American
Clinical Laboratory
Association

March 12, 2018

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3326–NC
P.O. Box 8016
Baltimore, MD 21244–8016

DELIVERED ELECTRONICALLY

Re: Request for Information -- Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (CMS-3326–NC)

Dear Sir or Madam:

The American Clinical Laboratory Association (ACLA) is pleased to submit these comments in response to the Centers for Medicare & Medicaid Services' (CMS's or the Agency's) request for information entitled, *Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)* (CMS-3326-NC) (the RFI).[1] ACLA is a trade association representing the nation's leading providers of clinical laboratory services, including regional and national laboratories. Its diverse membership includes a broad array of clinical laboratories: large national independent labs, reference labs, esoteric labs, hospital labs, and nursing home labs.

ACLA appreciates CMS issuing the RFI, which seeks public comment (including information such as evidence, research, and trends) regarding several items related to CLIA personnel and histocompatibility requirements. With limited exception, such CLIA requirements have rarely undergone revision since 1992.[2] Additionally, CMS has requested "general feedback from stakeholders on what other areas of CLIA they would potentially have recommendations for changing."[3] Given the various advancements and changes in science, technology, tools, laboratory services, and workflow over the last 25 years, ACLA commends CMS in recognizing it should "update the existing CLIA regulations through future rulemaking."[4]

In our comments below, ACLA directly addresses the questions posed in the RFI and provides additional feedback on other CLIA areas for the Agency's consideration. These additional areas include, among other things: (1) potential reforms to accommodate remote digital pathology and data interpretation by board-certified pathologists and laboratory professionals, and (2) expanding the list of

[1] 83 Fed. Reg. 1004 (Jan. 9, 2018).
[2] *Id*.
[3] *Id*. at 1009.
[4] *Id*. at 1004.

"authorized persons" to whom laboratories can provide test results to include "covered entities" and "business associates" as defined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. As noted below, ACLA has previously provided comments to CMS on these two important issues. ACLA is also providing comments on proposed revisions to the regulations at § 493.1274 (Standard: Cytology) and § 493.1291 (Standard: Test report), as well as a proposed revision relating to health information technology (as concerning CLIA).

I. Clarification of Degree(s)

Section A. Personnel Requirements: 1. Nursing Degrees

We are seeking public comment related to whether a bachelor's degree in nursing should be considered equivalent to a bachelor's degree in biological science or should be considered a qualifying degree to meet the CLIA requirements for moderate and high complexity testing personnel as well as for technical consultants.

ACLA recommends that a bachelor's degree in nursing, in addition to experience and training, be considered a qualifying degree to meet the CLIA requirements for moderate complexity testing personnel only.

Section A. Personnel Requirements: 2. Physical Science Degrees

We are seeking public comment on what is considered a physical science degree and if physical science degrees have the educational backgrounds such that all or some should to be considered a qualifying degree to meet the intent of the CLIA requirements at §§ 493.1405, 493.1411, 493.1423, 493.1443, 493.1449, 493.1461, and 493.1489.

ACLA considers clinical laboratory testing to be the use of physical science to understand biological science. We recommend that certain physical science degrees should be considered as qualifying degrees to meet the intent of the CLIA requirements specified above. As such, CMS should provide a narrow definition for "physical science degree" at 42 CFR § 493.2 that includes those natural science disciplines that primarily concern non-living systems but still include: (1) clinical laboratory testing principles, and (2) an element of the study of human biology. For example, Physics is a likely example of an applicable physical science degree that should meet the requirements. However, degrees such as Geology, Meteorology, and Astronomy would not meet this standard.

Section A. Personnel Requirements: 5. Non-Traditional Degrees

We are seeking public comment related to non-traditional degrees (for example, Regents Bachelor of Arts); specifically whether any of these types of degrees should be considered to meet the requirements for a chemical, physical, biological or clinical laboratory science, and/or medical laboratory technology degrees.

ACLA recommends that a non-traditional degree should be considered to meet the requirements for a chemical, physical, biological or clinical laboratory science, and/or medical laboratory technology degree, only if certain academic conditions and experience and training requirements are met. We would encourage CMS to set clear minimum standards for academic credits within the CLIA regulations, such as requiring that the non-traditional degree be based on similar requirements as outlined at 42 CFR § 493.1489(b)(2)(ii)(A), in addition to laboratory training.

II. Other Requirements for CLIA Personnel Categories

Section A. Personnel Requirements: 3. Personnel Competencies

We are seeking public comment regarding whether general supervisors should be allowed to perform competency assessment for testing personnel performing moderate complexity testing in laboratories that perform both moderate and high complexity testing.

ACLA recommends that general supervisors should be allowed to perform competency assessment for testing personnel performing moderate complexity testing in laboratories that perform both moderate and high complexity testing. The current inability of general supervisors to perform competency assessment for testing personnel performing moderate complexity testing appears to be a regulatory oversight without a sound rationale. An individual may qualify as a General Supervisor with an associate's degree in a laboratory science, or medical laboratory technology from an accredited institution and have at least 2 years of laboratory training or experience, or both, in high complexity testing. An individual so qualified with training or experience in moderate complexity testing should also be able to fulfill the responsibility of performing competency assessment for moderate complexity testing personnel.

Section A. Personnel Requirements: 4. Personnel Experience, Training and Skills

We are seeking public comment on what is appropriate laboratory training, experience and skills when qualifying all personnel to meet CLIA requirements, and what comprises appropriate documentation to verify the training, experience and skills for all personnel positions in part 493, subpart M.

Laboratories should maintain documentation for personnel concerning training, experience, and proficiency skills. ACLA recommends that this documentation may include a "certificate of completion" of such training. Appropriate documentation should reflect training in all type(s) (specialties and subspecialties) and complexity of testing for which the employee is responsible. Laboratories should keep documentation for each employee in individual files, which should be available upon request during an inspection.

III. Proficiency Testing Referral

Section B. Proficiency Testing Referral: 1. Discretion for Category 1 PT Referral

We are seeking public comment related to applying discretion in situations where we determine that a laboratory has referred its proficiency testing samples to another laboratory and has reported those results from another laboratory as their own, and under what circumstances should that discretion be applied.

As a general matter for Category 1 proficiency testing referrals, ACLA recommends that CMS should always use discretion in determining appropriate sanctions for a laboratory by looking at all relevant facts and circumstances. In particular, CMS should assess whether the facts and circumstances support a finding of subjective intent to circumvent the PT requirements, or whether the facts and circumstances are more supportive of a finding of an inadvertent failure resulting from inadequate internal controls and procedures.

The following circumstances may indicate that discretion should be applied to the laboratory sanctions for a Proficiency Testing Referral Category 1 violation:

- The referral was limited to reflex, distributive, or confirmatory testing in conformance with the standard operating procedure for patient testing;
- The laboratory has made progress toward improvement following a reasonable opportunity to correct a previous deficiency; or
- The laboratory's overall compliance history.

Section B. Proficiency Testing Referral: 2. Alternative Sanctions for PT Referral by Certificate of Waiver (CoW) Laboratories

We are seeking public comment regarding the feasibility of applying alternative sanctions in cases of PT referral that involve waived testing.

ACLA does not believe there is any reason to apply alternative sanctions in cases of proficiency testing referral that involve waived testing under a Certificate of Waiver (CoW).

IV. Histocompatibility

Section C. Histocompatibility 1. Crossmatching

We are seeking public comment on the acceptability and application of virtual crossmatching in lieu of physical crossmatching for transplantation. We are seeking public comment on appropriate criteria and decision algorithms under which virtual

crossmatching would be an appropriate substitute for physical crossmatching. We are also seeking public comment on the existence of commonly accepted current guidelines for virtual crossmatching in histocompatibility.

ACLA recommends that CMS should accept and apply virtual crossmatching in lieu of physical crossmatching for transplantation. The American Society for Histocompatibility and Immunogenetics (ASHI) has already accepted and applied this approach. A conforming change to the CLIA regulations is long overdue.

ACLA suggests that CMS should consult ASHI for appropriate criteria, decision algorithms, and guidelines in this area.

Section C. Histocompatibility 2. Updating the Histocompatibility Requirements

We are seeking public comment on histocompatibility regulations that are no longer necessary because they are obsolete or redundant with requirements found in other sections of the CLIA regulations. We are also seeking public comment on any histocompatibility regulations that should be modified to reflect current practices.

ACLA recommends that CMS review all histocompatibility regulations in a holistic fashion for possible revision, rather than focusing solely on particular provisions that may be obsolete, redundant, or in need of modification. ACLA would be glad to assist the Agency in consideration of a more holistic revision of the histocompatibility regulations.

V. CLIA Fees

Section D. CLIA Fees: 1. Fees for Revised Certificate

We are seeking public comments (including information such as evidence, research, and trends) on an alternate method to calculate the average hourly rate for each entity as outlined in § 493.649(b). We are also seeking comment on whether the method should be standardized and updated annually or as needed.

ACLA does not have any recommendations specific to this methodology. We note, however, that CMS is potentially requesting increases in CLIA fees at the same time the Agency is implementing sweeping reductions (approximately 30% over the 2018-2020 period) in Medicare reimbursement for clinical laboratory services under the Protecting Access to Medicare Act of 2014 (PAMA). At a minimum, CMS should provide a full accounting of all receipts and expenditures related to the CLIA program before proposing any new or increased fees. Further, any new or increased CLIA fees should be offset by corresponding increases in Medicare reimbursement for clinical laboratory services.

We are seeking public comment on a methodology that would set a fair and reasonable fee for revised certificate requests. We also seek comment as to

whether fees should be nominal and, if nominal, whether such fee would cover the costs associated with the task.

Subject to the comments in the immediately preceding paragraph, ACLA's view is that a fee for revised certificate requests should not exceed $5.00 based on the minimal effort associated with processing such requests, and that CMS should automate the process to make it even more efficient and more self-service oriented (including printing from a secured website). Fees associated with a revised certificate should be nominal and be based on the costs associated with the activities to complete the revision, including staff time to verify and make the edits in the data system, the contractor's time to print the revised certificate (if necessary), and the supplies required to print the revised certificate (again, if necessary).

Section D. CLIA Fees: 2. Compliance Determination, Additional Fees, and Methodology for Determining Fee Amounts

We are seeking public comment to update the fees for determination of program compliance as well as additional fees to accredited laboratories as outlined in §§ 493.643(b) and 493.645(b) respectively. We are also seeking comment on whether fees collected should be subject to the same ten schedules at § 493.643(c), and whether they should change based on any updates to the methodology for determining the average hourly rate.

ACLA does not have any recommendations specific to this methodology. We note, however, that CMS is potentially requesting increases in CLIA fees at the same time the Agency is implementing sweeping reductions (approximately 30% over the 2018-2020 period) in Medicare reimbursement for clinical laboratory services under PAMA. At a minimum, CMS should provide a full accounting of all receipts and expenditures related to the CLIA program before proposing any new or increased fees. Further, any new or increased CLIA fees should be offset by corresponding increases in Medicare reimbursement for clinical laboratory services.

We are seeking public comment on exploring an appropriate methodology for assessing a fair fee for other compliance determination activities to include performing follow-up visits, complaint investigations, and activities associated with imposition of sanctions.

ACLA believes that a "fair fee" for such activities must first consider that CMS is reducing Medicare reimbursement for clinical laboratory services by 30% over the next three years. A fee for complaint investigations should only be considered if the complaint is substantiated. Further, if any new activity-based CLIA fees are imposed and are not offset by corresponding increases in Medicare reimbursement for clinical laboratory services, such fees should be offset by corresponding decreases in volume-based CLIA fees.

VI. Additional Areas

The RFI states that CMS is also soliciting general feedback from stakeholders on what other areas of CLIA they would potentially have recommendations for changing. Accordingly, ACLA provides additional feedback concerning: (1) potential reforms to accommodate remote digital pathology and data interpretation by board-certified pathologists and laboratory professionals, and (2) expanding the list of "authorized persons" to whom laboratories can provide test results to include "covered entities" and "business associates" as defined in the HIPAA Privacy Rule.[5] ACLA has previously provided comments to CMS on these two important issues. ACLA is also providing comments on proposed revisions to the regulations at § 493.1274 (Standard: Cytology), and § 493.1291 (Standard: Test report), as well as a proposed revision relating to health information technology (as concerning CLIA).

Remote Digital Pathology

CLIA's purpose is to establish quality standards for laboratory tests performed on human specimens for diagnosis, prevention, or treatment of disease or for assessment of health.[6] ACLA recognizes that it is essential that the same standards are adhered to whether an activity occurs in a CLIA-certified laboratory facility or in a remote location associated with a CLIA-certified laboratory.

In some respects, however, the CLIA regulations have not kept pace with the tools that are widely available to pathologists and other laboratory professionals, nor with changes in their workflow, which enable performance at a remote location. When Congress enacted CLIA in 1988, the Internet did not exist as we know it today and secured personal computers in homes were rare. In 2003, when CLIA regulations most recently underwent major reform and reorganization, "digital pathology" was just in its infancy.[7] Neither the members of Congress who drafted and passed CLIA nor the regulators responsible for implementing the law could have anticipated the many changes in technology and workplaces that make remote digital pathology possible today.

As such, ACLA believes the CLIA regulations should be amended so that pathologists and laboratory professionals[8] are permitted to read digital slides and images and interpret data in locations other than the CLIA-certified laboratory,

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[5] On April 25, 2017, ACLA provided the Center for Clinical Standards and Quality (CCSQ) at CMS a letter concerning remote digital pathology. We subsequently met with CCSQ personnel to discuss this particular issue. Secondly, on September 21, 2006 and again on February 10, 2010, ACLA presented statements to the Clinical Laboratory Improvement Advisory Committee (CLIAC), including representatives of CMS, concerning the "authorized persons" concern.

[6] 42 U.S.C. § 263a(a).

[7] For a discussion of "remote digital pathology," "remote digital imaging," and additional digital pathology functions, please see pages 2-3 of our April 25, 2017 letter to CCSQ.

[8] We use the term "laboratory professional" to mean a board-certified Ph.D. in chemical, physical, biological, molecular genetics, or clinical laboratory science.

without the need for a separate CLIA certificate for each location where the reading and interpretation are performed. The review activities at the remote location should be covered under the certificate of the designated primary CLIA-certified laboratory.

By way of background, a laboratory is considered out of compliance with CLIA regulations unless it has a current CLIA certificate or is CLIA-exempt.[9] In general, a laboratory must file a separate CLIA application for each laboratory location (the term "laboratory location" is not defined). Currently, there are three exceptions to this rule in the regulations: mobile labs, non-profit or government laboratories performing limited public health testing, and hospital labs in contiguous buildings.[10] These entities may be covered under the certificate of the "designated primary site." In interpretive guidance, CCSQ has described "temporary testing sites" as those not used to permanently house instruments, equipment, personnel, and records.[11] In the preamble to the rule that finalized these exceptions, CMS seems to indicate that it allows for these exceptions because of the cost and burden on certain types of facilities of requiring separate CLIA certificates for each site.[12]

In the recent past, CMS has been open to the idea of exceptions and has acknowledged the cost and burden of obtaining separate CLIA certificates for each site. The Agency has at times allowed for multiple sites under the CLIA certificate of the designated primary CLIA-certified laboratory. The Agency also has allowed some portions of a laboratory service being performed in a location other than the licensed location, testing that is moderate- and/or high-complexity performed away from the licensed location, and central recordkeeping at the licensed location. ACLA finds several commonalities between the existing exceptions to the "laboratory location" rule and a location where a pathologist or a laboratory professional works. These remote locations would not permanently house instruments, equipment, personnel, or records. Digital pathology, digital imaging, and data interpretation do not require the use of instruments and equipment (other than a monitor and a computer with access to an LIS), and records are maintained on the main laboratory's server or other remote storage means. Like mobile labs, limited public health testing labs, and nearby hospital labs, the burden of obtaining a separate CLIA certificate for each and every remote pathology location would be prohibitive and unnecessary.

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[9] 42 CFR § 493.3.
[10] *Id*. §§ 493.35(b)(1)-(3); 493.43(b)(1)-(3); 493.55(b)(1)-(3).
[11] *See* State Operations Manual, Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services at 61 (Feb. 3, 2017), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_c_lab.pdf. *See also* Memo to State Survey Agency Directors from CCSQ (Dec. 2, 2011) ("Records, files, etc. for temporary testing sites are kept at the primary site or home base. The personnel, equipment, supplies, and reagents, etc. are not at the testing site permanently"), *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter12_09.pdf.
[12] 57 Fed. Reg. 7002, 7024 (Feb. 28, 1992).

Therefore, ACLA strongly recommends that CMS reform current CLIA regulations to accommodate digital services performed by pathologists and laboratory professionals when performed at remote locations, away from the primary laboratory site, without the need for a separate CLIA certificate for each remote location.

"Authorized Persons" and Provision of Test Results

CLIA regulations, in conjunction with applicable State law, govern the parties to whom a laboratory may transmit test results. CLIA regulations provide that in the absence of specific direction from the individual tested, 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."[13] "Authorized person" means an "individual authorized under State law to order tests or receive test results, or both."[14]

Most States either define "authorized person" narrowly (often including only the ordering provider) or fail to define authorized recipients of laboratory test results. Under this latter case, laboratories typically default to the CLIA provision referencing "the individual responsible for using the test results," which most interpret to mean the ordering provider or the individual tested.
Many parties other than the ordering provider and the individual tested need laboratory result data for legitimate purposes. These parties request such data directly from the laboratory rather than from the provider who ordered the test or from the individual tested. Assuming the HIPAA Privacy Rule would otherwise permit disclosure without patient authorization, most laboratories interpret CLIA and applicable State law to permit the lab to transmit test results to a non-ordering third party if either the recipient is defined as an "authorized person" under State law or the ordering provider authorizes the disclosure.

The rationale for this interpretation is that it would be unreasonable to interpret CLIA and State law to prohibit the laboratory from making a disclosure if authorized by the ordering provider, where the ordering provider could make the same disclosure to the same third party himself. While obtaining ordering provider authorization may not be difficult with respect to a single test result, it is far more difficult in the context of making millions of historical test results available for health information networks (e.g., for treatment purposes) or for peer-to-peer transmissions to entities who need large quantities of laboratory data for secondary uses (e.g., health plans who need lab data for quality improvement, disease or case management, patient safety, or value-based reimbursement initiatives). Similarly, obtaining authorization from individuals is often problematic for laboratories, which often have no direct contact with patients. Laboratories have attempted to address the issue of documenting ordering provider or individual authorization through

[13] (emphasis added). 42 CFR § 493.1291(f).
[14] *Id*. at § 493.2.

contractual representations and warranties from data recipients, but this "workaround" is extremely inefficient and is not always effective.

With regard to the CLIA regulations, ACLA proposes expanding the list of "authorized persons" to whom laboratories can send test results to include "covered entities" and "business associates" as defined in the HIPAA Privacy Rule (Proposed language attached as **Appendix 1**). This proposal operates as a targeted pre-emption of State "authorized person" laws. States would continue to be permitted to define "authorized person," so long as they do not exclude covered entities and business associates. ACLA believes such a change should not be construed to permit disclosure of any type of test result when disclosure of that type of test is otherwise prohibited (e.g., HIV). The intent here is only to expand the list of permissible recipients of test results in a responsible manner, not to expand the purposes for which test results may be used or disclosed, which are already governed by HIPAA. Uses and disclosures prohibited by HIPAA without patient authorization should still require such authorization.

Standard: Cytology

ACLA recommends that CMS change the word "examined" in 42 CFR § 493.1274 (Standard: Cytology) to "screened", as highlighted below.

§ 493.1274 (Standard: Cytology)

Current: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition…

Proposed: (d)(2) The maximum number of slides screened by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target.

Standard: Test Report

Over the past two decades, the federal government has pursued multiple initiatives and investments to encourage the electronic storage and transmission of patient-specific health information through secure and efficient methods. Including electronic health records (EHRs) and other health data, these initiatives have spanned multiple agencies and required several new laws, most recently the *21st Century Cures Act*. Part of the intent of the Health information technology provisions of the *21st Century Cures Act*, is to ease the regulatory and administrative burden associated with utilizing EHR, interoperability, and other health information technologies (HIT). ACLA, therefore, recommends that CMS move to harmonize electronic system

regulations under CLIA with those of other agencies, such as the Office of the National Coordinator for Health Information Technology (ONC), including amending 42 CFR § 493.1291(a) (Standard: Test Report) to allow laboratory compliance via use of EHR systems confirmed as certified by an ONC Authorized Certification Body (ONC-ACB). ONC-ACB certifications are a recognized standard to comply with Medicare meaningful use requirements associated with EHR use. ACLA recommends that § 493.1291(a) be amended to read:

> *"§ 493.1291 Standard: Test Report.*
> *(a) "The laboratory must have a means to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaces or entered manually) to final report destination, in a timely manner. A laboratory may comply with this requirement by confirming that the final report destination is an EHR system is certified by an Office of the National Coordinator for Health Information Technology Authorized Certification Body. This includes the following:".*

Additionally, ACLA believes that the CLIA regulation to include specimen source on the Test Report "when appropriate", is a very subjective directive (§ 493.1291(c)(5)). Guidance for this requirement would be better provided with the inclusion of the general information provided in the current Interpretive Guidelines. We recommend the follow revision:

§ 493.1291(c)(5) (Standard: Test report)

Current: Specimen source, when appropriate.

Proposed: Specimen source, when required for performance of the assay or reference range determination.

Finally, ACLA also suggests the following change to the Interpretive Guidelines for § 493.1291(c)(3):

Current: The date of the test report is the date results were generated as a final report and must not change on copies generated at a later date.

Proposed: The test report date is the date of the final laboratory report. This date must be represented on any of the copies of the laboratory report generated at a later date.

Update of the Survey and Certification Memorandum, S&C-10-12-CLIA (March 3, 2010)

In March, 2001 CMS issued CLIA updates to facilitate the electronic exchange of laboratory information. The ONC also issued a statement, reporting the Agency's achievements:

- "2010-03-01 Center for Medicaid and State Operations/Survey and Certification Group issued a memorandum. Subject: Clinical Laboratory Improvement Amendments of 1988 (CLIA) – Issuance of Revised Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services in Appendix C of the State Operations Manual to Facilitate the Electronic Exchange of Laboratory Information."

- "2010-03-03 - ONC blog post: Electronic Health Records (EHRs)s Now Permitted By CLIA.[15] This blog post reported that CMS, in collaboration with ONC, released guidance clarifying that the Clinical Laboratory Improvement Amendments (CLIA) permit labs to electronically exchange lab data and addressing some confusion regarding laboratory data and health IT."

This 2010 CLIA guidance referenced HL7 V2.5.1 and LOINC for laboratory results and "encouraged" laboratories to use these standards:

> "Many laboratories are interested in ascertaining which transmission and vocabulary standards will work best for their electronic transmission of laboratory data. Health Level Seven 2.5.1 and LOINC are two standards recognized by the Department as transmission and vocabulary standards for the electronic exchange of laboratory data. These standards support the Department's Initial Set of Standards, Implementation Specifications and proposed certification criteria for electronic health record technology, and *therefore CMS encourages laboratories to use these standards*."[16]

Beginning in 2011, ONC sponsored several projects through the ONC Standards & Interoperability Framework Lab US Realm initiatives[17] to define a suite of new Implementation Guides to further constrain the HL7 V2.5.1 standard, specifically for the implementation of interfaces supporting the electronic exchange of messages designed to support the laboratory/provider work flow; these include electronic exchange laboratory results, laboratory orders, and the laboratory's test compendium, or electronic directory of service (eDOS).

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[15] *See* Dr. David Blumenthal, "Electronic Health Records (EHR)s Now Permitted By CLIA" *HealthITBuzz* (Mar. 3, 2017), *available at* https://www.healthit.gov/buzz-blog/tag/clia/.
[16](*emphasis added).* FAQ Page 15. Available at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter10-12.pdf.
[17] *See* https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/Lab+US+Realm.

The level of specificity defined in these V2.5.1 Implementation Guides removes the ambiguity inherent in the V2.5.1 standard[18], enables the National Institute of Standards and Technology (NIST) developed testing tools[19] to certify an EHR's ability to correctly construct laboratory result electronic messages for Meaningful Use EHR certification, and addresses how the laboratory result implementation guide supports CLIA § 493.1291 (Standard: Test report) requirements.

The V2.5.1 implementation guide for lab results[20] was formally cited as a certification requirement in 2012. However, due to "loophole" language in the final rule, some vendors certified they supported the interface, but never implemented. One reason cited was the hesitation to disrupt existing CLIA certified interfaces to install a new interface that would have to be CLIA certified again. The opportunity to realize reduced interface costs, through implementation of a national standard, was lost.

Therefore, ACLA requests that CMS consider issuing an amendment to the Survey and Certification memorandum issued March 3, 2010 to state that ONC Certified interfaces supporting the V2.5.1 laboratory result interface (LRI) implementation guide[21] are considered to meet the CLIA regulations for an adequate electronic system for sending laboratory test results to the final report destination as specified in 42 CFR §493.1291.

We believe there is precedent for this action in the November 8, 2013 Survey and Certification letter, which named the Direct standard (secure email exchange of laboratory results) as meeting CLIA regulations.

- 2013-11-08 Center for Medicaid and State Operations/Survey and Certification Group issued a memorandum. Subject: Use of Direct for the Secure Transmission of Laboratory Test Results provides the following CLIA guidance: The Centers for Medicare & Medicaid Services (CMS) considers that laboratories utilizing the Direct transport protocols and fully supporting the Direct Implementation Guide for Delivery Notification requirements would *meet the CLIA regulations for an adequate electronic system for sending laboratory test results to the final report destination as specified in 42 CFR §493.1291(a).* (Ref: S&C: 14-05-CLIA)

[18] Re: levels of specificity, a standard is like going to the grocery store to get ingredients to make a cake; the cake produced could be slightly (or radically) different for each baker. An implementation guide is like following a recipe with exact ingredients and baking time; the cakes produced from the same recipe should all be comparable.
[19] https://hl7v2-lab-testing.nist.gov/mu-lab/.
[20] 2012-09-04 Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology Final Rule, HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface (LRI).
[21] *See* Health Level Seven International, "HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1- US Realm," *available at* http://www.hl7.org/implement/standards/product_brief.cfm?product_id=279.

This action is anticipated to have the following impacts:

- Remove barriers to LRI adoption by eliminating ”additional” CLIA certification requirement.
- Lower interface costs by encouraging implementation of a national standard meeting CLIA requirements “out of the box”.
- Reduce burdens relating to the use of electronic health records (21st Century Cures).

This could include elimination of CLIA’s “periodically verified” requirement unless the software is upgraded to a later release.

Conclusion

Thank you for the opportunity to submit these comments concerning the RFI. We look forward to working with CMS and other stakeholders on issues concerning the CLIA regulations. If you have any questions, please do not hesitate to contact me.

Thank you for your consideration of ACLA’s comments.

Sincerely,

Paul Sheives
Vice President, Reimbursement & Regulatory Policy
American Clinical Laboratory Association

Appendix 1

Proposed Regulatory Amendments Related to "Authorized Persons"

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

Except as provided in § 493.1291(l), 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 known by the laboratory as having been designated to receive the test results by the authorized person who ordered the test;

(b) For purposes of 42 CFR § 493.1291(f) only, a "covered entity", as defined in 45 C.F.R. § 160.103; and

(c) For purposes of 42 CFR § 493.1291(f) only, 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 known by the laboratory as having been designated to receive the test results by the authorized person who ordered the test;

(b) For purposes of 42 CFR § 493.1291(f) only, a "covered entity", as defined in 45 C.F.R. § 160.103; and

(c) For purposes of 42 CFR § 493.1291(f) only, 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.

Explanatory Note. Current law provides as follows:

42 C.F.R. § 493.1291(f): Except as provided in § 493.1291(l), test results must be released only to authorized persons and, if applicable, the persons responsible for using the test results and the laboratory that initially requested the test.

42 C.F.R. § 493.1291(l): Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process,

can be identified as belonging to that patient.

45 CFR 164.524(c)(3)(ii): If an individual's request for access directs the covered entity to transmit the copy of protected health information directly to another person designated by the individual, the covered entity must provide the copy to the person designated by the individual. The individual's request must be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of protected health information.

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