



UnityPoint Health

Government and External Affairs  
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August 11, 2022

Administrator Chiquita Brooks-LaSure  
Centers for Medicare and Medicaid Services (CMS)  
Department of Health and Human Services (HHS)  
Attention: CMS-3326-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

RE: CMS-3326-P Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories, published in Vol. 87 No. 142 Federal Register 44896-44942 on July 26, 2022.

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

Dear Administrator Books-LaSure,

UnityPoint Health appreciates this opportunity to provide comments on this proposed rule related to Clinical Laboratory Improvement Amendments (CLIA) Fees. UnityPoint Health is one of the nation's most integrated health care systems. Through more than 32,000 employees and our relationships with more than 480 physician clinics, 40 hospitals in urban and rural communities and 14 home health agencies throughout our 9 regions, UnityPoint Health provides care throughout Iowa, central Illinois, and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics and home health agencies provide a full range of coordinated care to patients and families through more than 8.4 million patient visits.

Serving as a critical diagnostic service for the system, UnityPoint Health laboratories provide comprehensive laboratory and 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 laboratories perform thousands of tests each day and over 8,000,000 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.

UnityPoint Health appreciates the time and effort of CMS in developing this proposed rule. Several of our UnityPoint Health laboratory team members are members of the American Society for Clinical Pathology (ASCP), and UnityPoint Health generally supports the ASCP's position on the 2023 CLIA proposed rule. We respectfully offer the following comments as it relates to UnityPoint Health.

### MODERATE AND HIGH COMPLEXITY TESTING PERFORMED BY NURSES

*CMS proposes to allow individuals with a nursing degree to perform waived testing as well as high and moderate complexity testing.*

**Comment:** UnityPoint Health supports the ability of nurses to perform waived and moderate complexity testing under the guidance of an appropriately trained technical consultant, however **UnityPoint Health does not support the performance of high complexity laboratory testing by individuals with a nursing degree without a specialized laboratory degree.** Crucial to quality care and patient safety, UnityPoint Health believes high complexity testing requires specific scientific and laboratory training as well as demonstrated competency to maintain accurate and reliable testing. Therefore, **UnityPoint Health respectfully requests that CMS withdraw this proposal to allow individuals with a nursing degree alone to perform and/or supervise high complexity testing.**

### TECHNICAL CONSULTANT (TC) QUALIFICATIONS

*CMS proposes to allow individuals with an associate degree in medical laboratory technology or clinical laboratory science and at least 4 years of laboratory training or experience, or both, to assess competency in laboratories that perform both moderate and high complexity testing and bring parity to professionals who perform competency assessments for all nonwaived laboratories while maintaining the laboratory's ability to produce accurate and reliable testing.*

**Comment:** UnityPoint Health supports this TC proposal. Individuals with associate degrees in Medical Laboratory Technology or Clinical Laboratory Science are well trained and competent. As laboratory professionals are becoming increasingly scarce and difficult to recruit, this change will likely increase the number of individuals able to perform nonwaived testing services and TC services as well as create a trajectory for those individuals to begin working in advance of pursuing and obtaining a bachelorette degree.

We are pleased to provide input on this proposed rule and its impact on our laboratories and health system, our patients, and communities served. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director, Government & External Affairs at [cathy.simmons@unitypoint.org](mailto:cathy.simmons@unitypoint.org) or 319-361-2336.

Sincerely,



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



Cathy Simmons, JD, MPP  
Executive Director Government & External Affairs