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HOSPITAL
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Health Policy and Advocacy*

April 5, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G Herbert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Subject: CMS–3355–P; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance, Proposed Rule; Federal Register (Vol. 84, No. 23), February 4, 2019

Dear Administrator Verma:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule that would make changes to proficiency testing (PT) referral regulations.

PT is a tool to ensure the accuracy and reliability of laboratory test results, and is an important part of ensuring quality and patient safety. CLIA requires laboratories that engage in moderate- or high-complexity testing to enroll in a PT program that covers all the specialties and subspecialties for which the laboratory is certified and all analytes listed in the CLIA regulations. However, laboratories that hold Certificates of Waiver (CoW) are exempt from the requirement to perform and pass PT because the laboratories only perform waived tests, which are defined by CLIA as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.”

CMS proposes to amend its regulations to clarify that moderate- and high-complexity laboratories that also perform waived tests are not required to perform PT for those waived tests. CHA supports the ability of moderate- and high-complexity labs to perform waived tests without being required to enroll in PT for those tests.

However, CMS also proposes that, should these laboratories voluntarily perform PT on waived tests, they would be subject to the full weight of sanctions for PT that is mishandled. This proposal would unnecessarily increase regulatory burden on laboratories. Currently, many hospital laboratories voluntarily perform PT on waived tests as part of the hospital’s ongoing quality assurance and improvement processes. The proposed rule would discourage these laboratories from performing PT on waived tests because the threat of possible PT referral sanctions for such simple tests would outweigh the benefits of the PT process. CHA urges CMS not to finalize this proposal and instead exercise discretion in applying sanctions for PT on waived tests to help ensure improved laboratory testing quality while reducing regulatory burden.

CHA appreciates the opportunity to provide comments on this proposed rule. If you have any questions, please do not hesitate to contact me at akeefe@calhospital.org or (202) 488-4688 or Megan Howard, senior policy analyst, at mhoward@calhospital.org or (202) 488-3742.

Sincerely,

/s/

Alyssa Keefe
Vice President, Federal Regulatory Affairs