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Meena Seshamani, MD, Ph.D, Deputy Administrator and Director of the Center for Medicare Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements. **Docket number CMS-2021-0119, file code CMS-1751-P.**

Dear Dr. Seshamani:

Thank you for soliciting feedback on the Centers for Medicare & Medicaid Services (CMS)'s proposed regulations to update the physician fee schedule and related Medicare requirements. Health care continues to face challenges as the country emerges from the COVID-19 pandemic, and the importance of high-quality data remains paramount. The Pew Charitable Trusts supports providing flexibility during this upcoming fiscal year and recommends that CMS considers opportunities to further strengthen the Medicare Promoting Interoperability program by addressing aspects of electronic health record (EHR) use that aid public health efforts, expand adoption and use of application programming interfaces (APIs), and improve patient safety. While the FY2022 proposed rule makes significant strides to improve data exchange and safety—specifically with requiring electronic case reporting, immunization registry reporting, and reporting on health IT safety—several gaps should be addressed before finalizing.

The Pew Charitable Trusts (Pew) 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 programs for providers and seeks comment, among other topics, on the Medicare Promoting Interoperability program—which encourages health care facilities to use EHRs in meaningful ways, such as electronically prescribing medications or providing patients with electronic access to their records. As proposed, the following health IT components in the rule would significantly improve how EHRs help inform public health agencies' activities, help ensure patients receive safe and effective care, and make it easier to automatically report data to authorities:

1. **Modifications to the Public Health Objective within the Promoting Interoperability program:**
 - Request for Information (RFI) Regarding the COVID-19 Vaccination by Clinicians Measure:

- Pew supports the inclusion of a COVID-19 vaccination by clinician measure within the quality measure set of the Merit-based Incentive Payment System (MIPS).
 - Pew supports making electronic case reporting and immunization registry reporting required elements, and further recommends the following:
 - Requiring submission of the syndromic surveillance measure in addition to case reporting and immunization registries, which will better align with the Promoting Interoperability requirements finalized as part of CMS’ Inpatient Prospective Payment Systems (IPPS) rule;
 - 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.
- 2. Safety Assurance for EHR Resilience (SAFER) Guides:**
 - Pew supports the addition of the Promoting Interoperability program requirement for hospitals to annually attest to the SAFER Guides.
- 3. Requests for Information (RFI):**
 - Pew is also submitting information in response to the following requests:
 - RFI on advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs;
 - RFI on Closing the Health Equity Gap in CMS Hospital Quality Programs;
 - RFI on additional objectives adopting FHIR®-based API standards; and,
 - RFI on patient access outcomes measures.

Proposed Changes to the Medicare Promoting Interoperability Programs

Request for Information Regarding the COVID-19 Vaccination by Clinicians Measure

CMS proposed the inclusion of a COVID-19 vaccination by clinicians measure within the quality measure set for MIPS. The measure would assess the percentage of patients over 18 who have completed the COVID-19 vaccination series during the measurement period. The exceptions for this measure include patients in hospice care, patient contraindication, or situations where lack of vaccine availability still exists.

Given the necessity of understanding vaccination rates to inform public health actions, Pew supports the inclusion of this measure within the MIPS quality measure set. We encourage CMS to include in the measure description that physicians can work with their regional Immunization Information System (IIS), or immunization registry, to ensure they are sending and receiving immunization data. Because many patients received COVID-19 vaccinations outside of their physicians’ offices—including pharmacies or mass vaccination sites—bidirectional connections between EHRs and immunization registries will ensure that physicians are reporting complete and accurate data for all patients.

Proposed Changes to the Provide Patients Electronic Access to their Health Information Measure under the Provider to Patient Exchange Objective

CMS updated the “Provide Patients Electronic Access to their Health Information” measure to remove any prior mention of time-limited access. The measure now ensures that patients will have continued access to their electronic health information using any application of their choice, as long as the

application meets API technical specifications. Pew agrees with the measure's update, as a survey conducted for Pew in June 2020 demonstrated that 81% of adults support increased access to health information for patients and providers.¹ Further, 61% of respondents stated that they wanted to be able to access their health information via apps or an online patient portal.²

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 demographic information, such as race and ethnicity, is absent in 85% of COVID-19 lab results.³ Manual case reporting, or the non-electronic transmission of results through modalities such as faxes, also results in widespread 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 medical encounters.⁴ Additionally, from early COVID-19 vaccine data, data on race and ethnicity was present in only 51.9% of reports.⁵ 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 within the Quality Payment Program (QPP) in prior program years. Providers could choose to report on two of five potential public health measures: electronic case reporting (eCR); immunization registry reporting; syndromic surveillance reporting; clinical data registry reporting; or public health registry reporting.

CMS's proposal to require electronic case reporting and immunization registry 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 these measures, as electronic reporting for these use cases will help ensure public health agencies receive the data they need to act swiftly and implement the best measures to keep communities safe.

The pandemic demonstrated the need for additional data to be shared electronically with public health agencies. Electronic lab reporting is vital to contact tracing and identifying hot spots for outbreaks both of which are crucial activities for stopping the spread of any infectious disease; accordingly, electronic lab reporting was required in the final IPPS rule. However, many outpatient providers utilize external laboratory vendors for lab testing and perform limited point-of-care tests (POCTs) in-house. While there may be a relevant future measure related to electronic reporting of POCT results—particularly for COVID-19, influenza, or other infectious diseases—at this time, electronic lab reporting should not be required within the public health objective for physician reporting, due to its limited applicability to the covered practitioners.

However, some outpatient physicians, such as those who practice at urgent care facilities, have meaningful syndromic surveillance data that would benefit public health agencies. Syndromic surveillance reporting provides public health officials with data that can help create situational awareness before they become crises. Further, syndromic surveillance is a required measure in the Promoting Interoperability Program within IPPS, and discrepancies in reporting between the programs could introduce confusion and unnecessary variability.

In earlier program years, required reporting of several of the public health objective measures 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.⁶ Immunization reporting was also a required measure in Stage 2 of Meaningful Use.⁷ 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.⁸ If the program required reporting for case reporting, immunization registries, and syndromic surveillance, electronic reporting to public health agencies could continue to grow across data types. Given their significance to current and future public health efforts, it is crucial for CMS to include these changes in the final rule.

Immunization Registry Reporting Measure

Vaccine data are stored in IISs, 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 IISs 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; following administration of any that were, they should also report which immunizations were given. At the population level, IISs provide aggregate data on vaccinations for use in surveillance and program operations, and can help guide public health action to improve vaccination rates, reduce the prevalence of vaccine-preventable diseases, and address any outbreaks that may occur.

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 an IIS at the point of care and report data back into them.

There are currently a total of 64 immunization registries across all 50 states, five cities, the District of Columbia, and eight territories. As of 2018, IISs captured 95% of the 0-6-year-old population and 80% of the 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 access in order to determine an individual's immunization status. However, not all EHRs have this functionality, and 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 and target outreach to audiences with lower uptake. However, from early COVID-19 vaccine reporting, data on race and ethnicity is present in only 51.9% of cases.¹⁰ These gaps hamper the ability of public health

authorities to identify and address disparities. Requiring connections to IISs, and ensuring adherence to data standards, can help increase the amount of incoming data and improve its quality and completeness. Pew supports CMS' requirement for reporting to immunization registries, and the agency 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 tuberculosis, Legionnaire's, and Lyme disease. Case reports contain clinical information, such as an individual's 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 manual web entry, faxes or phone calls for individual cases. The use of largely non-electronic forms of case reporting is burdensome for both providers and public health agencies; staff at a health care facility must fill out and fax a paper form or enter complex data for each patient outside of their EHR systems, and public health officials must then manually enter data into surveillance systems. This method is outdated and can delay timely action, including case investigation or connecting individuals to care. Paper-based reporting also magnifies the need for public health agencies to conduct follow-up calls with providers and patients to complete an investigation, as reports commonly lack important data elements. In structured interviews conducted with ambulatory care providers in Indiana in 2014, 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 or 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 case reports are automatically triggered and 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 the impact of 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—an increase that was likely the result of more complete reporting, which could allow public health agencies to recognize and respond to an ongoing public health crisis.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 with 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 reporting in this pandemic, and provide an option for providers and health care facilities to meet the required electronic case reporting measure.

Electronic case reporting can dramatically expand the data available to public health agencies and reduce the burden on providers, 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

Laboratory results for certain reportable conditions, such as tuberculosis or STIs, are required to be sent from a medical lab (which could be a commercial lab, one situated at a health care facility, or a public health lab) to a public health agency, which then uses the information to trigger case investigation, support contact tracing, educate and refer the individual for appropriate care, and conduct population-level analyses to track disease hotspots and inform mitigation strategies.

Requiring electronic laboratory reporting—and ensuring that reports contain complete data—would hasten contact tracing efforts and promote real-time disease monitoring. However, many outpatient physicians do not have in-house laboratories, and instead use external commercial laboratories. These laboratory facilities are then required—by state law—to report results to public health agencies, and regulated by CMS through the Clinical Laboratory Improvement Amendments, or CLIA. All state health agencies have systems for receiving electronic lab results, which demonstrates that state capabilities are not a barrier.¹⁵

In the proposed rule, CMS does not include a measure for electronic lab reporting. Given the limited applicability to the physicians covered under this rule, this is appropriate. However, CMS may consider in future program years a measure that tracks the electronic reporting of results from POCTs performed in-office by outpatient physicians.

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 or public health emergency. These data can also help establish trends, such as outcome disparities among certain communities, such as 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, and 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. 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.¹⁶

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, in addition to urgent care clinics, would provide important surveillance information to better inform public health officials of potential threats or early signs of a pandemic and provide improved situational awareness/tracking trends across the population during large outbreaks—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 or appropriate provider. For states that can accept syndromic surveillance data, Pew recommends CMS encourage public health agencies to develop a prioritization methodology for onboarding new reporters, including urgent care providers. Such prioritization could consider visit volume or geographic distribution. In IPPS, CMS required emergency departments to share syndromic surveillance data; CMS should also require urgent care providers to electronically report syndromic surveillance data to public health agencies.

Pew 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 critical data within their EHRs that public health agencies need, and the technology exists to send the information using automated, standard mechanisms. However, not all providers avail themselves of electronic data exchange. The above recommended changes to the Promoting Interoperability program will provide the incentive to providers to increase electronic data exchange and help improve the amount of public health data available to respond to COVID-19 and other future threats. However, CMS can go further and 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 three measures discussed above (case reporting, immunization registry reporting, and syndromic surveillance), to update the public health objective in the following ways for the 2022 program year:

- Align—where appropriate—the Promoting Interoperability programs across IPPS and this proposed rule and require three public health reporting measures: case reporting, immunization registry reporting, and syndromic surveillance;
- 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 public health objective should require reporting for three measures: case reporting, immunization registry reporting, and syndromic surveillance. The importance of each of these measures are outlined above; additionally, alignment between Promoting Interoperability programs should be a goal of CMS in order to eliminate confusion and streamline reporting for both hospitals and providers.

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 make clear that only active connections meet the requirements to attest “Yes” for any of the three use cases. An active connection must mean that quality, standard data is being shared for 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. 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 in order 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. 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 also be complete.* In order to attest “Yes” to actively sending data to a public health agency for the three use cases, providers must also attest that the connections send all of the necessary information as part of the established feeds. For example, electronic case reports must include phone numbers, patient address, and race/ethnicity data at a level 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 investigations 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.¹⁷ The proposed optional measure allows hospitals and physicians 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.¹⁸ 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.¹⁹

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. Additionally, CMS finalized the addition of this proposed safety measure in the Promoting Interoperability program within the Hospital Inpatient Prospective Payment Systems final rule. In order to ensure consistency between CMS programs, the inclusion of the same rule should also be finalized as part of the Physician Fee Schedule.

Despite their potential to offer support for 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.²⁰ 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.

Pew appreciates CMS including the SAFER attestation measures in the PI program. The CMS proposal will assist physicians with conducting self-assessments of their medical record systems, prioritizing processes for the safe use of health IT, and improving patient safety.

Requests for Information

Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs RFI

CMS solicited feedback on several areas related to shifting quality measures within MIPS to a digital platform using FHIR-based APIs. While Pew does not have specific recommendations on the digital quality measures at this time, our research shows the benefit of advancing the use of APIs. These interviews demonstrated provider and health care organizations' interest in the use of APIs that have a

clear value proposition. A reduction in reporting burden would provide clear value to providers and health care organizations and incentivize adoption of API-based quality reporting; additionally, using APIs could allow data from multiple providers to be included in measures, resulting in more accurate and complete reporting. However, we also learned from these interviews that provider and patient uptake of APIs remained minimal. Due to this, Pew recommends piloting the shift to digital quality measures with health care organizations that have participated in the early adoption and implementation of APIs.

Closing the Health Equity Gap in CMS Hospital Quality Programs RFI

CMS asked for comment regarding ways to advance health equity through improved data collection and analysis. Specifically, they requested information on (1) future potential stratification of quality measure results by race and ethnicity, and (2) improving demographic data collection. In order to provide disaggregated data analysis from quality measure reporting, the first step must be improving the collection and sharing of complete demographic data, including social determinants of health. COVID-19 vaccination data reporting has demonstrated current gaps in the collection and sharing of data on race and ethnicity; these elements were missing from 20% of CDC reports from December 2020 through May 31, 2021.²¹ However, as CMS states in this RFI, certified EHRs are required to be able to collect and share race and ethnicity information as part of USCDI. While not part of the required version of USCDI, social determinants of health data elements are also now part of the most recent version of this data set, and EHR vendors can choose to update their systems to collect and share these additional data elements. Social determinants of health can be essential information for providers and others when treating patients who face socioeconomic challenges or other barriers to care, and could provide valuable information to CMS on how such factors affect quality of care and patient outcomes.

Additional demographic data elements can also improve patient matching. Patient matching, or the ability to accurately link each individual's records from multiple places of care and different systems, remains a perennial problem in health care, and the pandemic has exacerbated this problem. Expanding the data elements collected, and incorporating them into patient matching algorithms, could help reduce matching errors. For example, research published in 2017 showed that email addresses are already being captured in more than half of patient records.²² The documentation of email is likely higher today, given the adoption of patient-facing tools, like portals, that often require emails to register.

Pew recommends collecting and reporting data on patients' primary language, in addition to other demographic elements. To ensure that race, ethnicity, and language data are appropriately collected and standardized, CMS should recommend compliance with the Agency for Healthcare Research and Quality's recommendations for improving demographic data collection across the health care system.²³ We further suggest that CMS work with CDC to monitor the collection of race, ethnicity, and language data for unintended consequences, and ensure compliance with CDC's "Policy on Public Health Research and Nonresearch Data Management and Access," which aims to protect privacy and confidentiality concerns and prevent any stigmatization of racial and ethnic minority populations.²⁴

CMS could help improve match rates by recommending an expanded set of demographic data elements be consistently documented—such as email address, mother's maiden name, or insurance policy identification number, in addition to race, ethnicity, sexual orientation and gender identity, and language preference. Such an expanded data set could help improve patient matching rates, as well as provide better, more complete information on patients and population to identify and address health disparities.

Request for information on additional objectives adopting FHIR®-based API standards

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 essential for the care they seek to provide. 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 will create 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 those 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. 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.”

COVID-19 is just the latest public health threat highlighting deficiencies in our public health data infrastructure, but it will not be the last health crisis the country faces. Alongside COVID-19, public health authorities still combat challenges such as vaping-related illnesses, chronic diseases such as diabetes and hypertension, and HIV. 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 electronic case report that is integrated into the provider workflow and automated.

A transition to FHIR-based electronic case reporting is feasible, given recent advances fueling electronic data exchange in health care and the prominence of electronic case reporting in the CDC Data Modernization Initiative. In fact, the shift to electronic case reporting 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.

Lastly, public health agencies are not financially incentivized to update current systems to be able to accept incoming FHIR-based APIs. While incentivizing providers and hospitals to adopt these advanced technologies for data exchange is important, it does not address the entirety of the problem. Many public health agencies do not have the resources—financial or human—to update or implement systems that are capable of interfacing with FHIR-based APIs. In order to accelerate the trend towards API-based public health data exchange, it is important to work with CDC and state public health agencies on system upgrades and adoption of new technologies.

Request for information on patient access outcomes measures

CMS is 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 allow them 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 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.²⁵ Pew conducted targeted interviews with hospital representatives on their API usage; 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.²⁶ 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 might 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 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 increase adoption of electronic reporting to public health agencies and enhance patient safety through attestation to the SAFER Guides. Pew strongly recommends that CMS require reporting for three public health use cases—case reporting, immunization registries, and syndromic surveillance—to ensure consistency across Promoting Interoperability programs, as well as to encourage providers to prioritize the implementation of active, electronic connections to public health agencies. 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 and safely using health IT systems, as well as help spur adoption of tools that could efficiently provide data to support patient care and address future health crises. The need 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 Project at The Pew Charitable Trusts, at 202.770.5376 or mmurray@pewtrusts.org.



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