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SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

Marilyn Tavenner, R.N.
Acting Administrator and Chief Operating Officer
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Farzad Mostashari, M.D.
Office of the National Coordinator for Health Information Technology
Patriots Plaza III
355 E Street, SW
Washington, DC 20201

Re: Request for Information on Advancing Interoperability and Health Information Exchange [CMS–0038–NC]

Dear Administrator Tavenner and Dr. Mostashari:

I am writing on behalf of a group of health care innovators who gathered together in Boston this past weekend, at the end of the week-long effort by local, state and federal law enforcement to apprehend the suspects in the Boston Marathon bombing. The conference we were to attend was canceled, so we created a replacement unconference.

Claudia Williams of ONC was present and facilitated a discussion of Meaningful Use Stage 3.

Following that discussion, a number of us, including Fred Trotter and I, focused on a few specific suggestions that we would like to offer in connection with the above-referenced RFI.

Here they are, keyed to the questions set forth in the RFI.

6. How can CMS leverage regulatory requirements for acceptable quality in the operation of health care entities, such as conditions of participation for hospitals or requirements for SNFs, NFs, and home health to support and accelerate electronic, interoperable health

information exchange? How could requirements for acceptable quality that involve health information exchange be phased in overtime? How might compliance with any such regulatory requirements be best assessed and enforced, especially since specialized HIT knowledge may be required to make such assessments?

CMS currently has a survey and certification program in place under which it reviews organizational and operational compliance of all provider types with the relevant Conditions of Participation, through complaint investigation surveys and periodic unannounced recertification surveys. We propose that the Instructions to Surveyors for each provider type be reviewed and revised so that survey instructions for each "tag" that may be affected by a failure of interoperability or health information exchange be revised to explicitly direct surveyors to cite providers for such failure, and thereby require providers to file and implement plans of correction that directly address health IT interoperability and/or health information exchange issues that are among the root causes of the deficiencies cited.

7. How could the EHR Incentives Program advance provider directories that would support exchange of health information between Eligible Professionals participating in the program. For example, could the attestation process capture provider identifiers that could be accessed to enable exchange among participating EPs?

The attestation process should link the attesting provider with its National Plan and Provider Enumeration System record, and a Direct address field should be added to the NPPES record (rather than simply using the Direct address to attest). This will automatically place Direct addresses into the NPPES as attestation takes place, thus creating a usable and accessible directory that may be used to enable exchange among participating EPs.

9. What CMS and ONC policies and programs would most impact patient access and use of their electronic health information in the management of their care and health? How should CMS and ONC develop, refine and/or implement policies and program to maximize beneficiary access to their health information and engagement in their care?

At present, reportedly only ten percent of patients access their own data through a PHR. There are clearly usability and transparency issues that are holding this figure down to such a low level. The agencies must bolster patient education efforts, as well as provider and vendor usability and transparency efforts, in order to increase this percentage swiftly.

10. What specific HHS policy changes would significantly increase standards based electronic exchange of laboratory results?

While we did not discuss this final issue at the unconference, Keith Boone and I discussed it on our blogs last month. Dr. Mostashari, you posted a tweet ("Lawyers: Would this work?") in response to Keith's proposal, which I answered on my blog. My blog post is attached in support of this proposal.

Keith proposed:

> Currently, laboratories covered under CLIA do not receive incentives for using standards specified under meaningful use. One of the requirements of clinical laboratories under CLIA is the production of a test report that meets requirements under 42 CFR 493, subsection 1291.
>
> One possible way to promote use of the standards would be to providing a deeming clause in subsection 1291 such that if transmission of test results is performed with Health Information technology that has been certified to conform to the criteria in 45 CFR 170, subsection 314(b)(6) [. . .] could be an incentive for laboratories to use those standards.

I responded:

> ONC, in its RFI, specifically requested suggestions for sub-regulatory policy changes that could catalyze interoperability of EHRs. Keith's suggestion is a regulatory amendment. However, since Farzad and Jodi have expressed an interest in this suggestion, and since there is a long-pending proposed rulemaking process out there connected to lab test results (see Lab Results for All! Of Data Liberation, Participatory Medicine, and Government 2.0), this flaw is not fatal, and the recommended change could be made through that rulemaking. In fact, it could help move that rulemaking along (it's been stalled since late 2011) by identifying a mechanism through which the lab test results may be communicated.

Thank you for the opportunity to provide feedback to your agencies through this RFI process.

Please do not hesitate to have a member of your staff contact me should you require any additional information.

Sincerely,

David C. Harlow

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March 17, 2013

Electronic Exchange of Lab Results: A social-media-prompted response to the ONC RFI on interoperability

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The final question posed in the recent request for information posted by ONC reads as follows:

> What specific HHS policy changes would significantly increase standards based electronic exchange of laboratory results?

Keith Boone, aka @motorcycle_guy, self-proclaimed GE standards geek and fellow member of the Society for Participatory Medicine, blogged about his thoughts on the subject in a post entitled: Promoting Laboratory Result Exchange through CLIA. Farzad Mostashari, aka @Farzad_ONC, the National Coordinator of Health IT, tweeted a link to Keith's post, asking lawyers whether this would work:

> Lawyers: would this work? "@motorcycle_guy: [MG] Promoting Laboratory Result Exchange through #CLIA goo.gl/fb/cQh3k #hie" @jodidaniel

Jodi Daniel (Director of the Office of Policy Planning at ONC) and Keith (among others) retweeted the request, and Keith tweeted it directly to me, so I thought I'd weigh in on the question.

Keith observes in his post that labs do not receive any meaningful use incentive payments for making their reports standards-compliant, and suggests that other incentives might be useful:

> Currently, laboratories covered under CLIA do not receive incentives for using standards specified under meaningful

> use. One of the requirements of clinical laboratories under CLIA is the production of a test report that meets requirements under 42 CFR 493, subsection 1291.
>
> One possible way to promote use of the standards would be to providing a deeming clause in subsection 1291 such that if transmission of test results is performed with Health Information technology that has been certified to conform to the criteria in 45 CFR 170, subsection 314(b)(6) [. . .] could be an incentive for laboratories to use those standards.

I have a three-part response:

1. ONC, in its RFI, specifically requested suggestions for sub-regulatory policy changes that could catalyze interoperability of EHRs. Keith's suggestion is a regulatory amendment. However, since Farzad and Jodi have expressed an interest in this suggestion, and since there is a long-pending proposed rulemaking process out there connected to lab test results (see Lab Results for All! Of Data Liberation, Participatory Medicine, and Government 2.0), this flaw is not fatal, and the recommended change could be made through that rulemaking. In fact, it could help move that rulemaking along (it's been stalled since late 2011) by identifying a mechanism through which the lab test results may be communicated.

2. The basic suggestion, which is to deem compliance with one standard to be compliance with another standard, is a reasonable one - assuming that the meaningful use standard for lab results applicable to inpatient EHRs (LOINC v. 2.40 + HL7 v. 2.5.1 + S&I Framework Lab Results Interface) referenced in 45 CFR 170.314(b)(6) is substantially equivalent to the lab test report standard in 42 CFR 493.1291. I would ask Keith to confirm that the two are substantially equivalent, or to explain in layman's terms the differences and why they are unimportant.

3. Related to item 2, the practical question remains: Given that labs are not provided a financial incentive by HHS to comply with interoperability standards, will the proposed deeming clause make it easier for them to do so? Are the meaningful use standards easier to meet than the lab test report standard? In other words, is the deeming clause enough of an incentive to motivate labs to conform to the meaningful use standard for lab results? I would want to know more about the current compliance profile of the clinical lab community. If labs are complying with the existing CLIA regulation lab test report standard, then perhaps we would want to flip the deeming around so that compliance with 42 CFR 1291 (CLIA) is deemed to satisfy 45 CFR 170.314(b)(6) (Meaningful Use). I'd be interested in feedback on this point from the clinical labs out there and the health care providers that deal with them on a regular basis on the issue of data transfer.

If the proposed change could increase the number of labs that are meaningful use standards compliant, and the labs could therefore significantly increase standards based exchange of lab results, then that would be a win.

I look forward to continuing the conversation with Keith and others and submitting a joint comment on the RFI to Farzad and Jodi. While they've asked for input via Twitter -- which I think is fantastic -- I assume they need to receive the input the old fashioned way so it can be made part of the record and all that.

David Harlow
The Harlow Group LLC
Health Care Law and Consulting

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Comments

Keith W. Boone (@motorcycle_guy) said...
David,

Yes, they are substantially equivalent. A set of requirements for each of the the two predecessors to the LRI Guide called out in the MU regs was to ensure that CLIA requirements for content were incorporated into them.

Keith

Reply March 18, 2013 at 11:30 AM

David Harlow said...
There is an interesting comment on Keith's post regarding the technical difficulties that have yet to be overcome, and expressing doubt that deeming alone will help ... see: http://shrd.by/sM8pc4

Reply March 18, 2013 at 03:25 PM
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