Centers for Medicare & Medicaid Services

42 CFR Parts 406, 407, 422, 423, 431, 438, 457, 482, and 485
45 CFR Part 156
[CMS–9115–P]
RIN 0938–AT79

Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally- Facilitated Exchanges and Health Care Providers

SUMMARY: This proposed rule is intended to move the health care ecosystem in the direction of interoperability, and to signal our commitment to the vision set out in the 21st Century Cures Act and Executive Order 13813 to improve access to, and the quality of, information that Americans need to make informed health care decisions, including data about health care prices and outcomes, while minimizing reporting burdens on affected plans, health care providers, or payers.

Submit comments: *Electronically.* You may submit electronic comments through *http://www.regulations.gov*.
Comments due to CMS: 5 p.m. on June 3, 2019

Overall Comment

Text:

N/A

Comment:

Please consider including a list of acronyms, definitions and hyperlinks when applicable in the final rule as its own section for easy reference while reading the guide.

Acronym Examples

- CHIP: Children's Health Insurance Program
- FFE: Children's Health Insurance Program
- MA: Medicare Advantage
- MCO: managed care organization
- MLR: Medical Loss Ratio
- PAHPs: prepaid ambulance health plan
- PHSA: Public Health Service Act
- PIHPs: prepaid inpatient health plans
- QHP: qualified health plans
- QIA: Quality improvement activity
- UPI: Unique Patient Identifier

Definition Examples

- You reference "API technology" multiple times in the proposed rule; please clarify the definition has the same meaning as in the ONC proposed rule: § b. Key Terms, page 7477.

- You reference “interoperability”, “access”, “exchange”, and “use” multiple times in the proposed rule; please clarify the definitions have the same meaning as in the ONC proposed rule: § 170.102 Definitions and § 171.102 Definitions, pages 7589, 7601 and 7602.
- You reference “health care provider” multiple times in the proposed rule; please clarify the definition has the same meaning as ‘‘health care provider’’ at 42 U.S.C. 300jj as stated in the ONC proposed rule: § 170.102 Definitions, page 7601.
- You reference “information blocking” multiple times in the proposed rule; please clarify the definition has the same meaning as ‘‘Information Blocking at 42 U.S.C. 300jj–52(a) and § 171.103 as stated in the ONC proposed rule: § 170.102 Definitions, page 7601.
- You reference “electronic health information”, “person”, and “protected health information” multiple times in the proposed rule; please clarify the definitions have the same meaning as defined in 45 CFR 160.103 as stated in the ONC proposed rule: § 170.102 Definitions, page 7601 and 7602.

Overall Comment

Text:

N/A

Comment:

As you finalize this ruling, you may want to consider the impact of laboratory results being shared with the patient from different sources due to potential for varying vocabularies (such as SNOMED, LOINC, RxNORM), standards formats, and result statuses as potential impacts to the data. Information sent to payers are not subject to the same regulatory requirements that exist between laboratories and the ordering/attending provider. Potential disparities in how the data is displayed and stored in these systems may further construe the information shared with the patient. We are concerned this may cause a patient safety risk.

We recommend that patient laboratory results be rendered to the patient from their ordering/attending provider as their trusted primary health care provider as data sent to the plan is traditionally for payment and not patient care.

Overall Comment

Text:

N/A

Comment:

The Trusted Exchange Framework and Common Agreement (TEFCA) is also out for public comment with a deadline of June 17, 2019. There may be some overlap in comments between the ONC Health IT Certification Program and TEFCA responses; therefore, we ask the agency to consider both when creating this final rule.

(Page 7614) 1. Patient Identifier and Interoperability

Text:

…
We continue to support ONC's work promoting the development of patient matching initiatives. Per Congress' guidance, ONC is looking at innovative ways to provide technical assistance to private sector-led initiatives to further develop accurate patient matching solutions in order to promote interoperability without requiring a UPI. We understand the significant health information privacy and security concerns raised around the development of a UPI standard and the current prohibition against using HHS funds to adopt a UPI standard. Recognizing Congress' statement regarding patient matching and stakeholder comments stating that a patient matching solution would accomplish the goals of a UPI, we seek comment for future consideration on ways for ONC and CMS to continue to facilitate private sector efforts on a workable and scalable patient matching strategy so that the lack of a specific UPI does not impede the free flow of information. We also seek comment on how we may leverage our program authority to provide support to those working to improve patient matching. In addition, we intend to use comments for the development of policy and future rulemaking.

Comment:

The American Clinical Laboratory Association (ACLA) developed a guidance document and best practice recommendation: ACLA Best Practice Recommendation for Administrative and Clinical Patient Gender used for Laboratory Testing and Reporting[1] which outlines existing and different concepts of "sex", e.g. 'sex' reported for administrative use (billing, claims, etc.) which may not be the same as the patient's clinical/biological/chromosomal gender or sex at birth. These different concepts represent different data elements which can also impact patient matching and laboratory results if not correctly managed as distinct concepts within EHR systems, HIEs, HIN, etc. Please consider these factors when developing patient matching policy.

(Page 7617) F. Summary of Major Provisions

Text:

…
We are proposing to require that a variety of information be made accessible to these impacted patients via ''openly published'' (or simply ''open'') APIs– that is, APIs for which the technical and other information required for a third party application to connect to them is publicly available. This will provide these patients with convenient access to their health care information in accordance with the HIPAA Privacy Rule access standard at 45 CFR 164.524, and an increase in their choice of applications with which to access and use their own electronic health information, as discussed above, and other information relevant to managing their health, enabling open APIs to improve competition and choice as they have in other industries.
…
We propose to require MA organizations, Medicaid state agencies, state CHIP agencies, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs (by requiring them to comply with the proposed ONC standard) to implement open APIs consistent with the API technical standards proposed by ONC for adoption by HHS and to use content and vocabulary standards adopted by HHS at 45 CFR part 162 and 42 CFR 423.160, and proposed by ONC for adoption by HHS at 45 CFR 170.213 (published elsewhere in this issue of the Federal Register).
…

[1] *http://www.acla.com/acla-best-practice-recommendation-for-administrative-and-clinical-patient-gender-used-for-laboratory-testing-and-reporting/*

We are proposing to require that all MA organizations, Medicaid and CHIP Managed Care entities (MCOs, PIHPs, and PAHPs), and QHP issuers in FFEs (with the exception of stand-alone dental plans (SADPs)) must participate in a trusted health information exchange network meeting criteria for interoperability. Further, we discuss an approach to payer-to-payer and payer to-provider interoperability which leverages such existing trusts networks. States and CMS routinely exchange data to support the administration of benefits to Medicare-Medicaid dually eligible beneficiaries.
…
We offered three different examples of activities which might be included under such an approach, including:
• Participation in, or serving as, a health information network which is part of the Trusted Exchange Framework and Common Agreement (TEFCA);
• Maintaining an open API which allows persistent access to third parties which enables patients to access their health information; and
• Participating in piloting and testing of new standards that support emerging interoperability use cases.

Comment:

ONC is recommending Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) based APIs. We suggest that CMS follow the same API recommendation as ONC, e.g. using the FHIR standard and Implementation Guides. This may be CMS's intent, but statements referencing "openly published (or simply "open") APIs" are confusing since they imply any API is acceptable as long as it is published. This could result in thousands of proprietary APIs that will deter interoperability by requiring customized point to point APIs. Proprietary point to point APIs also seems contrary to The National Technology Transfer and Advancement Act (NTTAA) and OMB A-119 requirements for federal agencies.[2]

Please clarify CMS statements referring to "open" APIs and "openly published" should be based on the FHIR based APIs recommended by ONC.

(Page 7621) under 2. Privacy and Security Concerns in the Context of APIs

Text:

…
Under the HIPAA Privacy Rule,14 individuals have the right of access to inspect and receive a copy of a defined set of their PHI as detailed at 45 CFR 164.501. Specifically, as OCR has indicated in regulations and guidance, an individual can exercise their right of access to direct a covered entity to send their information to a third party. When responding to an access request, ''the same requirements for providing the PHI to the individual, such as the timeliness requirements, fee limitations, prohibition on imposing unreasonable measures, and form and format requirements, apply when an individual directs that the PHI be sent to another person or entity.''

Comment:

[2] The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 et seq.) and the Office of Management and Budget (OMB) Circular A–119 require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. (Extract from March 4, 2019 ONC proposed rule), Federal Register Page 7439.

We recommend you include the guidance from HHS regarding HIPPA Access Rights for a health app API.

https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hippa-access-right-health-apps-apis/index.html
4. Q: Can a covered entity refuse to disclose ePHI to an app chosen by an individual because of concerns about how the app will use or disclose the ePHI it receives?

A: No. The HIPAA Privacy Rule generally prohibits a covered entity from refusing to disclose ePHI to a third-party app designated by the individual if the ePHI is readily producible in the form and format used by the app. See 45 CFR 164.524(a)(1), (c)(2)(ii), (c)(3)(ii). The HIPAA Rules do not impose any restrictions on how an individual or the individual's designee, such as an app, may use the health information that has been disclosed pursuant to the individual's right of access. For instance, a covered entity is not permitted to deny an individual's right of access to their ePHI where the individual directs the information to a third-party app because the app will share the individual's ePHI for research or because the app does not encrypt the individual's data when at rest. In addition, as discussed in Question 1 above, the HIPAA Rules do not apply to entities that do not meet the definition of a HIPAA covered entity or business associate.

(Page 7627) Open API Proposal for MA, Medicaid, CHIP, and QHP Issuers in FFEs

1. Introduction

Text:

We are proposing to add new provisions at 42 CFR 422.119, 431.60, 438.242(b)(6), 457.730, 457.1233(d) and 45 CFR 156.221, that would, respectively, require MA organizations, state Medicaid FFS programs, Medicaid managed care plans, CHIP FFS programs, CHIP managed care entities, and QHP issuers in FFEs (excluding issuers of SADPs) to implement, test, and monitor an openly-published API that is accessible to third-party applications and developers.

…
Under our proposal, the scope and volume of the information to be provided or made accessible through the open API would include: Adjudicated claims (including cost); encounters with capitated providers; provider remittances; enrollee cost-sharing; and clinical data, including laboratory results (where available). We propose that these programs and organizations, with the exception of the QHP issuers in FFEs, would also be required to make information regarding provider directories and formularies available through the open API. Sections 1852(c), 1932(a)(5), and 2103(f)(3) of the Act require that MA organizations and Medicaid MCOs, and CHIP managed care entities provide basic information to their enrollees on how to get covered benefits in the plan and to facilitate decision making about their health care.

Comment:

ONC is recommending Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) based APIs. We suggest that CMS follow the same API recommendation as ONC, e.g. using the FHIR standard and Implementation Guides. This may be CMS's intent, but statements referencing "openly published (or simply "open") APIs" are confusing since they imply any API is acceptable as long as it is published. This could result in thousands of proprietary APIs that will deter interoperability by requiring customized point to point APIs. Proprietary point to point

APIs also seems contrary to The National Technology Transfer and Advancement Act (NTTAA) and OMB A-119 requirements for federal agencies.[3]

Please clarify CMS statements referring to "open" APIs and "openly published" should be based on the FHIR based APIs recommended by ONC.

(Page 7674) 422.119 Access to and exchange of health data and plan information, Section (b) – Accessible content

Text:

…
(b) *Accessible content.* (1) An MA organization must make the following information accessible to its enrollees through the API described in paragraph
(a) of this section:
(i) Standardized data concerning adjudicated claims, including claims data for payment decisions that may be appealed, were appealed, or are in the process of appeal, and provider remittances and enrollee cost-sharing pertaining to such claims, no later than one (1) business day after a claim is processed;
(ii) Standardized encounter data, no later than one (1) business day after data concerning the encounter is received by the MA organization;
(iii) Provider directory data on the MA organization's network of addresses, phone numbers, and specialties, updated no later than 30 business days after changes are made to the provider directory; and (iv) Clinical data, including laboratory results, if the MA organization manages any such data, no later than one (1) business day after the data is received by the MA organization.

Comment:

There may be business and state legislative impacts to support a one (1) business day TAT for MA (Medicare Advantage) organization. For example, there are some physicians that want to review laboratory results before they are shared with patients based on the type of test and result which might require a direct conversation. Additionally, it is our understanding that states have varying laws regarding patient opt-in, opt-out and laboratory result release timings. Also, please clarity how this would impact February 2014's *CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports; Final Rule* which indicates that laboratory results must be provided to the patient within 30 days of the request.

(Page 7674) 422.119 Access to and exchange of health data and plan information, Section (c) - Technical requirements

Text:

[3] The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 et seq.) and the Office of Management and Budget (OMB) Circular A–119 require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. (Extract from March 4, 2019 ONC proposed rule), Federal Register Page 7439.

…
(c) *Technical requirements.* An MA organization:
(1) Must implement, maintain, and use API technology conformant with 45 CFR 170.215;
(2) Must conduct routine testing and monitoring to ensure the API functions properly, including assessments to verify that the API is fully and successfully implementing privacy and security features such as, but not limited to, those minimally required to comply with HIPAA privacy and security requirements in 45 CFR part 164, 42 CFR parts 2 and 3, and other applicable law protecting the privacy and security of individually identifiable data;
(3) Must comply with the following regulations regarding content and vocabulary standards for data available through the API, where applicable to the data type or data element, unless alternate standards are required by other applicable law:
(i) Content and vocabulary standards at 45 CFR 170.213 where such standards are the only available standards for the data type or element;
(ii) Content and vocabulary standards at 45 CFR part 162 and 42 CFR 423.160 where required by law or where such standards are the only available standards for the data type or element;
or
…

Comment:

As you finalize this ruling, you may want to consider the impact of laboratory results being shared with the patient from different sources due to potential for varying vocabularies (such as SNOMED, LOINC, RxNORM), standards formats, and result statuses as potential impacts to the data. Information sent to payers are not subject to the same regulatory requirements that exist between laboratories and the ordering/attending provider. Potential disparities in how the data is displayed and stored in these systems may further construe the information shared with the patient. We are concerned this may cause a patient safety risk.

We recommend that patient laboratory results be rendered to the patient from their ordering/attending provider as their trusted primary health care provider as data sent to the plan is traditionally for payment and not patient care.

(Page 7678) PART 482—CONDITIONS OF PARTICIPATION: HOSPITALS

Text:

…
* * * * *
(d) *Standard: Electronic notifications.* If the hospital utilizes an electronic medical records system with the capacity to generate information for patient event notifications in accordance with paragraph (d)(2) of this section, then the hospital must demonstrate that—
(1) The system's notification capacity is fully operational and that it operates in accordance with all State and Federal statutes and regulations regarding the exchange of patient health information;
(2) The system complies with the regulations regarding the content exchange standard at 45 CFR 170.205(a)(4)(i);
(3) The system sends notifications that must include the minimum patient health information (which must be patient name, treating practitioner name, sending institution name, and, if not prohibited by other applicable law,

patient diagnosis);
(4) At the time of the patient's admission to the hospital, the system sends notifications directly or through an intermediary that facilitates exchange of health information, to licensed and qualified practitioners, other patient care team members, and post-acute care services providers and suppliers:
(i) That receive the notification for treatment, care coordination, or quality improvement purposes;
(ii) That have an established care relationship with the patient relevant to his or her care; and
(iii) For whom the hospital has a reasonable certainty of receipt of notifications; and
(4) Either immediately prior to or at the time of the patient's discharge or transfer from the hospital, the system sends notifications directly or through an intermediary that facilitates exchange of health information, to licensed and qualified practitioners, other patient care team members, and post-acute care services providers and suppliers:
(i) That receive the notification for treatment, care coordination, or quality improvement purposes;
(ii) That have an established care relationship with the patient relevant to his or her care; and
(iii) For whom the hospital has a reasonable certainty of receipt of notifications.
■

Comment:

Patients may have certain medical conditions that they may want to restrict from sharing with other entities. Some examples include mental health and second opinions. If patients choose to block information, this should not be considered 'information blocking'. There is no easy way for a Patient to administer this level of blocking. Should there be consideration of a notification or awareness that the patient has intentionally blocked information from being disclosed. Examples for this would include medications that may have contraindications and patient risk if unknown. We do not want to sacrifice patient privacy at the expense of interoperability.