



April 2, 2019

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

Robert Redfield, MD, Director  
Centers for Disease Control and Prevention  
Attention: CMS–3355–P  
1600 Clifton Rd.  
Atlanta, GA 30333

Dear Administrator Verma and Director Redfield:

On behalf of the American Academy of Family Physicians (AAFP), which represents 131,400 family physicians and medical students across the country, I write in response to the [proposed rule](#) titled, “Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance” as published by the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) in the February 4, 2019, *Federal Register*.

The AAFP’s Proficiency Testing Program (AAFP-PT) is a CMS-CLIA-approved comprehensive program with more than 25 years of laboratory experience. AAFP-PT is the only laboratory proficiency testing provider to focus on the unique needs of physician office laboratories, urgent care centers, and small hospital laboratories. The AAFP believes that strengthening the Proficiency Testing (PT) program is in the best interests of patients. As the proposed rule notes, there will be an increased financial burden on laboratories as a result of these changes. These changes, along with the proposed increases on CLIA fees of 20% and the cuts in Medicare’s Clinical Laboratory Fee Schedule as a result of the *Protecting Access to Medicare Act (PAMA)*, make it difficult for laboratories to comply with CLIA. PAMA continues to be a negatively disruptive force within the laboratory community and if left unaddressed, poses the real possibility of adversely impacting patients’ ability to benefit from clinical laboratory services. The AAFP believes that CMS must be cognizant of the impact of PAMA on laboratories when implementing these changes to CLIA. The AAFP offers the following feedback to improve the final rule.

Initially, we note that the proposed rule does not address one of the biggest issues facing laboratories: the quality of waived tests. Each year, the availability of critical analytes being

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performed on waived platforms increases. These waived tests require very little oversight and quality assurance, while impacting the care of large numbers of patients. From a PT provider perspective, it is not the accredited laboratory impacting high quality patient care, but CLIA-waived laboratories. In addition, the AAFP is concerned that the changes in the proposed rule seem focused on punitive enforcement aimed at PT providers, rather than focusing on providing guidance for the greater good of laboratory medicine or focusing on increasing quality and safety for patients.

#### II.A. Proposed Changes to Microbiology PT

The AAFP finds the proposed changes leave too many requirements for individual interpretation. It is difficult to fully understand the potential impacts or requirements stated in this proposed rule. We therefore urge the agencies to clearly define the intent of the following sections:

1. Categories of Testing - Subpart I of the CLIA regulations includes PT requirements for each subspecialty of microbiology, §§493.911 through 493.919, which describe "Types of services offered by laboratories" for each subspecialty. It is not clear if susceptibility testing is optional if the laboratory performs identification and we urge CMS to clarify.
2. Major Groups of Microorganisms - More information is needed regarding annual PT program content including respiratory viruses, herpes viruses, enterovirus, and intestinal viruses to accommodate AAFP's PT program. Our program has samples designed on body origin, such as respiratory and gastrointestinal. It is unclear whether the proposed rule suggests a combination of viruses in one sample and AAFP urges the agencies to specify this in the final rule.
3. Declaration of Patient Reporting – The AAFP instructs our clients to report microbiology PT results to the same level they report patients. More defined criteria are needed for PT programs to be able to query, collate, and transmit information to CMS. While not obvious at first blush, this new requirement would significantly impact program operations. Therefore, the AAFP requests adequate time to implement the requirement if it is included in the final rule.
4. Gram Stain PT – While the AAFP understands that the Gram Stain is to include both reaction and morphology, we request further clarification as to whether gram stain PT is required when bacteriology identification is performed. For example, when a laboratory performs Streptococcus cultures on selective media to confirm a negative antigen detection test, it is unclear if CMS is also proposing that gram stain PT also must be included.
5. Mixed Culture Requirement – AAFP supports these changes.
6. Antimicrobial Susceptibility Testing – While AAFP supports the increase of 2 susceptibility challenges per event, the AAFP would suggest an annual requirement of 3-gram negative and 3-gram positive susceptibilities over the program year versus per event. Furthermore, CMS needs to clarify the susceptibility requirement at the subspecialty level and clarify if CMS is requesting susceptibility based on source in bacteriology.
7. Direct Antigen Testing – We support these changes.
8. Setting Target Values – We have no comments on this section.
9. Changing Acceptance Limits – The AAFP largely concurs with these changes, however some of the hematology analyzers and small chemistry benchtop analyzers frequently used in medical offices do not produce the accuracy and precision of high-throughput analyzers. As a result, we anticipate some medical office laboratories will experience increased failure rates. This will become an issue for accrediting organizations, who will have to discuss potential pitfalls of instrument accuracy and precision. In most cases, it is not the proficiency material that is the issue since many PT providers purchase PT

material from the same manufacturers. Sample identification will be different, but the material and expected ranges are equivalent.

### C. Additional Proposed Changes

For each of the new requirements in this proposed rule, we encourage CMS to clarify if these proposed changes apply to regulated and non-regulated analytes, or if they are limited to regulated analytes. If non-regulated analytes are held to the same rules as regulated, we ask for further clarity on how this will be enforced and what acceptance limits will be used.

In addition, CMS proposes to define peer groups as a “group of labs whose testing process utilizes similar instruments, methodologies, and/or reagents systems and is not to be assigned using the reagent lot number. PT programs should assign peer groups based on their own policies and procedures and not based on direction from any manufacturer.”

The AAFP is agreeable to this definition, however the proposed rule elsewhere states (in both “Setting Target Values” and section 493.901(a)), that if the PT program does not meet the minimum requirement of 10 participating laboratories for an analyte or module, HHS may withdraw approval for the analyte. **The AAFP strongly opposes language that imposes a minimum number of labs to define a peer group or an offering.** PT programs will grade results when there are fewer than 10 laboratories, particularly when PT programs are grading qualitative analytes as positive or negative. Furthermore, mandating a PT program to have a minimum of ten laboratory participants before offering any PT analytes would be crippling to the sustainability of smaller PT programs. With emerging technologies on the rise, asking PT providers to wait until 10 labs anticipate ordering and resulting is too burdensome of a requirement and will likely prevent smaller PT providers from adding new analytes to meet laboratory client needs.

Allowing HHS to withdraw approval for an analyte, specialty or subspecialty during an approved program year will be detrimental to the PT participants and PT program providers. For example, a PT program could begin the program year with 12 participants, but during the year, one small group of 4 labs is sold and testing is discontinued. In this scenario, only 8 participating labs would remain. If the proposed policies are finalized and enforced, those 8 remaining labs will be required to find another PT program in the midst of the program year. The labs will incur additional fees to enroll in another program. This proposed rule, coupled with current regulation, requiring laboratories to stay with the same PT provider for three consecutive events, over time, further decrease participation for smaller PT providers, consolidating all PT programs to just one or two large PT programs, decreasing competition, limiting laboratory choice, and potentially increasing the prices laboratories must pay to enroll in PT services. **The AAFP strongly opposes granting HHS the authority to remove approval during a program year.**

## III. Collection of Information Requirements

### B. Submission of PT Data by Laboratories

The agencies propose to add the requirement that either PT programs limit the participants' online submission of PT data to one submission or provide a method to track changes made to electronically reported results. While AAFP's program can track online submissions by the laboratory and provides an organizational user login and password, we cannot track each individual user. Doing so would be impossible to manage with current software system. This difficulty is compounded by frequent changes in laboratory staff.

In our system, if the laboratory wishes to edit the result after its final save, the lab must contact AAFP-PT to re-open the module to edit. This action is trackable and crucial for the accuracy of

peer groups. We must allow for this function since our system maintains previous method and units of measure per analyte. If this function is unavailable, peer group data will be flawed because inappropriate data may be included in the statistical analysis for grading.

It is common for our labs to notify us after results are entered and before the event closes that PT methods need to be updated. If the agencies goal is to facilitate the ability to see each phase of results entry, significant new programming would be required to update software. These updates would add to the financial burden of the PT provider. Furthermore, this new requirement creates an uneven playing field in that PT providers accepting fax or mail forms are not held to this standard. All PT providers should be held to the same standard. If the rule is finalized as currently drafted, PT providers must be given significant time to contract for and implement the required software changes.

#### C. Optional On-Site Visits to PT Programs

The rule proposes to allow HHS to conduct onsite visits for all initial PT program applicants and periodically for approved PT programs. The AAFP has no objection to this requirement; however, the site visit should be announced with a minimum of 45 days' notice because our program operates with a small number of staff and not all functions are shared. Advanced notice will foster adequate preparation and will help assure that program staff needed to facilitate the onsite visit are present.

#### D. PT Program Reapproval

CMS may require a currently approved PT program to reapply for approval if widespread or systemic problems are encountered during the reapproval process. The widespread or systemic problem that triggers the more rigorous initial application process should be well documented. In addition, the PT program must be made aware of any potential request before CMS enforces the initial application remedy. We encourage CMS to minimize use of this policy because the initial application process removes staff from time spent providing PT services and ensuring quality.

The proposed rule states that PT programs on occasion modified a laboratory's PT result submission by adding information that was inadvertently omitted by the laboratory (such as the testing methodology). CMS proposes to eliminate these additions. Unfortunately, our software system includes programming that does not allow the lab user to make changes to their account profile. Account changes are managed by technical staff; therefore, we are occasionally required to edit the account profile after results are submitted. Strictly enforcing this proposed rule to bar PT providers from changing methodologies distorts peer group data and will result in flawed data. Corrupting data in this way would be problematic if the final rule maintains peer groups with a minimum number of (10) labs reporting as the draft rule proposes.

#### E. Withdrawal of Approval of a PT Program

The proposed rule gives HHS new authority to withdraw the approval of a PT program at any point in the calendar year if the PT program provides false or misleading information. The AAFP is concerned that withdrawing approval at any point during a program year will impact the lab participants tremendously. Proficiency testing samples are manufactured by a limited number of suppliers. The manufacturers need time to create new samples and only produce sufficient amounts for contracted PT providers. If one PT provider is removed from providing services suddenly or with short notice, the remaining PT providers may not be equipped to absorb their laboratory clients and provide those clients with enough testing samples. Removing approval during a program year will create ripple effects among the labs served by all PT providers.

### Regulatory Impact Analysis

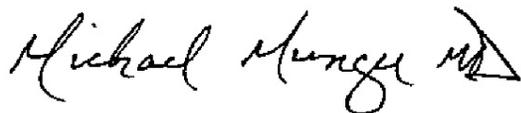
CMS proposes to add 29 analytes and remove 5 from the regulated analyte test list requiring proficiency testing; 5 samples, 3 times per year. The AAFP is concerned that the resulting cost impact (range between \$721-\$3218 per laboratory) will be far greater than forecasted in the proposed rule.

### PT Identification Codes

One item that was not addressed in the proposed rule is how the new analytes will be added to the PT identification code list. It is unclear whether a new list of codes will be created or new codes will be added to the existing list. Reassigning existing identification codes would be highly burdensome. AAFP strongly recommends new codes be added to the existing list. We urge CMS to include this clarification in the final rule.

We appreciate the opportunity to provide these comments. Please contact Christine Schimpf BS, MT (ASCP), Proficiency Testing Program Manager, at 913-906-6127 or [cschimpf@aafp.org](mailto:cschimpf@aafp.org) with any questions or concerns.

Sincerely,

A handwritten signature in black ink that reads "Michael Munger MD". The signature is written in a cursive style with a stylized "M" at the end.

Michael L. Munger, 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.