy procedures; and
(ii) Only performs tests authorized by the certificate of registration; and
(iii) Otherwise complies with all applicable requirements of this subdivision.[5]

As a result, adult care facilities seeking to provide only "waived" testing to residents, are required to register with the New York State Department of Health as a Limited Service Laboratory. As indicated above, we are seeking clarification from the Department whether resident care aides can assist residents in self-testing, without triggering the requirement for registration.

III. Overview of Requirements Applicable to Limited Services Laboratories

As indicated, Amendments to the New York State Public Health Law in 2008 authorized the Department of Health's processes for oversight and registration of Limited Service Laboratories. These requirements have been implemented through the New York State Department of Health's Clinical Laboratory Evaluation Program ("CLEP"), and generally require:

1. Completion of an Initial Limited Services Laboratory Registration Application, which requires the facility to identify the provider type (assisted living is included) and the specific waived tests that will be performed (with a $200 application fee and biennial registration fee);

[4] NY Laws of.2008, c. 204, § 3, eff. Aug. 6, 2008.
[5] NY PHL § 579(3)(a).

2. Designation of a laboratory director to oversee testing and establish policies and a quality assurance program;
3. Authorization of on-site inspections by the Department;
4. Maintenance of proper records; and
5. Where required, ensuring test results are properly reported.[6]

Additional details regarding the application, application instructions and "Standard Practices" for facilities performing waived testing are attached.

Limited laboratory registration certificate holders do not receive an actual CLIA certificate, but do receive a CLIA identification number and expiration date documented on the limited service laboratory registration certificate, which is used as proof that the laboratory is compliant with CLIA requirements. The registration certificate will also document what specific "waived" tests the limited services laboratory is authorized to perform.

IV. Requirements for Laboratory Director of a Limited Services Laboratory

In New York, all Limited Service Laboratories must have a laboratory director responsible for all testing performed. Importantly, these qualifications differ from the required qualifications of the laboratory director of a Clinical Laboratory, who is additionally required to hold a "Certificate of Qualification" to serve in this role.

Specifically, the law requires a facility operating a Limited Services Laboratory to:

> [D]esignate a qualified health care professional or qualified individual holding a certificate of qualification pursuant to [PHL § 573], who shall be responsible for:
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> (A) establishing, approving and continuously updating policies, procedures and personnel qualifications for each test employed;
> (B) establishing a comprehensive quality assurance system which includes, but is not limited to, test selection, test quality, laboratory proficiency and personnel competency;
> (C) ensuring all tests are performed in accordance with the manufacturers' instructions and standards of practice in laboratory medicine;
> (D) maintaining complete and accurate records of the tests performed, including but not limited to, the patient's name, results, person performing the test, and quality control data;
> (E) ensuring that persons do not participate in diagnostic or treatment decisions using such test results unless such persons are authorized by law to do so;
> (F) ensuring that provider-performed microscopy procedures are performed only by a qualified health care professional operating within the scope of practice for his or her profession

[6] See NY PHL § 579(c)

> and as part of the physical examination performed by such professional; and
> (G) complying with other applicable laws, rules and regulations.[7]

Although the Laboratory Director of a Clinical Laboratory in New York must meet heightened education requirements and hold a Certificate of Qualification,[8] the requirements for laboratory director of a Limited Services Laboratory are less restrictive. The qualifications are not otherwise set forth in regulation, and instead provided in guidance documents:

> All limited service laboratories must have a laboratory director responsible for the testing performed. New York State licensed medical doctors, doctors of osteopathy, dentists, nurse practitioners, certified nurse midwives or physician's assistants can act as laboratory director at laboratories performing waived or PPMP testing. Ph.D.s and individuals holding a Doctor of Science [and also holding a certificate of qualification][9] may act as director at laboratories conducting waived testing only. For facilities such as hospitals and clinics that have a fully-permitted laboratory on-site, the director of the permitted laboratory must also be the director for the limited services laboratory.[10]

In summary, adult care facilities performing "laboratory testing," including, for example, fingerstick glucose, urine dipstick, occult blood, and influenza testing are required to register with the Department of Health in order to obtain authorization to perform such testing. The registration, however, is more limited in nature than a full Clinical Laboratory license; instead, a Limited Service Laboratories registration would be required. In addition, all Limited Service Laboratories must have a laboratory director responsible for all testing performed. The qualifications for the laboratory directors of Limited Services Laboratories are less restrictive than those required for the laboratory director of a Clinical Laboratory. Specifically, New York State licensed medical doctors, doctors of osteopathy, dentists, nurse practitioners, certified nurse midwives or physician assistants may serve as a laboratory director at laboratories performing waived (i.e. Limited Services Laboratories) or provider-performed microscopy procedures (PPMP). In such instances, a Certificate of Qualification, is not required.

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[7] NYS PHL § 579(c) (Emphasis Added)
[8] See 10 NYCRR 19.2-19.3
[9] See *Initial Limited Service Laboratory Registration Application Instructions* at: http://www.wadsworth.org/sites/default/files/WebDoc/1171400483/FINAL_DOH-4081_Initial_LSL_App_Ins_0116.pdf
[10] See *New York State Guidance for following Standard Practices in Laboratory Medicine (For sites performing waived and/or provider-performed microscopy procedures under a Limited Service Laboratory Registration*) at: http://wadsworth.org/sites/default/files/WebDoc/1697462341/FINAL_Guidance%20FAQ%20document%2011_01_13_revised.pdf

Please contact us with any questions.

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