

## **Questions from the HIT Policy Committee / Information Exchange Workgroup:**

### **General Questions:**

**-What are the technology impediments to the electronic exchange of lab data?**

**-What are the business case impediments to the electronic exchange of lab data?**

*Many labs have made significant investments in existing peer-to-peer connectivity solutions for electronic transmission of laboratory test orders and results. Establishment and maintenance of a results-only interface with a Health Information Exchange (HIE) is costly, and at least in the short term is largely duplicative of existing connectivity solutions. Labs have little incentive to pay for a duplicative results interface when peer-to-peer connectivity already exists, and most entities requesting lab data feeds are not only unwilling to reimburse the lab for the cost of the interface, but wish to charge the lab for participation in the HIE, despite the fact that, unlike other participants, labs are generally not data recipients in today's HIEs, but data providers only. In the long term, provided that the operational needs of laboratories are addressed, HIEs could potentially reduce or eliminate the need for customized peer-to-peer connectivity and make lab connectivity available to smaller provider practices for whom the provision of such connectivity is not currently economically feasible, which could become a significant incentive for lab participation once test order functionality is included. However, the short term disincentives for lab involvement in HIEs are limiting the potential long term efficiencies.*

**-What are the operational impediments to the electronic exchange of lab data?**

**-What are the regulatory impediments to the electronic exchange of lab data?**

*CLIA (42 C.F.R. §§ 493.1291(f), 493.2) and most State laws narrowly define the "authorized persons" to whom a lab may transmit test results. CLIA (42 C.F.R. § 493.1291(a)) also holds the lab responsible for ensuring that test results reach the "final report destination" in a timely, accurate and reliable manner, despite the fact that the laboratory has no way to prevent third parties from making modifications to the displayed content and format of transmitted test results after the lab has sent them in a timely, accurate and reliable manner to the intended system.*

**-What is the low-hanging fruit for improving e-exchange of lab data?**

*ACLA has proposed Federal legislative and regulatory amendments to CLIA which would address the identified regulatory issues. Those amendments, attached hereto as Exhibit A, should be adopted.*

*Modification of the CLIA interpretive guidelines to address these issues might enable some interim relief; however, these guidelines do not have the force of law, lack the procedural protections available in legislation and notice and comment rulemaking, and are limited by the extent to which the existing regulations can reasonably be interpreted. Further, we believe that the interface issue is more amenable to relief*

*through modification of the CLIA interpretive guidelines than the authorized person issue.*

### **-What's a priority to facilitate easier/broader e-exchange of lab data, even if not low-hanging fruit/immediately actionable?**

*ACLA has proposed Federal legislative and regulatory amendments to CLIA which would address the identified regulatory issues. Those amendments, attached hereto as Exhibit A, should be adopted. States could also amend their "authorized person" statutes to similarly expand the list of permitted recipients of lab results to include HIPAA covered entities and business associates pending the enactment of amendments to Federal law; however, State law amendments are likely to result in considerable variation, and a Federal solution that pre-empts contrary State law is preferable to promote uniformity.*

*Two states, Tennessee and Florida, have recently amended their authorized person statutes in an attempt to address the authorized person issue, at least in part. On June 16, 2009, the Governor of Florida signed into law Senate Bill 162, which amended Section 483.181(2) of the Florida Statutes to provide that appropriate disclosure of test results may be made by the clinical laboratory, without a patient's consent, to other health care practitioners and providers involved in the care or treatment of the patient, in addition to the ordering provider. While this amendment is a positive step, it is insufficient to address the issue in its entirety. The State of Tennessee came closer to a comprehensive solution on May 30, 2007 when it enacted Senate Bill 2268, which amended Tennessee's authorized person statutes to permit clinical laboratories to transmit test results to a "designated entity", an entity that performs actions or functions on behalf of the provider, payer or patient for purposes of creating an electronic health record. Tenn. Code Ann. §§ 68-29-121(b), 68-29-103(7).*

*With respect to the interface issue, one non-regulatory approach that could be taken would be to ensure that certification criteria for EHRs, networks, and other systems designed to receive laboratory test results include a requirement that the system must display to the user all data fields required by CLIA to be included in a test result report, and cannot include functionality that would disable or mask any such data fields in the display. However, this approach would only affect newer systems, and the interface issue would continue to exist in legacy systems. Further, this approach would ignore user preferences and perhaps discourage accelerated EHR adoption and HIE participation.*

*Another approach that could be taken with respect to the interface issue would be to develop an automated acknowledgement transaction that could be used in lieu of visual verification of proper interface functionality. Standards and specifications for such an acknowledgement transaction would need to be referenced in the CLIA interpretive guidelines to 42 C.F.R. § 493.1291(a), if not in the regulation itself. Such a transaction would need to be designed in a manner that would minimize any associated tracking or audit responsibility for the laboratory.*

*Finally, the CLIA interpretive guidelines could be modified to interpret "final report destination" as meaning the system (e.g., EHR or HIE hub) to which the lab intended to send the results, so that as long as the result was delivered to the intended*

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*system in a CLIA-compliant manner, the lab would not be responsible for the content or format of the test result report as displayed on the user's terminal, or as displayed to other users who subsequently acquire the test result report indirectly.*

**- What best practices would you recommend in this area?**

**-What work-arounds for these impediments have you experienced/designed/observed?**

*With respect to the authorized person issue, typical "work-arounds" involve various forms of documentation of ordering provider authorization for the disclosure of test results to a non-ordering third party. Advance authorizations are encouraged whenever the need for disclosures is known in advance. For example, an ordering provider can specify in the test requisition that a copy of the result is to be sent to a particular specialist who is also treating the patient (or to any other party for any other purposes permitted by HIPAA). Advance authorizations can also be included in contracts between ordering providers and the health plans or HIEs with whom they are participating.*

*When advance authorizations do not exist, and a need arises to send historical test results to a non-ordering third party, the method of documentation of ordering provider authorization may vary depending on the nature of the disclosure sought. For example, if historical test results for a single patient are sought from a lab by a specialist to whom a patient has been referred, a written authorization from the ordering provider will generally be required before the results are released to the specialist. If historical test results for tens of thousands of patients are sought by a health plan for a period of several years for health care operations purposes as permitted under the HIPAA Privacy Rule at 45 C.F.R. § 164.506(c)(4), the health plan may be asked for a contractual warranty that the providers who ordered the tests, or other persons authorized to receive the test results, have authorized their disclosure by the lab to the health plan. Such contractual warranties are often difficult and sometimes impossible to negotiate and obtain.*

### **Specific Questions:**

**-Has your state's definition of "authorized person" limited the ability of health care entities to exchange lab data electronically?**

*Yes. The ability of health care entities to exchange lab data electronically is limited to some degree in every State by its definition of "authorized person" or its failure to define the term.*

**-How do you, your laboratory or EHR vendor view the requirements set forth in 42 C.F.R. § 493.1291 (Requirement that the test results and other patient-specific data are accurately and reliably sent from the point of data entry to final report destination, in a timely manner)? I.e. technical method or visual "eye-ball" inspection of every terminal/interface in an installation to ensure that data is displayed correctly.**

*We interpret this provision to require visual inspection of every known terminal/interface displaying the report of record in an installation to ensure that data is*

*displayed correctly, since we are unaware of any currently available reliable technical validation method.*

- How do you, your vendor, or state interpret “final report destination?” Does this interpretation hinder the electronic exchange of lab data?

*We have historically interpreted “final report destination” to mean the display visible to the intended recipient of lab test results sent through an electronic interface. Since no reliable technical validation method has been available, and since the lab has no way of knowing where the test result may be sent by the recipient, the display at the terminal of the intended recipient is the only destination with respect to which a lab has had any ability to perform a validation. However, we are concerned that this term could be interpreted as including every destination to which a test result report could be sent by the recipient and subsequent recipients. These interpretations hinder the electronic exchange of lab data not only because they appear to require visual verification of a CLIA-compliant display of the test results on the intended user’s system, but also because current EHR systems have the capability of customizing test result displays based on user preferences (which means the display could be changed by the user or EHR vendor subsequent to visual validation by the lab). Further, the concept of “final report destination” is meaningless in the current HIE environment, since the “final report destination” for any given test result report sent by a laboratory to an HIE (or to an ordering provider who participates in an HIE) is necessarily unknown. In this context, obligating labs to ensure the timely, accurate and reliable delivery of test results to every potential “final report destination” exposes labs to perceived risks of regulatory non-compliance that would tend to hinder lab participation in HIEs.*

-Do you believe that the adoption of a universal compendium/dictionary will reduce costs related to the implementation of lab interfaces and improve electronic exchange?

*A universal compendium is unrealistic due to variances in testing by laboratories. However, development of a standard test compendium framework, including standardized formats and field lengths for the compendium of each laboratory that could be downloaded to the EMR vendor’s systems, has the potential to reduce costs related to the implementation of lab interfaces and improve electronic exchange. ACLA is currently developing a test compendium framework that could improve lab interface implementation and maintenance.*

-Who is best suited to maintain a universal compendium?

*HL7 is best suited to maintain a standard test compendium framework; however, a universal compendium is unrealistic.*

-What standards, if any, would you recommend for the transmission of lab data?

*We recommend industry accepted transmission standards, including web services.*

- How do you ensure lab data is transmitted securely and confidentially?

*Adherence to HIPAA Security Rule standards helps ensure the secure and confidential transmission of lab data.*

-What are the obstacles preventing patients from receiving copies of their lab data?

*The following response represents the position of LabCorp.*

*There are no obstacles preventing patients from receiving copies of their lab results from the providers who ordered the tests, and this right of access is specifically protected by the HIPAA Privacy Rule at 45 C.F.R. § 164.524. In addition, approximately 13 States currently require clinical laboratories to provide test results to the individual for whom a test was performed, upon request. However, most States either expressly prohibit or do not authorize clinical laboratories to provide laboratory test results directly to patients, and the HIPAA Privacy Rule acknowledges this CLIA exception to the right to access at 45 C.F.R. § 164.524(a).*

*We respect the policy decisions that have been made in those States that currently have laws requiring labs to provide test results directly to patients upon request, and where State law currently requires the transmission of test results directly to the individual tested, we comply with those laws. However, as a matter of public policy, we do not support the adoption of such laws in other states, or at the Federal level. Our position is that patients who want access to their test results should obtain them from the ordering provider. There are several reasons supporting this position.*

*First, patients already have the right to obtain laboratory test results from their ordering providers in every State. The right of individual access to protected health information (PHI) granted to patients under the HIPAA Privacy Regulations at 45 C.F.R. § 164.524 includes the right of patient access to laboratory test results in the possession of the ordering provider, subject to only a few relatively narrow exceptions which, if applicable, would apply whether or not the PHI consisted of laboratory test results. We are unaware of any state that generally prohibits patient access to laboratory test results in the possession of the ordering provider. Therefore, requiring clinical laboratories to send test results directly to patients is unnecessary.*

*Second, the ordering provider is in the best position to interpret laboratory test results in the overall clinical context of the patient's care. As indirect providers, clinical laboratories typically never see the patient, and even if the patient visits a laboratory's patient service center to have a specimen taken by a phlebotomist, the laboratory is still not in a position to interpret the test results. In some cases, direct delivery of laboratory test results to patients without the intervening consultation of a provider could result in harmful patient reactions. From a patient care perspective, we should foster public policy that encourages and enhances the relationship between providers and their patients; requiring laboratories to transmit test results directly to patients tends to erode that relationship.*

*Finally, requiring clinical laboratories to send results directly to patients, in addition to the ordering providers, is administratively burdensome and costly. Even if every patient had the capability to receive test results electronically – which is certainly not the case today – the connectivity solutions necessary to accomplish such a task would likely represent many multiples of the connectivity solutions currently in place for electronic delivery of results to providers. Further, as indirect providers that typically have no direct contact with the patient, clinical laboratories generally rely upon the demographic information provided in the test requisition by the ordering provider for purposes of administrative transactions, and as a result, obtaining complete and accurate demographic information is often a challenge. With or without electronic capabilities for*

*patient receipt of test results, just obtaining accurate routing information could be very difficult and time consuming. In this context, it is important to keep in mind the tremendous volume of test results involved. Even if laboratories were only required to send results directly to patients upon request, it could be an expensive undertaking that would be inconsistent with the goal of reducing health care costs.*

*Promoting communication between providers and their patients, including patient access to laboratory test results already in the ordering provider's possession, is one of the best ways to improve patient care while lowering overall health care costs. Better informed patients will make better decisions regarding their own care, but requiring clinical laboratories to send test results directly to patients is not the best way to achieve that goal.*

## **EXHIBIT A**

### **LEGISLATIVE SPECIFICATIONS AND REGULATORY AMENDMENTS FOR RESOLUTION OF CLIA ISSUES IN LAB DATA EXCHANGE**

#### **I. The “Authorized Person” Issue**

A. Proposed Legislative Specifications. Chapter 6A of Title 42, United States Code (42 U.S.C. § 263a) shall be amended by adding the following new paragraphs:

(f)(5) Release of Test Results. A clinical laboratory must release test results to the authorized person who ordered the test and to any other authorized person to whom release of the test results is required by State or Federal law. In addition, notwithstanding any contrary State law defining who is a person authorized to order tests or receive test results or both, a clinical laboratory may release test results to:

- (A) The laboratory that initially requested the test, if applicable;
- (B) Any person designated to receive the test results by the authorized person who ordered the test;
- (C) A “covered entity”, as defined in 45 C.F.R. § 160.103; and
- (D) A “business associate” of a covered entity, as defined in 45 C.F.R. § 160.103.

(f)(6) Limitations on Release of Test Results. Nothing in paragraph (5) shall be construed to permit the disclosure of any specific type of test result to any of the persons named herein where the disclosure of test results of that type is otherwise prohibited by State or Federal law. Further, nothing in paragraph (5) 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.

B. Proposed Regulatory Amendments.

**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. 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.

**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. 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.

**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. 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.

C. Explanatory Note. Current law provides as follows:

42 C.F.R. § 493.1291(f): Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that

initially requested the test.

42 C.F.R. § 493.2: Authorized person means an individual authorized under State law to order tests or receive test results, or both.

## **II. The Interface Issue**

A. Proposed Legislative Specifications. Chapter 6A of Title 42, United States Code (42 U.S.C. § 263a) shall be amended by adding the following new paragraph:

(f)(7) Manner of Transmission of Test Results. 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.

B. Proposed Regulatory 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.

C. Explanatory Note. Current law provides as follows:

42 C.F.R. § 493.1291(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.