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June 25, 2018

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1694-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Docket ID: CMS-1694-P, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims

Thank you for the opportunity to comment on the Hospital Inpatient Prospective Payment System (HIPPS) proposed rule recently published by the Centers for Medicare & Medicaid Services (CMS). The proposed changes to Medicare payment programs that promote interoperability will enhance the ability for patients and clinicians to gain access to critical health data so that they have the necessary information when and where they need it to inform care decisions.

The Pew Charitable Trusts is a non-profit research and policy organization with a number of initiatives focused on improving the quality and safety of patient care, facilitating the development of new medical products and reducing costs.

CMS' efforts to promote interoperability through hospital payment programs face three key barriers: difficulties matching health records to the correct patient; inability to easily extract useful data from health records; and limited use of standard ways to describe clinical information. This proposed rule provides CMS opportunities to address these key barriers through policies that support health information exchange between care providers, patient access to their data, and electronic reporting to registries for syndromic surveillance. In addition, as CMS continues to emphasize the utility of health insurance claims for research, the agency should support efforts to ensure the data include critical information—namely the brand and model of implanted medical devices.

Barriers exist to widespread interoperability

EHRs are now ubiquitous in hospitals and provider offices, but the full promise of health record digitization has not yet been met. Health records are still siloed within care facilities and sharing

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them with others often involves faxing hundred-page documents or physically carrying around files from clinician to clinician.[1]

The 2019 HIPPS proposed rule replaces the Meaningful Use program—which required hospitals to use EHRs in certain ways—with a new set of interoperability-focused measures, including several provisions designed to advance data exchange. Throughout the proposed rule as part of revisions to several measures, CMS has opportunities to improve interoperability by addressing the following factors that affect the exchange and utility of health data.

- Better patient matching: Interoperability relies on the ability to accurately link records referring to the same individual when the files are held in different locations.
- Use of simple and transparent application programming interfaces (APIs): APIs—software tools that allow transfer of data between different systems—open pathways to exchange information across EHRs in care facilities.
- Standardized clinical terminologies: Along with increasing the availability of health data, ensuring that the information can be used to improve care requires standards and common definitions for clinical terms.

Improvements to patient matching is a key building block for interoperability

Patient matching is the ability to link a patient to his or her health records that may be held at multiple locations. Researchers have found match rates as low as 50 percent when attempting to link records held in different healthcare facilities. [2] As a result, this challenge in correctly linking an individual with his or her records impedes patients' and healthcare providers' ability to access critical data to inform care decisions. Improving patient matching is a necessary step in creating a healthcare system that provides high-quality care.

Pew is conducting research to better understand challenges with patient matching and evaluate solutions to this interoperability problem. For example, we are assessing whether the use of more detailed standards for demographic data—such as name and date of birth—could help enhance match rates, or whether individuals can be involved in matching their records—such as by using a smartphone application. Improving patient match rates is critical as we consider a system that allows patients to access care anywhere they wish to receive it, and has the potential to improve outcomes and lower healthcare costs. The foundation for achieving the interoperability goals CMS has outlined in this proposed rule starts with better patient matching.

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[1] Sarah Kliff, "The fax of life: Why American medicine still runs on fax machines," *Vox*, Jan. 12, 2018, https://www.vox.com/health-care/2017/10/30/16228054/american-medical-system-fax-machines-why.
[2] "Patient Matching Errors Risk Safety Issues, Raise Health Care Costs," The Pew Charitable Trusts, June 29, 2017, http://www.pewtrusts.org/en/multimedia/data-visualizations/2017/patient-matching-errors-risk-safety-issues-raise-health-care-costs.

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API access to data should be simple and with few restrictions

To achieve interoperability, data must be able to be extracted and effectively exchanged. APIs are tools that allow external software developers access to data stored inside systems like EHRs. Once the data are accessed, they can be used for many purposes—including transmission to clinicians and patients.

Federal regulations are progressing to advance the use of APIs for interoperability. The Office of the National Coordinator for Health Information Technology (ONC) has required that EHR developers provide patient access to some EHR data through APIs, and is in the process of drafting regulations to further expand the use of APIs. In parallel, CMS Administrator Seema Verma has expressed the importance of patient access to and control of their own health data.[3] This shift toward data availability via APIs can ensure that patient health information is readily accessible and easy to use while meeting security and privacy standards.

Standardizing clinical data will support decision making

EHRs receiving data from other systems must understand the codes used to represent clinical information so that they can properly interpret what is exchanged. Data that come from multiple locations, if not documented in a standard way, can prevent the information from being effectively integrated in the EHR. When that occurs, the information may be lost or stored in a manner that is not easily accessible to clinicians, making it difficult to use the data to inform care. Standardization of terminologies helps ensure that EHR systems speak the same language and facilitates the development and use of new tools to guide health care decisions such as indicating trends in patients' status or warning against potential complications.

CMS should examine challenges with each of these factors—patient matching, use of APIs, and standard terminologies—in the implementation of HIPPS objectives.

Health Information Exchange Objective

The HIPPS proposed rule modifies measures related to exchange of health information between different care facilities. Under the former Meaningful Use program, hospitals were required to send summary of care documents, receive and accept them from other facilities, and reconcile the information collected with existing EHR data. The new proposed measures—Support Electronic Referral Loops by Sending Health Information, and Support Electronic Referral Loops by Receiving and Incorporating Health Information—combine the receive and reconcile measures from Meaningful Use. The success of the proposed measures—where health records are effectively exchanged between clinicians caring for the same individual—relies on the ability to match

[3] "Trump Administration Announces MyHealthEData Initiative to Put Patients at the Center of the US Healthcare System," Centers for Medicare & Medicaid Services, Mar. 6, 2018, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-03-06.html.

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patients across care facilities, access to APIs to allow data exchange, and the use of standards to ensure the utility of information.

CMS also proposes to remove restrictions on the type of documents organizations can exchange so hospitals and providers do not need to add unnecessary information to conform to a specific template. Currently, federal regulations require use of three document types—Continuity of Care Documents, Referral Notes and Discharge Summaries. As part of the proposed rule, clinicians—and by association, their EHR vendors—would have the flexibility to use other templates, such as a Progress Note, or History and Physical. While this change will improve the ability to exchange more relevant information for better care coordination, CMS should work with ONC to provide examples of the appropriate document templates for specific use cases so clinicians do not fail to send important data during transitions.

These measures also emphasize the importance of automatic data reconciliation from summary of care records sent from other locations. The current requirements for reviewing and merging medication lists, medication allergies, and problem lists allow both automatic and manual processes. The proposed measures require automated information reconciliation so that EHRs—without the intervention of clinicians—can incorporate data received from external sources. To support this automated reconciliation, EHRs should use standardized vocabularies and code sets to ensure that different systems can effectively communicate and understand information they receive for reconciliation. For future editions of the HIPPS rule, CMS should examine expanding automatic reconciliation to additional data elements, such as laboratory tests, diagnoses, and other data elements that have widely adopted clinical standards. CMS should work with clinicians, hospitals, and EHR developers to identify appropriate standards that will enable further interoperability.

Provider to Patient Exchange Objective

CMS proposes to change several measures associated with promoting patient engagement and access to their health records. Currently there are several measures in these two categories which incentivized hospitals to engage patients in their care by viewing their health records and communicating with their care providers. The proposed rule would remove all measures except one, which would be renamed Provide Patients Electronic Access To Their Health Information, and require hospitals to provide "timely" access for patients to view, download and transmit their health information from any application of their choice that uses appropriately configured APIs. This marks a major change from previous policies where patients primarily gained access to their health data through web-based portals from their providers' EHR, and removes restrictions on how they can view and use their records. For example, under the proposed rule, patients would be able to receive their health data in more accessible ways, such as via smartphone applications, which would mark a significant shift in empowering patients to access and utilize their health information.

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These proposed changes encourage the use of API for data exchange to patients. However, there are still many technical challenges—including privacy and security—that CMS will need to address to ensure that APIs can be used effectively. One critical challenge involves the amount of data accessible through APIs. Current requirements from ONC indicate that EHR vendors must provide APIs that make a small set of critical health data—known as the Common Clinical Data Set—available to patients. If CMS' intent is to allow patients' access to their entire health record, access to just the CCDS is not enough and the agency should work closely with ONC to harmonize technical requirements with payment incentives to support interoperability for other data elements. For example, social determinants of health, medical images, and genomic information are not part of the CCDS and therefore may not be available to patients via APIs.

Public Health and Clinical Data Exchange Objective

The data stored inside EHRs can serve many purposes other than clinical care once exchanged among different technology systems. In the proposed rule, CMS recognizes that enhanced interoperability of data supports many public health purposes, including transmission to registries, which aggregate clinical information from multiple locations to evaluate outcomes for patients with similar medical conditions and identify emerging health risks. According to the Centers for Disease Control and Prevention, most of the data collected for syndromic surveillance—which is used to detect disease outbreaks, for example—comes from EHRs used in emergency care.[4] The ability to collect data once in EHRs and reuse them for many purposes is a key benefit of effective interoperability. Previously under Meaningful Use, hospitals were required to report to several public health and clinical data registries, but could manually fill out the necessary information. Now, CMS proposes to require that hospitals attest to the electronic reporting of data for syndromic surveillance and to an additional registry, such as one that tracks immunizations or public health.

These proposed changes are positive steps to encourage interoperability across the health care industry with the various electronic systems that EHRs interact with, including registries. However, to effectively use data from EHRs, the information should be formatted in a way that the registries are able to easily use and interpret; CMS should consider encouraging use of common data elements to meet that goal. For example, the definition for conditions like diabetes mellitus or myocardial infarction can differ between hospitals and clinical societies that operate registries. Use of common data elements and definitions in EHRs and registries would support interoperability by facilitating the submission of the same data to multiple systems. Pew is working with the Duke Clinical Research Institute to identify a set of common data elements that registries across the clinical spectrum collect, and identify appropriate existing standards to code that information.

[4] "National Syndromic Surveillance Program (NSSP)," Centers for Disease Control and Prevention, last modified June 5, 2018, https://www.cdc.gov/nssp/news.html.

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Request for Information

CMS also requests comments on other ways to encourage exchange of health data, including changes to the Conditions of Participation for the Medicare and Medicaid programs. Requiring that hospitals exchange patient records with other facilities upon transfer or discharge would improve the ability for care providers to obtain important information for care coordination. However, that information must be accurate, usable, and timely. To address these critical issues, CMS should consider how to support the previously mentioned barriers and coordinate with ONC, clinician organizations, hospitals, and other stakeholders.

In the future, CMS should examine ways that the agency can encourage and facilitate better patient matching. For example, CMS could encourage hospitals to use additional data elements to support matching—such as patients' email address—or better standards for existing information, such as address.

CMS could encourage hospitals to implement APIs that make all data elements in EHRs available for various purposes. ONC is expected to release regulations—as required by the 21st Century Cures Act—in the coming months to require that EHR developers have APIs that make all data elements within health records easily available. Once ONC finalizes the regulation, CMS should consider updating payment policies to require use of these APIs to further enhance interoperability for all data elements in EHRs. Such an approach would ensure that hospitals can use APIs for many purposes, including patient access to their records.

Finally, CMS could evaluate how commonly used data elements are formatted among different hospitals and encourage the use of standard vocabularies. For those standard terminologies that are widely used—though perhaps not uniformly among every hospital and health information technology system—CMS could consider whether and how to encourage their adoption.

Release of claims data incomplete

As part of CMS' efforts to make more data available to patients and researchers, Administrator Verma announced BlueButton 2.0, an expansion of an existing program that allows beneficiaries access to their Medicare claims data.[5] As CMS recognized in the proposed HIPPS rule, access to claims data could help beneficiaries better coordinate their care. Separately, CMS has also indicated it plans to make Medicare Advantage, Children's Health Insurance Program, and Medicaid claims data available for researchers.[6] Claims are especially useful for research because unlike other information sources, they contain data for nearly every encounter with the healthcare system for a specific individual. For example, claims information collected over many years may

[5] Greg Slabodkin, "CMS launches Blue Button 2.0 to free up claims data," *Health Data Management*, Mar. 22, 2018, https://www.healthdatamanagement.com/news/cms-launches-blue-button-20-to-free-up-claims-data.
[6] Greg Slabodkin, "CMS to release Medicare Advantage data to researchers for first time," *Health Data Management*, Apr. 30, 2018, https://www.healthdatamanagement.com/news/cms-to-release-medicare-advantage-data-to-researchers-for-first-time.

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contain data showing that a patient received a specific prescription drug, had surgery and visited the emergency department. Claims are already standardized for providers and payers, resulting in easier aggregation of information across the healthcare system; this characteristic has led to claims data being a valuable source of information for researchers to evaluate quality and safety.

CMS' efforts to have patients access their claims data and provide researchers with this information, while laudable, omits one critical element particularly important for the Medicare population. Currently, claims only indicate that a particular procedure was performed—for example, a total knee replacement—but not the brand and model of implant used. In parallel, the unique device identifier system developed by the Food and Drug Administration provides each medical device with a code corresponding to its brand and model. Adding the device identifier to claims can fill the gap, and provide patients, clinicians, and researchers with additional information on products used to sustain life and support care.

Incorporating device identifiers in claims can also generate savings. The Department of Health and Human Services Office of the Inspector General (OIG) has found that the failures of just seven types of cardiac implants cost Medicare $1.5 billion to treat affected patients, and an additional $140 million directly to beneficiaries in out-of-pocket costs.[7] OIG recommended the addition of device identifiers to claims to detect these problems sooner, saving lives and money. This policy also has support from the Medicare Payment Advisory Commission and other groups from across the healthcare system—including health plans, large hospital systems, clinical societies that represent physicians who implant these products, patient groups, and many other organizations. Adding device identifiers to claims has also generated bipartisan support in Congress. The private committee—called X12—responsible for maintaining the standard claims transaction used by Medicare, Medicaid and other health plans has issued draft recommendations to add device identifiers to claims as part of the next update to the transaction.

For CMS to effectively meet its objectives of ensuring that patients have access to their data—including from claims—and provide researchers with information to evaluate care, the agency should ensure that claims contain critical information on the products used, especially given that Medicare beneficiaries frequently receive implanted devices.[8] Consequently, we urge CMS to help further advance this commonsense policy by supporting the addition of device identifiers in the final X12 recommendation and adopting this change through rulemaking when the next version of the claims transaction are finalized.

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[7] Daniel R. Levinson, "Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices," Department of Health and Human Services Office of Inspector General, Sept. 2017, https://oig.hhs.gov/oas/reports/region1/11500504.asp.

[8] "New Medicare data available to increase transparency on hospital utilization," Centers for Medicare & Medicaid Services, June 1, 2015, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-06-01.html.

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Conclusion

CMS has indicated over the past several months that it will focus heavily on promoting the interoperability of EHRs and ensuring patients have access to their health data. The proposed changes in the HIPPS proposed rule marks an important step in ensuring that patients and clinicians have the data they need to inform care decisions—especially once additional progress is made on patient matching, effective use of APIs, and adoption of clinical data standards. Thank you for the opportunity to provide comments on the 2019 HIPPS proposed rule. Should CMS have any questions or if we can be of assistance, please contact me at 202-540-6333 or bmoscovitch@pewtrusts.org.

Sincerely,

Ben Moscovitch
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Appendix: Summary of Key Recommendations

Topic	Key Recommendations
Health Information Exchange Objective	• Consider how to support improved patient matching so health data are correctly exchanged across care facilities • Encourage hospitals to provide access to data through APIs to facilitate exchange • Work with ONC to provide use cases and examples of when to use certain document exchange templates • Evaluate expanding the categories of information and use of appropriate standards to facilitate automatic data reconciliation, and examine expanding reconciliation requirements in future payment rules
Provider to Patient Exchange Objective	• Consider expanding the categories of data available for provider to patient exchange beyond the CCDS in future payment rules
Public Health and Clinical Data Exchange Objective	• Support the use of standardized terminologies and data elements to facilitate EHR to registry interoperability
Request for Information	• Encourage standardizing demographic data used for patient matching or adding additional elements, such as e-mail address • Assess requiring the use of future ONC criteria for APIs to allow access to all data elements within a health record • Advance use of standardized terminologies for clinical data
Release of claims data	• Support the addition of device identifiers to claims in the X12 process and adopt the change through rulemaking