

September 25, 2022

Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore, Maryland 21244

RE: Proposed Rule: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories (CMS-3326-P)

Dear Administrator Brooks-LaSure:

On behalf of the American College of Medical Genetics and Genomics (ACMG), thank you for the opportunity to provide feedback on the proposed rule for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories (CMS-3326-P). 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. As 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 2,500 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 concerned about CMS's proposal to the degree requirements for directors of high complexity laboratories to include those without a traditional doctoral degree. Traditional doctoral programs train individuals to become research scientists, including how to assess a problem, formulate a possible solution, and develop a logical way to test that solution. This is demonstrated by several years of laboratory research in a specific discipline followed by successful completion of a dissertation component. The subsequent fellowship training builds upon that education to prepare individuals to become board-certified clinical testing laboratory directors by teaching the clinical knowledge needed to perform

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such tasks in a clinical setting. Master's level degrees do not encompass the same level of training, and individuals coming out of such programs would not have the proper hands-on training required to prepare an individual to direct a high complexity laboratory. This is further evidenced by the fact that individuals with master's level degrees are not eligible to sit for the majority of CMS recognized certifying boards. **As such, ACMG recommends that CMS not adopt the proposed amendment to §493.1443(b).**

Likewise, nontraditional doctoral degrees, such as a Doctorate in Clinical Laboratory Sciences (DCLS) degree, do not include the same rigor of discipline-specific training required for eligibility by the majority of CMS-recognized certifying boards. In the proposed rule, CMS states that they intend to create a new definition of doctoral degree which would include *“an earned post-baccalaureate degree with at least three years of graduate level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science or medical technology. For purposes of this part, doctoral degrees do not include doctors of medicine (MD), doctors of osteopathy (DO), doctors of podiatry, doctors of veterinary medicine (DVM) degrees, or honorary degrees.”* In the rationale, CMS states that *“A graduate of a DCLS program will be able to: provide appropriate test selection and interpretation of test results; monitor laboratory data and testing processes; improve the quality, efficiency, and safety of the overall diagnostic testing process; and direct laboratory operations to comply with all state and Federal laws and regulations.”* We note that these qualifications align more with the role of a laboratory manager or supervisor. The responsibilities of a high-complexity laboratory director extend well beyond this, such as providing clinical consultation to other clinical colleagues, interpreting test results in an individualized patient context, and developing new specialty-specific high-complexity clinical tests. Degrees that are not dissertation-driven, are short in length, and do not include a research component do not equip individuals with the training necessary to perform the full scope of requirements of a high-complexity laboratory director. **As such, ACMG recommends that CMS not expand their definition of doctoral degrees as proposed in this rule.**

High-complexity laboratories provide critical clinical services for patients, and changes that lessen the standards of such laboratories, including those for the laboratory directors, should be carefully scrutinized. It is unclear what problem is intended to be solved by the proposed changes highlighted above. **We suggest that the problem to be addressed be clearly communicated to the Clinical Laboratory Improvement Advisory Committee (CLIAC) and that the CLIAC be tasked with thoroughly exploring potential solutions through their standard processes, including public comment.**

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The ACMG appreciates the opportunity to provide this feedback and looks forward to continued discussions led by the CLIAC. For additional information, please contact Michelle McClure, PhD, ACMG Director of Public Policy.

Sincerely,



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American College of Medical Genetics and Genomics

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