American
Clinical Laboratory
Association

ACLA Testimony
to the
Clinical Laboratory Improvement Advisory Committee

Laboratory Interfaces

September 21, 2006

The American Clinical Laboratory Association ("ACLA") is pleased to provide testimony to the Clinical Laboratory Improvement Advisory Committee on interfaces between the laboratory and clinicians. ACLA is an association representing local, regional, and national clinical laboratories throughout the country.

Laboratories play a critical role in healthcare delivery by allowing for the rapid and timely utilization of health information by providers. Laboratories and the medical information they provide are the heart of the medical record. Laboratory data represent 60% of the medical record. Diagnostic tests comprise only 5 % of total hospital costs and only 1.6% of Medicare costs, but they influence a much larger portion (as much as 60-70%) of clinical decision-making that improves care and decreases cost. Virtually every health care community (i.e. Regional Health Information Organizations or RHIOs) that is trying to develop an electronic health information infrastructure is looking to laboratories first. The exchange of laboratory results happens in a myriad of ways: from laboratories themselves to the ordering physician, from the physician to other clinical care providers, health plans, data clearinghouses; or from laboratories to the aforementioned RHIOs. Each of these scenarios present challenges in the exchange of this pertinent clinical care data – challenges which can be resolved by making changes to existing state and Federal rules and regulations – among them CLIA. For the purposes of this group I will restrict my comments to those changes to CLIA and/or the interpretive guidelines which we believe will help facilitate the exchange of electronic laboratory results.

The first challenge laboratories face when exchanging laboratory results occurs when an EHR vendor makes changes in the test result report before providing it to the physician. The clinical laboratory is still responsible for the content and format of that report, in accordance with CLIA requirements. While many of these changes by the vendor are done at the behest of the physician, laboratories are ultimately responsible for the delivery of the final CLIA-compliant result report – despite the vendor's modifications. ACLA proposes two potential solutions to the problem:

Option 1: Amend the Interpretive Guidelines to clarify that the laboratory must only ensure that the CLIA-compliant report is received at either the client or the vendor (or other contractually obligated intermediary) system.

Option 2: Seek amendment to the CLIA regulations (42 CFR §493.1291(a)) to clarify that the results must be sent either to the client or to the intermediary.

The second challenge facing laboratories and the exchange of electronic laboratory results is when test result report information is disclosed by the physician to another entity (such as a RHIO), the clinical laboratory is still responsible for the final CLIA-compliant report, in accordance with CLIA requirements. ACLA believes the clinical laboratory's responsibility for the test result should end once the result is provided to the ordering physician or other vendor. The Interpretive Guidelines should make clear that the laboratory is not responsible for subsequent disclosure of test result information made by the physician.

The third challenge presented to laboratories is that in some states, if a RHIO or any person other than the ordering physician who ordered the test wishes to receive test results from the laboratory, the laboratory may not be permitted to make the disclosure, for two reasons. First, under the definitions in CLIA, the laboratory can only furnish the test result to an "authorized person," or the "individual responsible for using the test results," or the laboratory that requested the test, if applicable. An "authorized person" is whoever is permitted to order the test or receive the test results under state law, which is often restricted to the ordering physician. There is no definition of "individual responsible for using the test results." To deal with this CLIA issue, ACLA proposes that CMS amend the definition of "authorized person" to include not only a person authorized under state law to receive the test results, but also the authorized person's agent and other legitimate recipients of the results. Alternatively, CMS could define "individual responsible for using the results" in a similar manner, or revise the section governing result delivery accordingly.

In advance of today's meeting I have provided a copy of these challenges & solutions along with an appendix providing the specific changes ACLA is seeking to the CLIA interpretive guidelines and the regulations.

Thank you for this opportunity to present on the interfaces between the laboratory and clinicians. I'm happy to answer any questions at this time.