



March 12, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-3326-NC
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS-3326-NC; Request for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as published in *Vol. 83, No. 6 Federal Register 1004-1009 (Tuesday, January 9, 2018)*

Submitted electronically via <http://www.regulations.gov>

Dear Ms. Verma:

UnityPoint Health (“UPH”) appreciates the opportunity to provide input of the modernization of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). UPH is one of the nation’s most integrated healthcare systems – the 13th largest non-profit healthcare system and the fourth largest nondenominational healthcare system. Through more than 30,000 employees and our relationships with more than 290 physician clinics, 32 hospitals in metropolitan and rural communities and home care services throughout our 9 regions, UPH provides care throughout Iowa, western Illinois and southern Wisconsin. On an annual basis, UPH hospitals, clinics and home health provides a full range of coordinated care to patients and families through more than 6.2 million patient visits.

Serving as a critical diagnostic service for the system, UPH Laboratories provide comprehensive laboratory / pathology services to patients in our hospitals, clinics and home health settings. Laboratory services are also provided to nursing home residents, assisted living facilities, physician offices, and other hospitals in many regions. Our UPH Laboratories perform thousands of tests each day and over 10,000,000 tests per year. Testing is offered in all general laboratory disciplines and some specialty services for clinical and anatomical pathology. Our teams of dedicated individuals use their knowledge, expertise, skills, and

abilities to provide a high quality, full service laboratory for our providers, patients and families.

We respectfully offer the following comments.

Clarifications of Degree(s)

Although we understand that clarification of degrees is being considered to address workforce issues, particularly in rural areas; we are concerned that the proposals do not appropriately recognize the technical requirements and experience needed to meet the CLIA requirements for moderate and high complexity testing personnel as well as for technical consultants. In terms of a bachelor's degree in nursing, it is neither the equivalent to a bachelor's degree in biological science nor should it be considered a qualifying degree to meet CLIA requirements. The coursework and competencies are different. As for whether a physical science degree or non-traditional degrees should to be considered a qualifying degree for CLIA requirements, we believe the standards set forth by the American Society for Clinical Pathology (ASCP) should be the default. Their stance focuses not on the degree title, but on the underlying coursework successfully completed. Therefore, it would be possible for either physical science or non-traditional degree holders to meet CLIA requirements if they have completed 30 hours of biological and chemical sciences, including courses at an advanced level. Physics, Astronomy, geology and other earth sciences coursework should not be considered as educational background for CLIA educational requirements, nor should they be considered equivalent to the other qualifying degrees in Biology, Chemistry, and Medical Laboratory Science.

Other Requirements for CLIA Personnel Categories

We agree that general supervisors be allowed to perform competency assessment for testing personnel performing moderate complexity testing in laboratories that perform both moderate and high complexity testing. If a laboratory is certified or accredited for high complexity, it stands to reason that all non-waived tests should have the same competency requirements. Since the General Supervisor can perform competency on highly complex testing personnel, they should also be able to perform competency on the non-waived-moderately complex testing personnel. General supervisors should have a minimum of an Associates of Arts degree in the Medical Laboratory Technician / Medical Laboratory Science program.

Proficiency Testing Referral

We support the written comments offered by Clinical Laboratory Management Association (CLMA) on this issue. In particular, we are concerned that the intent of an individual may be attributed to the organization, regardless of causation and severity. We encourage

consideration of circumstances and mitigating factors when determine if and to what extent PT referral sanctions should be applied.

CLIA Fees

UnityPoint Health does not support any increase or the levying of any inspection, validation, reissuance of license or investigation fees as to do so would be inconsistent with the current reimbursement reduction of the Clinical Laboratory Fee Schedule imposed by CMS as of January 2018. As we noted in our October 23, 2017 letter related to the preliminary calendar year (CY) 2018 Medicare Clinical Laboratory Fee Schedule (CLFS) rates, we already fear that rates will negatively affect access to care, particularly for the most vulnerable populations, negatively impact health outcomes, and further exacerbate shortages for healthcare services in rural areas.

We appreciate the opportunity to provide comments related to this request for information. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, UnityPoint Health Government and External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,



Carol Collingsworth, MBA, MT(ASCP)SC
Laboratory Services Director, System Initiatives
UnityPoint Health



Cathy Simmons, JD, MPP
Executive Director, Regulatory Affairs
UnityPoint Health