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June 28, 2021

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: 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 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program

Dear Administrator Brooks-LaSure,

Thank you for soliciting feedback on the Centers for Medicare & Medicaid Services (CMS)'s proposed regulations to update hospital payment policies and reporting programs. Health care continues to face challenges as it emerges from the COVID-19 pandemic, and CMS' fiscal year 2022 payment rule strikes the right balance between supporting hospitals and encouraging improvements to practices. We support providing flexibility during this upcoming fiscal year, but recommend that CMS consider opportunities to further strengthen the Medicare Promoting Interoperability program by addressing aspects of electronic health record (EHR) use that aid public health efforts, expand health information exchanges (HIEs), and improve patient safety.

The Pew Charitable Trusts is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of patient care. Pew's health information technology initiative focuses on advancing the interoperable exchange of health data and improving the safe use of EHRs.

The proposed rule updates payment policies for hospitals and seeks comment on the Medicare Promoting Interoperability program—which encourages health care facilities to use EHRs in meaningful ways. As proposed, the following health IT components in the rule would significantly improve how EHRs help inform public health agencies' activities, ensure patients receive safe and effective care, and automatically report data to authorities:

- **Proposed New Health Information Exchange (HIE) Bi-Directional Exchange Measure**
    - Pew supports the focus on bidirectionality and use of HIEs.
- **Modifications to the Public Health and Clinical Data Exchange Objective**
    - Pew supports making all public health measures required elements, and further recommends the following:
        - Increasing the weighting of the public health objective from 10 points to 20 points;
        - Strengthening the individual measures by closing the participation and attestation loopholes;
        - Mandating adherence to specific standards in partnership with the Office of the National Coordinator for Health Information Technology (ONC); and,
        - Specifying that reporting measures must also consider completeness of data.
- **SAFER Guides**

    - Pew supports the addition of the Promoting Interoperability program requirement for hospitals to annually attest to the Safety Assurance for EHR Resilience (SAFER) Guides; and,
    - Pew recommends two additional health IT safety measures for the Promoting Interoperability program: Health IT safety reporting for clinical decision support (CDS) dismissal rates for high-risk conditions and implementing a health IT hazard reporting process.
- **Requests for Information (RFI)**
  Pew is also submitting information in response to the following requests:
    - RFI on Additional Objectives or Measures Adopting Fast Healthcare Interoperability Resources (FHIR)-based Application Programming Interface (API) standards
    - RFI on a Patient Access Outcomes Measures
    - RFI on Closing the Health Equity Gap in CMS Hospital Quality Programs
        - Pew recommends the use of existing standards to collect demographics to ensure more complete data and also improve patient matching between systems.

Proposed Changes to the Medicare Promoting Interoperability Programs

Proposed HIE bi-directional exchange measure

CMS proposed a new measure within the Promoting Interoperability program to incentivize use of bidirectional exchange between health care organizations' EHRs and HIEs. This measure would provide an alternative to the current electronical referral measure set: Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information. Organizations may forgo reporting on the referral loop measures, and instead attest to the HIE Bi-Directional Exchange measure.

Bidirectional exchange means that data is shared between HIEs and EHRs, and that providers can both view and incorporate information into EHRs, ensuring that critical clinical data becomes part of the medical record, regardless of where a patient received care. Without these connections, health information will remain segmented, meaning providers may continue to struggle to access complete data—which can lead to medication errors and expensive duplicative testing, among other risks.[1]

As CMS stated in the proposed rule, the majority of the country is covered by an HIE, yet participation lags. Incentivizing connectivity with HIEs may help increase participation; as more health care organizations exchange data with HIEs, patients will have more comprehensive records and providers can access more complete information. Additionally, were HIEs to provide another reporting option to public health agencies for providers, these connections could serve a triad purpose. As the current COVID-19 pandemic demonstrated, integrated, comprehensive medical records are essential for ensuring the delivery of appropriate care and preventative measures. Pew appreciates CMS's efforts to encourage and increase participation in HIEs, and the agency should include this measure in the final rule as written.

Proposed Modifications to the Reporting Requirements for the Public Health and Clinical Data Exchange Objective

Gaps in public health data have hindered the exact actions needed to emerge from the COVID-19 pandemic and restart the economy. For example, epidemiologists have indicated that patients' contact information is missing in more than half of COVID-19 lab results, while demographic information, such as race and ethnicity, is absent in 85% of them.[2] Manual case reporting, or the non-electronic transmission of results through modalities such as faxes, also results in wide-spread under-reporting. The Centers for Disease Control and Prevention (CDC) estimates that, in some circumstances, as few as 1 in 10 reportable cases are sent to public health agencies after a medical encounter.[3] Additionally, from early COVID-19 vaccine reporting, data on race and ethnicity is present in only 51.9% of cases.[4] Without this information, officials cannot adequately track the spread of a public health threat or understand its impact on different communities.

Despite the vital importance of these data to stem the pandemic, public health data exchange was an optional component in CMS's Promoting Interoperability program in prior program years. Hospitals and providers could choose to report on two of six potential public health measures: electronic laboratory result reporting; electronic case reporting (eCR); immunization registry reporting; syndromic surveillance reporting; clinical data registry reporting; or public health registry reporting.

CMS's proposal to require public health data exchange reporting is an excellent step toward improving real-time, electronic data exchange from hospitals and providers to public health agencies. Pew supports the new requirement for electronic reporting for lab reporting, case reporting, syndromic surveillance, and immunizations. Electronic reporting for these use cases will help ensure public health agencies receive the data they need to act and keep communities safe.

In earlier years of the program, requiring reporting of several of the public health objective measures has clearly yielded major improvements. For example, when electronic lab reporting was required in Stage 2 of the Meaningful Use program, 92% of hospitals reported sending lab results electronically to public health agencies—compared to the 55% that reported doing so in the prior program stage, when electronic lab reporting was not yet a required measure.[5] Immunization reporting was also a required measure in Stage 2 of Meaningful Use.[6] As providers advanced from stage 1 to stage 2 over the course of several program years, reporting to the immunization registry measure increased by almost half.[7] With the program now requiring reporting for four use cases, electronic reporting to public health agencies can similarly grow across data types. Given the significance to current and future public health efforts, it is important for CMS to include these changes in the final rule.

Syndromic Surveillance Reporting Measure

Unlike lab and case reporting that focus predominantly on collecting patient-level identifiable information, syndromic surveillance helps public health authorities address population-wide hazards through data on symptoms, behaviors, or similar signs that may occur before a diagnosis. For example, syndromic surveillance can help CDC and state and local health departments track the emergence of influenza-like illnesses, monitor changes in the opioid epidemic, and help jurisdictions monitor health conditions following a natural disaster. These data can also help establish trends, such as outcome disparities among certain communities—for example, different racial and ethnic groups.

Syndromic surveillance reporting requires health care facilities to opt-in and implement an electronic solution. Many states do not mandate syndromic surveillance reporting; additionally, it remains an optional measure in CMS' payment programs. In instances where such reporting is a requirement, it is often only mandated for emergency departments and, less frequently, urgent care clinics. Inpatient hospitals are not required to report. As such, uptake of the electronic solution remains limited. The CDC's National Syndromic Surveillance Program (NSSP) receives data from approximately 70% of emergency departments across the country, representing 73% of the nation's emergency department visits.[8] However, data completeness varies nationally; for example, much of California does not report data, and in some states, only single counties or facilities report. These gaps in data make a national surveillance picture challenging to create and track.

Data from all emergency departments, urgent care clinics, and hospital inpatient admissions would provide important surveillance information to better inform public health officials of potential threats or early signs of a pandemic—and any facility that uses a certified EHR is able to use the electronic solution. While not all local or state public health agencies may have syndromic surveillance systems for hospitals to report to, CDC's NSSP is an option for any health care facility. Pew supports the proposed requirement for emergency departments to electronically report syndromic surveillance data. However, when finalizing the rule, CMS should also require reporting from hospitalists and urgent care providers to ensure more complete, comprehensive surveillance data.

Immunization Registry Reporting Measure

Vaccine data are stored in immunization information systems (IIS), also called immunization or vaccine registries. These systems provide consolidated records of an individual's vaccination history, along with clinical decision support about immunizations that are due or past due. Health professionals and clinicians rely on IIS to assist with assessing and evaluating a patient's current immunization status, and determining whether to administer a dose. For example, prior to administering vaccines, clinicians should check the relevant IIS for a patient's record to determine whether vaccines are needed, and, following administration, report immunizations that were given. At the population level, IISs provide aggregate data on vaccinations for use in surveillance and program operations, and in guiding public health action with the goals of improving vaccination rates, reducing vaccine-preventable diseases, and addressing vaccine-preventable disease outbreaks.

Immunization registries have existed for more than 25 years and have been a source of data for immunization records—from varying sources—long before EHRs were widely used. Increasingly, pharmacies, hospitals, doctor offices and other locations can both query information from IISs at the point of care and report data back into them.

There are currently immunization registries in all 50 states, five cities, the District of Columbia, and eight territories: a total of 64 systems. As of 2018, IIS captured 95% of the 0-6-year-old population and 80% of the and adolescent population age 11-17 years, but only 56% of adults over 19 years old.[9] As a result, major gaps exist in the use of these systems outside young children. However, reporting to IISs for all patients is often not a state-level requirement; likewise, there are no federal regulations or incentives for reporting data on all patients to jurisdictional IISs.

Because bidirectional exchange is a component of the optional public health requirements in EHR certification and in the Promoting Interoperability program, some EHRs have the capacity to accept and display data from IISs as well. Such integration reduces the number of systems that users need to use in order to determine current immunization status. However, not all EHRs have this functionality; those that do may not be widely implemented in practice. Such optionality creates gaps in data submission to IISs.

The COVID-19 pandemic has also illustrated the vital role IISs play in pandemic response. Real-time, complete data on all patients, regardless of age, is needed to aid the vaccination campaign. However, from early COVID-19 vaccine reporting, data on race and ethnicity is present in only 51.9% of cases. These gaps hamper the ability of public health authorities to identify and address disparities.[10] Requiring connections to IISs, and ensuring adherence to data standards, can help increase incoming data and improve its quality and completeness. Pew supports CMS' requirement for reporting to immunization registries, and should include this required measure in the final rule.

Electronic case reporting

For some disease conditions, health care providers are required to submit a case report to their state or local public health agency. Such reporting helps public health officials identify and detect early possible public health threats and community outbreaks; initiate case investigations; and implement public health containment and management strategies, such as mitigation or education. There are over 80 nationally notifiable conditions on the federal level, though states have the authority to include additional diseases. Reportable conditions typically include infectious diseases, such as hepatitis or sexually transmitted infections (STIs); food-borne illnesses; and other diagnoses requiring public health action, such as Lyme disease. Case reports contain clinical information, such as current symptoms; date of diagnosis; other comorbidities; and complete demographic information, including phone number. In particular, contact information is essential for connecting individuals to care or investigating disease outbreaks.

Today, providers often complete case reporting through manual methods, such as faxes, e-mails, or phone calls. The use of largely non-electronic forms of case reporting requires manual intervention from both providers and public health agencies: staff at a health care facility must fill out and fax a paper form, and public health officials must then manually enter data into surveillance systems. This method is outdated and can delay timely action. Paper-based reporting also magnifies the need for public health agencies to have follow-up calls with providers and patients to complete an investigation, as reports commonly lack important data elements. In structured interviews conducted in 2014 of ambulatory care providers in Indiana, some providers confirmed that they intentionally submit incomplete reports when they deem the missing information is unnecessary, resulting in additional investigative work for public health staff.[11]

To receive complete, real-time data, case reporting should move from manual, paper-based processes to electronic submission. Electronic case reporting enables near real-time data for public health agencies, while also saving time for providers and health care staff since the cases are automatically reported. As a result, public health officials can conduct case investigations faster and receive more accurate case counts, since the data is automatically sent to them through electronic triggers. Massachusetts, for example, analyzed manual case reporting for STIs compared to a pilot of an electronic reporting system and saw a 39% increase in reported chlamydia cases and a 53% increase in reported gonorrhea cases in a single year—likely the result of more complete reporting.[12]

To move away from paper-based methods and shift to electronic case reporting, two fundamental things need to happen: providers must have systems in place to trigger case reports automatically, and public health agencies must have the ability to receive them. For providers, recent advancements in EHRs have facilitated automatic case reporting without any additional, manual steps. Through the use of eCR Now, a project jointly run by the CDC and several public health associations, health care organizations can work with their EHR vendors to set up fully automated electronic case reporting for centralized processing and delivery to the appropriate public health agencies. Health care facilities can implement electronic COVID-19 reporting in as little as 3 days with most EHR vendors, and can use traditional Health Level 7 (HL7) interfaces or standards-based APIs.[13] Furthermore, due to needs brought about by the COVID-19 pandemic, all public health agencies can now receive electronic case reports for COVID-19 infections.[14] This functionality could be used beyond COVID-19 reporting, and provide an option for providers and health care facilities to meet the required electronic case reporting measure.

Electronic case reporting can revolutionize the data available to public health agencies, and the technology to do so exists today. CMS should require this measure in the final rule to initiate a more complete shift to electronic case reporting.

Electronic lab reporting

Certain laboratory results for reportable conditions, such as tuberculosis or STIs, are required to be sent from a medical lab (which could be a commercial lab, at a health care facility, or public health lab) to a public health agency, which then uses the information to support contact tracing, educate and refer the individual for appropriate care, and conduct population-level analyses to track disease hotspots and inform mitigation strategies. However, lab orders often contained limited demographic data and are submitted via paper-based systems (e.g. fax), hindering their timely use by public health departments. For example, authorities in Austin, Texas, received more than 1000 reports of positive COVID cases per day via fax, resulting in a 7-10 day delay before contact tracing could even begin.[15] Additionally, during the COVID-19 outbreak, one public health official in Ohio reported that their office received so may lab reports their fax machine stopped working.[16]

Improving laboratory reporting would hasten contact tracing efforts and promote real-time disease monitoring. However, accomplishing this requires the elimination of paper-based reporting and the inclusion of complete demographic data. All state health agencies have systems for receiving electronic lab results, which demonstrates that state capabilities are not a barrier.[17] However, existing connections would need to be updated to include additional demographic data—a solution that is technically feasible, but requires incentives for providers to adopt.

In the proposed rule, CMS incentivizes provider use of electronic lab reporting. However, when finalizing the rule, CMS should also promote adhering to standards in the exchange of laboratory data—both in the test order and the result—to ensure that public health officials receive the information they need. Currently, HL7 interface specifications do not require patient demographic information in either the order or the result. CMS can require inclusion of complete demographic data—as defined by ONC in the United States Core Data for Interoperability (USCDI), which is the standard data set EHRs are required to document and share—so that current interface specifications could be updated to ensure public health agencies receive complete, electronic data within lab results. This additional requirement within the lab reporting measure could ensure not only that results are shared electronically, but that the data is complete.

Recommendations on additional adjustments for the current Promoting Interoperability Public Health Objective

Public health authorities obtain data from health care organizations in four main ways: electronic case reporting, electronic lab reporting, syndromic surveillance, and sharing of vaccination data. While public health authorities rely on data from health care providers—as evidenced by the COVID-19 pandemic—major gaps remain in the timeliness and completeness of this data. Providers typically have the data public health agencies need within EHRs, and the technology exists to send the information using automated, standard mechanisms. However, not all providers avail themselves of electronic data exchange. The proposed updates to the Promoting Interoperability program will provide the incentive to providers to drive adoption of electronic data exchange and improve public health data for COVID-19 and future threats. However, CMS can go further to ensure that the data public health agencies receive is complete and accurate, and improve the measures to better quantify standard data exchange and support automatic measurement.

Pew is undertaking a process to identify more robust measures in efforts to automate reporting from EHRs or through the use of claims data. However, as this process will not be complete in time to update measures for the 2022 program year, there are several other ways, in addition to requiring the measures, to update the public health objective in the following ways for the 2022 program year:

- Increase the weighting of the public health objective from 10 points to 20 points;
- Strengthen the individual measures by closing participation and attestation loopholes;
- Mandate adherence to specific standards in partnership with ONC; and,
- Specify that reporting to measures must also consider completeness of data.

The following recommendations should also be implemented for the 2022 program year to ensure more complete, standardized data is sent to public health agencies. We are also consulting experts to determine more robust—and potentially automated—measures that could be used in the 2023 program year and beyond.

Recommendation 1: The weight of the public health objective should be increased to 20 points. Currently, the public health objective is worth 10 points out of a total of 100 in the program. The importance of data access to public health has been demonstrated throughout the pandemic; that should be reflected in the weighting of these activities. Higher weighting will ensure the objective is prioritized by providers, given the measures' importance to public health.

Recommendation 2: Strengthen the individual measures by closing participation and attestation loopholes. Currently the public health measures are attestation-based, allowing providers or hospitals to report through a simple "Yes/No" response. However, attesting "Yes" to one of the public health measures could be accomplished by registering with a local public health agency to establish a connection, or by a facility's implementation status; the hospital or provider does not need to be actively sending data to attest "Yes."

To ensure that hospitals and providers are sending necessary, real-time information to public health agencies, CMS should indicate that only active connections meet the attestation "Yes" for any of the four use cases. An active connection must mean that quality, standard data is being shared for the at least part of the reporting period. For all the use cases, sufficient local, state or federal capabilities exist to enable some level of reporting. For example, all states can accept electronic case reports and electronic lab reports. Where state or local health departments don't have syndromic surveillance capabilities, providers and health care facilities could report directly to CDC's NSSP. Lastly, all states have an IIS in place. Therefore, for each use case, every provider has some kind of electronic reporting option enabled by local, state or federal authorities, meaning this requirement need not pose a significant burden to providers.

Recommendation 3: Mandate adherence to specific standards in partnership with ONC. For each of these use cases, CMS should work with ONC to identify new standards where appropriate, and require adherence to existing ones. Where they exist—often as HL7 implementation guides—adherence to such standards should be required to meet the Promoting Interoperability measures. For example, electronic case reporting could be achieved through participation in eCR Now or by adhering to the HL7 CDA R2 eICR or FHIR eCR implementation guides, as referenced in ONC optional certification. For electronic lab reporting, ONC points to HL7 implementation guides that could be referenced by CMS. Regarding syndromic surveillance, HL7 has a 2019 implementation guide that could serve as a starting point. And, finally, IIS connections should be bidirectional, and follow the HL7 2.5.1 Implementation Guide for Immunization Messaging that are also referenced in ONC certification. In addition, CMS could reference use of certain vocabularies, such as SNOMED and LOINC, where appropriate.

Recommendation 4: CMS should specify that reporting must also be complete. In order to attest "Yes" to actively sending data to a public health agency for the four use cases, providers and hospitals must also attest that the connections send all of the necessary information as part of the established feeds. For example, electronic case and electronic lab reports must include phone numbers, patient address, and race/ethnicity data at a greater than 95% completeness (that percent, while high, can include the indication that the patient opted out of providing that data). Completeness of race and ethnicity data is critical to support health equity, both during a crisis like the COVID-19 pandemic and for other reportable conditions that pose longer-term challenges. Additionally, complete information on reporters, providers, performing facilities, and specimen type is integral to timely public health investigation and follow up activities. The USCDI can serve as a guidepost for the data that must be included. Attestations to the measures must confirm that they are sending complete data according to the percent selected, which can be verified with audits. The development of more robust measures could help assess compliance more easily.

SAFER Guides

CMS proposes a required measure to the Promoting Interoperability program that can encourage the safe use of EHRs. Safety is paramount as the layout, design, customization, and implementation of systems can contribute to medical errors. Studies analyzing patient safety events have found that numerous safety issues are associated with poor EHR usability, which can result in serious patient harm.[18] The proposed optional measure allows hospitals to attest to conducting a self-assessment of using the nine SAFER Guides—safety checklists developed by ONC—beginning in the reporting period in the 2022 program year.

EHR safety challenges can arise, in part, due to system usability, which refers to whether clinicians can efficiently and effectively use the technology. Usability challenges can result from the initial design of systems, how they are customized by facilities, unique workflows, user training, and other factors.[19] Usability-related safety problems can emerge due to confusing screens used to complete tasks, the need to develop workarounds, an overabundance of unnecessary alerts, and many other issues given the central role that EHRs increasingly have in helping clinicians order procedures, review health information, and obtain clinical decision support.[20]

Pew supports CMS' proposal to use the Promoting Interoperability program to encourage the adoption of strategies to improve the safety of EHRs, and encourages its inclusion in the final rule. Despite their ability to assist with the safe implementation of EHRs, SAFER Guide uptake has been low; out of eight organizations surveyed, only 25 of 140—or 18%—of the recommendations were fully implemented.[21] Pew supports CMS' approach to use the Promoting Interoperability program—starting with the required attestation measure—to encourage health care providers to adopt strategies, such as the SAFER Guides, to improve the safety of EHRs and reduce medical errors. In future program years, CMS should include additional measures related to EHR safety, and provide bonus points for reporting these additional measures.

Additional EHR safety measures

The incorporation of a SAFER measure in the Promoting Interoperability program is an excellent start to ensuring safety remains a priority for hospitals. However, CMS should adopt additional EHR safety measures that could provide additional Promoting Interoperability payments.

Pew and the MedStar Health National Center for Human Factors in Healthcare published a report that informed these measures through ten health IT safety best practices for hospitals. Two of these best practices focused on CDS tools, which are tools that clinicians use to guide their care, and hazard reporting, or the process of documenting and sharing information on actual or potential safety issues. Pew developed two specific health IT safety measures for the Promoting Interoperability Program: Health IT safety reporting for CDS dismissal rates for high-risk conditions, and implementing a health IT hazard reporting process.

To help identify safety risks, such as clinicians overriding or dismissing alerts, EHRs can monitor the use of CDS tools.[22] This monitoring could be used as a specific measure to track how often clinicians are overriding or dismissing alerts for high-risk clinical scenarios. The measure for reporting dismissal rates for high-risk conditions calls for at least one EHR reporting period (90 days), and requires that the eligible hospital, critical access hospital (CAH), or dual-eligible hospital has a process in place to monitor how CDS tools are being used by clinicians and identify when they are being overridden for high-risk conditions. For this measure, the numerator is defined as the number of times CDS was dismissed when confronting a high-risk clinical scenario, and the denominator is the total number of times CDS was displayed to the clinician for high-risk clinical scenarios.

CMS should also include a measure for hazard reporting in future program years. For hazard reporting, facilities should have a process for reporting health IT hazards that staff may encounter during their work, and employees should also understand how to report events using the system. Specifically, for at least one EHR reporting period (365 days), the eligible hospital, CAH, or dual-eligible hospital must have a process in place to receive electronic health IT hazard reports from staff and let staff know that they have been received and whether a safety review is underway, has been completed, or been deemed not to be necessary. For this measure, the numerator is defined as the total number of hazard reports that were received and either had a safety review underway or completed, or where one was determined not to be necessary through the safety reporting process within the EHR reporting period, and the denominator is the total number of hazard reports received through the safety reporting process within the reporting period.

The National Quality Forum has also endorsed an additional measure that uses audit or log file data—the digital record of what happens within an EHR, such as the ordering of a medication and the retracting of that order—related to when clinicians order medications for the incorrect patient.[23] Implementation of this measure provides another means to improve safety within an EHR. Pew recommends providing bonus points for facilities that implement the retract and reorder measure.

Pew appreciates CMS including the SAFER attestation measures in the Promoting Interoperability program. The CMS proposal will assist hospitals with conducting self-assessments of their medical record systems, prioritizing processes for the safe use of health IT, and improving patient safety. Further, as CMS continues to offer and examine how to incorporate EHR safety into the Promoting Interoperability program, Pew's measure recommendations provide additional steps that health care providers can take to reduce harm associated with the use of technology.

Request for Information

CMS is soliciting comments on two RFIs related to APIs. The first is related to aligning Promoting Interoperability Program measures with FHIR API functionality, and the second seeks comments around patient access via APIs. Broadly, Pew supports the agency's efforts to use FHIR-based APIs to improve interoperability, reporting, and patient access.

Promoting Interoperability alignment with FHIR

CMS specifically asks "to what degree are stakeholders currently using or interested in using APIs to exchange information in support of the numerator/denominator measures under the HIE objective." APIs have been implemented to support patient access to data; however, they have been underutilized for other use cases, such as provider exchange and CDS tools.

Currently, health care facilities often exchange documents containing health data using other mechanisms, such as direct messaging or manual methods like faxes. This practice enables health care organizations to share information contained in a document, which could include a complete summary of care of the patient, or diagnostic images. However, this approach can lead to clinicians receiving more information than needed, which adds time reviewing unneeded data to locate the specific information needed for care. For example, a physician may need to know what medications a patient has taken or any allergies they may have. Instead of receiving that specific data, they may instead receive a lengthy document with unneeded information on blood pressure measurements, laboratory test results, or other background that is not needed. API-based exchange could improve communication between providers by segmenting information for more targeted exchange and allowing for more timely and easier access to that information. Rather than receiving the lengthy full record, a provider can receive just the information they need, such as current medications or recent imaging results.

ONC is developing a framework for the Trusted Exchange Framework and Common Agreement (TEFCA) which creates a series of requirements to enable the exchange of information across health care organizations. Initially, TEFCA will focus on the document-based exchange processes health care facilities currently use. In addition to documents-based processes, CMS should work with ONC to take the API infrastructure the agencies are already developing—as required by existing regulations—and examine how TEFCA could advance API-based data exchange among providers, enabling the transmission of only those data elements that patients and clinicians need and moving away from document-based exchange.

FHIR and public health
CMS is also looking for comments on "promising FHIR-based approaches to public health reporting use cases that ONC and CMS should explore for potential future consideration as part of the Promoting Interoperability program and the ONC Health IT Certification Program."

The United States is finally emerging from its second year of a pandemic that has exposed deadly gaps in our public health data infrastructure. However, COVID-19 is just the latest public health threat highlighting these deficiencies, and it will not be the last. Alongside COVID-19, public health authorities still combat vaping-related illnesses, chronic diseases such as diabetes and hypertension, and HIV, among other challenges. A strong public health infrastructure can help address these and future threats. Case reporting is one of the five key pillars of the CDC's Data Modernization Initiative, and core to the public health data infrastructure. As discussed in the case reporting section above, methods exist today to exchange needed information automatically from the EHR to public health agencies. Incentives are needed to encourage timely and complete transmission of data from health care to public health in the form of an eCR that is integrated into the provider workflow and automated.

A transition to FHIR-based eCR is both necessary and feasible, given recent advances fueling electronic data exchange in health care and the prominence of eCR in the CDC Data Modernization Initiative. In fact, the shift to eCR implementation has already begun, with over 7,000 facilities now sharing COVID-19 case reports electronically. The Association of Public Health Laboratories (APHL) has enabled APIs to pull data from EHRs to complete care reporting; however, most public health departments are not yet able to receive that information, meaning APHL must first translate it into HL7. CMS should consider offering incentives for public health agencies to update to systems that can accept API-based data exchange.

Patient access RFI
CMS is also seeking comment on useful ways to measure patients' access to their electronic health information using health IT methods such as patient portals and/or third-party applications.

Under prior regulations, CMS required health plans to make patient data—such as claims information—available to each individual via an API. Those rules were designed to equip individuals with their own health records to be able to take ownership of their care, such as by using an application to aggregate and analyze medication lists. Under another rule, CMS proposed that certain health plans—such as those that provide coverage under Medicaid and through federally-facilitated exchanges—submit quarterly metrics on whether patients are using APIs to obtain their health records. Each payer would need to report on the total number of unique patients that use APIs to download their records and the number of individuals that do so more than once. The latter metric would help ascertain whether individuals more regularly check their data and routinely incorporate the information into their care.

As the purpose of API-focused efforts is to equip patients with their records, collecting data on these metrics would help determine how widely that occurs. Recent research suggests that standard APIs are still being integrated into health care and have not yet been broadly adopted. One study found that approximately 10% of patients access their data, with only 1 percent doing so via an API. Given low reported usage of APIs, CMS rightfully identified metrics to measure their use.[24] Pew conducted targeted interviews with hospital representatives on their API usage and one expressed that while they had implemented a patient access API, they were not advertising that functionality to their patients. There are many other potential reasons for low uptake, and CMS is right to look for ways to measure how patients are accessing their information.

However, the proposal should go further in two ways. First, research released earlier this year examined the characteristics of patients using APIs to access their information and found they are most commonly male, young, and English-speaking.[25] Therefore, a singular focus on API use may inadvertently exacerbate care disparities for older and minority populations. To assess whether that trend continues, CMS should ensure that metrics for API use focus not only on how many patients are using APIs to access their data, but also the characteristics of those populations, such as race and gender. In the final rule, CMS should therefore consider additional reporting on API use by gender, race, ethnicity, age, income, primary language and other factors that could assess whether some patients will be left behind. This information could inform subsequent rulemaking from CMS to ensure that its policies don't exacerbate disparities.

Second, CMS should ensure that the metrics are made public. Having data on API use could help researchers, health plans and app developers create solutions to ensure that all patients know they can, and have, the ability to download their health records.

Conclusion

The COVID-19 pandemic highlighted gaps in data exchange that limited the effectiveness of public health action and failed to make the most of existing technologies. Through the proposed updates to the Promoting Interoperability program, CMS would help drive bi-directional use of HIEs, increase adoption of electronic reporting to public health agencies, and enhance patient safety through attestation to the SAFER Guides. Pew supports the requirement that hospitals and providers have active, electronic connections to public health agencies for case reporting, lab reporting, syndromic surveillance, and immunization information systems. Further, these connections should follow national standards and send all of the data elements that public health officials need—such as phone number, address, race, and ethnicity—to conduct contact tracing, investigate cases, assess disparities, and track the efficacy of treatments or vaccine distribution.

When the program required lab reporting and immunization registry participation in prior years, connections increased dramatically. Promoting Interoperability could provide the incentive needed to spur national adoption of public health data exchange, safe health IT practices, and increase adoption of APIs. Finalizing these requirements will ensure that providers and public health agencies are exchanging vital data needed for the current pandemic response, safely using health IT, and help spur adoption of tools that could provide data more efficiently for patient care and for future health crises. The cause for such action has never been clearer.

Should you have any questions, or if we can be of assistance, please contact Molly Murray, senior manager, health information technology at The Pew Charitable Trusts, at 202.770.5376 or mmurray@pewtrusts.org.

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