



American  
Clinical Laboratory  
Association

July 7, 2010

Mr. Tony Trenkle, Director  
Office of E-Health Standards and Services  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Mail Stop S2-26-17  
Baltimore, MD 21244

**Re: ICD-10-CM Regulatory Gaps**

Dear Mr. Trenkle:

I am writing on behalf of the American Clinical Laboratory Association (ACLA) to request your assistance in closing certain regulatory gaps that threaten to prevent successful implementation of the ICD-10-CM code set. ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories.

As covered entities under HIPAA, clinical laboratories are required to submit diagnosis codes in standard transactions where such codes are required. Similar Medicare billing rules apply, and private payors often impose comparable requirements. Generally, clinical laboratories must depend upon referring providers to generate the diagnosis codes to be used in HIPAA standard transactions. Unfortunately, for various reasons, clinical laboratories are often required to submit diagnosis codes in HIPAA standard transactions under circumstances in which there is no requirement for referring providers to submit such codes to the laboratory, and as a result, they are often not submitted by referring providers. Further, in some cases, there is no requirement for the recipient of a transaction to accept diagnosis codes from the laboratory at all, or to accept the code set currently mandated by HIPAA. These regulatory gaps are problematic for clinical laboratories, providers, health plans and patients today, using an ICD-9-CM code set with which the healthcare industry is familiar. If not resolved, they could become a much greater problem as the industry transitions to the new ICD-10-CM code set. The purpose of this letter is to identify these regulatory gaps in greater detail and to request your help in resolving them so that our transition to ICD-10-CM can be as effective as possible.

**Regulatory Requirements for Diagnosis Data Applicable to Clinical Laboratories**

Clinical laboratories are required to submit diagnosis codes in all electronic claims and most paper claims to third party payors, both public and private. There are two separate bases for these requirements: 1) HIPAA, and 2) payer policies.

The implementation guide for the Version 4010 837 Professional Claim / Encounter transaction, which is incorporated by reference in the HIPAA Transactions and Code Sets (TCS) regulations (*See* 45 C.F.R. § 162.1102), provides that a diagnosis code is required on all claims / encounters except claims for which there are no diagnoses (*e.g.*, taxi claims).<sup>1</sup> Version 5010 of the 837 Professional Claim / Encounter transaction, which must be used as of January 1, 2012, will require ICD-9-CM diagnosis codes for dates of service prior to October 1, 2013, and ICD-10-CM diagnosis codes for dates of service on and after October 1, 2013, for all claims or encounters to which diagnoses apply (including claims for clinical laboratory services). Since the HIPAA TCS regulations incorporate by reference the requirements of the Official Guidelines for Coding and Reporting for both ICD-9-CM and ICD-10-CM, and since the Official Guidelines for Coding and Reporting for both code sets require that diagnosis codes be used at the "highest level of specificity", the requirement to supply diagnosis codes at the highest level of specificity is a HIPAA requirement for the use of both code sets.

Under Medicare, National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) have been established for certain laboratory tests. For each NCD or LCD, a determination has been made that the test will be covered by Medicare only when certain diagnosis codes are present in the claim. To confirm the medical necessity of the claims, Medicare Administrative Contractors and carriers edit claims for laboratory services subject to an NCD or LCD to determine whether or not these particular diagnosis codes are present. Claims containing the identified diagnosis codes can be further adjudicated for reimbursement. Claims that lack one or more of the identified diagnosis codes are rejected or denied.

Like Medicare, private third party payer coverage policies often require particular diagnosis codes for medical necessity determination in claim adjudication, and claims that lack one or more of the identified diagnosis codes are rejected or denied.

Importantly, because diagnosis codes are required elements of electronic claims under HIPAA, Medicare Administrative Contractors and carriers edit claims for the validity of the diagnosis codes and to determine whether they have been submitted at the highest level of specificity, *whether or not the services are subject to an NCD or LCD*. Consequently, Medicare claims for laboratory services that are not subject to an NCD or LCD will still be rejected or denied if diagnosis codes are missing or if the diagnosis codes submitted are invalid or not at the highest level of specificity.

Further, except with respect to anatomic pathology services performed by clinical laboratories, in which case clinical laboratories providing such services are expected to render a diagnosis in the report returned to the referring provider, the HHS Office of Inspector General has made it clear that clinical laboratories are expressly prohibited from rendering or suggesting diagnoses if they are not supplied by the referring provider.

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<sup>1</sup> ASC X12N Insurance Subcommittee Implementation Guide 004010X098 – 2300 – HI, Health Care Diagnosis Code, page 265.

### Regulatory Requirements for Diagnosis Data Applicable to Referring Providers

HIPAA does not currently require referring providers to submit diagnosis data to clinical laboratories in test orders, and existing Medicare requirements have been narrowly interpreted.

#### 1) HIPAA

First, a laboratory test order is not a HIPAA standard transaction, even if submitted electronically. The wide variety in test offerings and methodologies among clinical laboratories has made it difficult to establish a standard test order vocabulary on which such a standard might be based, and although some efforts are currently underway to establish such a standard (using LOINC<sup>®</sup>), ACLA does not believe such efforts will result in a comprehensive, workable standard for all tests, and has proposed instead a standard test compendium framework that would permit referring providers to download the test compendium of any clinical laboratory to its electronic health record (EHR) system to facilitate test ordering, without the necessity of establishing a universal order code.

Second, because the HIPAA TCS regulations focus on transactions that are perceived primarily as "administrative" in nature, rather than clinical, test orders, which include administrative data but are perceived primarily as clinical transactions, have not been an area of focus for the TCS regulations.

Third, some referring providers are not HIPAA covered entities, because they do not engage in electronic standard transactions. For these providers, even if there was a HIPAA transaction standard for test orders that required the submission of diagnosis codes, it would not apply to them because they conduct their business on paper.

#### 2) Medicare Requirements

In addition, there is a Medicare requirement for submission of diagnosis data by referring providers to clinical laboratories in test orders, but it has been narrowly interpreted by CMS (too narrowly, in our view). In Section 4317(b) of the Balanced Budget Act of 1997 (BBA, 105 P.L. 33), Congress amended Section 1842(p) of the Social Security Act (42 U.S.C. § 1395u(p)), the statutory provisions relating to the administration of Medicare Part B, by adding the following new paragraph:

*"In the case of an item or service defined in paragraph (3), (6), (8), or (9) of subsection 1861(s) [[42 U.S.C § 1395x\(s\)](#)] ordered by a physician or a practitioner specified in subsection (b)(18)(C), but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic or other medical information in order for payment to be made to*

*the entity, the physician or practitioner shall provide that information to the entity at the time that the item or service is ordered by the physician or practitioner."*<sup>2</sup>

Diagnostic laboratory tests are among the items and services defined in paragraph (3) of subsection 1861(s) of the Social Security Act [42 U.S.C. § 1395x(s)]. Since CMS and its contractors require clinical laboratories to submit diagnosis codes *in all claims in order for payment to be made, whether or not the service is subject to an NCD or LCD*, it is the position of ACLA that this statute should be interpreted to mean that referring providers are required to provide diagnosis codes in all test orders for Medicare Part B beneficiaries. However, CMS has not interpreted it that way.

In the CMS Final Rule on the negotiated rulemaking to establish NCDs for lab services back in 2001, CMS noted in the preamble to the rule that "if the diagnostic information is required for claims payment, *such as where there is a published national or local policy*, physicians and practitioners are required under section 4317(b) of the BBA to provide diagnostic information at the time that the test is ordered."<sup>3</sup> CMS further indicated that "we will continue to study this issue"<sup>4</sup>, but to our knowledge has not addressed the issue since then.

Thus, despite the fact that Medicare Administrative Contractors and carriers reject or deny claims for clinical laboratory services that lack diagnosis codes or that contain invalid codes or codes that are not at the highest level of specificity, *even when those services are not subject to an NCD or LCD*, CMS appears to have taken the position that for purposes of applying 42 U.S.C. § 1395u(p)(4) and its requirement that referring providers submit diagnosis data to labs in test orders, the Secretary and her fiscal agents only require laboratories to submit diagnostic information in order for payment to be made when the service is covered by an NCD or LCD, and therefore referring providers are not required to submit diagnosis data in test orders when the test is not covered by an NCD or LCD. As a result, clinical laboratories are often required to submit diagnosis data that they are prohibited from generating themselves, and that no one is obligated to provide to them. We respectfully submit that this result is fundamentally unfair, and represents a misinterpretation of the applicable statute that is completely at odds with reality.

### **The Problem of Non-Covered Entities**

As we have discussed above, some referring providers are not HIPAA covered entities, and therefore would be exempt from a HIPAA requirement to submit diagnosis codes in test orders even if test orders became a standard transaction. As a result, non-covered referring providers are currently free to avoid adoption of ICD-10-CM altogether, but are also free to adopt and use ICD-10-CM for dates of service before October 1, 2013, and to use ICD-9-CM for dates of

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<sup>2</sup> 42 U.S.C. § 1395u(p)(4) (emphasis added).

<sup>3</sup> 66 *Fed. Reg.* 58791 (Nov. 23, 2001) (emphasis added).

<sup>4</sup> *Id.*

service after October 1, 2013. Each of these scenarios is problematic for clinical laboratories, but non-covered referring providers are not the only non-covered entities with whom clinical laboratories interact.

Even when clinical laboratories receive from referring providers the right diagnosis code at the highest level of specificity, there are some payors that, because they are not HIPAA covered entities, are not required to accept the code that the clinical laboratory is required to submit in a standard transaction. For example, worker's compensation carriers are not covered entities, and when a clinical laboratory submits a claim for laboratory services provided to an individual covered by worker's compensation, the carrier is not bound by the transactional requirements to which clinical laboratories are subject as covered entities. Today, many worker's compensation carriers voluntarily accept ICD-9-CM diagnosis codes in claims, consistent with the current HIPAA requirement to which clinical laboratories are subject. However, many worker's compensation carriers have already stated that they have no intention of converting to ICD-10-CM. What is a clinical laboratory to do after October 1, 2013 when it receives an ICD-10-CM code from a referring provider for services covered by worker's compensation, and the worker's compensation carrier will only accept lab claims with ICD-9-CM codes?

#### **Proposed Solutions to Close the Regulatory Gaps Related to Diagnosis Data Submission**

As a fundamental principle, as indirect treatment providers, clinical laboratories should not be required to submit data in HIPAA standard transactions that they are prohibited from generating themselves, that referring providers are not required to submit to them, or that payors are not required to accept. To fulfill this principle, regulatory amendments or re-interpretations are necessary to ensure that all referring providers are required to submit diagnosis codes at the highest level of specificity in all laboratory test orders, and that all payors are required to accept the diagnosis codes that clinical laboratories are required to submit. We urge CMS to consider the following policy options among others it may develop to close these regulatory gaps:

- **Amend or re-interpret Medicare rules to require referring providers to submit HIPAA-compliant diagnosis codes in all laboratory test orders as a condition of participation in Medicare, and encourage private payors to adopt similar policies.**

Congress clearly intended to align referring provider obligations for submission of diagnosis codes in test orders with the obligations of clinical laboratories to submit diagnosis codes for payment of Medicare claims when it amended the statutory provisions relating to administration of Medicare Part B in the BBA. Since Medicare Administrative Contractors and carriers edit for the validity and specificity of diagnosis codes in all Medicare claims, regardless of whether they are covered by NCDs or LCDs, and reject or deny payment for claims lacking sufficient diagnosis information, it is clear that the Secretary and her fiscal agents require clinical laboratories to provide diagnostic information *in order for payment to be made* even when the test is not covered by an NCD or LCD. Therefore, 42 U.S.C. § 1395u(p)(4) mandates that

referring providers must submit to the laboratory the diagnosis data needed by the laboratory at the time the test is ordered, whether or not the test is the subject of an NCD or LCD. CMS should clarify its interpretation of the statute accordingly, and amend its rules to the extent necessary to conform them to that interpretation.

Further, referring provider compliance will only be achieved with strong incentives related to enforcement, coupled with provider awareness. Even under the current interpretation of the statute, physicians have little incentive to provide diagnosis codes for tests subject to NCDs or LCDs because the consequences of failure to comply appear to be slight or non-existent. Requiring referring providers to submit HIPAA-compliant diagnosis codes in all laboratory test orders as a condition of participation in Medicare will provide the incentive needed to ensure compliance. Compliance should be closely monitored through audits, and CMS should publicize the requirement through *MLM Matters* articles, the CMS website, teleconferences, and other means of communication as warranted.

Since private payors and referring providers who do not participate in Medicare would not be affected by this statutory re-interpretation or rule amendment, CMS should use its influence to encourage private payors to adopt similar policies, perhaps through the use of financial incentives connected with private payor participation in Medicare Advantage plans or Medicaid HMO plans.

- **Amend the HIPAA regulations to require diagnosis codes in any non-standard transaction upon which a standard transaction is known to depend, and extend covered entity status to all referring providers and all payors for the limited purpose of complying with diagnosis code requirements.**

To resolve the regulatory gaps from a HIPAA perspective will require extending the reach of the TCS regulations to transactions that are not currently standard transactions and that are not anticipated to become standard transactions, as well as to entities that are currently not covered by the regulation. It is clear that there are non-standard transactions, such as laboratory test orders, on which certain standard transactions, such as claims, depend. A clinical laboratory needs HIPAA-compliant diagnosis codes in the test order to enable it to submit a HIPAA-compliant claim. To the extent that a standard transaction is known to depend upon a non-standard transaction, HIPAA should require that the non-standard transaction provide the data necessary for the standard transaction to occur in a compliant manner. To the extent that non-covered entities are parties to a non-standard transaction upon which a standard transaction depends, covered entity status should apply to such entities for the limited purpose of complying with the diagnosis code requirements. Likewise, payors such as worker's compensation carriers who are currently non-covered entities should be given covered entity status for the limited purpose of complying with diagnosis code requirements to which clinical laboratories and other covered entities are subject in the transactions in which they are trading partners.

As we have learned in previous HIPAA TCS transitions, coordination among trading partners is absolutely critical to success. The transition to ICD-10-CM will only be successful if everyone

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is on the same page. Our proposals to close the existing regulatory gaps relating to the provision and acceptance of diagnosis codes are necessary steps toward getting everyone on the same page, and we urge CMS to move quickly to adopt them. We would like to meet with you and with other CMS officials as appropriate to follow up on this request and work with you to achieve it. We appreciate your thoughtful consideration of these proposals and look forward to talking with you soon.

Very truly yours,

A handwritten signature in black ink, appearing to read 'JoAnne Glisson', written in a cursive style.

JoAnne Glisson  
Senior Vice President

cc: Jonathan Blum, Director, CMS Center for Medicare Management  
Dr. Douglas Fridsma, Acting Director, ONC Office of Standards and Interoperability  
Karen Trudel, Deputy Director, CMS Office of E-Health Standards and Services  
Justine M.Carr, M.D., Chair, National Committee on Vital and Health Statistics