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SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

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: CMS 1693-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

As President and CEO of DirectTrust.org, Inc. (DirectTrust), a large, inclusive, and diverse health IT industry alliance non-profit, it is my pleasure to offer the comments of our highly -engaged Patient and Consumer Participation Work-group on the recent CMS 1693-P document published by CMS. While we applaud the goal of reducing regulatory burdens on providers and industry and seeking market based alternatives to such regulation we believe that patient engagement is crucial to improving the health of patients, increasing their satisfaction with their care, and decreasing the rate of growth of healthcare costs. This goal is worth our collective continued investment.

In many public appearances, you have described your vision of “a future for healthcare, and a future for all of us, where our healthcare record begins from the time of [birth] and collects all of our data throughout our lifetime.” The team’s comments below reflect our recommendations for how to reach that future that you elegantly describe.

Executive Summary

For the best clinical and financial results, patients and their families need to be engaged in their care, to the extent that their conditions permit. Patients do better when they understand their illnesses and how their own actions can increase the chances of a favorable outcome. Patient self-efficacy means that patients hold themselves accountable for what they should do. Patient-provider communication is one way to augment patient engagement and patient self-efficacy. The relatively recent adoption of electronic health records has made it possible for patients to access their clinical data, to contribute data about their conditions to their providers, and to securely exchange messages with questions to and advice from their providers. Such changes in patient involvement will take time for broad adoption and we would like to see a continuation of the momentum that has been established by the HITECH Act.

The industry continues to need impetus for all the established interchange mechanisms including query by the IHE profiles and FHIR, downloads from patient portals and push by Direct Exchange. To that end we recommend the following:

- Retain the current 5% thresholds for the View, Download, and Transmit and Secure Electronic Messaging measures.
- Retain the Patient-Generated Health Data measure.
- Retain the Patient-Specific Education measure.
- Retain the Secure Messaging measure.
- Retain the View, Download, and Transmit measure.
- We support the inclusion of Supporting Electronic Referral Loops as a measure.
- CMS and ONC should endorse all 12 of the standard C-CDA document templates as an alternative to FHIR as the standard matures.
- CMS and ONC should endorse currently used health data exchange standards but eliminate optionality and insist on 24x7x365 online conformance testing.
- Modify current EHR certification standards to allow patients to enter their secure messaging address into their patient portals so they automatically receive their data.
- CMS and ONC should incrementally, predictably, and annually advance the standards for electronic health data exchange including the USCDI so that vendors and providers can adopt more effective information technology without significant burden.
- Patients need to be clearly, securely, and unambiguously identified using standards found in NIST Publication 800-63-3 to protect against malicious mis-representation.

Full explanations and comments for each recommendation are provided in subsequent pages.

Individual Sections and Specific Recommendations

III.E.4.a. Proposed Change to Objective 6 (Coordination of Care Through Patient Engagement) Therefore, we propose to amend § 495.24(d)(6)(i) such that the thresholds for Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging) of Meaningful Use Stage 3 EP Objective 6 (Coordination of care through patient engagement) would remain 5 percent for 2019 and subsequent years.

We agree with keeping the thresholds for View, Download, and Transmit and Secure Electronic Messaging at 5 percent for 2019 and retaining the HIT certification program.

Patient self-efficacy is the key to better health and more efficient use of health services. Providers, payers and communities that serve patients will be increasingly dependent on information outside of their own domains. Patients can act as intermediaries of information and exchange. The ecosystem to achieve this will depend on standards that are universally required for all EMR and providers.

III.H.3.h.(5)(f)(iv)(B) Proposed Removal of the Patient-Generated Health Data Measure

We are proposing to remove the Patient-Generated Health Data (PGHD) measure to reduce complexity and focus on the goal of using advanced EHR technology and functionalities to advance interoperability and health information exchange.

As finalized in the 2015 EHR Incentive Programs final rule at 80 FR 62851, the measure is not fully health IT based as we did not specify the manner in which health care providers would incorporate the data received.

We prefer that Patient Generated Health Data should remain a required measure with obligations to store the data in the EHR attributed to the patient. This should be supported by the general provenance requirements that remain in the certification rule.

Eliminating the requirement to support PGHD suggests that this information is not relevant to the provider. Many clinicians would take exception. In fact, testimony presented to ONC and the recently completed ONC white paper agree with this premise. “When used by clinicians and researchers, PGHD can provide a more holistic view of a patient’s health and quality of life over time, increase visibility into a patient’s adherence to a treatment plan or study protocol, and enable timely intervention before a costly care episode.”¹

¹ Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024 - https://www.healthit.gov/sites/default/files/onc_pghd_final_white_paper.pdf

Kaiser reports that 51% or more of their patient contacts are done electronically and integrated into the workflow. Secure messaging is one of the ways patients share information. There are apps already today that permit patients to generate health data and share them using standard formats. Patient-Generated Advance Care Plans (traditionally called “advance directives”) use an HL7 standard that is consistent with the Meaningful Use C-CDA standard, and there are companies that can generate and share Personal Advance Care Plans documents with providers using the same transport mechanisms that support sharing any other standard C-CDA document. There are applications that allow a user to take the C-CDA document they have downloaded from their patient portal or received via Direct secure messaging. Patients can then annotate it with feedback using standard C-CDA Clinical Notes templates that carry proper Data Provenance attributing it to the patient. The annotations provide data quality improvements, care planning information, and essential outcome information that can be collected only from the patient.

The problem is that many EHRs are not taking action to implement workflows for accepting PGHD. The measure is needed to monitor progress on this opportunity to engage patients in the co-creation of their health records, to help reduce the cost of unwanted care, and to improve the accuracy and completeness of health records. The technology exists to observe and measure rapid increases in the amount of PGHD being accepted into EHR systems. It is critical to track if progress is being made.

There are some HIT vendors supporting the acquisition of PGHD from wearables and mobile phone apps. More PGHD at or before intake may lead to reductions in physician burden. Many patients can do much of data entry required to fill out their Family History, Social History, Past Medical History, and the like, instead of handwriting the information on clipboards in each provider’s office. Harvesting and re-using PGHD from all those forms that patients fill out today could become a tremendous time-saver for physicians and improve patient satisfaction. For that reason alone, the measure should be retained.

This measure may be one of the best indicators of progress in “patient empowerment.” If we track improvements in this measure over the coming few years, we will be succeeding in our aim to engage patients more meaningfully in their care.

III.H.3.h.(5)(f)(iv)(C) Proposed Removal of the Patient-Specific Education Measure

We are proposing to remove the Patient-Specific Education measure as it has proven burdensome to MIPS eligible clinicians in ways that were unintended and detracts from their progress on current program priorities.

We believe that the Patient-Specific Education measure does not align with the current emphasis of the Promoting Interoperability performance category to increase interoperability, or reduce burden for MIPS eligible clinicians. In addition to not including

interoperability as a core focus, stakeholders have indicated that this measure does not capture many of the innovative activities around providing patient education, for instance new approaches to integrating patient education within clinical decision support modules. As a result of this lack of alignment, this measure could potentially increase clinician burden.

We suggest that patient-specific education standards as outlined in the 2015 edition of the Certified Electronic Health Records Technology (CEHRT) remain. In addition, we also suggest that the measures and subsequent reporting requirements be considered in the final rule’s performance-based scoring methodology for EHR reporting. Retaining such standards and measures around patient-specific education is vital for several reasons:

- **Improved health literacy empowers patient self-care, which reduces unnecessary utilization and decreases costs.**
- **Today’s technology standards are widely adopted and evolving, allowing for the measurement of health literacy for insight across care environments**
- **Harmony in standards and measures between varying regulations (e.g., Medicare Access and CHIP Reauthorization Act, Inpatient Prospective Payment System, etc.) reduces unnecessary bureaucracy and relieves clinician burden.**
- **Effective standards and technologies for patient-specific education can actually reduce burden on providers, EMR systems and HIT departments, while enhancing the workflow of all parties.**
- **Value-based care is in part dependent upon patient self-efficacy, and patient education is a critical component to such self-efficacy.**
- **Patient-specific education benefits society’s most vulnerable and those with chronic conditions, who are often the highest utilizers of care, which is extremely costly to the country’s healthcare system.**
- **Patient education provides both intuitive and low-cost intervention for national health crises, such as the opioid epidemic.**
- **The value of patients’ access to EMR and claims data is directly related to how well these data, which are often confusing and inconsistent, are understood.**

Secure messaging is an important part of supporting education as patients, their families, and the support communities all need to understand what the patient can do for themselves and with their help to achieve better outcomes.

III.H.3.h.(5)(f)(iv)(D) Proposed Removal of the Secure Messaging Measure

We are proposing to remove the Secure Messaging measure as it has proven burdensome to MIPS eligible clinicians in ways that were unintended and detracts from MIPS eligible clinicians’ progress on current program priorities.

As outlined above, we believe that the Secure Messaging measure does not align with the current emphasis of the Promoting Interoperability performance category to increase

interoperability or reduce burden for MIPS eligible clinicians. In addition, we believe there is burden associated with tracking secure messages, including the unintended consequences of workflows designed for the measure rather than for clinical and administrative effectiveness.

We believe Secure Messaging must remain a required measure.

The free flow of health information depends on consumers and patients who trust that their protected health information can be transmitted and received in ways that protect their privacy. Absent that trust, patients will withhold information and/or not participate in the electronic exchange of protected health information. Secure messaging is an important element in the reduction of fax traffic in healthcare. As demonstrated successfully by DirectTrust at the August 2018 ONC interoperability meeting, there is no question that secure messaging can be used to enable integration of data within the broader workflows of the provider community.

Secure messaging and its role in opioid addiction prevention: Mobilizing patient education in electronic communication is fundamental to encouraging the appropriate use of pain management medications. Secure messaging can connect patients securely with community services that may not be on CEHRT. If secure messaging to and from the EHR is removed and not encouraged, patients, providers, and community services with no EHR will be challenged to communicate with CEHRT users.

III.H.3.h.(5)(f)(iv) (E) Proposed Removal of the View, Download or Transmit Measure

We are proposing to remove the View, Download or Transmit measure as it has proven burdensome to MIPS eligible clinicians in ways that were unintended and detracts from their progress on current program priorities.

Stakeholders have indicated that successful submission of the measure is reliant upon the patient, who may face barriers to access which are outside a clinician's control.

We object to this proposal.

EHR companies have spent substantial resources making the patient's EHR data available to the patient. Many patients use EHR-connected patient portals to request refills, schedule appointments, and send messages to their care team. Patients already have logins and passwords to patient portals and it is convenient for them to download their data from within the portal.

Instead of removing the requirement to provide View, Download, and Transmit capabilities, CMS should instead make it easier for patients to download their data into an external personal health record by requiring portals to allow patients to

enter the electronic address (URL) of their PHR. Further, EHR-connected portals could be required to allow patients to request that any new data that the EHR receives be automatically downloaded to the patient’s PHR. This way, the patient builds a comprehensive, longitudinal, unified health record automatically after every provider encounter. View, Download, and Transmit already exists in all CEHRT and adding PHR address entry and automatic updating are very little burden for EHR vendors and no burden at all to providers, because it is automatically managed by software.

III.H.3.h.(5)(f)(iv) (F) Proposed Rule to Support Electronic Referral Loops

For the Health Information Exchange objective, we are proposing to change the name of the existing Send a Summary of Care measure to Support Electronic Referral Loops by Sending Health Information, and proposing a new measure which combines the functionality of the existing Request/ Accept Summary of Care and Clinical Information Reconciliation measures into a new measure, Support Electronic Referral Loops by Receiving and Incorporating Health Information.

We support the inclusion of the support for sending and receiving referral loops. Today most referrals are either faxed or are “tacit” – that is communicated verbally only. A study by the AAFP found that only half of the ambulatory referrals made were completed. We also believe that true “closed-loop referrals” should be the standard as outlined in the AAFP study and as exemplified by the emerging 360x Standard.

IV.A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

- If CMS were to propose a new CoP/ CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?

Unquestionably yes. There are specific, modest requirement changes that could help reduce information blocking. 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 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 in subsequent versions of U.S. Core Data for Interoperability (USCDI) capture all of the patient’s data at a given facility over time utilizing 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. CMS and ONC need to establish which version and profile is expected each year for a given standard. All providers receiving CMS funding should be required to use that standard, version, and profile for that year, and expect that there will be modest upgrades in the versions and profiles each year. Embedded self-service content testing, available 7x24x365, is crucial for developers, payers, and providers to be sure that their messages are compliant with current standards. If EHR vendors are given adequate notice of next year's changes, and providers, payers, and vendors expect progressive, incremental annual upgrades, then the burden on providers can be reasonable and more data can flow to patients and other providers.

- **Should CMS propose new CoPs/ CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?**

Yes. Until secure and affordable FHIR APIs are commonplace in the consumer marketplace, patients and caregivers continue to need access to patient data via EHR-connected patient portals. As noted above, modest changes to patient portals will allow patients and their caregivers to sign up once to have their data flow automatically to a third party app of their choosing (a PHR or equivalent) after the first and every subsequent visit. Further, the patient or caregiver can point the portals of all of the patient's providers to the same PHR and collect their EHR, genomic, and patient-generated data in one place as Administrator Verma described at the Blue Button 2.0 Developer Conference in Washington DC on 13 August 2018.

- **Are new or revised CMS CoPs/CfCs/ RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–91), and implementation of relevant policies in the 21st Century Cures Act?**

Yes. It is crucial for CMS to gradually and predictably require that more and more of the patient's data within EHRs be mapped to one of the 12 C-CDA document templates as well as

to the appropriate FHIR resource, so that it can be transported to the patient's chosen third-party app "without special effort" both by query and in "push" methodologies. Current applications, such as Apple Health, have demonstrated how easy it is for patients to receive their data from their providers' EHRs and store it all in one place, regardless how many providers and different EHRs are involved. But the Apple Health FHIR API is accessing only a very small subset of all the useful patient data in the EHR (e.g., the problem list, medication list, allergy list, procedure list, vital signs, lab results, immunization list, and smoking status). This is a great start, but gradually and predictably (so that EHR vendors have sufficient time to enhance their FHIR APIs) CMS needs to require more and more of the patient's clinical data in the EHR to be accessible by View, Download, and Transmit via C-CDA documents and by FHIR APIs. The most important additional data element is Clinical Notes (e.g., history and physicals, consultation notes, operative notes, procedure notes, pathology notes, diagnostic imaging interpretations, discharge summaries, and office visit notes). To its credit, ONC has suggested that Clinical Notes be included in the 2018 version of USCDI along with Provenance.

- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?

As ONC has suggested with its proposed annually updated USCDI, it is reasonable for CMS to gradually and predictably require that more and more of the patient's data in EHRs be made available via View, Download, and Transmit C-CDA documents and via FHIR APIs, both of which are functional in 2015 CEHRT. Allow EHR vendors a year to make the modest upgrades in their patient portals and FHIR APIs and allow providers a year after that to upgrade to the next incremental version of their EHRs. We do not expect EHR vendors and providers to suffer massive new versions each year. In the same way that Microsoft Windows, Apple MacOS, Android, and Apple iOS make regular, small incremental upgrades to computer and mobile phone operating systems, EHR vendors can make regular, small incremental updates in the data elements sent to patients and their caregivers.

- Are there any other operational or legal considerations (for example, implementing regulations related to the HIPAA privacy and security standards), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?

Yes. Patients need to be clearly, securely, and unambiguously identified to prevent inappropriate access by malicious mis-representation. NIST Publication 800-63-3 has specified the criteria for secure identity proofing. DirectTrust, its member companies, and multiple federal health agencies are all using versions of this standard to identify providers, payers, and patients. At scale and for a few dollars per patient, each patient can have an

unambiguous, secure digital identity that they can use for healthcare and potentially for other internet transactions.

Conclusion

In summary, it is important to maintain the momentum of engaging patients in their care by continuing to use existing information technology standards while implementing and learning from new information exchange standards. It is the nature of information technology to have two or three generations of standards in use at any given time. Given time, new standards will be optimized and adopted into common use and the older standards will fall into disuse. DirectTrust strongly recommends that CMS continue to measure View, Download, and Transmit, Secure Messaging, Patient-Specific Education, and Patient-Generated Health Data. Providing a measure for closed-loop referrals is an important addition to the rule. CMS should continue to support the widely-implemented C-CDA standard while eliminating optionality and calling for continuously-available online testing. Transmission and content standards need to be updated annually. Patients need to have a secure, unambiguous digital identity. These steps will assure a robust, sustainable ecosystem of personal health data where patients and families will have access to the information they need to use healthcare resources wisely.

Regardless of the content of the final rule, DirectTrust looks forward to collaborating with CMS and the ONC on improving interoperability use and usability for the good of all healthcare constituencies.

Yours truly,

Scott Stuewe
President and CEO