



January 28, 2019

Dr. Donald Rucker
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

DELIVERED ELECTRONICALLY

RE: Request for Public Comments: *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*

Dear Dr. Rucker:

I am submitting the attached comments on behalf of the American Clinical Laboratory Association (ACLA) in response to the *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*.

ACLA is a non-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, end-stage renal disease, hospital, and nursing home laboratories. The clinical laboratory industry employs nearly 277,000 people directly and generates over 115,000 additional jobs in supplier industries. Clinical laboratories are at the forefront of personalized medicine, driving diagnostic innovation and contributing more than \$100 billion annually to the nation's economy.

ACLA applauds your leadership in releasing the Draft in order to further advance health information technology (HIT) interoperability, a critical and vital goal for improving the quality of care for patients. ACLA member laboratories appreciate the opportunity to comment on the Advisory as a living document and hope these comments serve to continue to move interoperability forward.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Thomas B. Sparkman', is written over a light blue horizontal line.

Thomas B. Sparkman, RPh, MPP, JD
Vice President, Government Relations

ATTACHMENT

Agency: Department of Health and Human Services (DHHS); Office of National Coordinator (ONC)

Title: Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs

ACLA Comments:

General Comment:

For final publication, please add navigation panel/bookmarks to the .pdf.

Page #12-13

Text:

The section identifies several areas where EHR and health care IT products can be improved to reduce burden experienced by clinicians using these products, including: alignment of health care IT (e.g., EHR) with the clinical workflow; improvements to the graphical user interface (GUI); increasing standardization around presentation of clinical content within the EHR, such as medication ordering and laboratory result displays; and improved processes around the configuration and implementation of EHRs, which proactively engage the end user.

Comment:

We strongly suggest that the laboratory community be consulted for input on the display of laboratory results, for example, through the American Clinical Laboratory Association. Without proper coordination with the laboratory industry, new initiatives could conflict with existing requirements under other existing regulations. For example, CLIA regulations exist which may impact design decisions, which should be coordinated with CMS:

The CLIA Regulations at [42 CFR 493.1291 - Test Report](#) define the items that must appear on a clinical laboratory report. Note that the value(s) of some items that are supplied on the order and flow through to the Test Report are defined in [42 CFR 493.1241 - Test Request](#), [42 CFR 493.1273 – Histopathology](#), [42 CFR 493.1274 – Cytology](#), [42 CFR 493.1276 – Clinical Cytogenetics](#), and [42 CFR 493.1278 - Histocompatibility](#).

“Access to health information should not be prohibited by boundaries such as location, organization or technical platforms. The goal of interoperability for electronic data exchange is to allow health information to follow a patient where and when it is needed. Collaboration and shared laboratory information across all settings allows providers, patients and laboratories to engage more fully with each other and do so in a timely, efficient and accurate manner. Through the use of data standards and shared vocabularies, all entities can interact in a seamless way in order to unlock laboratory data, not only for the benefit of patient care, but to also significantly impact the ability to correlate and mine data received from multiple sources.” Source: <https://www.acla.com/issues/value-of-health-it-data-standards/>

Page #13

Text:

EHR Reporting

This section looks at the EHR-related burden associated with federal programs that require health care providers to report performance data using health IT, particularly the Promoting Interoperability Programs, formerly known as the Medicare and Medicaid EHR Incentive Programs, and MIPS.

The current design and administration of these programs may impose burden on clinicians in a variety of ways. For instance, regulatory requirements and timelines are often misaligned across programs and subject to frequent updates, which require significant investments from clinicians to ensure annual compliance. Government requirements are often also poorly aligned with the reporting requirements across many of the federal payer programs in which clinicians may participate, thus, requiring additional work on the part of the health care provider.

Comment:

To minimize provider burden, we strongly support federal agency efforts to harmonize/align federal program reporting requirements across agencies. Confusion and duplicative regulation, requirements or guidance can often result if multiple government agencies are concurrently governing Health IT and EHR realms. Ultimately, such confusion or duplication could hamper proper coordination for patient care and impede progress for both interoperability and better utilization of EHRs. To the extent possible, Health IT and EHR realms should be governed through a single, coordinated government process or body.

Page #31

Text:

EHRs and Cognitive Support for Clinical Workflow

EHRs have evolved into more than just serving as an electronic patient chart; they have become an important tool that can facilitate a myriad of clinical and administrative tasks. In addition to maintaining copies of a patient's clinical documentation, EHRs also serve as an interface to laboratory, imaging, and other diagnostic study results, a correspondence medium serving as a dedicated clinical e-mail system, and, importantly, a powerful tool for initiating clinician orders. As EHRs continue to evolve, it is imperative that they support the workflows that have been established in clinical practice so as not to add to clinician burden. While EHRs have improved some aspects of the clinical workflow—for example, a patient's medical history is now available at a glance and electronic prescribing is widely regarded as a success story—areas for improvement still remain.

Comment:

In the US, laboratory interfaces are required to meet CLIA regulations. In keeping with the goal to decrease provider burden, we strongly recommend that federal agencies collaborate to eliminate duplicative requirements. We suggest that EHR systems certified **and implementing** the “**HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI)**” (originally developed through ONC’s Standards & Interoperability Framework) should not be required to additionally secure CLIA accreditation.

In keeping with 21st Century Cures Actⁱ principles to reduce regulatory or administrative burdens relating to the use of electronic health records,ⁱⁱ and to promote Interoperabilityⁱⁱⁱ we request that CMS consider issuing an amendment to the Survey and Certification memorandum issued March 3, 2010. (Ref: [S&C-10-12-CLIA](#)). The justification for this suggestion is explained below.

In March, 2001 CMS issued CLIA updates to facilitate the electronic exchange of laboratory information. The Office of National Coordinator (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) Now Permitted By CLIA^{iv}. 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.

The level of specificity defined in these V2.5.1 Implementation Guides removes the ambiguity inherent in the V2.5.1 standard^v, enables the National Institute of Standards and Technology (NIST) developed testing tools^{vi} 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^{vii} 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, we request 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^{viii} 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^{ix}.

We believe there is precedence 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](#))

This action is anticipated to have the following impacts:

Remove barriers to LRI adoption by eliminating ‘additional’ CLIA certification requirement.

Text:

Clinical documentation tasks in EHRs present another major challenge to clinician workflow.^{x47} EHRs are the primary vehicles for clinicians to document what has happened during the course of care. Clinical documentation has traditionally taken the form of a written narrative that includes history, findings, assessment, and a plan of care. EHRs have added features to aid clinician documentation: document templates; “smart” features, such as click buttons that help dynamically generate text; and the incorporation of medications, laboratory results, vital signs, and other clinical information found elsewhere in EHRs. Unfortunately, these features can create documents that read more like completed check lists than comprehensive histories, making it difficult for health care providers to locate the information they need. Similarly, use of copy-and-paste functionality as part of the documentation process can make it easy for physicians to fail to update or correct copied information and continue to propagate outdated or false information.^{xi48}

Comment:

We agree with concerns regarding copy-and-paste functionality and would like to incorporate additional references to partial and/or incomplete information propagated across different platforms for the same patient encounters.

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Text:

Standardized Order Entry and Results Display

EHRs can also create burden for clinicians when they enter orders for medication, treatment, and diagnostics. Clinical end users who place medical orders are routinely confronted with lengthy drop-down menus that are not standardized and may be difficult to navigate. This is particularly evident when ordering medications.⁵⁶ In addition to the frustration inherent in trying to find the correct medication from an extensive drop-down list, medication selection also presents patient safety issues as the names of medications may be similar and only differ by a few letters.⁵⁷ Compounding this issue, medications in the United States are typically referred to by both their brand and generic names. The formulation, dosage, and schedule information can also appear differently depending on the EHR system. Each of these issues adds an additional layer of cognitive load on the end user, increasing burden.

Treatment, laboratory test, and diagnostic imaging orders present similar issues. Frequently, ordering clinicians are presented with long lists of possible choices with display values that are very similar and only differ by a few characters.⁵⁸ Moreover, the information presented in these lists does not always appropriately align with the medical product or service requested.⁵⁹ This may result in order mistakes, with either the wrong test being carried out or extra communication required between the ordering clinician and laboratory or radiology staff to determine which test was initially intended. Similarly, the display of laboratory test results can also cause confusion.⁶⁰ Laboratory results for a patient are typically displayed in a tabular fashion similar to a spreadsheet, with test names displayed as rows and result dates displayed as columns. The actual result value is found in the appropriate cell of the table. Different EHRs, however, lay out the laboratory results table in different configurations, most notably with regards to chronology. Some systems display the oldest results to the left, others display the newest results to the left, and still other systems allow the end user to configure this as an option. Results screens that a user is not familiar with can increase the likelihood of error.⁶¹

There are design features that could reduce burden, increase safety, and help clinicians find the appropriate option more quickly. Features such as screen emphasis, typography, and color choices can make it substantially easier for a user to locate the correct medication or diagnostic order.⁶² For example, by writing part of a drug’s name in upper case letters to help distinguish look-alike drugs from one another (“tall man lettering”),⁶³ end users would be able to more quickly identify the appropriate medication, thus reducing health care provider burden. There is currently no certification requirement that health IT designers use a standardized design format.

Comment:

We strongly suggest that the laboratory community be consulted for input on the display of laboratory results, for example, through the American Clinical Laboratory Association. Without proper coordination with the laboratory industry, new initiatives could conflict with existing requirements under other existing regulations. For example, CLIA regulations exist which may impact design decisions, which should be coordinated with CMS:

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Text:**Inconsistent Public Health and Grant Funding Requirements across Federal Agencies**

Currently, public health reporting and reporting related to population health data under federal grant programs require clinicians to create and support numerous interfaces to public health entities, each of which may require custom changes to reports and/or duplicative entry into unique forms. Moreover, while many implementation guides advise health care providers to submit syndromic surveillance feeds to state health departments every 24 hours, certification cannot enforce this reporting timeline and some jurisdictions require differing timelines. This burden of creating numerous interfaces also exists within programs and for entities receiving funding from multiple federal agencies. For example, CDC, SAMHSA, HRSA, and the United States Department of Agriculture (USDA) all require the capture and reporting of data elements typically found in EHRs. However, these requirements are not harmonized across state and local public health agencies collecting data from health care providers. This is particularly burdensome for participants—as well as the health IT developers and public health agencies supporting them—in programs that support multi-agency efforts, such as those related to Zika and/or HIV response, which require frequent data reporting in order to remain eligible for continued funding. Moreover, due to lack of resources for interoperable reporting infrastructure on the state, local, territorial, or tribal level, many of these data collection activities still require paper-based reporting or manual data entry into web portals, despite much of the data being available in an electronic format that could facilitate transmission if messaging/data standards were appropriately applied.

Text Con't:

Even with the standardization and electronic reporting of public health data enabled through MIPS and the Promoting Interoperability Programs (formerly known as the EHR Incentive Programs) and the ONC Health IT Certification Program, many burdens remain for health care providers. While implementation guides dictate the submission formats for public health data using health IT, these guides still allow for some variability in order to allow for variation in state, local, territorial, and tribal mandates. Unlike EHRs, receiving systems at the public health agencies are not certified and often have significant variation across jurisdictions. This variation makes it difficult and expensive for vendors as well as large health care provider organizations that reach across jurisdictional boundaries. Variation in the transport of electronic information to public health agencies also creates health care provider burden. Even within one public health jurisdiction, different transport requirements may be required for different public health options. For example, Simple Object Access Protocol (SOAP) web services may be required for immunization reporting while secure File Transfer Protocol (FTP) may be required for syndromic surveillance.

Health care providers regularly report to a wide range of additional public health registries and similar systems. The majority of this reporting is funded by the CDC with reporting occurring to state and local public health agencies. As with the scenarios described above, much of the data already exists electronically within the EHR. Most of these systems are registries that collect information about reportable disease/outbreak investigation (e.g., salmonella) or those that are utilized for chronic disease surveillance (e.g., cancer). Note that a positive laboratory test of a reportable disease may result in additional follow-up to track the treatment of the disease. Many public health registries collect information from health care providers reporting to state systems; in some cases, the states report the information to the CDC. The variation resulting from state differences poses problems as EHR data are used to populate electronic reporting to these state-based systems.

In addition to the numerous public health reporting requirements, CDC, SAMSHA, FDA, HRSA, and USDA also fund state and local public health jurisdictions to collect clinical data from health care providers. Many of these reporting requirements overlap with each other and with requirements from the CDC. Although reporting requirements vary by state, any facility with publicly funded clients are required to report their data to their state health department as part of the Treatment Episode Data Set (TEDS) submission. HRSA provides funding to state and local jurisdictions, as well as directly to health care providers through various aspects of the Ryan White HIV/AIDS Program funding.⁸⁴ Many of the recipients of these funds include community-based primary care facilities, including federally qualified health centers. As part of the conditions of funding, these facilities are required to submit extensive data to their state or local health departments. Although many of the data elements overlap with other public health reporting requirements, the format of these extracts is unique to HRSA reporting.

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Comment:

This section summarizes multiple issues, but does not identify a resolution. ACLA strongly supports developing a unified, federal strategy to migrate to a common reporting format, using a consistent standard, for all agencies to migrate to in future.

Text:

HEALTH IT USABILITY AND THE USER EXPERIENCE

Strategy 2: Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction.

Recommendation 1: Harmonize user actions for basic clinical operations across EHRs.

Clinicians often serve at different clinical locations and often need to become proficient in the use of multiple EHRs. EHRs currently have widely divergent GUIs and workflow steps required to complete clinical tasks. Consistent with antitrust requirements, health IT developers should have the opportunity to discuss and jointly arrive at a shared understanding of common interface and workflow design elements for common clinical tasks, beginning with those workflows that directly impact patient safety.^{xiii}107 Harmonizing these common workflows could significantly reduce the cognitive load on the end user by reducing the need to remember a series of divergent workflows for the same basic task. Examples of functionalities that health IT developers could standardize might include, but are not limited to medication reconciliation; medication, laboratory and imaging ordering; results review; problem list interaction; medical history interaction; and clinical documentation authoring and review. Similarly, harmonizing laboratory test codes could support better mapping across systems, better presentation of laboratory information, and better laboratory order entry as part of the clinical workflow. The Electronic Health Records Association's (EHRA) *Design Patterns for Patient Safety*^{xiii}108 is a good example of this type of developer collaboration. Clinicians and clinical professional societies have the opportunity to collaborate with health IT developers to best inform how to potentially harmonize these across health IT systems.

Comment:

We strongly suggest that the laboratory community be consulted for input on the display of laboratory results, for example, through the American Clinical Laboratory Association. Without proper coordination with the laboratory industry, new initiatives could conflict with existing requirements under other existing regulations. For example, CLIA regulations exist which may impact design decisions, which should be coordinated with CMS:

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Text:

HEALTH IT USABILITY AND THE USER EXPERIENCE

Strategy 3: Promote harmonization surrounding clinical content contained in health IT to reduce burden.

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Recommendation 2: Standardize order entry content within health IT.

Order entry for laboratory orders, imaging orders, and procedure orders can be burdensome for end users due to the number of test options available. Frequently, differences in selectable orders are represented by variances of only several characters.^{xiv}117 EHR developers have the opportunity to collaborate with each other and relevant stakeholders to refine descriptions for unique imaging tests that are clear, concise, and reduce confusion. Similarly, laboratory orders also contain potentially confusing options. Organizations such as the CMS Division of Laboratory Improvement and Quality (which regulates CLIA), the American College of Pathology, the Regenstrief Institute (which administers the Logical Observation Identifiers Names and Codes (LOINC) code set), and commercial laboratory corporations can refine test codes and names that are clear, concise, and reduce burden. To increasing the clarity of test options, developers and their collaborators can further improve this functionality by improving default listings of common tests and “favorites” capabilities so that the end result also shortens the available list to reduce end user cognitive load.^{xv}118 Health care institutions can refer to ONC's *SAFER Guide: Computer Provider Order Entry with Decision Support* to further help optimize systems in this area and reduce clinician burden.

Comment:

We strongly suggest that the laboratory community be consulted for input on the display of laboratory results, for example, through the American Clinical Laboratory Association. Without proper coordination with the laboratory industry, new initiatives could conflict with existing requirements under other existing regulations. For example, CLIA regulations exist which may impact design decisions, which should be coordinated with CMS:

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Text:

HEALTH IT USABILITY AND THE USER EXPERIENCE

Strategy 3: Promote harmonization surrounding clinical content contained in health IT to reduce burden.

Recommendation 3: Standardize results display conventions within health IT.

Currently, there is wide variation within health IT in how clinical results are displayed to the clinician. Clinicians may miss important results due to the design of the results screen.¹¹⁹ EHR developers can collaboratively work to identify a common format for displaying results. For example, optimizing and standardizing the display of laboratory test results would allow critical information to be reported first and reduce the overall number of clicks required by physicians. Developers can arrive at a standard for chronological display (older results on left vs. right), abnormal display (flag symbols vs. different colors), and reference range inclusion. Health care institutions can check to see that they have followed *ONC’s SAFER Guide: Test Results Reporting and Follow up*¹²⁰ to both improve patient safety and reduce clinician burden in this area.

Comment:

We strongly suggest that the laboratory community be consulted for input on the display of laboratory results, for example, through the American Clinical Laboratory Association. Without proper coordination with the laboratory industry, new initiatives could conflict with existing requirements under other existing regulations. For example, CLIA regulations exist which may impact design decisions, which should be coordinated with CMS:

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“Access to health information should not be prohibited by boundaries such as location, organization or technical platforms. The goal of interoperability for electronic data exchange is to allow health information to follow a patient where and when it is needed. Collaboration and shared laboratory information across all settings allows providers, patients and laboratories to engage more fully with each other and do so in a timely, efficient and accurate manner. Through the use of data standards and shared vocabularies, all entities can interact in a seamless way in order to unlock laboratory data, not only for the benefit of patient care, but to also significantly impact the ability to correlate and mine data received from multiple sources.” Source:

<https://www.acla.com/issues/value-of-health-it-data-standards/>

ⁱ <https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf>

ⁱⁱ §4001, §13103, (a) REDUCTION IN BURDENS GOAL, (1)... relating to the use of electronic health records

ⁱⁱⁱ §4003. INTEROPERABILITY

^{iv} <https://www.healthit.gov/buzz-blog/tag/clia/>

^v 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.

^{vi} <http://hl7v2-lab-testing.nist.gov/mu-lab/>

^{vii} 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).

^{viii} http://www.hl7.org/implement/standards/product_brief.cfm?product_id=279

^{ix} http://www.cdc.gov/clia/regs/subpart_k.aspx#493.1291

^x Footnote 47: RAND Corporation. Research Report: Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy. 2013.

^{xi} Footnote 48: ECRI Institute. Partnership for Health IT Patient Safety Health IT Safe Practices: Toolkit for the Safe Use of Copy and Paste. 2016. Available at: https://www.ecri.org/Resources/HIT/CP_Toolkit/Toolkit_CopyPaste_final.pdf

^{xii} Footnote 107: ¹⁰⁷ Middleton B, et al. Enhancing Patient Safety and Quality of Care by Improving the Usability of Electronic Health Record Systems: Recommendations from AMIA. J Am Med Inform Assoc. 2013;20:e2-8.

^{xiii} Footnote 107: ¹⁰⁸ Electronic Health Records Association. Design Patterns for Patient Safety. 2017. Available at: <http://www.himss.org/sites/himssorg/files/ehra-design-patterns-for-safety.pdf>

^{xiv} Footnote 117: ¹¹⁷ Belden J, et al. Inspired EHRs: Make It Easy to Find the Right Orders. Curators of the University of Missouri. 2014. Available at: <http://inspiredehrs.org/designing-for-clinicians/e-prescribing.php>

^{xv} Footnote 118: ¹¹⁸ Ibid.