May 17, 2012

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code CMS-0040-P
RIN 0938-AQ13
Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for ICD-10-CM and ICD-10-PCS Medical Data Code Sets

Ladies and Gentlemen:

The American Clinical Laboratory Association ("ACLA") is pleased to submit the following comments in response to the above-captioned proposed rule published on April 17, 2012 at 77 Fed. Reg. 22950 ("Proposed Rule"). ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. ACLA member laboratories conduct millions of HIPAA standard electronic transactions each year, and therefore would be impacted directly by the Proposed Rule. Our comments focus on the proposed Health Plan Identifier ("HPID"), the proposed Other Entity Identifier ("OEID"), and the implementation issues accompanying the proposed change to the compliance date for ICD-10-CM.[1]

I. Overview of Comments on the HPID, OEID and ICD-10-CM Extension

While ACLA strongly supports standardized unique identification of health plans, the Proposed Rule stops far short of achieving the kind of standardized unique health plan identification that clinical laboratories and other industry stakeholders need for effective and efficient claim processing and adjudication. By mandating the acquisition of an HPID only by a controlling health plan ("CHP"), the Proposed Rule would leave thousands of subhealth plans ("SHPs") without standardized unique identification, and without requiring standardized unique identification of each health plan's various benefit packages, even the HPID of a CHP will be of somewhat limited utility.

[1] ICD-10-PCS does not apply to procedures performed by clinical laboratories, and is therefore not addressed in these comments.

We urge HHS to amend the Proposed Rule to require standardized unique identification of all health plans, including both CHPs and SHPs, and to further require standardized unique identification of each health plan's various benefit packages. More specifically, HHS should require Type 1 identifiers for particular health insurance products or employee health benefit plans or other products defining the patient's coverage (referred to throughout these comments as "benefit packages"), and Type 2 identifiers for the organizations that perform health plan functions. In addition, HHS should clarify CHP and SHP responsibilities with respect to applying for and maintaining an HPID; adopt a standard health plan ID card format at the same time the HPID is adopted; ensure that the HPID format will accommodate future additional capacity needs; add legacy identifiers to the HPID database for cross reference; and establish at minimum a six-month window for testing.

We commend HHS for recognizing the need for an OEID, but as long as it is voluntary, it will be of limited utility. We urge HHS to require OEID acquisition by any entity that needs to be identified in a transaction for which the Secretary has adopted a standard.

With respect to the proposal to extend the compliance date for ICD-10-CM, HHS needs to take this opportunity to address several issues that threaten successful implementation of ICD-10-CM even under an extended compliance date. To resolve these issues, HHS should:

- Clarify and enforce a requirement that ordering providers must submit valid diagnosis codes at the highest level of specificity to clinical laboratories at the time a laboratory test is ordered;

- Authorize laboratories to use default ICD-10-CM codes for claim submission when ordering providers fail to provide diagnosis codes in test orders;

- Require ICD-10-CM compliance certification for covered entities and their systems;

- 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 that is more specific than the General Equivalence Mappings (GEMs); and

- Coordinate ICD-10-CM implementation with other overlapping initiatives.

Below, we address each of these issues in further detail.

II. The Unique Health Plan Identifier (HPID)

A. HHS Should Mandate HPIDs for All Health Plans and Their Benefit Packages

To obtain payment for its services from a health plan, a laboratory must be able to identify not only the responsible health plan, but also the specific benefit package of that health

plan under which the services were performed[2]. This process is difficult today due to the lack of standardized unique health plan identifiers, and the attempt in the Proposed Rule to establish an HPID is certainly a step in the right direction. However, the only entity for whom an HPID is mandatory in the Proposed Rule is the CHP. HPIDs would be optional for SHPs under the Proposed Rule.[3]

Therefore, if the Proposed Rule is finalized without modification, it is likely that some SHPs will voluntarily acquire HPIDs, either on their own or through their CHP, while many more SHPs will not acquire HPIDs. Further, there is no mechanism in the Proposed Rule for the assignment of an HPID to a particular benefit package for a health plan that offers multiple benefit packages, even for those CHPs for whom acquisition of an HPID is mandatory.

As a result, the HPID provisions of the Proposed Rule do little more than exchange the proprietary identifiers of CHPs for new standard ones, while leaving SHPs identified in both standard and non-standard ways, depending on what SHPs and CHPs choose to do, and fails to address the issue of benefit package identification at all. We urge HHS to amend the Proposed Rule to require unique standardized identification of all health plans, including both CHPs and SHPs, and to further require unique standardized identification of each health plan's benefit packages.

Whether a laboratory has a contract with a CHP or a SHP, that health plan is likely to offer multiple benefit packages. It is not uncommon for a laboratory to contract with a payer in one geographic area under a fee for service agreement and in a different geographic area with a capitation agreement. Payers often run into challenges adjudicating claims when both capitation and fee for service contracts exist for the same provider. Health plan systems may be unable to process claims correctly due to having two contract types for the same provider. To address this challenge, payers have developed legacy payer identifiers for providers to use when filing capitation claims and a different payer identifier for use with fee for service claims. These legacy payer identifiers provide an independent pointer for the payers to use when there are different contracts for a given provider. We see no reason why these kinds of legacy payer identifiers could not be standardized within the HPID rule as Type 1 identifiers.

HHS acknowledges that stakeholders at the NCVHS hearings expressed different viewpoints on the appropriate level of health plan enumeration, including enumeration at the benefit package level, but that the Agency determined that much of the information stakeholders wanted to obtain through the HPID might already be available in other parts of the transaction standards and associated operating rules, including the new operating rules for the Version 5010 270/271 eligibility inquiry / response standard, or could be made available in future versions of the transaction standards and operating rules.[4] HHS also argues that requiring health plans to

[2] Laboratories often need a payer ID, a plan ID, and a group ID, in addition to the patient ID, formulary ID and coverage ID for billing purposes; all of these IDs should be standardized and included in a publicly accessible database.
[3] If Medicare Administrative Contractors would qualify as either SHPs or entities eligible for OEIDs, even they would not be required to obtain standardized identifiers.
[4] 77 Fed. Reg.22950, 22961-22962.

enumerate at a more granular level might be burdensome due to frequent changes in benefit package offerings.[5]

We respectfully disagree that the information necessary to identify benefit packages in a standard format is readily available through transactions today, and have little confidence that they will be available in future versions of the standards or operating rules in the absence of an identifier standard such as the HPID. Further, while more granular enumeration may involve some additional burden, we believe the benefits would far outweigh the burden. HHS has failed to take into account the net benefits that more granular enumeration would produce. These benefits would include avoidance of rejected claims, avoidance of the additional work associated with correction and resubmission of claims, and avoidance of patient billing for otherwise covered services.

Another challenge faced by laboratories and other providers with more than one kind of contract with a health plan is that they will often experience a backlog of claims without a response from the health plan. Since capitation claims are filed with the health plan to report encounters only, many health plans do not send back an acknowledgement or confirm the receipt of the claims. If both capitation and fee for service claims are filed under one legacy identifier, the health plan will sort the claims into the appropriate bucket and adjudicate the fee for service claims. If the health plan does not provide confirmation that it received every claim and does not provide guidance on how the claims will be processed, the provider will end up with a population of claims that require manual research to verify appropriate adjudication. In the event that the Proposed Rule is not modified to provide for HPID assignment for specific insurance products or reimbursement arrangements for a health plan, the final rule should require health plans to return an acknowledgement for every claim, identify the proper insurance benefit package applicable to the claim, and adjudicate the claim according to the appropriate contract with the provider.

B. HHS Should Clarify Obligations of CHPs and SHPs to Obtain and Maintain HPIDs

The proposed HPID implementation specifications for health plans at 45 C.F.R. §162.512 are sufficiently unclear with respect to assigning responsibility for obtaining HPIDs that HHS found it necessary to "encourage CHPs and SHPs to coordinate their HPID applications to prevent duplicative and unnecessary numbers."[6] Rather than rely on coordination among health plans that may not occur, HHS should clarify the respective obligations of CHPs and SHPs to avoid the need for such coordination in the first place. There should be a clear and defined responsible party for both the HPID application process and the HPID maintenance process.

Duplicate numbers which could result from the current unclear standard would make it difficult to steer necessary claims data between physician practice management systems, indirect provider systems, clearinghouse systems, and health plan systems. If each system does not have

[5] *Id.*
[6] 77 Fed. Reg. at 22958.

the same number mapped for a health plan when duplicates are present, then the automated process will fail, necessitating burdensome and costly manual intervention.

C. HHS Should Adopt a Standard Health Identification Card Format Together With the HPID

We urge HHS to adopt a standard health identification card format at the same time the HPID is adopted. Every health plan currently has a different card for its members, and card formats vary widely. It is frustrating for providers to have to constantly analyze the different card formats to ensure that the correct information is captured for billing. Some health plans stack the Plan ID on top of the Insured ID on their cards; not only are these numbers often in close proximity on the card, but it is not unusual for the two numbers to share the same format. Data entry personnel will often pick up the first number associated with the term "ID" on the card. This challenge generates many rejected claims for providers, and could be avoided with a standard card format.

As health plans are reformatting their health care cards for the HPID, now is the perfect time to standardize the data elements and format of the health ID cards as well. Doing so would streamline the data entry process, improve the quality of the data, and create a positive return on investment. The Workgroup on Electronic Data Interchange (WEDI) has created a standard for a health ID card that could be adopted by HHS.

D. HHS Should Ensure That the HPID (and OEID) Format Will Accommodate Future Capacity Needs

The proposed format of the HPID standard is a 10 digit, all numeric identifier with a Luhn check digit as the tenth digit, which is the same format used for the enumeration of health care providers through the national provider identifier (NPI) as well as the new OEID.[7] HHS notes that the number of digits of the HPID would not exceed the number permitted for identifiers in the relevant data fields of the standard transactions, and that if additional capacity for HPIDs were needed in the future, the relevant data fields would permit additional numeric digits to be added at that time.[8] However, numbers that do not meet the Luhn check digit logic will not be eligible for use as identifiers, and the eligible combination of numbers will be further limited by using the start digit to distinguish between the different identifiers and the fact that numbers cannot be reused. Given the multiple healthcare initiatives on the horizon for many years to come, being proactive and avoiding additional rework in the future is very important.

We urge HHS to adopt a format that is not in danger of exceeding the available number combinations and that will avoid the need for additional programming and testing in the future.

E. HHS Should Include Legacy Identifiers in the HPID Database

[7] 77 Fed. Reg. at 22962.
[8] *Id.*

We applaud HHS for proposing that the enumeration system would disseminate HPID information through a publicly available, searchable database or through downloadable files.[9] A searchable database along with downloadable files for the HPIDs of CHPs and SHPs will improve the process of collecting the new HPIDs from trading partners. However, we urge HHS to go further by including legacy identifiers within the database to ensure that providers and clearinghouses are able to link the new HPIDs to the appropriate health plans as previously identified using automated processes. The legacy identifiers included in the database could include National Association of Insurance Commissioners (NAIC) codes, Employer Identification Numbers, Tax Identification Numbers, and proprietary numbers previously assigned by health plans and clearinghouses. In addition, we urge HHS to ensure that queries can be run in the database to allow access to terminated, reactivated and new numbers as well as to allow downloading of a full file of identifiers. Providers may only have the resources to load a full file on an annual basis, but may be able to support file maintenance for new identifiers and changed data on a regular basis.

F. HHS Should Establish a Six-Month Window for Testing the HPID

If the Proposed Rule is finalized, the health care industry will be programming for, testing and implementing the HPID, OEID, Stage 2 of the EHR meaningful use incentives and ICD-10-CM simultaneously. Each of these initiatives requires substantial internal and external testing environments as well as support personnel. We urge HHS to establish a six month window for testing the HPID, while considering the need for sequencing testing for other initiatives, to ensure that the industry does not allow any of the current initiatives to be placed on the back burner and jeopardize the compliance dates. To the extent that adoption of the HPID could occur on a rolling basis as testing is successfully completed among trading partners, it should be permitted.

III. The Other Entity Identifier (OEID)

HHS has correctly acknowledged in the Proposed Rule that health plans often use the services of other non-health plan, non-provider entities to conduct certain financial and administrative transactions on their behalf; that they need to be identified in the same transaction data fields in which a health plan would need to be identified because they perform very similar functions; and that those entities currently lack standard identifiers.[10] The same is true with respect to certain entities that do not act on behalf of a health plan, but act on their own behalf, such as workers compensation carriers. As healthcare reform models continue to evolve, more such entities are expected to perform similar roles.

We therefore applaud HHS for proposing the adoption of the OEID, which would provide a standard identifier for such entities. However, as proposed, acquisition of the OEID by such entities would be optional. Some may obtain one, but many will not. As a result, the utility of the OEID will be quite limited. We urge HHS to require OEID acquisition by any entity that needs to be identified in a transaction for which the Secretary has adopted a standard. It makes

[9] 77 Fed. Reg. at 22963.
[10] *Id.*

no sense to require the use of a standard that cannot be used as intended because entities that need to be identified in the standard are not required to identify themselves.

IV. ICD-10-CM Implementation Issues

By letter of March 28, 2012, ACLA wrote to HHS Secretary Kathleen Sebelius asking that HHS address several of the ICD-10-CM implementation issues raised in this letter as part of any regulatory proceeding to extend the compliance date for ICD-10-CM. HHS responded to the ACLA letter in an April 19, 2012 letter from Robert S. Tagalicod, Director of the CMS Office of E-Health Standards and Services. Each of these letters is attached.

The CMS response was encouraging with respect to the possibility of establishment of a certification program for validating ICD-10-CM compliance, in that it indicated that HHS is exploring the legality and feasibility of such a program in conjunction with NCVHS and the HHS Office of General Counsel. However, the response to the other issues we raised was less than satisfactory. We address the issues to which CMS responded, as well as one additional issue, below.

A. Even With an Extended Compliance Date, Inadequate Diagnosis Data in Laboratory Test Orders Will Increase with ICD-10-CM Without Enforcement Action by HHS

According to a recent ACLA survey, despite decades of experience with ICD-9-CM, 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. If laboratory efforts to educate the ordering provider community about the necessity of providing diagnosis codes on test orders were the answer to this issue, it would have been resolved decades ago. Without action by HHS, the number of test orders lacking required diagnostic information will likely grow significantly upon implementation of ICD-10-CM.

We respectfully disagree with the CMS suggestion that in lieu of regulatory relief, the issue of inadequate diagnosis data in laboratory test orders could and should be more expeditiously resolved by a disclaimer printed on laboratory test order forms stating that the laboratory test cannot be performed without the provider first rendering a diagnosis code. There are several reasons why implementation of this proposal would be both inappropriate and ineffective, and why clarification and enforcement of existing law is urgently needed instead. The CMS suggestion is inappropriate not only because it disregards the responsibility of HHS to enforce existing law, but also because it amounts to an attempt to resolve an administrative issue by encouraging clinical laboratories to delay (which will likely result in degradation of the sample's integrity) or deny medically necessary services to Medicare beneficiaries.

As explained in the attached March 28, 2012 letter to HHS from ACLA, it is our view that 42 U.S.C. § 1395u(p)(4) already requires ordering providers to provide diagnosis codes at the highest level of specificity to clinical laboratories at the time a laboratory test is ordered, because laboratories must provide diagnosis codes at the highest level of specificity to Medicare

Administrative Contractors in order for payment to be made to the laboratory. Congress enacted that provision because it would be fundamentally unfair to require a laboratory to submit for payment data that it can only obtain from an ordering provider, if the ordering provider had no obligation to provide the data to the laboratory.

However, laboratories are not in a position to enforce this statutory requirement; HHS is, but is not enforcing it. HHS should educate ordering providers about the requirement, and identify and apply an enforcement mechanism to ensure ordering provider compliance as it relates to Medicare transactions. If HHS were to do so and encourage private payers to do likewise, we believe they would follow, and it is likely that ordering provider non-compliance would be significantly reduced.

A laboratory policy to refuse to accept a test order or perform a test without a diagnosis code would more likely result in the delay or denial of care to a Medicare beneficiary than to result in the submission of accurate and complete diagnosis codes with the test order. Providers who regularly omit diagnosis codes from, or submit inadequate diagnosis data in, test orders today after decades of laboratory education on the issue would be unlikely to change that practice simply because a laboratory prints a reminder on an already crowded test order form.

Once the specimen is collected from the patient and is forwarded to the laboratory with the test order, and it lacks a diagnosis code, does HHS really expect the laboratory to hold the specimen hostage until the ordering provider submits a diagnosis code? Specimen integrity could easily degrade to the point it is unusable (or could produce inaccurate results) while the laboratory waits for a diagnosis code that may never arrive, because ordering providers currently lack sufficient incentive to submit it - it is only the laboratory that will not be paid if a diagnosis code is not submitted, and ordering providers know that HHS is not currently enforcing the law requiring the ordering provider to submit the code to the laboratory.

So, if the CMS suggestion were adopted, if a diagnosis code is never submitted for a specimen waiting to be tested, it would not be tested at all; if a diagnosis code is submitted after the specimen has degraded, either a new specimen would have to be obtained from the patient with a new test order (which, like the first deficient order, would also require a diagnosis code), or the degraded specimen might be tested, but could provide misleading information to the provider. Either way, the Medicare beneficiary would suffer, which is sufficient reason to reject the CMS suggestion.

To help resolve this issue, HHS should clarify and enforce the existing statutory requirement that ordering providers submit valid diagnosis codes at the highest level of specificity to clinical laboratories at the time a laboratory test is ordered for a Medicare beneficiary, and encourage private health plans to do likewise. We urge HHS to begin adopting this approach without delay and include it in the final rule on the ICD-10-CM compliance date extension.

B. Even With an Extended Compliance Date and Enforcement Effort by HHS, Some Ordering Providers May Still Be Unable or Unwilling to Provide Diagnosis Codes; Lab Use of Default Codes Should Be Authorized

It is likely that as of October 1, 2014 (or any other compliance date HHS may choose), some ordering providers will still be unable or unwilling to provide ICD-10-CM codes to laboratories in their test orders. As much as we believe HHS enforcement would significantly reduce these incidences, it would remain unfair to deprive laboratories of payment for covered services rendered to Medicare beneficiaries if ordering providers still fail to provide the necessary diagnosis codes for laboratories to bill successfully for their covered services. HHS should amend the Proposed Rule to establish a policy under which a laboratory that does not receive a diagnosis code in a test order would be allowed to submit a default diagnosis code that would be recognized as sufficient for payment purposes. CMS could use claims with such codes to identify ordering providers that fail to submit to laboratories the statutorily required diagnostic information – for informational or enforcement purposes.

C. Even With an Extended Compliance Date, Lack of ICD-10-CM Compliance Certification for Covered Entities and Their Systems Will Hamper Implementation

We are pleased that HHS is considering the establishment of a certification program for validating conversion to ICD-10-CM as well as other code sets and new versions of the HIPAA standard transactions, but we urge HHS to move expeditiously to implement such a program. Currently, in the absence of such a certification program, each covered entity must test with each of its trading partners to confirm their ability to transmit or receive a particular code set or transaction version. This effort can be a challenge even for small entities, but for larger ones, hundreds or even thousands of separate tests must be scheduled and conducted. This is a tremendous waste of valuable resources. Given the successful implementation of a certification program for electronic health records (EHRs), we believe HHS can and should expeditiously proceed to establish a certification program for HIPAA code sets and transactions, including ICD-10-CM.

D. Even with an Extended Compliance Date, Lack 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 That is More Specific Than the General Equivalence Mappings (GEMs) Will Hamper Implementation.

The GEMs are just what they purport to be – general equivalence mappings, not crosswalks. As such, they are not sufficiently specific to be useful for forward or backward crosswalking in automated billing systems. Indirect providers such as clinical laboratories need a forward crosswalk 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, particularly where there is a one-to-many relationship between the code sets. HHS should establish true forward and backward crosswalks that eliminate the ambiguity of the GEMs for billing and reimbursement purposes while providing a single authoritative standard for the industry.

E. Even With an Extended Compliance Date, a Lack of Coordination of Multiple Overlapping Initiatives Could Threaten ICD-10-CM Implementation.

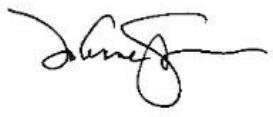
ICD-10-CM is the single largest conversion in the history of the health care industry, and yet it is being undertaken at the same time as several other major initiatives for which compliance is mandated on or near October 1, 2014. At any given entity, many of the same personnel will likely be engaged in each of these efforts. There is a limit to what covered entities can achieve in a given timeframe. Any further HIPAA or health IT mandates added to the current mix between now and October 1, 2014 would threaten not only timely ICD-10-CM implementation, but timely implementation of the other initiatives as well.

We also note in this context that the HHS estimate of the costs of the proposed one-year delay is underestimated. HHS appears to have estimated a 30% increase in the cost of conversion to ICD-10-CM as a result of the proposed one-year extension by assuming that the extension by one year of a three year compliance plan would increase costs by roughly one-third. However, this method of calculation does not address the cost of re-evaluation of trading partner timelines and additional rework for the overall project plan for those entities that had been diligently following the NCHICA / WEDI timeline for compliance by October 1, 2013. Further, the simultaneous testing for ICD-10-CM, the HPID, the OEID, and Stage 2 of EHR meaningful use standards will require additional resources that would not have been necessary with appropriate coordination and sequencing.

V. Conclusion

In the Proposed Rule, HHS has taken important steps toward realization of the goals of HIPAA administrative simplification – to reduce overall healthcare costs by making it easier for the health care industry to conduct administrative transactions. However, the additional steps outlined in these comments are necessary to maximize this opportunity. We look forward to working with HHS to implement the changes to the Proposed Rule that are needed to ensure that the goals of administrative simplification are fully achieved.

Very truly yours,



JoAnne Glisson
Senior Vice President

Attachments

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)

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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Office of E-Health Standards and Services

APR 19 2012

Alan Mertz, President
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Washington, D.C. 20005

Dear Mr. Mertz:

Thank you for your letter to U.S. Department of Health and Human Services (HHS) Secretary Kathleen Sebelius regarding the American Clinical Laboratory Association's issues related to the implementation of the ICD-10 medical code set. I have been asked to respond to you on her behalf.

We support ICD-10 for its many potential benefits, such as improved accuracy in reimbursement for medical services, fraud detection, and historical claims and diagnoses analysis for the health care system.

As you explained, clinical laboratories, covered entities under the Health Insurance Portability and Affordability Act (HIPAA), are required to submit diagnosis codes in standard transactions where such codes are required. Laboratories must depend upon referring providers to generate the diagnosis codes, in this case ICD-9-CM codes, in HIPAA standard transactions. However, there are circumstances in which there is no requirement for referring providers to submit such codes to the laboratories. Further, there is no requirement for the recipient of a transaction to accept codes from the laboratory. You expressed concern that if this practice continues, the transition to the new ICD-10 CM code set will be negatively impacted.

It is true that a laboratory test order is not a HIPAA standard transaction, even if submitted electronically. While some referring providers are not HIPAA covered entities and are exempt from HIPAA requirements to submit diagnosis codes, we believe that with the great majority of the health care industry working to transition to ICD-10 code use referring providers will follow suit in order to avoid potential reimbursement delays.

We also believe that in lieu of regulatory relief, there is a business case for requiring the use of diagnosis codes, and that is a policy established by clinical laboratories that the referring provider give a diagnosis code on the laboratory test order, in order for the test to be performed by the laboratory. As most laboratories provide physician offices with their laboratory test order form either on line or via paper, we continue to believe that a disclaimer printed on the form stating that the laboratory test cannot be performed without the provider first rendering a diagnosis code, is a more expeditious and easier solution.

In Section 1104 of the Affordable Care Act, Congress noted that should a crosswalk be used for the transition between ICD-9CM and ICD-10-CM codes, and vice versa, that the version that must be used is the one posted to the CMS website at http://www.cms.gov/ICD-10. We share the concern that the use of proprietary crosswalks would produce inconsistent results and create confusion, and the use of this mandated forward and backward crosswalk should help to alleviate that potential situation.

We also have been apprised by the health care industry of its interest in a certification program for validating vendor systems and software, as well as the readiness of providers and clearinghouses covered under the Health Insurance Portability and Accountability Act (HIPAA) for their conversion to ICD-10 CM, as well as other new and updated versions of the HIPAA standards. We are taking this issue under advisement and will explore the legality and feasibility of such a program, working in conjunction with the National Committee on Vital and Health Statistics (NCVHS), which advises the Secretary on standards adoption and other related issues, and our Office of General Counsel.

We also acknowledge your concern about the many overlapping mandates and reporting requirements that demand industry attention and resources. As the industry moves forward with these initiatives, we remain open to new ways to align the requirements of various programs to minimize implementation and reporting burdens. While we understand that addressing the requirements of each of these programs can be time and resource intensive, we also believe that initiatives like the Physician Quality Reporting System (PQRS), e-prescribing, and meaningful use of health information technology through the Electronic Health Records (EHR) Incentive Programs, are fundamental to effecting the kind of payment and delivery reforms envisioned by the Affordable Care Act.

Thank you for bringing your concerns to our attention, and we look forward to continued discussion and collaboration with the ACLA.

Sincerely,

Robert S. Tagalicod
Director
Office of E-Health Standards and Services