

May 31, 2019

Administrator Seema Verma
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-3355-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS-1714-P - Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance; published at Vol. 84, No. 23 Federal Register 1536-1567 on February 4, 2019.

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

Dear Administrator Verma,

UnityPoint Health (“UPH”) appreciates this opportunity to provide comment on this proposed rule update proficiency testing (PT) regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). UPH is one of the nation’s most integrated healthcare systems. Through more than 32,000 employees and our relationships with more than 310 physician clinics, 39 hospitals in metropolitan and rural communities and 19 home health agencies throughout our 9 regions, UPH provides care throughout Iowa, central Illinois and southern Wisconsin. On an annual basis, UPH hospitals, clinics and home health provide 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 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.

UPH appreciates the time and effort of CMS in developing this proposed rule and respectfully offers the following comments.


GENERAL COMMENTS


UHP generally supports the changes to proficiency testing proposed in this rule. We understand the importance of assuring the accuracy and reliability of laboratory testing, and this issue was overdue to be addressed in a more comprehensive fashion. We also appreciate that CMS requested stakeholder input from the Clinical Laboratory Improvement Advisory Committee in the development of these rules.

We do have one area of concern related to the fiscal implications of this proposal. There are associated costs to this expanded testing that will need to be absorbed within our current operating structure. As estimated by CMS, proposed analytes and tests would cost between \$26.5 million and \$118.3 million in 2017 dollars. These new costs are in addition to the significant reimbursement reduction in the Clinical Laboratory Fee Schedule as of January 2018 as well as the administrative time and effort required during the present cycle for collecting and reporting data for the private payor rate-based payment system. While CMS is soliciting comments and data on non-quantifiable impacts related to the specific proficiency testing changes, we would encourage CMS to include a more comprehensive impact analysis and indicate this rule's cumulative impact with the Protecting Access to Medicare Act of 2014 (PAMA). We believe that increasing costs while reducing 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. It is our hope that CMS is actively monitoring clinical laboratories and tests to note trends in consolidation as well as geographic spread of specialties and subspecialties.

We are pleased to provide input on this proposed rule and its impact on our integrated health system and the individuals and communities we serve. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, UnityPoint Health Government & 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
UPH Government & External Affairs