American
Clinical Laboratory
Association

ACLA Statement
to the
Clinical Laboratory Improvement Advisory Committee

Electronic Transmission of Laboratory Information

February 9-10, 2010

The American Clinical Laboratory Association ("ACLA") is pleased to provide a statement to the Clinical Laboratory Improvement Advisory Committee on CLIA issues affecting laboratory data exchange. ACLA testified before CLIAC on this very issue on September 21, 2006. While that statement is more than three years old, many of the issues we raised then remain a concern today. ACLA is an association representing local, regional, and national clinical laboratories throughout the country.

The exchange of laboratory results happens in a myriad of ways. Whether results are sent from laboratories to the ordering physician, or from laboratories to health information exchanges (HIEs) or other recipients authorized by the ordering physician, or from the physician to other clinical care providers or health plans, each of these scenarios presents challenges in the exchange of this pertinent clinical care data – among them those challenges created by CLIA. For the purposes of this statement, 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 data. Specifically, I will make mention of three distinct scenarios which remain challenging for laboratories in the transmission of electronic laboratory data.

The first challenge is that laboratories must visually verify that CLIA-compliant result reports are being displayed on the screens of end users of lab result interfaces. While CLIA does not currently specify the manner in which interface verification must occur, there is currently no automated verification method, so as a practical matter, visual verification is required to ensure compliance. This requirement is resource-intensive and hampers access to electronic lab data exchange. CLIA and/or the interpretive guidelines should clarify that a results interface will be deemed verified if results are sent to an EHR certified under requirements established by the Secretary.

The second challenge laboratories face when exchanging laboratory data occurs when an electronic health record (EHR) vendor makes changes in the test result report before providing it to the physician by configuring the EHR to modify the result report display.

The clinical laboratory is still responsible for the content 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. Likewise, when test result report information is disclosed by the physician to another entity (such as an HIE), the clinical laboratory is still responsible for the final CLIA-compliant report, in accordance with CLIA requirements, despite modifications in the report that may occur in this subsequent transmission. The clinical laboratory's responsibility for the result report should end once the result is provided to the destination intended by the clinical laboratory transmitting the result, or to an intermediary contractually obligated to send the results to the intended destination. The Interpretive Guidelines should make clear that the laboratory is not responsible for subsequent modifications of test result information made by the physician or other third parties.

ACLA proposes two potential solutions to this second challenge. First, the Interpretive Guidelines could be amended to clarify that the laboratory must only ensure that the CLIA-compliant report is received at either the intended destination or the vendor (or other contractually obligated intermediary) system. Second, the CLIA regulations (42 CFR §493.1291(a)) could be amended to clarify that the results must be sent either to the intended destination or to the intermediary.

The third challenge laboratories are facing is that in many states, if a HIE 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 without ordering physician authorization, 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 resolve this third 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.

ACLA is providing with this statement a copy of the specific changes ACLA is seeking to the CLIA interpretive guidelines and the regulations.

At this time I'm happy to answer any questions.

PROPOSED REGULATORY AMENDMENTS

I. First and Second Challenges – Interface Verification and Laboratory Responsibility for Changes to Result Report by Third Parties

Proposed Regulatory Amendment / Interpretive Guideline Amendment.

42 C.F.R. § 493.1291(a): The laboratory must have an adequate manual or electronic system in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to the intended destination, or to an intermediary contractually obligated to send the results or other patient-specific data directly or through other intermediaries to the intended destination, in a timely manner. Verification of transmission of test results and other patient-specific data in a timely manner to an electronic health record (EHR) system certified in accordance with requirements established by the Secretary shall be deemed adequate to ensure accurate and reliable transmission, without visual inspection.

II. Third Challenge – Release of Test Results to Entities Other Than the Ordering Physician

Option 1: Revision of 42 CFR § 493.1291(f) / Interpretive Guideline Amendment

Test results must be released only to the authorized person who ordered the test. In addition, notwithstanding any contrary State law defining who is an individual authorized to order tests or receive test results or both, test results may be released to:

(1) The laboratory that initially requested the test, if applicable;

(2) Any person designated to receive the test results by the authorized person who ordered the test;

(3) A “covered entity”, as defined in 45 C.F.R. § 160.103; and

(4) A “business associate” of a covered entity, as defined in 45 C.F.R. § 160.103.

This section shall not be construed to permit the disclosure of any specific type of test result to any of the persons or entities named herein where the disclosure of test results of that type is otherwise prohibited by State or Federal law. Further, nothing in this section shall be construed to permit the disclosure of any test result to any of the persons named herein where the disclosure would be prohibited under the HIPAA Privacy Regulations, 45 C.F.R. Parts 160 and 164, except where the disclosure would otherwise be prohibited by more stringent State law defining persons authorized to order tests or receive test results in a manner contrary to this paragraph.

Option 2: New Addition to 42 CFR § 493.2 / Interpretive Guideline Amendment

Individual responsible for using the test results means, notwithstanding any contrary State law defining who is an individual authorized to order tests or receive test results or both:

(a) Any person designated to receive the test results by the authorized person who ordered the test;

(b) A "covered entity", as defined in 45 C.F.R. § 160.103; and

(c) A "business associate" of a covered entity, as defined in 45 C.F.R. § 160.103.

This definition shall not be construed to permit the disclosure of any specific type of test result to any of the persons or entities named herein where the disclosure of test results of that type is otherwise prohibited by State or Federal law. Further, nothing in this section shall be construed to permit the disclosure of any test result to any of the persons named herein where the disclosure would be prohibited under the HIPAA Privacy Regulations, 45 C.F.R. Parts 160 and 164, except where the disclosure would otherwise be prohibited by more stringent State law defining persons authorized to order tests or receive test results in a manner contrary to this paragraph.

Option 3: Addition to 42 CFR § 493.2 / Interpretive Guideline Amendment

Authorized person means an individual authorized under State law to order tests or receive test results, or both. In addition, notwithstanding any contrary State law defining who is an individual authorized to order tests or receive test results or both, authorized person means:

(a) Any person designated to receive the test results by the authorized person who ordered the test;

(b) A "covered entity", as defined in 45 C.F.R. § 160.103; and

(c) A "business associate" of a covered entity, as defined in 45 C.F.R. § 160.103.

This definition shall not be construed to permit the disclosure of any specific type of test result to any of the persons or entities named herein where the disclosure of test results of that type is otherwise prohibited by State or Federal law. Further, nothing in this section shall be construed to permit the disclosure of any test result to any of the persons named herein where the disclosure would be prohibited under the HIPAA Privacy Regulations, 45 C.F.R. Parts 160 and 164, except where the disclosure would otherwise be prohibited by more stringent State law defining persons authorized to order tests or receive test results in a manner contrary to this paragraph.