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May 5, 2023

New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower, Empire State Plaza, Rm. 2438
Albany, New York 12237-0031

RE: Notice of Revised Rulemaking: Amendment of Subpart 58-1 of Title 10 NYCRR (Clinical Laboratories and Blood Banks)

To Whom It May Concern:

The American College of Medical Genetics and Genomics (ACMG) appreciates the opportunity to provide feedback on the proposed amendment of Subpart 58-1 of Title 10 NYCRR. The ACMG is a prominent authority in the field of medical genetics and genomics and the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics. The only medical specialty society in the US that represents the full spectrum of medical genetics disciplines in a single organization, the ACMG provides education, resources and a voice for more than 2,600 clinical and laboratory geneticists, genetic counselors, and other healthcare professionals. ACMG's mission is to improve health through the clinical and laboratory practice of medical genetics as well as through advocacy, education, and clinical research, and to guide the safe and effective integration of genetics and genomics into all of medicine and healthcare, resulting in improved personal and public health.

The ACMG is seeking clarification on issues related to the proposed requirement for laboratory directors to be onsite for a minimum of 8 hours per week (Section 58-1.2(c)), especially as it applies to laboratories with more than one director. We pose the following questions for clarification.

1. If a laboratory has multiple laboratory directors with a New York State (NYS) Certificate of Qualification (CoQ), do all laboratory directors employed at that laboratory need to be onsite for at least 8 hours per week?

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2. If there is at least one laboratory director with a NYS CoQ onsite fulltime, are other laboratory directors required to be onsite for at least 8 hours per week also?
3. Can the onsite availability be shared by two or more laboratory directors? (E.g., two laboratory directors work onsite 4 hours per week each for a total of 8 hours)

Additionally, this change creates a new requirement for onsite time that differs from that already established by federal regulations, the rationale for which is unclear. Tracking and complying with a growing number of divergent policies adds additional burden to laboratories, and such divergences should be avoided unless there is clear evidence demonstrating an impact to quality or safety.

We would also like clarification on how requests for accommodations account for Titles I and IV of the Americans with Disabilities Act and/or the NYS Human Rights Law (NYS Executive Law, Article 15, §296). Section 58-1.2(c)(2) of the proposed amendment states that "*requests for a laboratory director to be on-site less than eight hours per week will be considered pending a review of the number of permit categories for which they are responsible, the volume and complexity of testing at the clinical laboratory or blood bank, and the performance history of the clinical laboratory or blood bank during inspections and proficiency testing*". However, this provision does not describe how NYS or employers seeking NYS accreditation can facilitate requests for accommodations under federal and state disability and human rights laws while also complying with the proposed amendment. Similar challenges may exist with local laws and regulations, such as Title 8 of the Administrative Code of the City of New York, NYC Human Rights, which prohibits disparate treatment of individuals with disabilities, special needs, or other protected characteristics. In some instances, an employer may need to accommodate a more flexible remote work schedule due to a laboratory director's disability, genetic predisposition, or other special needs. Clarification is needed around the proposed amendment in section 58-1.2(c) to ensure that employers are able to accommodate such requests in accordance with federal, state, and local laws and regulations.

Although not part of the language proposed for amendment, we also want to draw attention to section 58-1.1(d)(2) which states that "*provisional permits*

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shall not be available in the categories of cytogenetics-general, mycology, mycobacteriology, human immunodeficiency virus screening and /or confirmatory testing, or virology". It is unclear why provisional permits would be prohibited for cytogenetics. Cytogenetics tests and the resulting findings do not have the same risks or concerns as the other categories described in section 58-1.1(d)(2). While the NYS Department of Health is actively reviewing subpart 58-1 of Title 10 NYCRR, we strongly encourage the Department to revisit the rationale for precluding cytogenetics from eligibility for provisional licenses.

For additional information or questions, please contact Dr. Michelle McClure, ACMG Director of Public Policy, at mmcclure@acmg.net.

Sincerely,

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