American
Clinical Laboratory
Association

Statement of the American Clinical Laboratory Association Before the National Committee on Vital and Health Statistics Standards Subcommittee

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Version 5010 and ICD-10 Implementation Issues for Clinical Laboratories

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Introduction

Mr. Blair, Dr. Warren, and members of the Subcommittee and staff, thank you for the opportunity to testify today on behalf of both the American Clinical Laboratory Association (ACLA) and LabCorp regarding the issues faced by clinical laboratories in implementing Version 5010 of the HIPAA standard transactions and the ICD-10 code set. ACLA represents national, regional and local laboratories, and its members, including LabCorp, play a critical role in our health care system, providing accurate, timely, reliable and objective clinical laboratory test results which influence over 70 percent of all medical decisions.

The ability of clinical laboratories to perform this vital role is in part dependent upon their ability, and the ability of their trading partners, to conduct administrative transactions in an efficient and effective manner. As a result, the transition to Version 5010 of the HIPAA standard transactions and the ICD-10 code set is of significant importance to the clinical laboratory industry, and we are committed to working toward the most seamless implementation of those standards possible. The issues that clinical laboratories face in implementing Version 5010 and ICD-10 are not insignificant, and their resolution will require cooperation from multiple stakeholders in industry and government. While we share many of the implementation issues faced by other health care providers, some issues, or their degree of impact, are unique to indirect providers such as clinical laboratories, and those differences must be taken into account to ensure a successful transition for all. My testimony today will focus on:

1) The current state of planning for Version 5010 and ICD-10 in the clinical laboratory industry;
2) The effect of other high priority initiatives and the current state of the economy on planning for and implementation of Version 5010 and ICD-10 by clinical laboratories;
3) The issues facing clinical laboratories regarding the transition to Version 5010 and ICD-10, their effect on effort and progress, and their comparison to issues faced by clinical laboratories during the initial implementation of the HIPAA standard transactions and code sets;
4) The key priorities for clinical laboratories while planning for and implementing Version 5010 and ICD-10; and
5) The key risk areas for clinical laboratories related to the transition to Version 5010 and ICD-10.

The Current State of Planning for Version 5010 and ICD-10 in the Clinical Laboratory Industry

State of Planning for Version 5010

While there is some variation within the clinical laboratory industry with respect to the current state of planning for Version 5010, most clinical laboratories have made measurable progress. Few if any clinical laboratories have not yet begun implementation planning for Version 5010, but few if any have completed implementation planning, either. The degree of completion of implementation planning ranges between 25% and 75%. Most clinical laboratories have formed a Version 5010 project team or are in the process of doing so; have begun to contact information system vendors and payers regarding Version 5010 implementation, but have not been informed of when major vendors will be delivering Version 5010 software; and are planning to upgrade the 837 (claim), 835 (remittance advice), 270/271 (eligibility inquiry and response), 276/277 (claims status inquiry and response), and 278 (prior authorization / referral) transactions to Version 5010 by the January 1, 2012 compliance date. However, there is more variation among clinical laboratories in their estimated dates for completion of Version 5010 internal testing, as some expect to complete internal testing between September 1 and December 31, 2010, while others do not expect to complete internal testing until sometime in 2011.

State of Planning for ICD-10

There is greater variation among clinical laboratories with respect to the current state of planning for ICD-10 than for Version 5010. The sense of urgency among clinical laboratories to plan for ICD-10 ranges from "very urgent" to "on the radar, but not much action". Some clinical laboratories have started work on ICD-10 implementation, while others have not. The degree of completion of ICD-10 impact assessments in the clinical laboratory industry, involving a determination of the impact of ICD-10 on business processes, systems, and trading partner relationships, currently ranges between 0% and 75%. The same range is applicable to the degree of completion of ICD-10 implementation budget estimates. Very few, if any, clinical laboratories have received estimated delivery dates for ICD-10 upgrades from their vendors or determined training needs or methodologies for their organizations. Virtually all clinical laboratories expect to complete internal testing for ICD-10 sometime after March 2013.

The Effect of Other High Priority Initiatives and the Current State of the Economy on Planning For and Implementation of Version 5010 and ICD-10 by Clinical Laboratories

Effect on Version 5010

Due to the unique clinical and administrative requirements applicable to clinical laboratories and the tremendous volume of transactions they process, many clinical laboratories utilize internal software development resources for both their laboratory information systems and their billing systems. The same resources needed for transition to Version 5010 are also needed for the transition to ICD-10, other contemplated HIPAA transaction and code set changes such as final adoption of the proposed claim attachment standard and a National Health Plan Identifier (NHPI), and implementation of standards for electronic laboratory orders and results

transmission being developed, harmonized or adopted in electronic health record system certification criteria by organizations such as HL7, the Health Information Technology Standards Panel (HITSP), and the Certification Commission for Health Information Technology (CCHIT). The resources available to clinical laboratories to devote to these initiatives are finite, and projects are prioritized and budgeted based on their value to the laboratory. The current state of the economy has further constrained the resources available to devote to these initiatives, and as a result, progress in implementation of Version 5010 has been slower than it would have been in the absence of these challenges.

Effect on ICD-10

Implementation of ICD-10 by clinical laboratories is generally subject to the same effects of other high priority initiatives and the current state of the economy as implementation of Version 5010, but to a greater degree. Since the compliance date for Version 5010, another high priority initiative, will arrive before the compliance date for ICD-10, and the same resources, constrained by a down economy, must be used for implementation of both, planning for and implementation of Version 5010 is currently given a higher priority than planning for and implementation of ICD-10 among most clinical laboratories. Consequently, progress in implementation of ICD-10 has been slower than progress in implementation of Version 5010, and slower than it would have been in the absence of other high priority initiatives and economic pressures. However, a requirement to implement Version 5010 and ICD-10 simultaneously would have been far worse, and we are grateful that the Department of Health and Human Services (HHS) recognized the need for staggered implementation of these standards and provided for additional time for compliance in the final rule adopting ICD-10.

Issues Facing Clinical Laboratories Regarding the Transition to Version 5010 and ICD-10, Their Effect on Effort and Progress, and Comparison to Initial HIPAA Transaction and Code Set Implementation

Version 5010 Issues

The most significant issue facing clinical laboratories in the transition to Version 5010 relates to how Version 5010 requires the National Provider Identifier (NPI) to be utilized. According to HHS, Version 5010 provides clear and precise rules that clarify how and when the NPI should be reported. 73 *Fed. Reg.* at 49747. By contrast, Version 4010 has been ambiguous on how to populate the NPI field for claims transactions. Version 4010 is unclear as to whether providers should use the NPI of the organization or corporation or the NPI at the subpart level (*i.e.*, name and location of provider for providers with multiple locations). As a result, while Medicare has required the use of subpart NPIs in claim submission, most private payers have required the use of organizational NPIs rather than subpart NPIs. Version 5010, however, requires that for transactions with all payers, the NPI at the most specific level be reported.

This is a serious concern for laboratories in their claims transactions with private payers because laboratories often have multiple locations. Some laboratories have hundreds of subparts. As a result, transition to Version 5010 will amount to a major second round of NPI implementation

that could dwarf the first, since there are many more private payers than Medicare carriers and Medicare Administrative Contractors (MACs).

As we experienced with Medicare in the initial implementation of NPI, laboratories will need to work with each private payer to ensure that the payer's system loads the correct NPIs for all of the laboratory's subparts. During the initial NPI implementation, it often took several attempts and several months for Medicare carriers and MACs to get it right, despite re-enrollment of multiple locations by laboratories. New enrollment and credentialing procedures will likely need to be implemented by private payers and complied with by laboratories to accommodate this new round of NPI implementation. Just as cash flow was threatened for many providers during the initial NPI implementation, unless private payers work efficiently and effectively with clinical laboratories, clinical laboratories could be particularly susceptible to cash flow issues under this second NPI implementation associated with the transition to Version 5010.

Further, given the significant number of changes involved in the shift from Version 4010 to Version 5010, the importance of a reliable crosswalk that assists providers, clearinghouses, and payers in transitioning from Version 4010 to Version 5010 cannot be overemphasized. Unfortunately, we have identified several errors in the comparison document prepared by the Centers for Medicare and Medicaid Services (CMS). A comparison guide with the type of errors we have identified will only result in delays in processing claims by payers and delays in reimbursement to providers. We therefore urge NCVHS to recommend that CMS revisit the comparison guide to correct the errors that are present, as well as to fill in the gaps where the agency has omitted necessary comparisons.

Yet another issue relates to identification of patients and subscribers. The Technical Report document ("TR3") pertaining to the submissions of electronic claims within the 837 transaction format for Version 5010 indicates the following:

> *"If a patient is a dependent of a subscriber and can be uniquely identified to the payer by a unique Identification Number, then the patient is considered the subscriber and is to be identified in the Subscriber Level." (P.142)*

Although current electronic submissions can reasonably accommodate such a standard for Medicare and Medicaid submissions based on the understanding that each Medicare or Medicaid number is unique to the patient, such universal rules are not applicable for commercial insurance plans. Currently, without electronic eligibility data from every electronic payer, there is no definite way for the provider to know whether the subscriber number on file is truly unique to the patient or whether the patient is a dependent of a subscriber, sharing the same number. Knowing whether or not to convey that the patient is the subscriber or a dependent of the subscriber is critical to establishing the correct electronic structure for the claim. Not structuring the data correctly is likely to lead to claim rejections, denials, or incorrect adjudication.

Therefore, this change in how dependent patients can be represented in Version 5010 will force providers to understand how each plan will enumerate their members, understand how each plan will edit against the patient/subscriber data submitted on the claim, and establish plans and corrective measures for new or increased rejections and denials related to this change once Version 5010 is implemented.

These issues have increased the effort necessary to convert to Version 5010, and have slowed progress toward that goal. While the transition to Version 5010 is not comparable in scope to the initial implementation of the HIPAA transaction and code set requirements, the implementation issues associated with it could result in adverse impacts just as significant as a failure to implement the initial requirements would have been.

ICD-10 Issues

Many of the implementation challenges that clinical laboratories face in the transition to ICD-10-CM relate to their status as indirect providers. The specimen on which a laboratory conducts testing is typically obtained in a physician's office or other provider's office and delivered to the laboratory. Even if the laboratory collects the specimen, the laboratory has no direct knowledge of the patient's condition or medical record. For compliance reasons, laboratories may not make diagnosis determinations for purposes of clinical laboratory testing on behalf of the treating provider, but must instead rely on the ordering provider to supply that information to them. The only circumstance in which a laboratory can provide its own diagnosis code is where the laboratory is offering anatomic pathology services through an employed or contracted pathologist. In those cases, the pathologist renders his or her own diagnosis with the pathology report.

Despite their inability to render or determine diagnosis codes for clinical laboratory testing, clinical laboratories are required to submit diagnosis codes in all electronic claims and in most paper claims to third party payers. Ordering providers, however, are not currently required by law to submit diagnosis codes in test orders to clinical laboratories, and missing, inadequate, inappropriate or narrative diagnosis data requiring translation to a code is not uncommon in test requisitions. As a result, after 30 years of experience with ICD-9-CM, insufficient diagnosis coding data from ordering providers remains the single biggest billing problem for labs. Front end claims suspensions, rejections or denials of claims due to inadequate diagnosis information requires follow up with the ordering provider and wastes valuable resources. Based on their experience with ICD-9-CM and the increased complexity and newness of ICD-10-CM, labs are understandably concerned about the potential impact of ICD-10-CM.

Given the indirect provider status of clinical laboratories, the importance of educating and training ordering providers and their office staffs on ICD-10-CM cannot be overstated. ACLA is willing to assist in this effort and is well-positioned to participate in outreach to the ordering provider community. However, aggressive and creative outreach from CMS and other government and industry organizations will also be needed to ensure adequate preparation of the ordering provider community. Passive education and training methodologies, such as posting educational and training material on a website, may be helpful, but will be insufficient to achieve

the goal of ordering provider competency in ICD-10-CM. Periodic interactive webcasts or conference calls offered to provide information and answer questions may also be helpful, but would not be sufficient. This information will need to be pushed to the ordering provider community to the point of saturation, in an appropriately timed manner, to achieve the competency necessary for a smooth transition as of October 1, 2013.

The indirect provider status of clinical laboratories also affects their internal training and hiring needs in the transition to ICD-10-CM. Currently, when ordering providers use narrative diagnoses instead of ICD-9-CM codes, appropriately trained laboratory personnel translate the narrative diagnoses into ICD-9-CM codes. However, given the significantly increased complexity of ICD-10-CM, laboratories anticipate the need to hire dedicated certified professional coders to perform these translations in addition to training existing translators, since the level of expertise needed for translation of narrative diagnoses will likely exceed the capabilities of many current translators, who typically have multiple responsibilities in addition to narrative diagnosis translation. Larger laboratories may need to hire hundreds of certified professional coders. It is already difficult to find certified professional coders, and this challenge will be intensified if more doctors increase their use of narrative diagnoses after the transition to ICD-10-CM. Additional billing staff will also need to be hired to follow up on anticipated increases in the rate of missing diagnosis data in test requisitions after the transition to ICD-10-CM. These new hires represent permanent increases in operational costs for clinical laboratories as a result of the transition to ICD-10-CM.

For those clinical laboratories that offer anatomic pathology services through employed or contracted pathologists, those pathologists will have to be trained to use ICD-10-CM in rendering the diagnoses that they submit in their pathology reports. The greater level of specificity in the codes will require pathologists to more thoroughly document their findings to support the diagnoses. The production of results during the transition is expected to slow, which could result in negative impacts to patient care.

Like other providers, clinical laboratories will have to change any system or data point that currently includes ICD-9-CM codes. For laboratories, the impact will reach across all of their main information technology systems – order entry, laboratory, billing, reporting, data warehousing, and client products. This includes business rule development, programming, testing and implementation for hundreds of internal software programs, as well as changes with respect to screens, reports, requisitions, forms (printed and electronic), interfaces, contracts, and policy manuals. In addition, because ICD-10-CM codes are more descriptive than ICD-9-CM codes, laboratories and other providers will need to develop storage to accommodate the longer descriptions by making file and database changes. These changes will also translate into the need for screens, displays, forms, and reports that must accommodate drop down menus with new descriptions with larger data fields. As such, laboratories will have to invest significant resources to implement all of the necessary system changes to accommodate ICD-10-CM.

However, again, the indirect provider status of clinical laboratories, as well as the geographical reach of larger laboratories, intensifies the impact of the system changes that must be made for ICD-10-CM. Laboratories will be required to remap hundreds of external client interfaces with electronic health record (EHR) systems to accommodate ICD-10-CM in test orders, while also

dealing with the need for end-to-end testing with hundreds of payers and other trading partners, although few such opportunities existed for end-to-end testing during the initial HIPAA transaction and code set conversion.

As we have learned from past HIPAA transaction and code set implementation efforts, sequencing and coordination of ICD-10-CM implementation efforts must follow a rational plan to avoid systemic disruptions. Each past attempt to implement HIPAA transaction and code set standards has required a contingency plan to avoid disruptions in our health care system. In several cases, these contingency plans became necessary as a result of not having an appropriate sequencing plan for implementation. For the transition to ICD-10-CM, not only will the industry need a rational test sequencing plan, but the massive scope of ICD-10-CM implementation must be prioritized against other HIPAA implementation efforts (e.g., claim attachments) and efforts to accelerate health information technology adoption and health information exchange (e.g., "meaningful use" of EHRs). It is important for HHS to emphasize that there will be no contingency plan for ICD-10-CM so that procrastination in planning and implementation will not turn the transition into a last minute panic.

Standardization of crosswalks and crosswalk implementation is important not just for payers, but for clinical laboratories and other providers as well. The General Equivalence Mappings (GEMs) for forward and backward crosswalks between ICD-9-CM and ICD-10-CM are helpful in understanding general relationships between the code sets, but as a practical matter they are insufficient because they are not one-to-one comparisons. Further, to the extent that different crosswalks can be implemented by different parties, and the same crosswalks can be implemented in different ways, inconsistent results are possible. CMS has recognized this issue on the payer side by developing a one-to-one Reimbursement Mapping from ICD-10-CM to ICD-9-CM. However, indirect providers such as clinical laboratories need a corresponding one-to-one 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. While we recognize that it is more difficult to establish a one-to-one forward mapping from ICD-9-CM to ICD-10-CM than a backward mapping, it would be unfair to allow payers to use a Reimbursement Mapping while denying providers the opportunity to use a Claim Submission Mapping. We would appreciate the opportunity to work with HHS and others in developing such a forward mapping that could be adopted industry-wide for use under prescribed circumstances.

Early adoption, late adoption and non-adoption of ICD-10-CM in non-standard transactions (*i.e.*, laboratory test orders) could threaten the ability of clinical laboratories to process compliant claims. Early adoption of ICD-10-CM in laboratory test orders, which the final rule adopting ICD-10-CM does not prohibit, could seriously disrupt billing for labs that are not yet prepared to use ICD-10-CM. Likewise, late or non-adoption of ICD-10-CM in non-standard transactions such as test orders, which the final rule also does not prohibit, would adversely affect the ability of labs to bill using ICD-10-CM codes for dates of service after the compliance date. While our educational and training efforts will seek to minimize early, late and non-adoption of ICD-10-CM in test orders and other non-standard transactions, and while we hope to further minimize these impacts through standardization of crosswalks, regulatory changes may be necessary to address the use of ICD-10-CM in transactions not covered by HIPAA due to their potential

impact on HIPAA-covered transactions. We would like to work with HHS to find a way to prohibit, or otherwise effectively discourage, early adoption, late adoption and non-adoption of ICD-10-CM in non-standard transactions that affect standard transactions in which diagnosis codes are used.

The magnitude of the transition to ICD-10-CM and its many implementation issues have inspired some laboratories to recognize the urgency of early planning and ongoing implementation, which has in turn resulted in efforts that have already led to measurable progress. Other laboratories appear to be either less concerned about the transition, due to its October 1, 2013 implementation date, or convinced that a contingency plan will ultimately have to be established to extend the compliance date to avoid systemic disruptions, or are so overwhelmed by the prospect of the transition that they are unsure where to start, or are so hampered by current economic restraints and other more pressing priorities, that they have not yet made significant efforts in planning for or implementing ICD-10-CM and have therefore made little progress.

The scope of implementation issues facing clinical laboratories in the transition to ICD-10-CM is significantly greater than the scope of issues associated with the initial implementation of the HIPAA transaction and code sets. The initial implementation of HIPAA transaction and code sets involved existing code sets with which clinical laboratories, ordering providers, clearinghouses and payers were already familiar, and implementation of the new transaction standards was primarily a billing project with information technology support. By contrast, the transition to ICD-10-CM, a new, restructured code set with which laboratories, ordering providers, clearinghouses and payers will need to become familiar, involves virtually every aspect of a clinical laboratory's operations, and will implicate fundamental business decisions of a kind that were never necessitated by the initial implementation of HIPAA transaction and code set requirements.

Key Priorities for Clinical Laboratories While Planning For and Implementing Version 5010 and ICD-10

Key Priorities for Version 5010

While planning for and implementing Version 5010, clinical laboratories will be focused on ensuring that they meet the January 1, 2012 compliance date to avoid interruptions in cash flow. Coordination of implementation with payers, on a payer by payer basis, will be necessary to achieve this goal. Addressing the NPI implementation issues associated with the transition to Version 5010, together with testing, will be key priorities as labs seek to coordinate the transition with payers.

Key Priorities for ICD-10

For the transition to ICD-10-CM, clinical laboratories will be focused on ensuring that they meet the October 1, 2013 compliance date to avoid interruptions in cash flow. Training and education of ordering providers is a top priority for clinical laboratories in the transition to ICD-10-CM, given the dependence of clinical laboratories on ordering providers to submit the diagnosis data

that labs must submit to payers to obtain reimbursement for their services. Other key priorities include appropriate sequencing and coordination of ICD-10-CM implementation efforts pursuant to a rational plan; standardization of crosswalks and crosswalk implementation, including the development and adoption of a Claim Submission Mapping from ICD-9-CM to ICD-10-CM; and the adoption of methods to prohibit, or otherwise effectively discourage, early adoption, late adoption and non-adoption of ICD-10-CM in non-standard transactions that affect HIPAA covered transactions.

Risk Areas for Clinical Laboratories Related to the Transition to Version 5010 and ICD-10

Risk Areas for Version 5010

The key risk areas for clinical laboratories in implementation of Version 5010 are inadequate readiness for testing and implementation on the part of payers and information technology vendors, as well as payer-specific interpretations and requirements relating to Version 5010. The inability of payers to accept clinical laboratory subpart NPIs and load them into their systems correctly and efficiently is also a major risk area.

Risk Areas for ICD-10

The key risk areas for clinical laboratories in implementation of ICD-10-CM include procrastination and inadequate education and training of ordering providers; variations in payer adoption and adapting; absence of useful crosswalks or variations in crosswalks and their implementation; changes to payer coverage policies based on medical necessity, which could adversely affect reimbursement; and inadequate readiness of payers and information technology vendors for testing and implementation.

Conclusion

We commend the Subcommittee for holding hearings on the issues related to planning for and implementation of Version 5010 and ICD-10, and encourage the Subcommittee to continue to monitor closely the progress being made on implementation of both of these standards. We ask the Subcommittee to carefully consider the issues faced by clinical laboratories in these transitions as well as the solutions we have suggested, and to make appropriate recommendations for HHS to take action to address these issues accordingly in a prompt and effective manner. Thank you again for the opportunity to testify, and I look forward to your questions.