March 28, 2012

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: ICD-10-CM Implementation

Dear Secretary Sebelius,

I am writing to you on behalf of the American Clinical Laboratory Association (ACLA) to urge the Department of Health and Human Services (HHS) to adopt several important recommendations as the Department considers an extended timeline for implementation of the ICD-10-CM code set. ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. Our recommendations, which we urge HHS to adopt as part of any rulemaking or other administrative procedure to extend the compliance date for ICD-10-CM implementation, are as follows:

1) <u>Resolve the Regulatory Gap Between Ordering Providers and Laboratories:</u> Clarify and enforce a requirement that at the time of ordering a laboratory test, an ordering provider must submit to the laboratory appropriate diagnosis codes at the highest level of specificity, whether or not the ordered tests are covered by a national coverage decision (NCD) or local coverage decision (LCD).

2) <u>Require Certification:</u> Require ICD-10-CM compliance certification for health plans, clearinghouses, providers and their respective systems.

3) <u>Establish Authoritative Crosswalks:</u> Identify and mandate the use of a single forward crosswalk from ICD-9-CM to ICD-10-CM and a single backward crosswalk from ICD-10-CM to ICD-9-CM.

4) <u>Coordinate Overlapping Initiatives:</u> Coordinate ICD-10-CM implementation with overlapping initiatives such as the Medicare and Medicaid EHR Incentive Programs.

Below, we elaborate upon each of these recommendations.

Resolve the Regulatory Gap Between Ordering Providers and Laboratories

As covered entities under HIPAA, clinical laboratories are required to submit diagnosis codes in standard transactions where such codes are required. Medicare contractors and private payers typically require such codes through coverage decisions, but also edit claims for diagnosis codes at the highest level of specificity regardless of whether the test is subject to an NCD or LCD. A clinical laboratory depends upon referring providers to provide the diagnosis codes that the laboratory must submit in HIPAA standard transactions, such as claims for reimbursement. Unfortunately, for various reasons, clinical laboratories are required to submit diagnosis codes in HIPAA standard transactions when there is no currently enforced requirement for referring providers to provide such codes to the laboratory. The act of requesting a laboratory test is not a standard transaction under HIPAA, and therefore the HIPAA requirements pertaining to diagnosis codes applicable to the claim, which is a standard transaction, do not apply to test orders, which are not.

According to an ACLA survey of its member laboratories with regard to ICD-9-CM codes, approximately 9% of all laboratory test orders for which diagnosis codes are required for payment to the laboratory either lack diagnosis data altogether or contain diagnosis data that is deficient in some manner. Laboratories that receive test orders with insufficient diagnosis data must contact the ordering provider to obtain the missing or deficient data, resulting in significant inefficiencies. This regulatory gap is problematic for clinical laboratories, providers, health plans and patients today, using the ICD-9-CM code set with which the healthcare industry is familiar. If not resolved, the failure to provide diagnosis codes could become a much greater problem as the industry transitions to the new ICD-10-CM code set, which is a much larger set of codes that most physicians are not familiar with. ACLA is requesting your help in resolving this issue so that our transition to ICD-10-CM can be as effective as possible.

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 to apply only to tests covered by NCDs or LCDs, and has been rarely if ever enforced. 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."*[1]

[1] 42 U.S.C. § 1395u(p)(4) (emphasis added).

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 at the highest level of specificity 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 at the highest level of specificity in all test orders for Medicare Part B beneficiaries. Notwithstanding the statutory requirement, it is not clear what enforcement mechanism CMS might use to ensure compliance by ordering providers. Requiring CMS to interpret the statute as we have described, to educate ordering providers about the requirement, and to identify and apply an enforcement mechanism to ensure ordering provider compliance would help to resolve this issue as it relates to Medicare transactions, and if CMS were to encourage private payers to do likewise, we believe they would follow.

Require Certification

In the interest of administrative simplification, ACLA urges HHS to establish a certification program for validating conversion to ICD-10-CM as well as other code sets and new versions of the HIPAA standard transactions. Designated Standards Maintenance Organizations (DSMOs) could evaluate candidate entities to serve as the certifying body and to ensure that its certification program would appropriately validate the published standards. Payers and providers could submit test files to this entity for certification. Once certified, a covered entity's trading partners would be required to accept the certified entity's transactions.

This proposal has several advantages. Payers and providers would only have to test with one entity instead of every trading partner. The certifying body could maintain a list of certified organizations, which could be used to assess industry readiness. The certification process would encourage the adoption of the transactions and code sets without payer or provider special requests due to system challenges. In addition, the certification process could be funded with the savings each organization would save under the streamlined approach.

Establish Authoritative Crosswalks

Standardization of crosswalks and crosswalk implementation is important not just for payers, but for clinical laboratories and other providers as well. Just as payers have expressed interest in "backward" mappings from ICD-10-CM to ICD-9-CM for internal processing purposes, indirect providers such as clinical laboratories need a forward mapping from ICD-9-CM to ICD-10-CM for claim submission purposes for those instances in which an ICD-9-CM code is received from an ordering provider when an ICD-10-CM code must be reported to the payer. Both backward and forward crosswalks should be standardized across the industry to avoid inconsistent results, and laboratories should be authorized to convert physician submitted codes according to the standardized crosswalks. HHS is the only entity that can establish a single authoritative standard.

Coordinate Overlapping Initiatives

Just as sequencing is important for successful implementation of a single initiative like ICD-10-CM, coordination is essential when covered entities are simultaneously subject to multiple initiatives. ICD-10-CM is the single largest conversion in the history of the health care industry, and yet it is being undertaken at the same time as other major initiatives such as the incentive programs to promote meaningful use of electronic health records (EHRs). At any given entity, many of the same personnel will likely be engaged in each of these efforts. There is a limit to what covered entities can achieve in a given timeframe. More appropriate coordination and sequencing of multiple initiatives would alleviate much of the stress currently experienced by the industry and would help to ensure that each of the initiatives is implemented effectively and efficiently.

ACLA looks forward to working with HHS to implement these recommendations.

Sincerely,

Alan Mertz
President

CC: Marilyn Tavenner, Acting Administrator, CMS
Robert Tagalicod, Director, Office of eHealth Standards and Services (OESS-CMS)
Lorraine Tunis Doo, Acting Deputy Director and Senior Policy Advisor (OESS-CMS)