American Clinical Laboratory Association

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Mr. Marc Hartstein
Acting Director, Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services
Center for Medicare
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Dear Mr. Hartstein,

The American Clinical Laboratory Association (ACLA) is writing to thank you and your colleagues for the time you took in March to discuss ACLA's concerns about Transmittal 2407, Revised and Clarified Place of Service (POS) Coding Instructions (the Transmittal).[1] We were especially appreciative of your decision to rescind the Transmittal to allow time for a fuller exploration of the issues that it created. We are writing this letter to provide additional background on the impact of CMS' proposed changes to the POS coding instructions and to suggest a possible solution.

As you know, on several occasions, ACLA and other laboratory groups have expressed concerns with the POS rules as they apply to clinical laboratories and pathology services. These concerns have arisen because the POS is designed to identify where a patient receives services, and for most laboratory services, the patient does not receive laboratory services as part of a "face-to-face encounter," the term used by CMS to establish the appropriate POS.

Many of the rules applicable to establishing the POS, while relatively clear for other types of services, are difficult to apply for laboratory services. This was demonstrated by the proposed changes in the recent Transmittal. The approach proposed by CMS in the Transmittal is counterintuitive and likely to lead to confusion, and it would make the laboratory responsible for attesting to information that it may not be able to verify independently. Finally, such changes, if required, would take a great deal of time and money to implement. While the POS rules may work well for providers who see patients directly, laboratories most often do not, and it is far more difficult for them to obtain information about patients. These changes place a large burden on laboratories because they have to rely on others for accurate information about patients.

[1] Transmittal 2407, Revised and Clarified Place of Service Coding Instructions (Feb. 3, 2012), *available at*: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2407CP.pdf.

ACLA continues to urge CMS to take the simplest and most direct approach to this issue: require laboratories to use the POS that reflects where a service actually occurs.

I. Background on Transmittal

In February, 2012 CMS issued a new Transmittal that modified several sections of the Medicare Claims Processing Manual with regard to Place of Service. In the summary of the Transmittal, CMS states:

> This [Change Request] revises and clarifies national policy for POS code assignment. Instructions are provided regarding the assignment of place of service (POS) for all services paid under the Medicare Physician Fee Schedule and for certain services provided by independent labs. In addition to establishing a national policy for the correct assignment of POS codes, instructions are provided for the interpretation or professional component (PC) and the technical component (TC) of diagnostic tests.

The instruction continued that for all services, with two exceptions, the POS is to reflect the setting "in which the beneficiary received the face-to-face service." The two exceptions were for services furnished to patients receiving inpatient and outpatient hospital services. The Transmittal also stated that "where is face-to-face requirement is obviated such as those when a physician/practitioner provides the professional component (PC) interpretation of a diagnostic test from a distant site, the POS code assigned by the physician/practitioner shall be the setting in which the beneficiary received the technical component (TC) service."[2]

In this policy, CMS was to change provisions in the following chapters of the Claims Processing Manual: (1) Chapter 12—Physicians/Nonphysician Practitioners; (2) Chapter 13—Radiology Services and Other Diagnostic Procedures: and (3) Chapter 26—Completing and Processing Form CMS-1500 Data Set.

The changes in Chapter 12 were fairly minor and simply clarified which institutions were considered facilities for purposes of the Physician Fee Schedule Rule and which were considered nonfacilities. The changes clarified that, for services furnished in independent laboratories, the services would be paid at the nonfacility rate. Although the chapter includes a discussion of the coverage and payment of pathology services in Section 60, in fact CMS did not change any of those provisions. (It is also worth noting that Chapter 16, which applies directly to laboratory services, was not modified by the Transmittal, either.)

In Chapter 13, CMS further explained that where there is no face-to-face requirement, such as the PC of a diagnostic test, then the POS would be where the beneficiary received the TC of the service. However, as is clear from the chapter heading, this chapter applies only to radiology services and other imaging services. It does not appear to have any applicability to pathology or laboratory services.

[2] *See* "Attachment—Business Requirements" in the "General Information" discussion at page 4 of the Transmittal.

Chapter 26 is the only place there is any significant discussion of issues related to laboratories. It states the general rules that "the POS code is generally used to reflect the actual setting where the beneficiary receives the face-to-face service" (emphasis added). It specifically references the new provisions of Chapter 13 for further explanation of how to assign the POS for PC and TC of diagnostic tests, but as noted, that chapter does not actually apply to laboratory services. It also sets out the requirement that if the patient is an inpatient or an outpatient of a hospital, then the appropriate POS code for those localities is to be used. POS 21 for inpatient hospital and POS 22 for outpatient hospital.

The Transmittal also made some conforming changes to another paragraph in Chapter 26, Sec. 10.6 of the Medicare Claims Processing Manual that specifically discusses laboratory services::

> If the physician bills for a lab service furnished by an independent lab, the code for "Independent Laboratory" is used. Items 21 and 22 on the Form CMS-1500 must be completed for all laboratory work performed outside a physician's office. If an indecent lab bills, the place where the sample was taken is shown. An independent laboratory taking a sample in its laboratory shows "81" as place of service. If an independent laboratory bills for a test on a sample drawn on a*n inpatient or outpatient of a hospital*, it uses the code for *the inpatient (POS code 21) or outpatient hospital (POS code 22), respectively.*[3]

As we have discussed on prior occasions, based on discussions with ACLA members, few laboratories use the POS of where the sample is taken. Many laboratories in fact were specifically instructed by contractors not to do so, because the contractors' own systems would then deny claims inappropriately.

In sum, the Transmittal was confusing and inconsistent with regard to pathology services. It seemed to make some changes that could be applicable to pathology services, but the changes were not made in the sections affecting these services. Moreover, it enacted a new provision that requires the PC to be the same as the TC where no face-to-face service occurs, but this is of little use for laboratory services where the TC does not require a face-to-face service. It left unchanged other language with regard to laboratory services that is inappropriate and has not been followed. Finally, it imposed a new requirement for hospital patients without consideration of how that change would affect laboratories' long-standing billing practices.

In the section that follows, we discuss the current state of the POS rules and the confusion regarding them. Then, we propose a solution that we continue to believe is the simplest and most direct: use the POS that reflects where the service actually is performed.

II. The Current Rules are Confusing and Inconsistent.

As they stand, the current requirements for POS for laboratory services are confusing and inconsistent. The rescinded Transmittal would have added to that confusion for reasons

[3] The italicized portions reflect changes made by the Transmittal.

described above. As a result, we urge CMS to consider carefully the impact of any new POS rules on laboratories and pathologists.

The rules suggest that if a laboratory bills, the POS it uses is where the specimen was drawn, but if a physician bills for services performed in a laboratory, then it should use the POS for independent laboratory. Under this interpretation, the only time a laboratory would bill using POS code 81 for independent laboratory is where it takes a specimen in its own laboratory—a circumstance that almost never occurs. Thus, the POS for independent laboratory would seldom ever be used by the laboratory. Under this policy set forth in Section 10.6, the only entity that would use the POS code 81 is a *physician* when he or she bills for a service performed by an outside laboratory. It is difficult to understand why a physician would use the POS code 81 in this circumstance, especially if the sample were taken in the physician's office. (In fact, in most instances, a laboratory would be prohibited from billing a physician for clinical laboratory services, so it is difficult to see when this situation would occur.)

Furthermore, it is most laboratories' experience that contractors do not want them to bill using the POS where a sample was collected because their systems then would deny the claim inappropriately. For example, if a laboratory billed for a service that it performed, but it used a physician office POS, then the service might deny because, as noted above, a laboratory is not permitted to bill a physician for a laboratory service that it performs. Further, when the "TC Grandfather" provision was in place, if a laboratory billed using the POS codes 21 or 22, then the service would be denied incorrectly. The contractor would assume it was an improperly billed service. Therefore, laboratories usually were instructed to use the POS code 81 as a way of indicating that the service was covered by the "TC Grandfather" provision.

In addition, the Transmittal suggested that it is important to use the respective POS for inpatients and outpatients, when appropriate, in order to ensure payments properly reflect the site-of-service differential between facility and nonfacility services. However, that concept has no impact on laboratory services. There is no site-of-service differential for the PC of pathology services; they are paid the same regardless of if they are provided to a hospital or nonhospital patient. There is no site-of-service for the TC, either, because Medicare currently does not pay for the TC of pathology service when furnished to a hospital patient. Therefore, the TC should not be billed to Medicare in the first place.[4]

This confusion is exacerbated by the fact that laboratories, like all suppliers, have to submit on the Medicare claim form in Item 32 the address where they provided the services. The address has to be the address of the actual laboratory furnishing the service because, as CMS noted in the Transmittal, that address is what is used for determining the correct payment location. Thus, it seems confusing to use the address of the laboratory in one circumstance but to use a POS for an entirely different entity in another field.

[4] Under the "TC Grandfather" provision, it was permissible for laboratories to bill Medicare for the TC furnished to hospital patients, in certain cases; however, the "TC Grandfather" recently was eliminated, effective July 1, 2012.

In short, ACLA believes that when CMS ultimately reissues this Transmittal, it must clearly explain the rules applicable to independent laboratories, including the rules that apply when laboratories furnish the TC and PC of pathology services. We believe it would be most useful if that discussion were included in the sections of the Manual addressing those specific services. As noted, we also believe that the best solution would be to use the POS where the service is performed, which also would reflect the entity that is listed in Item 32 of the claim form.

III. Concerns with CMS' Proposed Approach

For the reasons stated above, it is unclear at this point precisely what POS CMS expects laboratories to use when billing for the services they provide, and in particular, the TC and PC of pathology services. However, CMS appears to want all suppliers, including laboratories, to use the POS for inpatient and outpatient hospital patients where services are furnished to those patients. And, that appears to be the case for the TC and PC of laboratory services as well. ACLA has several specific concerns with this approach.

First, of course, the proposed approach would not reflect what actually happened. The "place of service" would not in any sense be the hospital, because the service would be performed at an independent laboratory. Thus, CMS appears to be requiring laboratories to do something that is incorrect. In our experience, such counterintuitive rules lead to questions and problems. Despite laboratories' best efforts to train billing employees on the rules, those performing the billing naturally do what makes sense, and an illogical billing rule is less likely to be followed consistently. From a practical standpoint, it is easier to impose a rule that reflects the facts as they actually are.

Second, the laboratory often is hundreds or thousands of miles away from the hospital in question. The laboratory has no way to know for sure the status of the patient. The laboratory often will have to rely on the hospital to inform the laboratory whether the patient is an inpatient or an outpatient. It can be difficult for laboratories to obtain this type of information consistently. Moreover, there are number of complications that also may occur in this area. In some instances, a patient also may qualify as a "nonpatient," meaning that the hospital picked up specimens from a doctor's office that it then referred to the laboratory. However, hospitals do not all track patients the same way or use the same standards to describe them. Also, a patient's status may change over time, from inpatient to outpatient or the reverse, or a patient may be transferred from another facility (such as a SNF) that may be part of a hospital system. A reference laboratory, which tests specimens it receives from other laboratories, may have an even more difficult time getting the proper information for a claim because it is even further removed from the hospital where the specimen originated.

It is true that today, laboratories already must try to track the status of the patient because certain services cannot be billed to Medicare. Laboratories do attempt to collect this information. However, a laboratory may know only that a patient was at the hospital for services, but not whether he or she was an inpatient or an outpatient. Laboratories use their best efforts to obtain the correct information, but they cannot verify every patient's status before billing for a service. Such an effort would require the billing process to be slowed unacceptably and would create an untenable situation not only for laboratories but for hospital billing

departments that would have to verify the information. Today, laboratories make their best efforts to obtain the correct information and understand that Medicare's payment systems will issue a denial where a service is billed erroneously for a hospital patient.

However, under the current system, laboratories typically bill using the POS for independent laboratory or, possibly, physician office (such as when there is an arrangement with a pathologist group)—information they can be certain is accurate. If the POS rule is changed to require that the laboratory reflect the patient's status, as received from the hospital, laboratories would have to attest to information of which they have no direct knowledge. Laboratories are concerned that billing with information supplied by the hospital may open them up to liability if that information ultimately turns out to be incorrect. Changing the POS rules in this situation could have serious, unintended consequences for laboratories that are not present under the current rules.

Furthermore, the rule seems the wrong solution to CMS' concerns. The point of CMS' requirement appears to be to ensure that CMS does not pay inappropriately for services furnished to hospital patients. That is certainly a reasonable and important goal; however, laboratories pose little risk in this area. First, there is no site-of-service differential for the PC of a pathology service, so the payment will be the same whether a laboratory uses the POS for an independent laboratory or a hospital patient. Second, in the case of the TC, there is no site-of-service at all, because the TC of a service furnished to a hospital patient is not billable to Medicare. Thus, the laboratory should not be billing Medicare for that service in the first place; it should be billing the hospital. The only way that Medicare will ever see a claim with the TC for a pathology service and a POS for a hospital inpatient or outpatient is if the laboratory bills incorrectly. It seems unnecessary to establish a rule that would apply only when an entity bills erroneously. It would be easier and more efficient to educate laboratories on the rules applicable to hospital billing—rules that we expect most laboratories are very familiar with. The best check on inappropriate billings of hospital services could be for CMS billing systems to determine whether a patient was a hospital patient on the date-of-service being billed by the laboratory.

Finally, if CMS were to require these new POS requirements, then virtually every laboratory in the country will have to re-program its systems to bill using the POS of the hospital or other source of the specimen, rather than the POS code 81, which currently is used. In addition, laboratories also will have to establish new processes to obtain this information from each referrer. This will mean additional "back-end" systems to try to capture the information where it is not provided or not provided at a sufficient level of detail—an inevitable outcome whenever referrers must provide additional information to a laboratory. All of these processes will take a substantial time to design, implement, and test and will require a significant investment of resources.

Moreover, these changes will only apply to Medicare. Private payors typically expect laboratories to use the POS code 81. The POS for private payor claims is exactly that: where the service is performed, regardless of whether there is a face-to-face encounter and, if there is one, where it is performed. Applying the Medicare POS rules to private payors' claims would likely result in massive numbers of incorrect denials. Thus, if Medicare enacts the rule that it proposed in the Transmittal, laboratories would have to program their billing systems for Medicare claims

and for private payors in different ways, a circumstance that will only exacerbate the effort and expense involved. Moreover, such a result seems inconsistent with the purpose behind HIPAA's Administrative Simplification Requirements. This is also at a time when programmers have many other changes to implement concurrently, such as those related to "meaningful use" requirements for electronic health records, the conversion to ICD-10 diagnosis codes, and the version 5010 standard for electronic health care transactions.

For all of these reasons, we respectfully ask CMS to reconsider the POS rules set out in the Transmittal.

IV. ACLA's Solution

As noted above, we think CMS should issue a clear set of POS standards that specifically address the unique issues confronted by laboratories. We continue to believe that the simplest and most direct solution is the best one: use the POS that actually reflects what is done. That is, if a service is done in an independent laboratory, a laboratory would bill using POS code 81 because that is where the service is performed. That is consistent with the basic rules for POS coding, which are designed to reflect where a service is performed. Given the confusion that exists in this area already, the simplest and most direct approach is likely to result in the easiest implementation and the fewest mistakes. Further, using this POS for a laboratory service will have no impact on issues related to site of service differential.

For the foregoing reasons, we urge CMS to direct Medicare contractors to continue to permit independent clinical laboratories to bill for a pathology service using the POS code that corresponds to the location where the pathology service actually is performed. If a laboratory performs both the TC and the PC services in a laboratory, it should be permitted to use POS code 81 for both. If one of the services is performed elsewhere, it should use the appropriate POS code for that service and continue to use the POS code 81 for the service performed in the independent clinical laboratory.

Thank you again for your attention to this matter. We look forward to hearing from you.

Sincerely,

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Senior Vice President

cc: Chris Ritter
Anne Tayloe-Hauswald
Pamela West