American
Clinical Laboratory
Association

May 26, 2015

Terri Deutsch, MS, RN
NCVHS Standards Subcommittee and Review Committee
Office of E-Health Standards and Services
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 2-244

Dear Ms. Deutsch:

I am submitting the attached letter to the Centers for Medicare and Medicaid Services (CMS) regarding the adoption of ICD-10 for inclusion in the hearing record of the June 16-17 meeting of the National Committee on Vital and Health Statistics (NCVHS.

The purpose of the June meeting is to review currently adopted HIPAA transactions and code sets. A thoughtful review of the adoption of ICD-10 as a HIPAA code set cannot be complete without assessing the manner in which it is being implemented, particularly when it appears that it is being implemented in a manner that was not intended. As explained in the attached letter, it has come to our attention that certain Medicare Administrative Contractors (MACs) are using the process of converting local coverage determinations (LCDs) from ICD-9 to ICD-10 as an excuse to limit coverage without following applicable procedural requirements for coverage changes, rather than the objective crosswalking exercise that it was intended to be and for which the General Equivalence Mappings (GEMs) were designed. It is important for NCVHS to be aware of this misuse of the ICD-10 implementation process and to make appropriate recommendations to CMS to protect the integrity of the HIPAA code set adoption and implementation process in general and to preserve the intent of ICD-10 adoption in particular.

If you have any questions or I can provide additional information, please do not hesitate to contact me.

Sincerely,

JoAnne Glisson
Senior Vice President

Attachment

American
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May 15, 2015

Shana Olshan
Director, National Standards Group
Office of Enterprise Information
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Tamara Syrek Jensen, J.D.
Director, Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Via email: shana.olshan@cms.hhs.gov, tamara.syrekjensen@cms.hhs.gov

Dear Ms. Olshan and Ms. Syrek Jensen,

We are writing to request a joint meeting with you regarding the transition later this year from ICD-9 to ICD-10 and specifically, certain Medicare Administrative Contractors' ("MACs'") interpretations of the crosswalks to the new ICD-10 codes. As you know, ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of laboratory services for Medicare beneficiaries each year, ACLA member companies are deeply invested in ensuring proper coding for their services and in a smooth transition to ICD-10.

ACLA members are preparing themselves for the transition to ICD-10 and, as part of those preparations, have reviewed the MACs' future Local Coverage Determinations ("LCDs") for clinical laboratory services that are to become effective on October 1, 2015. We have found that several of the future LCDs do not include the full range of ICD-10 codes that map to the ICD-9 codes in the current policies. This may result in non-coverage for some currently-covered laboratory services, without the benefit of comment and notice periods, and it also may result in laboratories having to code improperly in some cases to be paid for their services. It may be that some MACs did not use the ICD-10 General Equivalency Mapping ("GEM") tools made available to the public, or that those contractors simply chose to limit the ICD-10 codes they have included in future policies. In any event, we are concerned about the operational and claims processing effects of contractors' coding decisions.

A. Non-coverage of currently-covered services

Certain future LCDs will not recognize the full range of ICD-10 codes that map to the ICD-9 codes contained in the corresponding LCD currently in effect. As an example, Palmetto GBA's

current LCD on flow cytometry,[1] a common laboratory service used in the diagnosis and treatment of blood cancers and in transplantation, includes 812 ICD-9 codes relevant to medical necessity, but the corresponding future LCD[2] includes just 689 ICD-10 codes. The 812 ICD-9 codes in the currently-active LCD actually map to more than 1,100 ICD-10 codes. This means that over 400 cross-walked ICD-10 codes are not included in the future LCD. There even are instances in Palmetto's policy in which an ICD-9 code included in the current LCD maps to only one ICD-10 code, and yet the one corresponding ICD-10 code is not included in the future LCD. An example of this is ICD-9 code 151.3 (Malignant neoplasm of fundus of stomach), which is included in the current LCD as supporting medical necessity of flow cytometry, but the corresponding ICD-10 code C16.1 is not included in the future LCD as supporting the service's medical necessity.

Another example of the disparity between ICD codes included in current and future LCDs is National Government Services' LCD for a RAST type test, an allergy test. The LCD currently in effect[3] includes 36 ICD-9 codes, which map to 369 ICD-10 codes. However, the corresponding future LCD[4] includes only 58 of those corresponding 369 ICD-10 codes, meaning that the contractor has omitted more than 300 ICD-10 codes from the future policy.

We are concerned that the transition to ICD-10 may be used by some MACs as a way to limit coverage for clinical laboratory services without first allowing stakeholders to comment. In the Medicare Program Integrity Manual, the types of LCDs that require a comment and notice period include "Revised LCDs that Restrict Existing LCDs – Examples: adding non-covered indications to an existing LCD; deleting previously covered ICD-9 codes."[5] We believe that all MACs should be required to use a notice-and-comment process if they intend to limit the indications for which certain tests are considered medically necessary.

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[1] Local Coverage Determination: Flow Cytometry (L32337), *available at* http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=32337&ContrId=229&ver=23&ContrVer=1&DocType=Active&Cntrctr=233&CntrctrSelected=233*1&name=Palmetto+GBA+(11502%2c+MAC+-+Part+B)&LCntrctr=233*1&bc=AgIAAAAAAAAAAA%3d%3d&.

[2] Future Local Coverage Determination: Flow Cytometry (L34513), *available at* http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34513&ContrId=229&ver=4&ContrVer=1&DocType=Future&Cntrctr=233&CntrctrSelected=233*1&name=Palmetto+GBA+(11502%2c+MAC+-+Part+B)&LCntrctr=233*1&bc=AgIAAAAAAAAAAA%3d%3d&.

[3] Local Coverage Determination: RAST Type Tests (L28463), *available at* http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=28463&ContrId=273&ver=39&ContrVer=1&Date=01%2f01%2f2015&DocID=L28463&SearchType=Advanced&bc=KAAAAAgAAAAAAA%3d%3d&.

[4] Future Local Coverage Determination: RAST Type Tests (L33591), *available at* http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33591&ContrId=273&ver=2&ContrVer=1&CntrctrSelected=273*1&Cntrctr=273&name=National+Government+Services%2c+Inc.+(06102%2c+MAC+-+Part+B)&LCntrctr=273*1&DocType=Future&bc=AgACAAIAAAAAAA%3d%3d&.

[5] Medicare Program Integrity Manual, Pub. No. 100-08, Ch. 13, Sec. 13.7.2.

B. Specificity

ACLA members also are concerned about the specificity of some of the codes included in the future LCDs. As you know, the CMS-approved coding guidelines for ICD-10 require coding at the highest level of specificity, such that a covered entity is to use the most specific diagnosis code that describes a disease or condition.[6]

In some cases, the ICD-10 codes that are included in certain future LCDs would cause labs to use codes on claims that are not the most specific codes available. One example of this is in the National Government Services' future LCD for a RAST type test. ICD-9 code 989.5 (toxic effect of venom) maps to 152 more granular ICD-10 codes. However, just seven of the 152 ICD-10 codes are in the future LCD. Each of those seven ICD-10 codes included in the future LCD are for "undetermined" venomous animal types, yet the ICD-10 codes in the "T63" family of codes are far more specific about the type of venomous animal involved in the injury or accident. A laboratory covered entity may know that it is conducting a test because of a patient's accidental encounter with a coral snake (ICD-10 code T63.021A), but in order to get paid for the test, the lab would be required to include the ICD-10 code for "toxic effect of venom of other snake, undetermined, initial encounter" (ICD-10 code T63.094A). This would contradict long-standing CMS policy and HIPAA coding basics, and it would put labs in the untenable position of coding properly or coding to be paid.

C. Conclusion

We welcome the first opportunity available to meet with you to discuss these issues related to the transition to ICD-10 later this year. I will follow up with you, and you also may reach me at 202-637-9466 or at glisson@acla.com. Thank you for your attention to our concerns.

Sincerely,

JoAnne Glisson, Senior Vice President
American Clinical Laboratory Association

[6] ICD-10-CM Official Guidelines for Coding and Reporting, Sec. I.B.2, *available at* http://www.cdc.gov/nchs/data/icd/ICD10cmguidelines_2015%209_26_2014.pdf.