November 20, 2015

American
Clinical Laboratory
Association

VIA EMAIL

Diane Kovach, Director
Provider Billing Group
Centers for Medicare & Medicaid Services
Mail Stop C4-02-17
7500 Security Boulevard
Baltimore, MD 21244

Re: Implementation of New NPI Edit on Reference Laboratory Claims

Dear Ms. Kovach:

On behalf of the American Clinical Laboratory Association ("ACLA"), I am writing to express our great concern with the significant payment disruptions that have resulted from a new edit that CMS implemented on October 1, 2015. As you know, ACLA represents local, regional and national laboratories across the country, nearly all of which are adversely affected by this new policy. As detailed below, this new policy has resulted in inappropriate denials of millions of dollars in claims to ACLA members, all as a result of issues with CMS's payment programs and systems. Although the CMS staff has worked assiduously to solve this problem, they have now admitted that it is unclear how long it will take to fully resolve the issue. Given the large financial impact on laboratories—the significance of which becomes especially great as we head into the end of the year—we urge CMS to place this edit on hold until the issue can be resolved. We will be contacting your office shortly to set up a call to discuss this issue further.

I. Background on the Problem

Because of the number and variety of laboratory services that are available to physicians, a laboratory may not perform all the services it offers at each of its locations. And, in some instances, it may not perform the test at all, but instead may have a contract with another laboratory to perform the necessary services. For example, in some instances, a specimen may come into a laboratory location where it is accessioned, but because the requested test is not performed at that location, the specimen will then be sent to another laboratory, which acts as a reference laboratory. In other instances, some tests will be performed at the receiving location, but other tests requested will be performed at another laboratory, which may perform a test that the original laboratory does not. (In some instances, there may even be more than one reference laboratory that performs services on the specimen, depending on the range of services requested.) In the first situation, there will be only one place of service on the claim reflecting the single reference laboratory that performed the services, while in the other examples, there will multiple places of service on the claim.

In both situations, however, Medicare requirements are clear that the original laboratory that received the specimen is the entity that bills for all of the services and it submits the claim to

its own contractor. The billing laboratory is to use a "-90" modifier on the tests that are referred out, as a way of indicating that the tests were performed by another laboratory and additional information about the performing laboratory is also included on the line item applicable to the referred services.

This procedure is quite explicit in the Claims Processing Manual, which states:

> Billing laboratory performs some laboratory testing; some testing is referred to another laboratory: The claim will not be split; CLIA numbers from both the filling and reference laboratories must be submitted on the same claim…The presence of the '90' modifier at the line item service identifies the referral tests. Referral laboratory claims are only permitted for independently billing clinical laboratories, specialty code 69. [1]

This system, which CMS put in place several years ago, ensures that one contractor can process the entire laboratory claim, and when necessary, recognize referred services and apply the correct fee schedule amount for the jurisdiction where they were performed. The system ensures that claims can be processed efficiently and with a minimum of duplication.

On May 8, 2015, however, CMS instituted a new policy that required the billing laboratory to submit not just the CLIA number of the referring laboratory, but also the NPI of the performing physician or supplier. [2] According to the Transmittal, this change was precipitated in part by concerns about the anti-markup rule, which is unlikely to be applicable to most independent clinical laboratories. As the Transmittal itself notes, the anti-markup rule is only applicable to services billed under the Medicare Physician Fee Schedule, whereas the reference laboratory services at issue here will usually be paid under the Clinical Laboratory Fee Schedule ("CLFS"). Under 42 C.F.R. §414.50, it is clear that the anti-markup rule does not apply to services paid on the CLFS. Moreover, as that same provision notes, the anti-markup rule only applies where the physician or supplier both orders the service and bills for it. Because clinical laboratories cannot order services themselves, but require the treating physician to order them, it would be very rare for a clinical laboratory even to be subject to the anti-markup rule in the first instance.

II. Impact of the Recent Transmittal Change.

As noted, although the anti-markup has little relevance to billing by independent laboratories, the recent change is creating havoc for them.

All ACLA laboratories are reporting that they are receiving an unusually large number of denials in the case of claims with reference laboratory billing, even though they are adding the NPI of the reference laboratory as required and that entity is properly enrolled in the PECOS

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[1] Medicare Claims Processing Manual, Chap. 16, §40.1.1.2

[2] CMS Manual System, Trans. 3255, Chge, Req. 9150 (May 8, 2015). *See also,* Trans. 3103, Chge Req. 8806 (Nov. 3, 2014.)

system. Even though the policy was only effective in early October, large laboratories have several million dollars in improper denials. Smaller laboratories, which may be especially in need of the funds, have hundreds of thousands of dollars in such denials. Moreover, such shortages are unwelcome at any time, but especially so at the end of the year, when cash needs are likely to be greatest.

The reason for these problems is not totally clear. Most importantly, for some reason, the NPIs of many laboratories simply do not show up in the CMS billing system when the laboratory is listed as a reference laboratory on a claim, thus causing inappropriate denials. This is not a problem that results from a failure of either the billing laboratory or the reference laboratory. Both entities are properly enrolled in the system; however, the contractors report that they cannot find a record of the NPI for the reference laboratory, even though it is clear that the entity should be in the system. The contractors are unable, or unwilling, to fix this problem on their own. For example, one contractor has acknowledged there are gaps in the PECOS file, but has requested that the affected laboratory call the contractor's customer service line and verify the NPI of each reference laboratory for which the laboratory is billing. So far, this laboratory, which is of modest size, has had to manually cull out 300 individual claims and is calling the contractor to verify the individual NPI code of each reference laboratory included on its claims. However, the contractor only allows the laboratory to verify three NPIs per call, which means it will require one hundred individual calls to complete that task and there is no assurance that the effort will actually resolve the issue.

ACLA members have worked with Susan Webster, Director of the Division of Claims Processing, and her staff and they have been very sympathetic to our concerns. They have acknowledged that there is a problem with the PECOS system and, it is our understanding that at least some of the denied claims will now be subject to a one-time mass adjustment, but even that will not occur until sometime in early December. Moreover it is not clear that the underlying problem has been resolved.

Our understanding is that CMS believes it may have a fix for the claims that involve a single place of service, such as where the laboratory receiving the specimen does not perform any requested services, but simply sends the specimen on to another reference laboratory to perform the services. However, it is not clear when that fix can be put in place. Further, it is our understanding that CMS does not yet have a fix for the reference laboratory claims with multiple places of service; i.e., where the billing laboratory performs some of the requested services but then refers out other tests to one or more reference laboratories. We have been advised that the only short term solution to that issue may be for the laboratory to split the claim, i.e., to bill separately for each laboratory performing the services. This is, of course, flatly at odds with CMS's own instructions on this issue; would require a massive re-programming effort by all laboratories at a time when there are dealing with the impact of ICD-10 and preparing for the implementation of PAMA; and will increase the work for laboratories and contractors alike for no good reason. Moreover, it will mean that beneficiaries would get multiple EOBs for the same group of services, which is likely to cause confusion.

As a result, ACLA is urgently requesting that CMS immediately place the current edit on hold until this issue can be resolved. As noted, the financial impact is extremely severe, and there is absolutely nothing that laboratories can reasonably do to avoid the consequences of this problem. Moreover, as noted, it appears that the underlying purpose of the change has little to do with reference laboratory billing anyway. Laboratories are happy to do whatever they can to assist CMS in resolving this issue; however, until a solution can be found, it seems only fair for CMS to stop applying the edit.

We will be following up with your office to set up a time to discuss this issue further. In the meantime, if you have any questions or need any further information, do not hesitate to contact me.

Sincerely,

JoAnne Glisson
Senior Vice-President

cc: Susan Webster
Director, Division of Supplier Claims Processing

Zabeen G. Chong
Director, Program Enrollment and Oversight Group