American College of Physicians
Leading Internal Medicine, Improving Lives

April 5, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department for Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

Re: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance [CMS-3355-P]

Dear Administrator Verma,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Center for Medicare and Medicaid Services' (CMS) proposed rule regarding Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

Services offered by ACP include the ACP Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) program. We help maintain the quality of ACP member and non-member clinical laboratories, to ensure precision and accuracy of patient results. ACP-MLE clients include a wide array of public and private clinical laboratories in over 15 countries. The MLE proficiency-testing program provides the technical and educational tools necessary to assess, monitor and improve the quality of laboratory testing for our internal medicine community, which include many small labs and POL's. As a proficiency testing entity, we would like to thank CMS, HHS, and the CDC for their continuing efforts to improve on the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and for including us in this process through our comments. We appreciate your consideration our comments, recommendations, requests for clarification that we have made.

Supported Proposals

Section II -Subpart A (2): Provisions to remove the list of specific example organisms from bacteriology as stated in section 493.911(a) (3) and include a more general list of medically important aerobic and anaerobic bacteria from the six major groups of bacteria currently listed in the regulations.

ACP Comment: The College supports this recommendation as proposed.

Section II -Subpart A (4): Modifications to 493.911(a) and 493.911(b) to require morphology for gram stains, and to include bacterial morphology as part of the performance criterion for scoring gram stains, respectively.

ACP Comment: The College supports this recommendation as proposed.

Section II -Subpart A (5): Proposed changes to the mixed culture requirements for bacteriology in section 493.911(a) (2) from 50 percent to 25 percent.

ACP Comment: The College supports this recommendation as proposed.

Section II – Subpart A (493.915): The proposal to add detection of growth or no growth in culture media to the mycology PT identification.

ACP Comment: The College supports this recommendation as proposed.

Specific Analytes Proposed for Addition: Section II.B.3 and II.B.4: We support the proposed analyte additions for regulation, as it will benefit patient outcomes.

ACP Comment: The College supports this recommendation as proposed.

Section II – Subpart C: (493.911(b)(1), 493.913(b)(1), 493.915(b)(1), 493.917(b)(1), 493.919(b)(1), 493.923(b)(1), 493.927(c)(1), 493.931(c)(1), 493.933(c)(1), 493.937(c)(1), 493.941(c)(1), and 493.959(d)(1)): Provisions for amendments to these sections pertaining to participant consensus and grading criteria. Specifically that PT programs must attempt to grade using both participant and referee laboratories prior to determining the sample ungradable. At MLE, we have been utilizing this criterion to achieve our consensus.

ACP Comment: The College supports this recommendation as proposed.

Section II- Subpart C: Modification of 493.2 to definition of Peer Group to include the wording "…and is not to be assigned using the reagent lot number." This reflects our current practice.

ACP Comment: The College supports this recommendation as proposed.

Section II – Subpart C: Provisions to amend 493.861 for satisfactory performance criteria for unexpected antibody detection from ‘‘at least 80 percent’’ to ‘‘100 percent.’’

ACP Comment: The College supports this recommendation as proposed.

Proposals Needing Clarification

Section II – Subpart 3 (493.801(b)): The recommendation states “Laboratories should declare their patient reporting practices for organisms included in each PT challenge. However, PT programs should only gather this information as it is the inspecting agency’s responsibility to review and take action if necessary.”

ACP Comment: The College requests clarification as to what specific information the PT program must gather. We would further like to know whether this information is to be used by the PT program for grading purposes. It is unclear to ACP if the PT program would be responsible for transmitting this information to CMS and/or state agencies.

Section II – Subpart C (493.901(c)(6)): “In an effort to assist in PT referral investigations and determinations, an audit trail that includes all instances of reported results...”

ACP Comment: The College is concerned that adding a time stamp for each correction of data would be cumbersome to the PT program, requiring significant upgrades to our current online reporting system. Currently, our program allows online submission corrections prior to the event deadline in cases where the “Final Submit” button on the website was activated by the lab. We will unlock the submission portal only upon the request of the laboratory, and only within the event submission timeframe. However, we do not have the capability to monitor the result iterations for each laboratory during the event and prior to their “Final Submit” submission.

We request clarification regarding whether PT programs will be required to create and submit all audit trails to CMS or is it only to be made available to CMS/agencies by request for laboratories under investigation for PT referral. Further, it is unclear how the PT program should submit the result submission tracking data to CMS.

Section II – Subpart C (493.903(a) (3): MLE is aware that PT programs should not any change data submitted from laboratories. MLE does not add or change results, methodology, or units of measure when a lab makes a clerical error or inadvertently omits information. We do have specified areas on the website and result forms where a lab may manually type or write in methods not listed on the form. (For example, a new kit or instrument that we have not yet added to our method list.)

ACP Comment: The College would like to know, as indicated in the above scenario, if CMS considers it an alteration of data for the PT program to enter a method code, when the method was manually submitted in the designated reporting area prior to the reporting deadline.

Section II – Subpart C (493.941): Regarding the passage "In addition, we propose to require laboratories that perform both cell counts and differentials to conduct PT for both (that is, the ''or'' would be changed to an ''and'')."

ACP Comment: The College notes that a precedence is currently in place to transmit one or the other. We are unclear if CMS would receive separate analyte scores for cell identification and WBC differential, or if the two would be averaged.

Section II – Subpart A (2) (493.919(a) (3)): the proposal states that annual program content "must include respiratory viruses, herpes viruses, enterovirus, and intestinal viruses, if appropriate for the sample sources."

ACP Comment: The College is unsure if a PT program must offer all content stated in the proposal, from all sources, in order to be approved for Virology.

Section II – Subpart A (6) (493.911(a)(4)): The proposal states that " …at least two PT samples per event for susceptibility or resistance testing including one gram – positive and one gram – negative organism with a predetermined pattern of susceptibility or resistance to common anti-microbial agents…"

ACP Comment: The College requests clarification on whether a PT program must offer susceptibility for all sources or if urine suffices.

<u>Concerns and Suggestions</u>

Cost and Feasibility of Implementation: Section II.B.2.d

ACP Comment: The College feels that the cost burden to the laboratories will be higher than calculated. The added costs of testing newly regulated analytes combined with the PAMA cuts and increased license fees might force labs to decrease their test menus or discontinue testing all together. This is especially difficult for small entities such as single physician office laboratories.

Specific Analytes Proposed for Addition: Section II.B.3 and II.B.4

ACP Comment: While the College believes this increase in costs will affect the smaller POLs, we would like to suggest the inclusion of these analytes for these reasons:

- Regular CRP: Requiring both regular CRP and HS – CRP for reporting consistency.
- UIBC: Unsaturated Iron Binding Capacity is a direct measure and we feel that it should be subject to the same criteria as TIBC (Total Iron Binding Capacity).

Minimum Peer Group Size: Section II.C. Additional Proposed Changes: Section 493.901(a)

ACP Comment: The College disagrees with the proposal to require enrollment of a minimum of ten laboratory participants before offering any PT analyte and requests clarification whether this requirement is to be only for CMS-regulated analytes, or to all PT for all analytes offered by the PT program.

ACP suggests having no minimum number of participating laboratories to offer a new analyte, but if there is to be a minimum number, we suggest clarifying that the requirement applies only to the CMS-regulated analytes specified in the regulations. If this requirement were to pertain to non-regulated analytes, it would diminish the ability of smaller programs such as MLE to compete with programs having a larger pool of existing participants to start with. We would need sufficient time to market the new analyte and recruit participants in order to build a peer group.

The College disagrees with the statement that "PT programs do not grade results when there are fewer than ten laboratory participants." MLE grades most quantitative analytes to a minimum of 10 labs. However, in some cases, for instrument specific modules, we grade to a minimum peer group of five labs. In this scenario, if one lab misses a given sample, 80% consensus can still be reached. For qualitative analytes, MLE grades to a minimum peer group of five labs. Again, 80% consensus can be reached if one lab misses a given sample. We understand that the purpose is to avoid ungraded challenges. However, we believe that the PT program should be able to determine the statistical validity of a peer group. The minimum requirement of 10 participating laboratories would increase the number of ungraded challenges. A required minimum of ten labs for grading would be a burden for labs that would be forced to change programs due to ungraded analytes.

We also disagree with the proposal to add that HHS may withdraw the approval of an analyte, specialty or subspecialty at any time if a PT program does not meet the minimum requirement of 10 participating laboratories for an analyte or module. The withdrawal of approval at any time during the program year would be a burden for both laboratories and PT programs. PT programs order specimens based on enrollment, and some samples are ordered a year in advance. Revoking a PT program's approval mid-year may result in laboratories being unable to find a PT program that would have samples available thus causing a lab to be given a "failure to participate" and endangering their license.

Criteria for Acceptable Performance –Routine Chemistry: Section 493.931

ACP Comment: The College supports Hemoglobin A1C becoming a regulated analyte but do not agree with the proposed grading criteria. MLE currently grades this analyte at 6 percent, which is the current recommendation of the NGSP (National Glycohemoglobin Standardization Program) which proposes 5 percent in 2020. We currently have an acceptable miss rate for this analyte, and feel that moving back to 10 percent would be detrimental to patient health. We suggest making the grading criteria 6 percent.

Criteria for Acceptable Performance – Hematology: Section 493.941

ACP Comment: Previously, MLE provided CMS and the CDC with simulations on the proposed Acceptable Limits changes, and agree with most of the final recommendations. However, we have concerns with the following proposed criteria:

- Leukocyte count - The proposed changes to the acceptable limits of Leukocyte count from 10% to 5 % can prove limiting to labs using small analyzers, as these instruments are not as sensitive as the large analyzers. Labs using smaller analyzers in small doctors' offices will have an increase in failure rates. Furthermore, the percentages published were never run during PT simulations provided to the CDC and CMS. We ran a simulation at 10% but the proposed change is 5%. We propose to change Leukocyte count to 10%.

- WBC differential – We disagree with keeping the grading criteria at ±3SD. We would like to see a percentage based criteria applied. Every testing event, a number of labs will report the absolute value instead of the percent. With the proposed criteria of ±3SD, this will cause extremely wide ranges and require manual removal of outliers. A percentage based grading criteria would quickly identify and remove outliers automatically.

Section III – Subpart C

ACP Comment: The College agrees with the provisions for on-site visits by HHS for all initial PT program applicants, and periodically for HHS-approved PT programs added to 493.901(e). However, we would appreciate advanced notice to help with staff scheduling.

Conclusion

We appreciate the opportunity to provide our feedback and suggestions on this proposed rule. Please contact Christine Myers, Senior Associate, MLE Operations Manager by phone at 202-261-4513 or email at cmyers@acponline.org if you have any questions or need additional information.

Sincerely,

Jacqueline W. Fincher, MD, MACP
Chair, Medical Practice and Quality Committee
American College of Physicians