



American  
Clinical Laboratory  
Association

February 23, 2010

Kimberly Brandt  
Director, Program Integrity Group  
Office of Financial Management  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Mail Stop C3-02-16  
Baltimore, MD 21244-1850

**Re: Medically Unlikely Edit (MUE) Denials and Advance Beneficiary Notices of Noncoverage (ABNs)**

Dear Ms. Brandt:

I am writing on behalf of the American Clinical Laboratory Association (ACLA) regarding the recent Program Transmittal that was issued relating to MUEs.<sup>1</sup> As you know, ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. During the past year we have worked extensively with your staff and with Dr. Niles Rosen, Medical Director of the National Correct Coding Initiative, regarding the temporary suspension of certain pathology MUEs that significantly impact our clinical laboratories. As CMS begins to implement these MUEs, and in light of the recent Program Transmittal and correspondence with Dr. Rosen, we would like to take this opportunity to request that CMS reconsider its position on the limitations on using an Advance Beneficiary Notice of Noncoverage (ABN) with MUE denials. In addition, we would like to seek clarification on CMS' guidance for reporting units of service (UOS) that may exceed an MUE value.

**Advance Beneficiary Notices of Noncoverage**

According to the recent Program Transmittal, "a denial of services due to an MUE is a coding denial, not a medical necessity denial. A provider/supplier shall not issue an [ABN] in connection with services denied due to an MUE and cannot bill the beneficiary for units of service denied based on an MUE."<sup>2</sup> We believe that this policy is incorrect and inconsistent with the statutory and regulatory provisions relating to ABNs. Where a clinical laboratory knows that it is going to provide testing that Medicare will likely deny because the UOS billed will exceed the MUE, the clinical laboratory should be permitted to obtain an ABN. Although laboratories would prefer not to bill beneficiaries for these services, if CMS intends to enforce its MUEs, laboratories also do not believe they should be required to appeal each MUE denial or to provide such services free of charge.

---

<sup>1</sup> Program Transmittal 617, Change Request 6712 (Jan. 8, 2010) (hereinafter the "Program Transmittal")

<sup>2</sup> *Id.* at 5.

According to CMS, an MUE for a Healthcare Common Procedure Coding System (HCPCS)/Current Procedural Terminology (CPT) code is the maximum UOS under most circumstances that a provider would report for that code for a single beneficiary on a single date of service. By virtue of the program's description, CMS has determined that UOS that exceed the MUE value are "medically unlikely," which seems virtually identical to "not medically necessary." Indeed, in our various discussions, CMS has indicated that certain MUEs, such as flow cytometry, were clinically, rather than statistically based. That is, CMS has made a determination that it is seldom medically necessary to perform more than some specified UOS. As such, it is clear that CMS associates an MUE denial with a medically necessary determination. To argue that an MUE denial is anything other than a medical necessity denial seems purely semantics.

Given that an MUE denial is a determination based on whether UOS are medically reasonable and necessary, it logically follows that an ABN should be permitted so the laboratory can bill the beneficiary. As is generally the case, where a service will likely be denied because it is determined not to be medically reasonable and necessary under Medicare coverage guidelines, a provider is permitted to obtain an ABN, and to bill the patient in the case of a denial.<sup>3</sup> In the case of MUEs, the situation is no different. Under the MUE program, CMS is denying payment because the UOS has exceeded what CMS believes is the medically necessary UOS. Accordingly, providers should be permitted to obtain the ABN. This would permit patients to determine whether or not they wish to obtain the services at their own expense, and permit laboratories to be paid for the services. Again, laboratories are not in favor of billing patients for services that they believe are medically necessary. Instead, laboratories believe the appropriate course is for Medicare to make an individual determination based on each patient concerning the medical necessity of the UOS billed. However, if CMS institutes an across the board rule establishing what it believes to be appropriate UOS, then laboratories should be able to obtain ABNs when they believe such limits will be exceeded, and the claim denied.<sup>4</sup>

We note that there are other situations where an ABN is permitted in comparable situations. For example, under the rules applicable to Durable Medical Equipment (DME), an ABN is appropriate when Medicare is expected to issue a partial denial of a more extensive part of a usually covered item or service. Among the examples of such excess services are "increased charges attributable to furnishing something that is more in number, more frequent ... or has added features" than would otherwise be considered medically necessary.<sup>5</sup> The additional UOS being denied by CMS pursuant to the MUEs are in fact no different. That is, the additional UOS represent additional services that are greater in number than Medicare considers appropriate.<sup>6</sup> Thus, as with DME, an ABN is appropriate to cover those charges for those additional services.<sup>7</sup>

---

<sup>3</sup> See 42 USC § 1395pp; see also 42 CFR § 411.404(b).

<sup>4</sup> We recognize that the laboratory could appeal the denial if it wished. However, that is true for any denied service. Where a provider obtains an ABN, it always has the option of appealing the denial or billing based on the ABN.

<sup>5</sup> Medicare Claims Processing Manual, Chap. 30, § 50.8.

<sup>6</sup> Under the MUE process, Medicare actually denies the entire service. However, where the laboratory indicates it has obtained an ABN, Medicare should simply pay up to the MUE limit and deny the excess, a process that would permit the laboratory to bill for the excess. This is what happens in the DME situation described above.

<sup>7</sup> In fact, an MUE is similar to the denial for frequency where Medicare has determined that a test has been provided too often and denies the claim, in which case an ABN is permitted. An MUE denial is based on a similar

Accordingly, we cannot find any adequate justification for why laboratories would be precluded from giving an ABN to a beneficiary that notifies the beneficiary that Medicare may not pay for the number of UOS for medically necessity reasons. The ABN permits the beneficiary to make an informed decision whether to receive the tests for which he or she may be financially liable. If a patient's physician determines that certain UOS are medically necessary to accurately diagnose and treat the patient, and the patient is notified and willing to accept financial responsibility for the tests, there should be no reason a valid ABN cannot be executed in order for the laboratory to be reimbursed for the furnished services.

As such, we request that CMS revisit its position on the use of ABNs for MUE denials and make clear that ABNs are permitted where it is likely that the UOS will exceed the MUE value. To the extent that CMS disagrees with this analysis, we would like to meet with you to understand the reasons for your views.

### **MUE “Workaround”**

While ACLA strongly believes that laboratories should be permitted to submit ABNs for MUE denials, we also note that CMS has stated on several occasions that there is a “workaround” for the MUE limits. Based on the Program Transmittal and on letters from Dr. Rosen, ACLA has been instructed to split the UOS on separate lines of a claim with the use of certain CPT modifiers in order to be reimbursed for UOS that exceed an MUE. Specifically, for purposes of reporting medically reasonable and necessary UOS in excess of the MUE value, laboratories have been directed to use modifiers 59 or 91 to report the same code on more than one line of a claim as each line will be adjudicated separately against the MUE value for the code on that claim line. In using this approach, CMS suggests that laboratories will be reimbursed for medically reasonable and necessary UOS that may exceed the MUE.<sup>8</sup>

However, our concern with CMS' “workaround” approach is two-fold. First, although CMS' method appears to address the issue of being reimbursed for medically reasonable and necessary UOS that exceed MUEs, we are concerned that this solution may raise compliance issues in the future. We are especially concerned that the government will take the position at some time in the future that such billing constitutes improper unbundling of services or an attempt to circumvent Medicare billing requirements. Such concerns are especially real given the prevalence of potential audits and claims reviews by Medicare contractors under the Recovery Audit Contractor (RAC) and Comprehensive Error Rate Testing (CERT) programs. As a result, we are asking that CMS confirm our understanding that it is permissible for laboratories to split services into two separate line items in order to avoid triggering MUE edits when the laboratory believes that it is appropriate to bill for all the UOS of the services billed.

---

premise – Medicare has determined that the UOS for a particular test has exceeded a given medically necessary amount of testing under specific circumstances. Thus, it is difficult to argue that an MUE denial is, in fact, not a medical necessity denial because Medicare has essentially determined that the billed UOS are not medically necessary for the beneficiary.

<sup>8</sup> Letter from Niles R. Rosen, MD, Medical Director, Medically Unlikely Edit Program, National Coding Initiative, Correct Coding Solutions, LLC, to David Mongillo, ACLA (May 21, 2009) (on file with ACLA); Tranmittal, at 3.

Additionally, to the extent that claims are denied despite the use of the workaround, laboratories should not be required to appeal medically reasonable and necessary claims that are appropriately billed to the Medicare program. Indeed, permitting providers and suppliers to submit ABNs where UOS exceed MUEs is the most appropriate and logical solution. However, in lieu of permitting ABNs, we request that CMS ensure that in using the workaround medically reasonable and necessary UOS that exceed an MUE value will not be denied and providers and suppliers will be held harmless from any potential liability that may result from following CMS' guidance to use the workaround method.

**Conclusion**

It is our hope that we can continue to work with you to resolve our issues with respect to MUE denials. We would like to discuss the use of ABNs further with CMS, and its legal counsel, to further review this issue.

Sincerely,

A handwritten signature in black ink, appearing to read 'JoAnne Glisson', with a stylized flourish at the end.

JoAnne Glisson  
Senior Vice President

cc: Valeria Allen, Program Integrity Group  
John Stewart, Program Integrity Group