About this Issue Brief Series: As the American healthcare system shifts to reward value rather than volume, improving quality and lowering costs are high priorities among healthcare stakeholders. Increased access to data across settings has the potential to greatly improve the quality of health care delivery and care coordination. However, using and exchanging health information across the care continuum to support these priorities requires interoperable data sharing systems.

On February 11, 2019, the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) released proposed rules to "support seamless and secure access, exchange, and use of electronic health information." Both rules have similar themes and share the same goal of interoperability but apply to different programs. CMS, which has authority over the Medicare and Medicaid programs, focuses on creating standards that Medicare and Medicaid providers must follow that will support interoperability. ONC, which promotes the adoption and use of health information technology, focuses more broadly on the use and exchange of health information across the healthcare system.

To help raise awareness and understanding of the rules, Health Information and the Law has identified key topics related to the proposed rules and how they affect interoperability. The following is the first in a series of Issue Briefs that focuses on Application Programming Interfaces (APIs) and how both CMS and ONC are addressing the use of this technology.

APIs and the Proposed Rules:

Application programming interfaces (APIs) are sets of rules and protocols that govern the interactions between two software applications (to learn more about the basic functionality of APIs, visit our Fast Facts **here**). When health information technology (health IT) developers do not publish their APIs, it may not be possible for information to flow between electronic health record (EHR) systems. The 21st Century Cures Act addressed APIs by adding conditions for technology certification. Entities must have "published application programming interfaces that allows health information from such technology to be accessed, exchanged, and used without special effort." To implement this section of the Cures Act, both CMS and ONC have addressed the use of open APIs in their proposed rules and have highlighted the importance of making APIs standardized, transparent, and pro-competitive.

CMS Proposed Rule:

CMS has launched several initiatives designed to enable Medicare beneficiaries to better access their healthcare information. For example, in 2018, CMS announced the launch of MyHealthEData, an initiative that aims to increase patient access to their own health data by removing barriers that may make it difficult for patients to access their full health records. As a part of this initiative, CMS later released the Blue Button 2.0 API, which

allows various mobile applications to use the API to give Medicare fee-for-service (FFS) beneficiaries access to their claims data directly. When creating this program, CMS used Health Level Seven (HL7) Fast Healthcare Interoperability Resources Specification (FHIR) as a standard.

In the section titled "Patient Access Through APIs" in the 2019 proposed rule, CMS suggests creating an open API requirement (essentially expanding Blue Button 2.0) to be used by Medicare Advantage (MA), Medicaid and CHIP FFS programs, and Medicaid and CHIP managed care organizations (MCOs).[1] These APIs would be consistent with the standards laid out by ONC in their proposed rule. While CMS is suggesting requirements similar to those outlined by ONC, it is not proposing requiring that health systems gain ONC certification. Information that would be made accessible by the API includes: adjudicated claims, encounters with capitated providers, provider remittances, enrollee cost-sharing, and clinical data, including laboratory tests. It is CMS' intent to give patients quick and easy access to their health information and enable them to be more active participants in making decisions about their health care.

In addition to increasing access to patient data through the use of open APIs, CMS proposes including access to some plan-level data as well through the addition of provider directory data to APIs. Both patients and providers would benefit from this addition. Patients can use this information when deciding which plan or provider best meets their needs. Providers can reference the directory to find contact information for other providers for referrals or to improve coordination of care for enrollees. CMS proposes using HL7 FHIR standards for this information as well.

ONC Proposed Rule:

ONC has the authority to set certification standards that developers creating APIs for health IT purposes will follow. Previously, ONC released the 2015 Edition Health IT Certification Criteria (2015 Edition), which enabled the exchange of health information through "enhanced certification criteria, standards, and implementation specifications." In the new proposed rule, ONC included an updated set of certification and maintenance requirements for API developers.[2]

To gain certification, health IT developers must meet various technical and security requirements when creating APIs, which must be standardized, transparent, and pro-competitive. ONC is proposing using HL7 FHIR as a base standard for all APIs so information can be shared easily between different health information systems. The proposed rule also includes the following specific criteria:

- Transparency—technology suppliers must publish all terms and conditions applicable to their API;
- Permitted Fees—API suppliers are allowed to charge organizations that use API technology and persons or entities that interact with API technology under specific conditions:
    - Fees to recover costs of API usage that fall out of general access, exchange, and use;

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[1] CMS-9115-P. 84 FR 7610 (Proposed March 4,2019)

[2] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. 84 FR 7424. (Proposed March 4, 2019) (To be codified at 45 CFR 170.315(g)(10)).

- o   Fees for "value-added" services;
        - o   Any other fees charged by API developers are not allowed;
- Openness and Pro-competitiveness – developers must follow protocols to promote an open and pro-competitive marketplace:
        - o   Non-discriminatory access and use;
        - o   Rights to access and use API technology to share health information;
        - o   Provide support services necessary to promote easy adoption and use of this technology.

Certification maintenance is a new addition to the 2015 Edition standards. To maintain their status as a certified API, health IT developers will have to continuously meet certain requirements including registering and enabling applications for production use within one business day of certification.

See our fast facts on APIs **here** and Myth Buster on APIs and EHRs **here.**

For more information on the proposed rules, click **here.**

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