March 6, 2018

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

Dear Administrator Verma:

On behalf of the American Academy of Family Physicians (AAFP), which represents 129,000 family physicians and medical students across the country, I write in response to the request for information titled, "Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)" as published by the Centers for Medicare & Medicaid Services (CMS) in the January 9, 2018, *Federal Register*.

The AAFP appreciates that CMS seeks comments regarding CLIA requirements since they have not been updated since 1992. We hope this feedback assists the agency in drafting further proposals to modernize CLIA policy.

A. Personnel Requirements

Summary

CMS seeks comments on how to update the existing CLIA personnel regulations through future rulemaking. The topics listed in this request for information are areas that the Centers for Disease Control and Prevention (CDC), CMS, stakeholders and State Agency surveyors identified as concepts that should be relevant to efforts to update the CLIA personnel requirements to better reflect current knowledge, changes in the academic context, and advancements in laboratory testing.

AAFP Response

The AAFP disagrees with the assertion made in this request for information and in the CMS Survey & Certification Letter (16–18–CLIA) that a bachelor's degree in nursing is equivalent to a bachelor's degree in biological sciences, chemistry, clinical laboratory science, or medical technology (BS-MT). BS-MT education has a much higher focus on biological sciences at the cellular level, chemistry, mathematics with emphasis on statistics, and testing methodologies. Nursing personnel do not have a viable understanding of testing methodologies related to predictive negative and predictive positive values, conformity to procedures, and specificity of tests. Individuals with a bachelor's degree in nursing can perform moderate and high complexity testing (with the technical oversight and competency verification by a board-certified Medical Technologist (MT)/Clinical Laboratory Scientist (CLS)), however individuals with a bachelor's degree in nursing are not properly educated to technically consult on moderate or high complexity laboratory tests.

To meet the CLIA educational requirements, the AAFP urges CMS to only consider physical science degrees in chemistry. Individuals with physical science degrees such as astronomy, physics, and other inorganic fields are not properly prepared for biological clinical lab work.

Concerning non-traditional degrees that may include job experience in lieu of coursework and that typically do not include a major concentration of study (for example, biology or chemistry), but are instead classified as general education degrees, the AAFP believes such non-traditional bachelor degrees are not qualified to work as "moderate complex testing" personnel. Non-traditional degree holders who successfully complete a medical technology clinical rotation at an approved facility should be qualified to take the CLS board of registry.

The AAFP believes that a competency assessment should be performed by a person who meets the minimum qualifications of a Technical Consultant in a moderate complexity laboratory, or a person who meets the minimum qualifications of a Technical Supervisor in a high complexity laboratory. However, competency assessments should not be performed by a person who only meets the minimum qualifications of a General Supervisor. In our experience in conducting surveys nationwide, those qualified as "General Supervisors" do not have the training and expertise to properly conduct a competency assessment in a laboratory

B. Proficiency Testing Referral
Summary
CMS has discretion as to which sanctions may be applied to cases of intentional proficiency testing referral. Such discretion may in some circumstances replace the automatic revocation of the laboratory's CLIA certificate and subsequent imposition of the two-year ban on the laboratory's owner or operator, which would prevent them from owning or operating a CLIA-certified laboratory for two years. CMS seeks comment related to applying discretion in situations where CMS determines that a laboratory has referred its proficiency testing samples to another laboratory and has reported the other laboratory's proficiency testing results as its own. CMS also seeks comments on alternative sanctions for proficiency testing referrals by Certificate of Waiver (CoW) laboratories.

AAFP Response
Referring proficiency testing samples to another testing location is inappropriate. If reinstatement samples are tested and the inspecting agency can determine the deficiency is a one-time error or is self-reported within a defined time (such as 15 days post evaluation), the alternative sanctions could be appropriate. Repeated offenses should trigger the strictest sanctions for violating labs and lab directors.

CoW laboratories should have the same alternative sanctions available to them in the event of proficiency testing referral.

C. Histocompatibility
Summary
CMS seeks comments on how to update the existing CLIA histocompatibility regulations.

AAFP Response
Because of changes in histocompatibility testing technology, performing a ''virtual crossmatch'' has replaced the use of a ''physical crossmatch'' to determine compatibility between the donor and

recipient. The AAFP agrees that virtual crossmatches (i.e. electronic or computer crossmatches) are reliable and appropriate for transfusion and transplant patients and donors and supports such revision to the CLIA requirements.

II. Solicitation of comments:
Summary
CMS seeks comments on several areas pertaining to CLIA.

AAFP Response
The AAFP reminds CMS that medical laboratory testing and methods are far more advanced than when CLIA was established. For example, the regulated test list is extremely outdated. The AAFP recommends that the entire list of nonwaived regulated analytes be reviewed with recommendations for deletions and additions. The list of regulated analytes should also be reviewed on a routine schedule to ensure that CLIA is reflecting modern laboratory testing. This would also show that the most important nonwaived, regulated analytes are being included in a regulated PT program.

The market is currently flooded with a large number of waived testing methods and point-of-care devices available on the market. Proper oversight and testing of these devices is currently lacking. We maintain that some external quality check must be in place to ensure accurate lab results are provided to the physician at the time he or she is making a diagnosis based on the test performed at time of treatment (point-of-care testing). Laboratories with CoW are consistently performing tests outside the applicable standard: “waived tests pose no reasonable risk of harm to patients in the event the test is incorrectly preformed.” External quality control processes such as proficiency testing need to be required on many, if not all, waived tests for the safety of the patient. The Food and Drug Administration’s approval of a waived Complete Blood Count analyzer is a perfect example of the risk to patient safety, with no external quality assurance or oversight required. The AAFP believes that all physicians whose practices accommodate clinical laboratory procedures in the physician’s office should be encouraged to participate in a recognized laboratory accreditation program, the cornerstone of which should be an approved proficiency testing program.

We appreciate the opportunity to provide these comments. Please contact Christine Schimpf BS, MT (ASCP), Proficiency Testing Program Manager, at (913) 906-6000, ext. 4140 or cschimpf@aafp.org with any questions or concerns.

Sincerely,

John Meigs, Jr., MD, FAAFP
Board Chair

About Family Medicine
Family physicians conduct approximately one in five of the total medical office visits in the United States per year – more than any other specialty. Family physicians provide comprehensive, evidence-

based, and cost-effective care dedicated to improving the health of patients, families and communities. Family medicine's cornerstone is an ongoing and personal patient-physician relationship where the family physician serves as the hub of each patient's integrated care team. More Americans depend on family physicians than on any other medical specialty.