American
Clinical Laboratory
Association

June 7, 2010

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

RE: Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements (CMS-6010-IFC)

Dear Acting Administrator Tavenner:

On behalf of the American Clinical Laboratory Association (ACLA), we are submitting comments on the *Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements Interim Final Rule with Comment Period ("Interim Final Rule")* issued by the Centers for Medicare & Medicaid Services (CMS).[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. ACLA's member companies provide laboratory testing for a countless number of the nation's physicians for their Medicare and Medicaid beneficiaries and perform well over 1 billion laboratory tests a year. The Interim Final Rule will, therefore, directly impact our member laboratories.

While ACLA and its member companies recognize the importance of ensuring covered services are provided by Medicare enrolled and qualified providers and suppliers, CMS should achieve this goal in a manner that is fair to all providers. It seems especially unfair to penalize clinical laboratories because ordering or referring physicians are not enrolled in Medicare's Provider Enrollment, Chain, and Ownership System (PECOS), a circumstance over which laboratories have no control. As discussed in greater detail below, we are concerned by CMS' efforts to expand the scope of the Interim Final Rule beyond that which Congress intended in its enactment of the Patient Protection and Affordable Care Act (PPACA). Specifically, ACLA's comments will focus on the reasons why the Interim Final Rule should not apply to clinical laboratory services and then turn to our concerns relating to CMS not being in a position to implement the Interim Final Rule altogether.

[1] 75 *Fed. Reg*. 24437 (May 5, 2010).

In sum, ACLA believes that it is inappropriate for CMS to refuse payment for laboratory services or other Medicare Part B services when the ordering or referring physician is not enrolled in the PECOS file. First, the laboratory has no way to compel physicians to enroll in PECOS. Second, and perhaps even more important, it seems clear that the issues created with regard to the PECOS file result not from physicians' failure to enroll, but largely from CMS' inability to manage the PECOS file. That is, in many instances, physicians are not in PECOS because of failures within CMS, not because they have failed to enroll. As a result, it is especially inappropriate to penalize laboratories and other providers for a failure that appears to be, to a large extent, a problem of CMS' own making.

The Interim Final Rule <u>Should Not</u> Apply to Clinical Laboratory Services

Of primary concern to ACLA and its member companies is the application of the Interim Final Rule to Medicare Part B claims for covered clinical laboratory services beginning on July 6, 2010. Section 6405(a) and (b) of PPACA require that ordering or referring physicians of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and home health services be enrolled in the Medicare program by July 1, 2010 (referred to herein as the "PPACA deadline"). However, Section 6405(c) of PPACA gives the Secretary of the Department of Health and Human Services, through CMS, the discretion to expand that enrollment requirement to other Medicare items and services that are ordered or referred by a physician. In exercising its discretion, beginning July 6, 2010, CMS announced its intention in the Interim Final Rule to require that for items of DMEPOS, home health services, and certain other Medicare Part B covered services, including laboratory services, the ordering or referring physician must be uniquely identified on the claim.[2]

In particular, the following requirements must be met: (1) the ordering or referring physician must have an approved enrollment record in PECOS; and (2) the ordering or referring physician must be identified on the claim by his or her legal name and by his or her own NPI. According to the Interim Final Rule, Medicare contractors will be directed to reject claims for covered laboratory services if the legal names and the NPIs are not reported on the claims and if the ordering or referring physician does not have an approved enrollment record in PECOS, unless the physician has opted out of the Medicare program. In other words, Medicare Part B claims for covered laboratory services will be denied if the ordering or referring physician does not have an NPI and is not enrolled in the PECOS file.

The requirement that the ordering or referring physician be enrolled in PECOS by July 6, 2010 raises a number of issues for ACLA and its member laboratories, as it has for the physicians who order or refer laboratory services. First, laboratories are unable to determine whether the ordering or referring physician has an "approved enrollment record" in the PECOS file prior to performing testing, nor should it be the responsibility of laboratories to do so. ACLA member laboratories submit tens of thousands of claims on an automated basis each day and cannot halt this process to manually verify an ordering or referring physician's enrollment status in PECOS. One of

[2] Despite the PPACA deadline of July 1, 2010, the Interim Final Rule has an effective date of July 6, 2010 to allow for a 60-day comment period. For purposes of our comments, when referring to PPACA we use the July 1, 2010 date and when referring to the effective date of the Interim Final Rule we use the July 6, 2010 date.

the primary purposes of administrative simplification has been to streamline the billing process such that it is more efficient for providers and suppliers. Requiring laboratories to manually check an over 11,000 page PECOS file prior to submitting an automated claim is entirely contrary to this purpose and would be costly and significantly administratively burdensome to laboratories. Further, even if it would make sense for laboratories to verify an ordering or referring physician's status in the PECOS file, once a specimen gets to the laboratory, laboratories usually consider themselves ethically and legally obligated to perform the test. And, because of the fragility of the test specimen, laboratories cannot simply hold the specimen until the physician's enrollment in PECOS is verified. As a result, it seems unfair to penalize laboratories in the event the ordering or referring physician is not yet enrolled in PECOS.

Second, CMS is imposing this deadline on clinical laboratories even though no such mandate is required by PPACA. Under PPACA, CMS has the discretion to determine the items and services to which the PPACA deadline should apply beyond items of DMEPOS and home health services. However, in the Interim Final Rule, CMS elects to exercise its discretion to expand the scope of the mandate set forth in PPACA to include clinical laboratory services without a compelling reason to do so. While Congress required CMS to apply this requirement to DMEPOS and home health services, no such requirement exists for laboratory services.

CMS Is Not Ready To Implement the Interim Final Rule

Notwithstanding ACLA's position that the Interim Final Rule should not apply to clinical laboratory services on July 6, 2010, the fact remains that the Interim Final Rule is clearly not ready to be implemented with respect to any Medicare Part B claims by this deadline. This is evidenced by CMS' repeated efforts to delay the deadline by which ordering and referring physicians of Part B services were required to be enrolled in the PECOS file and by CMS' own acknowledgement in the Interim Final Rule. The mere enactment of PPACA has not changed the fact that so far CMS has been unable to effectively implement the PECOS file. Specifically, with respect to CMS' repeated delays, on October 2, 2009, the Medicare program issued program instructions that expanded the scope of editing for ordering or referring providers for claims processed by Medicare carriers and Part B Medicare Administrative Contractors (MACs).[3] The program instructions outlined a two-phase edit that would verify ordering or referring providers on Medicare Part B claims. Under Phase 1, any Medicare Part B claim that required an ordering or referring provider to be included on the claim would need to be verified to ensure that the ordering or referring provider was enrolled in the national PECOS file. If the ordering or referring provider was not in the national PECOS file (or the contractor's provider file), the claim would continue to process, but a message would be included on the remittance advice notifying the billing provider that the claims may not be paid in the future if the ordering or referring provider is not enrolled in Medicare. Phase 2, followed the same verification process as under Phase 1, but would result in a rejection of the claim altogether if the ordering or referring provider was not found in the PECOS file.

The program instructions for the two-part edit were to be implemented as of October 5, 2009. However, because CMS was unable to populate the PECOS file by its own deadline, Phase 2 of the program instructions was not implemented. To date, only Phase 1 of the edit has been

[3] One-Time Notification (Pub 100-20), CR 6417, Trans. 572 (Oct. 2, 2009).

implemented and Phase 2 has been delayed by CMS on two separate occasions. On November 23, 2009, CMS delayed the implementation of Phase 2 of the PECOS edit until April 5, 2010 to allow Medicare providers and suppliers sufficient time to enroll in Medicare or take the necessary actions to establish a current enrollment record in Medicare prior to the implementation of Phase 2.[4] Then, on February 26, 2010, CMS extended the implementation of Phase 2 of the program instructions yet again until January 3, 2011 for the very same reason.[5] In short, CMS has itself noted that the information required is not available in the PECOS file. However, despite this failure, CMS has now decided that it will deny payments if laboratories are unable to obtain this very same information.

Throughout these delays, ACLA has communicated to CMS its member laboratories' concerns regarding the agency's inability to ensure that ordering or referring physicians are effectively uploaded into the PECOS file given the number of warning messages that our member laboratories have received since the initial October 5, 2009 deadline. During one of these communications with CMS prior to the first deadline delay, we were told that CMS would be manually uploading the ordering or referring providers' NPIs into the PECOS in December 2009 to ensure that all providers with NPIs would be enrolled in the PECOS file. However, it has been the experience of our member laboratories that this manual upload from the National Plan and Provider Enumeration System (NPPES) could not have worked because our laboratories continue to receive warnings for 8 to over 30 percent of their submitted claims, which is unacceptable.

As further evidence of the confusion resulting from this PECOS enrollment process, some of ACLA's member companies have been informed by their physician customers that these physicians have attempted to enroll in the PECOS file by updating their enrollment applications pursuant to CMS' instructions, but have had their applications returned to them with instructions that there is no need for their applications to be updated at this time. This one example illustrates the disconnect within CMS regarding the need for physicians to be enrolled in the PECOS file and the way in which to do so. Additionally, we have heard directly from Medicare contractors that CMS is not in a position to implement this Interim Final Rule by the July 6, 2010 deadline given contractors' lack of resources and time.

Furthermore, CMS, itself, acknowledges in the Interim Final Rule that not all physicians will be enrolled in the PECOS file by the effective date of the Interim Final Rule. According to CMS, any provider or supplier who enrolled in the Medicare program more than 6 years ago and has not updated their enrollment information in the past 6 years will need to submit new enrollment applications to be enrolled in the PECOS file. CMS goes on to state that "[w]e expect that most, if not all, [physicians and eligible professionals] will have submitted enrollment applications before *the end of 2010*, including those who are enrolling solely to continue to order and refer."[6] Of course, the new requirement is effective *July 6, 2010,* so CMS' statement that it expects most physicians to be enrolled *six months later* is quite telling. By this statement alone, CMS confirms that it is fully aware that not all physicians will be enrolled in the PECOS file by July 6, 2010, the date on and after which Medicare Part B claims will be denied under the Interim Final Rule. As

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4 *See* Notice from CMS to All Provider Partners, Delay in Implementing Phase 2 of CRs 6417 and 6421 (Nov. 23, 2009).

5 One-Time Notification (Pub 100-20), CR 6417, Trans. 642 (Feb. 26, 2010).

6 75 *Fed. Reg*. at 24443 (emphasis added).

such, it is clear that this is an enrollment problem that CMS needs to ultimately resolve on its end before penalizing billing providers and suppliers by denying claims.

In summary, given the repeated delays for implementing the PECOS edit and CMS' own acknowledgement that physicians will not be properly enrolled in the PECOS file by July 6, 2010, it is clear that CMS is not in any position to implement the Interim Final Rule for laboratory services. For CMS to deny claims for laboratory services that have been ordered or referred to the laboratory in the event the ordering or referring physician is not enrolled in the PECOS file beginning on July 6, 2010 when CMS is fully aware of the fact that not all physicians will be enrolled in the PECOS file until the end of the year constitutes the most quintessential arbitrary and capricious action by the agency and, thus, a clear violation of the Administrative Procedure Act (APA). ACLA member laboratories should not be precluded from payment due to an ordering or referring physicians' inability to enroll in the PECOS file and/or CMS' inability to effectively populate the same.

If Clinical Lab Services are Not Exempted Entirely, CMS Should Extend the Interim Final Rule Deadline for Clinical Laboratory Services

If CMS intended to make use of its discretion to apply the PPACA deadline to additional Medicare items and services that were not required in PPACA, CMS should have followed notice and comment rulemaking. To waive this procedure, the agency must have a compelling reason to do so. In addition, there is an exception that permits the agency to waive notice and comment rulemaking where the statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute. However, neither of these justifications would apply in the case of laboratory services. First, CMS has shown no compelling reason to apply the PPACA deadline to laboratory services. Second, while it may have been necessary to waive notice and comment rulemaking to meet the statutorily mandated PPACA deadline for items of DMEPOS and home health services because the deadline is less than 150 days from the date of PPACA's enactment, laboratory services were not subject to this deadline. Although CMS acknowledges this point by stating there are portions of the Interim Final Rule that are not subject to this exception, CMS claims that these portions of the Interim Final Rule will not "add any new burdens for Medicare and Medicaid providers and suppliers."[7] However, this could not be any further from the truth. As we have discussed, both the PPACA deadline and effective date of the Interim Final Rule (July 6, 2010) will be significantly burdensome on laboratories as ordering and referring physicians have yet to be properly enrolled in the PECOS file and laboratories are unable to verify their enrollment prior to the performance of testing. Thus, laboratories will be forced to perform testing for which they may not receive payment for a countless number of claims.

As such, there are obvious reasons why the Interim Final Rule should not apply to clinical laboratory services beginning on July 6, 2010. Instead, pursuant to CMS' most recent program instructions, which we discussed earlier, the deadline should be extended to January 3, 2011, if clinical laboratory services are not exempted completely from the Interim Final Rule, as we are requesting. CMS' program instructions, dated February 26, 2010, delayed the denial of claims – Phase 2 of the PECOS edit – until January 3, 2011. Under these instructions, in the event that an

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7 *Id.* at 24446.

ordering or referring physician is not enrolled in the PECOS file the laboratory receives a warning message indicating that payment may not be made in the future because the ordering or referring physician is not enrolled in the Medicare program. However, the payment for the performed laboratory services is not denied. Additionally, claims submitted by the billing laboratory will also not be denied if the laboratory uses its own billing provider NPI on the submitted claim if after repeated attempts the laboratory is unable to obtain the ordering or referring physician's NPI. These program instructions have avoided a multitude of claims denials that would result if Phase 2 of the PECOS edit was in effect today. If clinical laboratory services are not exempted from the Interim Final Rule as we are requesting, we ask that CMS maintain these instructions for their duration.

Again, we urge CMS to exempt clinical laboratory services from the Interim Final Rule entirely. However, if clinical laboratory services are not to be exempt, based on the timeframe in which CMS expects physicians to be *completely* uploaded into the PECOS file, CMS should implement the January 3, 2011 deadline for clinical laboratories and to continue to permit the billing laboratory to use its own NPI on claims until such date as well. CMS is clearly not ready to implement the Interim Final Rule for items and services not mandated in PPACA, such as laboratory services, and laboratories should not have their claims denied before CMS' enrollment files to which the edits apply are in place.

CONCLUSION

In closing, we appreciate the opportunity comment on the Interim Final Rule. If you have any questions or need any further information, please do not hesitate to contact us.

Sincerely,

Joanne Glisson
Senior Vice President