November 15, 2013

American Clinical Laboratory Association

Ms. Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Service
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

**RE: CMS-1443-P: Medicare Program; Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral; Proposed Rule**

Dear Ms. Tavenner,

The American Clinical Laboratory Association hereby submits comments on the Centers for Medicare and Medicaid Services' ("CMS's" or "the Agency's") proposed rule regarding enforcement actions for proficiency testing referrals under regulations implementing the Clinical Laboratory Improvement Amendments of 1988 ("CLIA").[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of clinical diagnostic laboratory services for patients each year, ACLA member companies have a direct stake in ensuring that the requirements for maintaining laboratory certification are workable, fair, and rational, including the requirements for laboratory proficiency testing ("PT").

In sum, ACLA believes that CMS has not taken full advantage of the flexibility that Congress granted the Secretary to consider the circumstances under which a PT sample was sent to another laboratory and to impose lesser sanctions for referrals that may have been unintended or inadvertent. CMS should retain maximum flexibility and apply a "facts and circumstances" analysis when a laboratory sends out a PT sample, which would allow it to respond more appropriately to innocent PT referrals and to concentrate its corrective efforts on referrals whose purpose is to circumvent the PT program. The sanctions the Agency imposes for different situations also should be more flexible than what has been proposed. Finally, CMS should abandon its historical interpretation of when a referral is "intentional" and codify a new definition that describes a referral made for the purpose of holding another laboratory's results out as its own.

## A. Background

### 1. Statutory Provisions Relevant to Proficiency Testing Samples

CMS regulates all laboratory testing (except research) performed on humans in the U.S. through CLIA. CLIA regulations require, among other things, that CLIA laboratories treat PT samples in the same manner as it treats other samples in the ordinary course of business. CLIA

[1] 78 Fed. Reg. 58386 (Sept. 23, 2013) ("Proposed Rule").

directs the Secretary to establish standards for the PT program.[2] Until passage of the Taking Essential Steps for Testing Act of 2012 ("the TEST Act"),[3] the relevant statute section imposed mandatory penalties on a laboratory violating standards for PT samples: "Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis shall have its certificate revoked for at least one year and shall be subject to appropriate fines and penalties." Also, until amended by the TEST Act, CLIA required that a person who owns or operates a laboratory whose certification has been revoked may not own or operate a CLIA-certified laboratory within two years of revocation, a provision that resulted in the laboratory director also losing his or her ability to direct a laboratory for two years.

In December 2012, Congress passed the TEST Act and President Obama signed it into law, giving the Secretary discretion to substitute intermediate sanctions for violations of the PT referral prohibition, rather than the mandatory two-year prohibition on ownership and operation, and making the one-year certificate revocation optional, rather than mandatory.[4] The law also clarifies that PT samples may not be referred to another laboratory, even if such referral would be part of the testing lab's standard confirmation or reflex procedure for patient specimens. In February 2013, CMS issued a proposed rule that would alter some portions of the regulations that implement the PT program but that would not implement the TEST Act, per se. In part, CMS proposed to amend PT program regulations to read: "If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with §493.1804(c), but not intentional."[5]

### 2. The Problem of PT Referrals

Although laboratories should not send PT samples to other laboratories in order to check their results, in most instances, PT referrals happen inadvertently and for purely innocent reasons. Frequently when a laboratory obtains a positive result on a test (for example, on an HIV test), that test result must be confirmed by another test. If the laboratory does not perform that confirmatory test in-house, it will send the sample to another laboratory for the test. Today, because of the increasing automation of laboratory processes, the referral to the other laboratory often happens without any human intervention.

The PT referral prohibition is implicated in two ways. First, because the rules specifically say that a laboratory must treat a PT specimen in the same way as any other specimen, laboratory testing personnel can become confused about how to treat a positive result that requires confirmatory testing. Second, because laboratories are highly automated, the

[2] 42 U.S.C. § 263a(f)(3).
[3] Pub. L. 112-202.
[4] *See* 42 U.S.C. §§ 263a(i)(3,4).
[5] Medicare and Medicaid Programs; Part II – Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction, 78 Fed. Reg. 9216, 9230 (Feb. 7, 2013) (proposing to amend 42 C.F.R. § 493.801(b)(4)).

laboratory must create a "work-around" to prevent the automated referral of a positive PT sample that would be referred out if it were a regular specimen. Despite the best efforts of laboratories, however, sometimes these work-arounds fail, and the PT sample inadvertently is sent for confirmatory testing to another laboratory. Again, the purpose of this referral is not to check the laboratory's own results on the PT sample or to report out another laboratory's results as its own, because in most instances the laboratory does not even perform the test for which the specimen is being referred.

But for the narrow exception CMS proposed earlier this year, in the past, CMS has taken the position that inadvertent referrals still are "intentional referrals" that violate PT program requirements because the laboratory had the intention to make the referral, regardless of whether it had the intention to circumvent the PT program and report another laboratory's results as its own.[6] Whether the motive behind the referral was innocent has been considered irrelevant. CMS always has taken the position that it has no discretion about how it must respond in these situations, and it nearly always has required that the offending laboratory lose its license for two years, which results in the laboratory director losing his or her license, as well. In most instances, the laboratory then has to outsource the management of the laboratory to another entity so that it can stay in business, and the expenses associated with outsourcing can be substantial. In addition, as noted, the laboratory director, who may have had no direct involvement in the prohibited referral, will lose his or her position with the laboratory. All of this cost and difficulty stem from what usually are honest and accidental errors.

When the TEST Act was passed, the House of Representatives lamented the fact that "Under current law, the Secretary has almost no discretion in imposing penalties for laboratories that make such improper referrals, even if, for example, the improper referral was a mistake made by a new employee."[7] The purpose of the TEST Act, then, is to give CMS greater discretion in dealing with inadvertent referrals so that the Agency does not always have to impose the most severe sanction of license revocation, regardless of the circumstances surrounding the particular referral.

### 3. The Proposed Rule

CMS proposes to add "three categories of sanctions for PT referrals based on the severity and extent of the violation."[8] The Agency's stated purpose is "to frame policies that will achieve a better correlation between the nature and extent of intentional PT referrals at a given laboratory, and the scope and type of sanctions of corrective actions that are imposed on that laboratory and its owners and operators, as well as any consequences to other laboratories owned or operated by those owners and operators."[9]

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[6] *See* 78 Fed. Reg. 58400. 42 C.F.R. § 493.801(b)(4) states: "Any laboratory that CMS determines *intentionally referred* its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year." (Emphasis added.)

[7] Statement of the House Energy & Commerce Committee on H.R. 6118, the "Taking Essential Steps for Testing Act of 2012."

[8] 78 Fed. Reg. 58388.

[9] *Id*. at 58400.

CMS characterizes the three categories of intentional PT referrals as follows:[10]

> Category One would encompass the most "serious, egregious violations," consisting of repeat PT referrals and cases where a laboratory reports another laboratory's test results as its own. CMS would revoke the laboratory's CLIA certificate for at least one year, ban the owner and operator from owning or operating a CLIA-certified laboratory for at least one year, and possibly impose a Civil Monetary Penalty ("CMP").
>
> Category Two would include instances in which a laboratory refers PT samples to a laboratory that operates under a different CLIA number, and while the laboratory reports its own results to the PT program, it receives results from the second laboratory prior to the PT event close date. CMS would suspend or limit the CLIA certificate for less than a year and impose alternative sanctions, including required training of staff.
>
> Category Three would be those PT referral scenarios in which the referring laboratory does not receive test results prior to the event cut-off date from another laboratory as a result of the PT referral. The laboratory always would be required to pay a CMP and comply with a directed plan of action, including required training of staff.

In the Proposed Rule, CMS said that it believes its proposal "would provide the necessary detail to fairly and uniformly apply the discretion granted to the Secretary under the TEST Act, without being so specific as to defeat the intent to provide appropriate flexibility when taking punitive or remedial action in the context of a PT referral finding."[11]

In CMS's proposed formulation, the severity of the penalty is determined by when the erroneous referral is discovered. If the laboratory makes a referral but does not receive the results back prior to the cutoff date, then the penalty is the least severe. If the laboratory does receive the results back prior to the cutoff date, then the sanction is more severe. If the laboratory receives the results before the cutoff date *and* submits the results as its own, then the sanction is the most severe. The main thing that changes is when the error was discovered. As we discuss further below, we think a more reasonable and just approach is one that looks at all of the circumstances surrounding an erroneous referral.

[10] *Id.* at 58400-58401.

[11] *Id.* at 58401. We note that Category Two and Category Three potentially overlap with CMS's description of an "improper" yet not "intentional" referral that it included in its proposal from earlier this year. CMS should clarify that the type of reflex or confirmatory test the Agency described in its proposal from earlier this year is not encompassed by the second and third categories in its current proposal because it is not "intentional."

## B. Comments on CMS's Proposal

### 1. General Comments

In general, we believe that CMS has failed to take full advantage of the flexibility Congress conferred upon the Secretary to craft a new system of sanctions for PT referrals. The three categories of referrals are overly specific, leaving little room for consideration of whether or not a PT specimen was sent out accidentally and whether a laboratory should be subject to sanctions. ACLA does not object to the creation of different categories of PT referrals and associated sanctions, based on the severity of the violation. However, we believe it is not necessary for the categories to be extremely detailed in order for the associated sanctions to be applied uniformly. It would be preferable for the categories to be based generally on the level of culpability and on the risk of harm to patients and the PT program, rather than being tied to a specific fact pattern. Undoubtedly, many PT referrals will not fall neatly into one of the three categories CMS proposes, undermining the Agency's goal of "uniformly apply[ing] the discretion granted to the Secretary under the TEST Act."

CMS should devise a sanctions regime that focuses on the facts and circumstances of each PT referral, including whether a referral was accidental or done for the purpose of circumventing the PT program. As proposed, CMS categorizes PT referrals based generally on whether and when a laboratory receives test results from the laboratory to which a sample was sent, rather than on the totality of the circumstances. When Congress passed CLIA, the House Energy & Commerce Committee, which drafted the legislation, said that with regard to PT referrals and other condition-level deficiencies, a laboratory's whole body of actions and its intentions ought to be taken into consideration:

> The Committee notes that a directed plan of correction would be particularly appropriate where a laboratory is out of compliance with [the Standards section of CLIA], but where imposition of such a sanction in lieu of revocation, suspension, or limitation would not place the health of patients in jeopardy. *The Secretary may also wish to impose such sanctions where the laboratory has made a good faith effort to comply with the law*. Such sanctions may be appropriate for certain proficiency testing, quality assurance, and quality control violations.[12]

Currently, the sanctions proposed for each category of PT referral are overly prescriptive. CMS should retain the flexibility to apply appropriate sanctions for each category of PT referral, based on all of the facts and circumstances surrounding the referral. For example, CMS should be able to consider factors such as the adequacy of a laboratory's operating procedures, the degree of automation in the laboratory, the training and experience of the individual who made the referral, the laboratory's history of referrals, and other relevant factors as appropriate.

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[12] H.R. Rep. No. 899, 100th Cong., 2nd Sess. 1988 (emphasis added). The report also states that, in preparing to draft the legislation, "The Committee was disturbed by a lack of a flexible response to poor proficiency testing. It received evidence of the need for education and technical assistance for laboratories seeking to comply with the law and of the need for a variety of sanctions for those who are unable or unwilling to comply."

To effectuate Congress's intent that a laboratory's intention to comply with the PT program – or not – should be a major factor that CMS takes under consideration in applying sanctions for PT referrals, CMS should define "intentionally referred" in the PT sample context as "knowingly and willfully sent a PT sample to another laboratory for the purpose of using that laboratory's test results as its own or as a comparison for its own results." After incorporating this into CLIA definitions 42 C.F.R. § 493.2, CMS would need to revise its proposed categories of PT referrals to accommodate those that are not "intentionally referred." (As proposed, the introductory paragraph to all three categories includes the phrase "intentionally referred.")

Our specific comments on CMS's three categories of referrals and sanctions follow.

### 2. Category One, Proposed 42 C.F.R § 493.1840(b)(1)

ACLA agrees with CMS that the most severe sanctions should be reserved for a laboratory that purposely reports out another laboratory's results on a PT sample as its own, or for a laboratory that makes little or no effort to comply with CMS's proficiency testing program, as evidenced by repeat PT referrals. We do believe that rather than prescribing the minimum sanctions that must be applied in these situations, CMS should retain the flexibility to determine the appropriate sanctions, based on all of the facts and circumstances.

This category includes what CMS would define as "repeat proficiency testing referrals."[13] We disagree with CMS's proposal not to take under consideration the reason for the referral. It is conceivable that two minor, innocuous mistakes could result in these draconian sanctions if a laboratory accidentally refers a PT sample twice but has no intent to circumvent the PT program. While some sanction may be appropriate in that case, CMS has not left itself any flexibility.

Also, it is not clear whether the reflex or confirmatory referral described by CMS in its proposal earlier this year could be considered the first of two events in a "repeat" referral. Although CMS proposed to consider such a referral to be improper but not intentional, it still would be a referral under the earlier proposal. If a laboratory sends out a PT sample for reflex testing in a manner that conforms to CMS's proposal for amending 42 C.F.R. § 493.801(b)(4), it would be subject to alternative sanctions; if it sends out a PT sample for reflex testing in the next survey cycle, would it be subject to the full force of the proposed Category One penalties?

### 3. Category Two, Proposed 42 C.F.R. § 493.1840(b)(2)

CMS proposes that a laboratory that receives test results from another laboratory prior to the proficiency testing event close date would have its CLIA certificate suspended or limited for up to a year, be subject to CMPs, and have a directed plan of correction. This is regardless of whether the laboratory intended to circumvent the PT program and despite the fact that it does not use the results as its own. As we stated previously, we do not believe that PT referrals should be characterized based on when a laboratory received results back from another lab –

[13] This would mean "a second instance in which a proficiency testing sample, or a portion of a sample, is referred, for any reason, to another laboratory for analysis, prior to the laboratory's proficiency testing program event cut-off date within the period of time encompassing the two prior survey cycles (including initial certification, recertification, or the equivalent for laboratories surveyed by an approved accreditation organization)."

before or after the PT event close date – but rather on the laboratory's purpose for sending the sample out in the first place (if any), the policies and procedures in place, and lab personnel's level of experience.

#### 4. Category Three, Proposed 42 C.F.R. § 493.1840(b)(3)

Under Category Three, "a PT referral has occurred, but no test results are received prior to the event close date by the referring laboratory from the laboratory that received the referral." Again, CMS has left itself little flexibility, and this category is where it is needed most. The scenario CMS describes in the preamble to the Proposed Rule is more aptly characterized as an "accident" or "misunderstanding" than a referral. Moreover, it is clear from CMS's own vignette that the "referring" laboratory had no intention to circumvent the PT program and acted swiftly and appropriately to rectify the situation:

> For example, a laboratory may place PT samples in an area where other patient specimens are picked up by courier to take to a reference laboratory. The reference laboratory courier may take the PT samples along with the patients' specimens. The laboratory personnel notice that that PT samples are missing and contact the reference laboratory to inquire if they have received the PT samples along with the patient specimens. The reference laboratory is instructed to discard the PT samples and not test them since they were picked up in error. In this case, the "referring" laboratory realized the error, contacted the receiving laboratory and did not receive results back for any of the PT samples.

Even using CMS's traditional, cramped interpretation for "intentionally referred," CMS should impose no sanctions on a laboratory in this situation. This laboratory did not intend to refer the PT samples, let alone intend to circumvent the PT program. If the laboratory intended to refer the PT samples out, it would not have noticed that anything was amiss, even if it noticed that the PT samples were missing. The involvement of a courier picking up other samples "from the area" where other specimens are picked up introduces another variable that militates in favor of a "facts and circumstances" analysis to account for this sort of situation in which there is no chance of harm to patients or to the PT program.

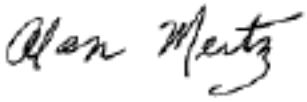
We do not believe that this situation – which entails placing samples too close to a courier pick-up location – warrants any sanctions whatsoever, in that it is not an "intentional" referral, and monetary penalties certainly should not be imposed. The harshest penalty that should be levied in any event is a directed plan of correction, which theoretically could decrease the likelihood that the laboratory would allow such an accident in the future and preserve CMS's resources for true intentional referrals.

### C. Conclusion

In sum, we believe that the categories that CMS has outlined are too restrictive, and they inappropriately tie the severity of the sanction to the point in time when the error is discovered, rather than on the laboratory's degree of culpability. We urge CMS to restructure its proposal to

account for the many factors that may contribute to a PT sample referral and to build in flexibility in imposing sanctions. Thank you for your consideration of ACLA's comments.

Sincerely,



Alan Mertz, President
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