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Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System, etc. [CMS–1694–P]

Dear Administrator Verma:

I am writing on behalf of the Health Record Banking Alliance[1] (HRBA), which promotes technology to enable consumer-owned and controlled longitudinal, lifetime, aggregated, computable, easily used, digital health records stored securely in consumers' accounts in private sector repositories. HRBA is committed to three key principles:

1. Each patient's records should be functionally stored in one place (but not all patient records in the same place);
2. Each patient should control access to his/her own medical records; and
3. Medical records should be stored under patient control by a trusted organization.

Regulatory Context

CMS should consider these comments in the context of comments HRBA filed earlier with the Office of the National Coordinator for Health Information Technology (ONC). Those comments respond to ONC's proposed implementation of the Trusted Exchange Framework and Common Agreement (TEFCA). They point out that both HITECH and the Cures Act require ONC to

[1] The Health Record Banking Alliance is recognized as a business league by the Internal Revenue Service under Section 501(c)(6) of the Internal Revenue Code.

promulgate a national digital health data exchange standard. The Cures Act amends HITECH to reinforce Congress's intent that ONC must fulfill this mandate. The Cures Act adds detailed specifications of features and functions — engineering design requirements — that must be part of the exchange standard ONC proposes, adopts, and implements.

Despite these statutory requirements, ONC has neither implemented nor proposed in TEFCA a national digital health information exchange standard. We do not address here the legal implications of ONC's failure. HRBA addresses those issues in its TEFCA comments. HRBA's purpose in these IPPS comments, rather, is to point out the practical regulatory consequences created by the absence of a national health data exchange standard.

That absence is a barrier to routine, secure, affordable, convenient exchange of health records. Its impact is nationwide. It creates unnecessary, otherwise intractable barriers to health information exchange. Patients, clinicians, medical institutions, and regulators (among others) are denied the benefits of digital information exchange with the ease and functionality that Congress has long sought.

In particular for purposes of CMS's proposed rule here, these barriers complicate and frustrate CMS's attempts to meet its statutory obligations and to design efficient regulations that comply with HITECH and the Cures Act. CMS, like ONC, must design regulations to attempt working around the fact that health records by and large remain siloed rather than exchangeable. CMS's and ONC's definitions of "interoperability" and "interoperable" thus continue to be artifices. That is, they permit clinical data systems to be certified as "interoperable" for purposes of regulatory compliance even though those systems, and the regulatory framework itself, fail to meet the fundamental requisites of HITECH and the Cures Act regarding digital data exchange.

In these comments, HRBA takes these regulatory deficiencies as a given condition. HRBA recognizes that CMS's regulatory proposals must perforce be based on the fiction that ONC's existing and proposed regulatory framework for promoting "interoperability" is consistent with applicable statutes (HITECH and Cures) even though it is not. Thus HRBA's approach is to identify inconsistencies and discrepancies in the IPPS proposal that CMS must do its best to address, even though none of these proposed regulations can compensate for the lack of a data exchange standard.

Therefore, nothing here should be interpreted as HRBA's retracting or otherwise departing from its comments on TEFCA. In HRBA's view, ONC's TEFCA proposal remains unworkable as an engineering systems design and as a regulatory scheme to implement data exchange under HITECH and Cures. Those deficiencies have a direct, negative impact on the regulatory options open to CMS as it seeks to fulfill its regulatory responsibilities. So HRBA's task in these comments is to address as practical matters the operational barriers CMS is facing. CMS must deal with Certified Electronic Health Record Technology that, in fact, should not be certified under HITECH and Cures because it does not meet the *statutory* requisites for digital health data exchange.

In that context, we offer the following.

Proposed Changes to the Medicare and Medicaid EHR Incentive Programs (now referred to as the Medicare and Medicaid Promoting Interoperability Programs)

CMS Proposal: CMS is proposing that beginning with the electronic health record (EHR) reporting period in CY2019, the 2015 Edition of Certified Electronic Health Record Technology (CEHRT) will be required.

HRBA Comments: HRBA agrees that 2015 CEHRT should be required in CY2019. Further, very little new functionality is required to make 2015 Edition CEHRT patient data more available to patients and their designated apps without any significant labor on the part of providers. CMS should work with HHS's Office of the National Coordinator of Health Information Technology (ONC) to ensure that future editions of CEHRT require that EHR patient portals allow patients to enter their email address, secure Direct messaging address, and their approved third-party app to receive their patient data and to automatically receive any additional data whenever the provider EHR receives new data. Also, CMS should work with ONC to ensure that future versions of US Core Data for Interoperability (USCDI) capture all of the patient's data at a given facility, as required by HIPAA, using all 12 of the standard C-CDA document templates, which can be cross-mapped to FHIR resources, which use the required Application Programming Interfaces (APIs).

National and international standards exist for transmitting nearly all patients' data in EHRs (all 12 C-CDA document templates and the equivalent FHIR resources for APIs). These standards are listed in ONC's Interoperability Standards Advisory. But these consensus standards do not adequately support interoperability in clinical practice because they contain too many optional fields for important data and there is not an easy way for a provider or EHR vendor to test their ability to send or receive a fully conformant C-CDA document. Therefore, the US does not yet have a useful standard for health data exchange.

HRBA Recommendations: HRBA supports CMS's proposal to require use of 2015 Edition CEHRT in 2019, and agrees that this upgrade will better support interoperable exchange of health information and improve clinical workflows. CMS, using public and private sector consensus recommendation, needs to eliminate any optionality in the use of C-CDA documents and FHIR APIs and establish 7x24 online testing sites where providers and payers can continually test their interoperable documents and receive complete and competent assessment of their documents' conformance to the standards. Also, CMS and ONC should establish an annual schedule for gradually endorsing more and more of the consensus interoperability standards, as ONC is planning for USCDI.

Proposed Modifications to Provide Patient Access Measure

CMS Proposal: CMS is proposing to change the name of the Provide Patient Access Measure to the Provide Patients Electronic Access to Their Health Information, which would require the following:

- The patient (or the patient's authorized representative) is provided timely access to view online, download, and transmit his or her health information; and
- The eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital or CAH's CEHRT.

HRBA Comments: With nearly all providers using EHRs, HRBA agrees that it is time to discontinue use of paper-based formats and instead use electronic file formats to deliver health records to patients. CMS, the HHS Office of Civil Rights, and the HHS Office of the National Coordinator of Health Information technology are all encouraging patients to get and use their health records, which are now available in electronic form because most providers use EHRs. However, each agency is using different terminology in referring to patients' health records.

There are four different consumer concepts of health records used by the Federal Government.

- 2014 EHR Certification: "View, Download, and Transmit" (VDT).
    - The "View" part is provided by a portal tethered to the provider's EHR. Typically the portal displays the Summary of Care C-CDA: approximately 17 total data elements including but not limited to the following: problem list, medication list, allergy list, immunizations list, vital signs, lab results, and smoking status.
    - The "Download" part is also in the portal and the patient can download a Summary of Care C-CDA both in xml and pdf. The data elements are the same as above under View.
    - The "Transmit" part again uses the portal to have the patient enter a provider's name and street mailing address, to which is sent the above Summary of Care C-CDA.
- 2015 EHR Certification: requires use of APIs, in all likelihood, FHIR APIs. Apps like Apple Health and Care Evolution's MyFHR use the FHIR URL address of the provider's EHR. Currently, the data downloaded via the APIs is the same as View, Download, and Transmit above. These apps are nice to have but they capture only a fraction of a patient's useful healthcare record data.
- ONC's push to get patients to obtain their health records ("The Guide to Getting and Using Your Health Records") talks about patients requesting their medical records through a provider's EHR portal but says nothing about "View, Download, and Transmit." The web site then goes on to tell patients to go to their provider and request their health records and that their provider can charge a "reasonable fee" to provide them with their records. There is no mention of VDT or APIs. HIPAA entitles consumers to ask for and receive their "designated_record_set," which is all the data the provider has on the patient with which to

diagnose, treat, and bill the patient, even beyond just the data in the EHR. The designated record set can include other systems like imaging systems, lab systems, and so on.
- CMS promotes MyHealthEData, which is the iBlueButton 2.0 initiative to download one's Medicare Fee for Service claims data from CMS. Again, their no mention of View, Download, and Transmit, APIs, or "The Guide to Getting and Using Your Health Records."

There is lack of clarity about what it is going to cost consumers to get their health data.
- VDT, APIs, and iBlueButton 2.0 are all free so far but provide only a fraction of patients' data.
- But if a patient goes to their provider (presumably a hospital but perhaps their doctor's office, too), HIPAA and OCR allow providers to charge a "reasonable fee" to provide them with their records. That fee cannot include finding their record within their system but it can include charging for copying pages (not done much anymore), for providing a physical electronic copy (DVD or USB drive), and for mailing it. But there is no mention of a "reasonable fee" when all the provider has to do is press a button within their EHR to collect nearly all of the record into a long text document. Also, there is no mention of emailing the resulting document to the patient nor any mention of sending the record to the patient's Direct address (225,000 patients have secure Direct addresses). CMS should require hospitals to give patients an electronic copy of their entire health record for free because EHRs, subsidized by taxpayer dollars, make that task nearly labor-free.

HRBA Recommendations:
- **HRBA supports the Provide Patients Electronic Access to Their Health Information proposal.** In addition, CMS should work with ONC to ensure that future edition CEHRT requires that EHR patient portals allow patients to enter their email address, secure Direct messaging address, or their approved third-party app to receive their patient data and to automatically receive any additional data as the provider EHR receives new data. Also, CMS should work with ONC to ensure that future versions of US Core Data for Interoperability (USCDI) capture all of the patient's healthcare record at a given facility, as required by HIPAA, using all of the standard C-CDA document templates, which can be cross-mapped to FHIR resources, which use the required APIs.
- **CMS should use a consistent vocabulary when speaking about patient access to their healthcare records.**
    - A **limited clinical data set** is available from their provider's EHR portal, via View, Download and Transmit, and from apps connected to FHIR APIs.
    - A **full clinical data set** can be sent from their provider's EHR to their email address, their secure Direct address, or to a personal health record app requested by the patient. Put the entire designated record set in a long text file at no charge to the patient because it is very little labor for the provider. Later all these data can be mapped to the 12 C-CDA document templates and their corresponding FHIR resources. But send all the data the patient now, on their request.
    - **Claims data** from payers to augment clinical data from providers.

- **CMS should require patient access to all of their healthcare record at a given facility with automatic updates.** There is no longer any reason for patients to have to physically go to the health information management department of their provider unless they want to. Working with ONC, CMS should require certified EHRs to have a place for the patient to enter their email address, their secure Direct address, or the address of their personal health record app where the provider's EHR is to send all their health data, not just a limited data set. Additionally, each time the provider receives new data on the patient, the EHR should automatically send the patient a copy at the designated address. None of this takes any human effort after the functions are set up in the EHR. There are a number of private companies that are fully capable of making sense of a large, complex healthcare record data set received in a long text document and providing useful information to the patient.
- **CMS should require providers make their full electronic records free to patients via electronic methods.** Since few providers need to go to the copy machine to produce healthcare records for patients, CMS and OCR need to require providers to allow patients to download free copies of all their healthcare data at that facility, initially as common text documents, and later, as standardized C-CDA documents and FHIR data elements via APIs, where photocopying records and physically mailing DVDs and USB drives are not involved. CMS and OCR need to specify that patients' downloading their full records from patient portals or providers' EHRs electronically sending full records to patients' secure Direct addresses or apps is free.

Proposed Removal of the Secure Messaging Measure

CMS Proposal: CMS is proposing to remove the Secure Messaging measure because it has been felt to be burdensome to eligible hospitals and CAHs.

HRBA Comments: Patients who utilize secure messaging usually do so in the context of an ongoing outpatient relationship with a clinician, more so than with hospitals. However, many patients do need their hospital records for further care and being able to send protected health information via secure messaging helps patients and family care givers, who currently struggle with collecting their healthcare data. Also, with nearly all hospitals using EHRs, providing an entry form within their patient portal would allow patients and their proxies to enter an email address, a secure Direct messaging address, or a third-party app address for automatically receiving their healthcare data without inconveniencing hospital staff. There are already 225,000 patients with secure Direct addresses and this number is growing.

HRBA Recommendation: HRBA believes that Secure Messaging should continue to be required of hospitals and CEHRT.

Proposed Removal of the View, Download or Transmit Measure

CMS Proposal: CMS is proposing to remove the View, Download or Transmit measure because it has been felt to be burdensome to eligible hospitals and CAHs.

HRBA Comments: As noted above, it is crucial for patients and their family caregivers to be able to obtain patients' full healthcare record sets when they seek care with a new provider, change health insurance companies, move geographically, or wish to participate in clinical trials and research. With more than 95% of hospitals using EHRs and with all certified EHRs offering patient portals, it is not difficult to make the View, Download, and Transmit function available automatically. According to ONC, the percent of hospitals that enable patients to electronically view, download and transmit their health information grew almost 7-fold between 2013 and 2015.[2] Moreover, there is a demand for this information. Kaiser Permanente, a pioneer in patient portal use, reports that more than half of its 9 million members are active users of its My Health Manager service, and more than 70% of eligible members have registered to use it.[3]

Instead of requiring just one patient to use View, Download, and Transmit, we propose that that requirement be increased to 10% of an eligible organization's patient population that must view, download, or transmit their health data, for the following reasons:

- Patient access to both technology and health data has grown dramatically.
- Healthcare providers report patient platform usage rates as high as 85%.
- Patients follow doctor recommendations related to digital health.
- Engaged patients are critical for the success of value-based payment models.
- Patient and consumer use of digital health tools boosts the economy overall.

HRBA Recommendation: HRBA believes the View, Download, and Transmit measure should continue to be required through the Provide Patients Electronic Access to Their Health Information measure and that the requirement should be increased to 10% of an eligible organization's patient population.

Respectfully submitted,
The Health Record Banking Alliance

By

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[2] https://dashboard.healthit.gov/evaluations/data-briefs/hospitals-patient-engagement-electronic-capabilities-2015.php

[3] http://www.healthcareitnews.com/news/patient-portals-prove-prowess-kaiser and https://www.healthaffairs.org/do/10.1377/hblog20160407.054362/full/