THE PEW CHARITABLE TRUSTS

2005 Market Street, Suite 1700 215.575.9050 Phone
Philadelphia, PA 19103-7077 215.575.4939 Fax

901 E Street NW, 10th Floor 202.552.2000 Phone
Washington, DC 20004 202.552.2299 Fax
www.pewtrusts.org

January 4, 2021

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., S.W.
Washington, DC 20201

Re: Revisions to Promote Patient's Electronic Access to Healthcare Information and Improve Interoperability for Medicare and Medicaid Participating Providers and Suppliers (CMS-9123-P)

Dear Administrator Verma,

Thank you for soliciting comments on the Centers for Medicare & Medicaid Services (CMS)'s proposed rule that will improve the electronic exchange of health care data among payers, providers, and patients. The proposed rule addresses a longstanding congressional priority: ensuring that patients and clinicians have individuals' complete health history and other information they need to improve medical decision-making and the coordination of care. Once finalized, this rule will equip patients with information they need to be more involved in their care, ensure that the federal government is measuring the effectiveness of policies to spur data exchange, and codify existing regulations to simplify future rulemaking.

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 and improving public health. Pew's health information technology initiative focuses on advancing the interoperable exchange of health data and improving the safe use of electronic health records (EHRs).

The CMS proposed rule builds on two recent regulations finalized in May: the agency's Interoperability and Patient Access final rule as well as the 21st Century Cures Act rule on Interoperability, Information Blocking, and Health IT Certification Programs from the Office of the National Coordinator for Health Information Technology (ONC), which oversees EHRs.

Building on those rules, much of this new proposed regulation advances the use of standards-based application programming interfaces (APIs), which are tools that allow two systems or software applications to communicate with each other. APIs are the backbone of the modern internet. These tools allow websites to aggregate flight information, track personal financial habits, and display social media posts in real time. Once standard APIs are used more robustly in health care, they can help fuel data exchange more broadly and help EHRs achieve their promise in making care more safe, coordinated, and efficient.

Through this proposed rule, CMS takes key steps to advance interoperability by:

- Implementing metrics for measuring the use of APIs, which should be expanded and made public;
- Collecting a privacy attestation from apps to ensure patients know how their data will be used, an approach that reflects patient preferences;
- Codifying interoperability specifications into CMS policies to streamline future rulemaking;
- Giving patients access to data about prior authorization decisions; and
- Requesting comment on how to support data exchange related to social factors.

Collect and publish robust metrics on API use

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. In this proposed rule, CMS would require certain health plans—such as those that provide coverage under Medicaid and through federally-facilitated exchanges—to submit quarterly metrics on whether patients are using APIs to obtain their health records. Each payer would 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 incorporate the information routinely 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. As standard APIs are still new to health care, recent research suggests they are not broadly adopted.[1] One study found that approximately 10% of patients access their data, with only 1% of that number doing so via an API. Given low reported usage of APIs, CMS rightfully identified metrics to measure use.

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.[2] Therefore, the focus of CMS policy on API use may inadvertently exacerbate care disparities for minority populations. To assess whether that continues to occur, 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 require reporting on API use by gender, race, ethnicity, age, income, 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.

Implement privacy attestation for APIs that reflect patient preferences

When patients use APIs to download their health records onto personal devices, the information may lose some privacy protections. In many cases, provisions from the Health Information Portability and Accountability Act (HIPAA) no longer apply, and instead privacy is governed by the terms and conditions of the app itself. To address this issue, the proposed rule requires health plans to collect certain privacy attestations from each app used by patients. Through the API, apps used by patients would attest to whether it has:

- A publicly available privacy policy that plainly states how the beneficiary's information is accessed, shared, or sold;
- A requirement for express consent from a beneficiary before their health information is accessed, exchanged, or used, including receiving express consent before health information is shared or sold;
- If the app will access other data on the device, such as location; and
- A policy for how a beneficiary can discontinue app access to their data.

Within 24 hours of requesting the attestation, the patient must be informed of the attestation status- positive, negative, or no response, with a clear explanation of what each means. If the beneficiary does not respond in the next 24 hours, the API connection will go forward to download the records. This potentially introduces a 48 hour delay in patients accessing their information.

This provision mirrors concerns recently unveiled in a nationally representative Pew poll of more than 1200 Americans about privacy in relation to health data access. While individuals surveyed overwhelmingly supported access to their data and the exchange of information among health care providers, many respondents indicated significant privacy concerns when notified that HIPAA would no longer apply to their data. For example, 62% of respondents said they were either extremely or very concerned about the privacy of their data when not covered by federal privacy laws, such as HIPAA. Most respondents were comfortable with apps that had been either approved by an independent certification board or by their providers, with only 15% indicating comfort with apps that had been not be preapproved in some way. These results demonstrate that most Americans seek some assurance that their data is in safe hands.

CMS' proposal provides an opportunity to give patients more information about how apps will use their data. However, disclosure may not be sufficient as privacy policies are often difficult to understand and few people read them.[3] News reports of health apps selling data, sometimes to employers, have made patients wary and uncomfortable.[4] The waiting period may also inadvertently introduce an additional burden on patients accessing their information—and CMS should ensure that the delay does not hinder the ability for individuals to promptly obtain their information. CMS should closely monitor whether this waiting period approach results in patients not accessing their data and, if necessary, require additional steps of health plans to expedite the app approval process. For example, once an app has already provided privacy attestations to the health plan for a single patient, that same attestation could be used for future patients—obviating the need for the first 24 hour waiting period (so long as this occurred within a short enough time-span or other assurances from the app to mitigate the risk of privacy policies changing).

As the federal government—including ONC and CMS—examine further opportunities to address these privacy concerns, we encourage you to assess recent private sector attempts to mitigate risks and data on whether they have been successful. For example, Apple has instituted a "privacy nutrition panel" to help consumers understand how different apps are using data.[5] In parallel, the CARIN Alliance—a coalition of more than 60 electronic health record (EHR) vendors, consumer technology companies, application developers, and health care providers—proposed a voluntary code of conduct for handling patient health care data shared through APIs.

Codify ONC-designated standards to promote greater interoperability writ large

While CMS focuses primarily on payment policies, ONC has authority to designate the necessary standards that can be used for data exchange and mandate their use in EHRs For example, as part of the 21st Century Cures regulations finalized earlier this year, ONC specified the requirements for APIs. Those requirements included both use of the Fast Healthcare Interoperability Resources (FHIR) standard and associated implementation guides that can help ensure consistent use of the standard to make it easier for different systems to communicate.

As part of this proposed rule, CMS proposes to incorporate references to a series of ONC-designated standards into CMS regulations. This approach, in essence, allows CMS to rely on ONC's authorities to set standards and require their use across a broad range of CMS policies. Furthermore, this approach helps scale ONC-designated standards across health care and further establishes a nationwide interoperability approach, and reflects how health data should generally be shared: through the use of nationally recognized standards that can be used for multiple purposes, and with many federal policies referencing those same standards.

ONC, CMS and other federal agencies—such as the Centers for Disease Control and Prevention (CDC)—should continue to consider opportunities that take this approach, whereby a single set of standards are identified and then referenced to by other policies. In fact, the recently passed Consolidated Appropriations Act of 2021 requires ONC to set standards for public health data exchange, and then mandates adherence to those standards by states in order to obtain CDC funding.[6]

Give patients access to additional data on prior authorizations

Much of the rule is focused on improving prior authorization, the process by which a health plan determines whether a service, treatment plan, prescription drug or durable medical equipment is medically necessary and will be covered. The proposed rule would give patients access to information about pending and active prior authorization decisions via APIs, increasing transparency to patients on their care.

This policy reflects patient preferences. In the aforementioned Pew poll on data sharing, 84% of respondents indicated that they want "insurance billing and claims information," which—while not asked explicitly—may include prior authorization details. Access to data puts patients at the center of their care, and—as prior authorization decisions could affect whether patients are able to access a particular medication, device, therapy, or procedure—this information is also vital to give patients timely information on next steps in their care. As CMS continues to advance APIbased policies to give patient more data, the agency should continue to prioritize individual access to more information on their care.

Requests information on social determinants of health

The proposed rule also contains several requests for information (RFI), including one on "barriers to adopting standards, and opportunities to accelerate adoption of standards, related to social risk data."

This RFI rightly reflects the notion that each person's health is affected by a complex array of social and environmental factors that have historically been viewed as outside the medical context. Increasingly, the medical community has become interested in viewing the patient in a more wholistic context by understanding the social and environmental factor that impact their health, such as housing and employment status. In order to address these factors, or social determinants of health (SDOH), in a comprehensive and coordinated way, different facilities may seek to integrate this information into patient records. For example, the incorporation of housing insecurity into patients' records could provide specific decision support tools or guidance for clinicians that could affect care or enable them to provide resources for the patient.

While important to individuals' health, SDOH are also highly sensitive, with patients having different preferences on the sharing of this. According to the nationwide Pew poll referenced earlier, 75% of respondents were comfortable discussing homelessness, hunger, or exposure to violence with their clinicians. However, some patients expressed reservations in the sharing of this data among different providers. In particular, only 48% said they wanted information on social factors—such as, exposure to violence or history of physical abuse, hunger or lack of access to healthy food, or homelessness or lack of access to housing—shared among providers, including only 41% of non-White respondents wanting the information shared. Education on the benefits of sharing this data helped assuage some of these concerns; when respondents were told in a follow-up question about the benefits of clinicians being informed on their patients' social factors, 55% of respondents expressed comfort with having this data. The latter point echoes the results of previous Pew-led focus groups, where participants revealed concerns about sharing data on SDOH because they felt they could be prejudged by their health care provider.[7]

While factoring in patient preferences, SDOH should be documented and shared in a standard manner—an effort some organizations are already advancing. For example, the Gravity Project is an initiative to develop FHIR-based standards for food security, housing stability and transportation access to incorporate these social data effectively into EHRs and for exchange via APIs. Additionally, researchers at the University of California, San Francisco, developed the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences toolkit to aid providers in collecting SDOH in EHRs.

As these social factors are increasingly documented in patients' records, CMS should work with ONC to identify SDOH data elements and their associated standards to ensure greater consistency across technologies in the communication of this information. In parallel as this information becomes more interoperable, CMS should also work to identify safeguards to ensure that patient preferences are respected in the use of this information.

Conclusion

This proposed rule includes several provisions that will make health data more accessible and available to patients and clinicians. In finalizing the regulations, CMS should refine the rules further by:

- Ensuring metrics for API use capture not just the number of patients accessing their information, but also characteristics about those individuals to identify opportunities to reduce disparities in access to data;
- Assessing further opportunities to provide patients with actionable information about how their data—accessed via APIs—are used;
- Codifying further nationwide standards into regulations to improve interoperability;
- Increasing the types of data individuals can access via APIs; and
- Identifying policies that support the exchange of social factors information while respecting patient privacy.

Thank you for the opportunity to provide comments on this proposed rule. Should you have any questions or if we can be of assistance, please contact me at 202-540-6333 or bmoscovitch@pewtrusts.org.

Ben Moscovitch
Project Director, Health Information Technology
The Pew Charitable Trusts

---

[1] S.C. Lin et al., "Are Patients Electronically Accessing Their Medical Records? Evidence from National Hospital Data," *Health Affairs* 38, no. 11 (2019), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.05437.

[2] W.J. Gordon et al., "Characteristics of Patients Using Patient-Facing Application Programming Interface Technology at a Us Health Care System," *JAMA Network Open* 3, no. 10 (2020): e2022408, 10.1001/jamanetworkopen.2020.22408.

[3] J. Turow, M. Hennessy, and N. Draper, "Persistent Misperceptions: Americans' Misplaced Confidence in Privacy Policies, 2003–2015," *Journal of Broadcasting & Electronic Media* 62, no. 3 (2018), https://doi.org/10.1080/08838151.2018.1451867.

[4] A. Martyn, "Pregnancy App-Maker Ovia Health Is Selling Data to Employers," Consumer Affairs, April 12, 2019, https://www.consumeraffairs.com/news/pregnancy-app-maker-ovia-health-is-selling-data-to-employers-041219.html.

[5] Apple Inc., "App Privacy Details on the App Store," accessed December 22, 2020, https://developer.apple.com/app-store/app-privacy-details/.

[6] Consolidated Appropriations Act, 2021, H.R 133SA, 116th U.S House of Representatives (2020), https://rules.house.gov/sites/democrats.rules.house.gov/files/BILLS-116HR133SA-RCP-116-68.pdf.

[7] B. Moscovitch, "Patients Seek Better Exchange of Health Data among Their Care Providers," The Pew Charitable Trusts, March 17, 2020, https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2020/03/patients-seek-better-exchange-of-health-data-among-their-care-providers.