August 23, 2006

American Clinical Laboratory Association

HIPAA/CLIA ISSUES

Problem 1: When an EHR vendor changes the test result report that is provided to the physician, the clinical laboratory is still responsible for the content and format of that report, in accordance with CLIA requirements.

Solution: There are two potential solutions to this 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.

Please see the Appendix for suggested language.

Problem 2: When test result report information is disclosed by the physician to the RHIO, the clinical laboratory is still responsible for the final CLIA-compliant report, in accordance with CLIA requirements.

Solution: 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. Please see the Appendix for suggested language.

Problem 3: 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 under state law to receive the test results, which is often restricted to the ordering physician. There is no definition of "individual responsible for using the test results."

Second, under HIPAA, the laboratory is not permitted to disclose the information to the RHIO or other entity, unless the disclosure falls within the definition of "payment, treatment or operations," an authorization has been obtained, or another exception applies. Further, since HIPAA does not preempt more stringent

state laws, a disclosure of test results otherwise permissible under HIPAA is prohibited if forbidden under state law.

Solution: To deal with the CLIA issue, CMS could 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. Please see the Appendix for suggested language.

The proposed revisions of the CLIA regulations would also resolve the HIPAA issue raised by deference to more stringent state law as applied to the disclosure of test results, since the CLIA regulations would preempt such state laws. To deal with the other HIPAA issues without having to obtain patient authorization, the laboratory would need to ensure that the RHIO has a business associate agreement with the appropriate covered entity or that the RHIO otherwise qualifies as a permissible recipient of PHI (*e.g.*, a health oversight agency), and that the disclosure is for a purpose (and to an entity) for which patient authorization is not required. A business associate is an entity furnishing a function or activity involving the use or disclosure of PHI to, for, or on behalf of a covered entity.

APPENDIX

Problem 1

To address the issue identified in Problem 1 using Option 1, we recommend the following change to the CLIA Interpretive Guidelines for 42 C.F.R. § 493.1291(a):

D5801

§493.1291 Standard: Test report.

(a) The laboratory must have an adequate manual or electronic system(s) 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 final report destination, in a timely manner. This includes the following:

Interpretive Guidelines §493.1291(a):

The regulations apply to manual as well as automated record systems, i.e., a laboratory information system or LIS. However, the regulations do not specify the mechanism or frequency for which a laboratory should evaluate its record storage and retrieval system(s).

Probes §493.1291(a):

*How does the laboratory ensure that transmitted reports are **clear?***

Is there a documented system in operation to periodically verify that patient results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to all types of patient reports (both paper and video displays)?

NOTE: This includes evaluation of data transmitted from the LIS to other computer systems and their output devices. Reference ranges and comments, as well as actual patient results, must be evaluated. When multiple copies of tables are maintained within more than one computer system, they must be periodically compared to ensure consistency among all copies in use.

This applies only to interfaces through which laboratory information systems directly send or receive data. For example, if the laboratory information system is interfaced with the client or vendors information system, the laboratory must verify the accuracy of patient results transmitted from the laboratory system to the initial client or vendor system.

How does the laboratory ensure results were sent to the intended destination?

*If the laboratory uses a LIS or facsimile, what security measures have been instituted to ensure that transmitted reports go directly from the device sending reports only to the authorized individual, their location **or their designated** electronic system?*

§493.1291 Standard: Test report.
(a)(1) Results reported from calculated data.
(a)(2) Results and patient-specific data electronically reported to network or interfaced systems.
(a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

Interpretive Guidelines §493.1291(a)(3):
Manually transcribed results from an outside referral laboratory or from within the laboratory system (e.g., satellite or point-of-care testing locations) must be periodically verified for accuracy and timely reporting.

Electronically transmitted results from an outside referral laboratory or from within the laboratory system (e.g., satellite or point-of-care testing locations) must be periodically verified for acknowledgement of successful communication delivery.
The laboratory should establish a time tolerance limit for results reporting to the output device. Also, the laboratory should periodically monitor the performance of its reporting systems.

To address the issue identified in Problem 1 using Option 2, we recommend the following change to the regulatory text of 42 C.F.R. § 493.1291(a):

In the event that the changes to the CLIA Interpretive Guidelines that we have proposed to Judy Yost are not adopted, the first sentence of this section of the regulations should be revised to read as follows:

"The laboratory must have an adequate manual or electronic system(s) 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....."

Problem 2

We also recommend the solution identified above to address the issue identified in Problem 2.

Problem 3

To address the CLIA issue identified in Problem 3, we recommend the follow change(s) to the regulatory text of 42 C.F.R. § 493.1291(f) and/or § 493.2:

Alternative 1: Revision of 42 CFR § 493.1291(f)

Test results must be released 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.

Alternative 2: Addition to 42 CFR § 493.2

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.

Alternative 3: Addition to 42 CFR § 493.2

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.