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Exchanging health information in a digital world

HHS issues final rules on interoperability and information blocking

Over the last decade there has been an increased bipartisan push in Congress for improving digital health. Through a series of new laws[1] Congress made clear that, with respect to the delivery of health care in the future, there are three main goals:

1. Providers must share in the financial risk of care delivery;
2. Financial risk and reward will be tied to the provision of high quality and cost-effective care; and
3. Providers must be able to communicate with each other and with patients to coordinate care – even when outside contracted arrangements or networks – to create a truly interoperable health care system.

Efforts are underway on the first two goals, but the push toward interoperability – making health information available to individuals in an easily shareable format – has been slow to follow. Bringing the exchange of health information into the digital age has continued with the Trump administration. The administration has made the promotion of interoperability a major priority to help rein in health care costs, improve coordination of care, and enhance patient access and choice. In addition to interoperability, the Trump administration has called for increased price transparency within the health care system to assist patients in making choices about their care armed with new pricing data and online tools, ushering in a new era of a more empowered health care consumer.

On March 9, 2020, the Department of Health and Human Services (HHS) along with the Office of the National Coordinator for Health Information Technology (ONC) released its final rule aimed at promoting interoperability and implementing the "information blocking" prohibition of the 21st Century Cures Act of 2016. (The prohibition on information blocking is designed to penalize organizations that impede the accessibility and sharing of health information within the constructs of interoperability.) On the same day, the Centers for Medicare and Medicaid (CMS) also issued its final rule aimed at placing requirements on CMS-regulated payers and agencies to implement application programming interfaces (APIs) to a allow for health care information to be more easily accessible by patients and shared with health care providers and other payers.

These interoperability rules have become contentious, with some stakeholders touting them as transformative, while others are cautious and cite concerns over privacy risks to patient data and a fast approaching compliance date of January 1, 2021.

Specific concerns have surrounded the lack of new privacy and security requirements specified within the proposed interoperability rules for APIs and opening access to patient data to third party app developers. To address some of the privacy concerns raised in the comments to the proposed rule, the interoperability final rules added language that allows payers to ask third-party application developers to attest to certain privacy provisions, including whether the app developer's privacy policy specifies secondary data uses. The final rule would permit plans to inform individuals about such attestations from app developers.

Influenced by their experiences in other industries, especially technology, financial services, and retail, consumers now more than ever expect their health care information sharing that is seamless and instantaneous. We expect to get same day appointments, our records to be available "on-demand," and our providers to understand us and our medical history when we show up for an appointment. It is not about who "owns" medical information. It is about access, shareability, and transparency. It is about consumers being in control of their health care.

The CMS and ONC interoperability rules received a significant number of comments from individuals, not just companies and organizations. These individuals often shared personal stories about how improved access and shareability of their medical information and the ability to fully understand medical costs would greatly improve their and their family's health and financial wellbeing. It is difficult not to see these comments by individuals as signaling to the administration that many vocal health care consumers are more than ready for greater access and shareability of their health information and are frustrated at the slow adoption of these functionalities by the health care industry.

There is no doubt that the implementation of the interoperability rules with their ambitious effective date, present complex clinical, operational, and security challenges to payers, hospitals, and health IT developers. Hospitals and other care providers, payers, and health IT organizations will need to strategize round how to maximize the benefit from these policies while also recognizing that investment in and commitment to technical infrastructure, including cybersecurity, is increasingly vital. But it's clear that the administration is not waiting around any longer to make significant steps in the modernization of our health care system that takes advantage of technology to offer better health care experiences and patient outcomes.

In light of the potential confluence of compliance deadlines on January 1, 2021, it will be critically important for health care stakeholders to evaluate interoperability, information blocking, and price transparency efforts cohesively as they prepare for the strategic, competitive, clinical, and technology opportunities and challenges that the initiatives present.

The CMS Interoperability and Patient Access Rule

Basics of the rule

The final rule is intended to make it easier for patients to access certain claims and encounter information (including cost) in a readily shareable format and establishes new requirements for hospitals to send automated electronic notifications when an individual is admitted, discharged and/or transferred to another facility.

The final rule builds upon CMS' experience with the Blue Button 2.0 approach by requiring Medicare Advantage (MA) organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and issuers of qualified health plans (QHPs) in federally-facilitated Exchanges (FFEs) established under the Affordable Care Act (ACA) to implement, test, and monitor an open, standards-based application programming interface (API) to make patient claims and other health information available to patients through third-party applications and developers of the individual's choice.

The information required to be made accessible under the open API includes:

- Adjudicated claims (including provider remittances and enrollee cost-sharing)
- Encounters with capitated providers
- Clinical data, including laboratory results (where available)

This data must be made available no later than one (1) business day after a claim is adjudicated or encounter data are received. Payers also are required to make information regarding provider directories available through an open API; Part D plans face a similar requirement for formularies.

In addition to requiring the use of APIs and making certain data elements available, the final rule also requires a payer – to – payer data exchange. Government programs are required to exchange certain patient clinical data (the U.S. Core Data for Interoperability (USCDI) version 1 data set) at the member's request. Payers will be required to share information they maintain with a date of service on or after January 1, 2016.

The final rule also modifies the Conditions of Participation (CoPs) for Medicare by requiring hospitals, including psychiatric hospitals and critical access hospitals (CAHs), to send electronic patient event notifications of patient's admission, discharge, and or transfer to another health care facility or another health care provider. The requirement applies specifically to hospitals with EHR systems that support such notification capabilities.

However, CMS did decide not to finalize its proposal to require CMS programs to participate in a trusted exchange network wherein plan and providers could share information without regard to the network to which they belong. This decision was based-off of concerns commenters raised regarding the need for a mature Trusted Exchange Framework and Common Agreement (TEFCA) to be in place first. Currently, work on TEFCA is still ongoing.

Applicability
This rule and the above mentioned provisions apply to CMS regulated payers, specifically MA organizations, Medicaid Fee-for-service (FFS) programs, Medicaid managed care plans, CHIP FFS programs, CHIPS managed care entities, and QHP issuers on FFEs (excluding issuers offering only Stand-alone dental plans (SADPs) and QHP issuers offering coverage in the federally-facilitated Small Business Health Options Program (FF-SHOP)).

Important compliance dates
There are several important and fast approaching compliance dates to remember in connection to this final rule. These dates include:

- Six months after publication date of the rule (i.e., Fall 2020) for the electronic patient event notification of admission, discharge, or transfer
- January 1, 2021 for the Patient Access API
- January 1, 2021 for the Provider directory, formulary APIs
- January 1, 2022 for the Payer-to-Payer data exchange

Interoperability, information blocking, and the ONC Health IT Certification Program

Basics of the rule
This final rule aims at supporting interoperability activities by adopting certain technical updates and new standards for health IT certification and Patient APIs and clarifying the exceptions to the prohibition on information blocking.

This ONC final rule is focused on implementing key provisions of the 21st Century Cures Act. The final rule identifies and finalizes the reasonable and necessary activities that do not constitute information blocking while also establishing new rules to prevent information blocking practices. The final rule also requires electronic health records to provide the clinical data necessary (including core data classes and elements) to promote new business models of care.

In additional to finalizing requirements around information blocking, the final rule also makes several changes to the existing 2015 Edition Health IT Certification Criteria and establishes standardized application programming interfaces (APIs) requirements to support patient access and control of their health data. The aim of this provision is to allow patients to securely and easily obtain and use their health data from their provider's Medicare record for free using a smartphone app of their choosing.

Applicability
The information blocking provisions associated with this rule apply to health care providers, health IT developers, health information exchanges, and health information networks. While many of the technical updates to the 2015 Edition Health IT Certification Criteria will be immediately applicable to health IT developers, it will be important for hospitals and health systems to understand what changes have been made and to make sure they are utilizing certified open APIs. In addition, future updates to the Promoting Interoperability programs for hospitals and clinicians could reflect the updated certification criteria for health IT and require hospitals and care providers to demonstrate use of the new capabilities.

Important compliance dates
Important compliance dates associated with this final rule include:

- Six months from publication of the final rule (i.e., Fall 2020) for compliance to begin regarding information blocking practices.[2]
- Six months from publication of the final rule (i.e., Fall 2020) for compliance to being on specific requirements associated with several Conditions of Certification (including information blocking, assurances, and APIs).

Price transparency efforts

On November 15, 2019, the Department of Health and Human Services (HHS) released two rules aimed at increasing price transparency. One rule is final and sets out price transparency requirements for hospitals to make "standard charges" public. The second rule has been proposed and would set out transparency in coverage requirements for health care payers, including employers that offer self-funded coverage.

Price transparency requirements for hospitals to make standard charges public

Basics of the rule
The final rule requires hospitals to make public, in a comprehensive machine-readable file, "standard charges" (which includes payer-specific negotiated charges) for all items and services. The rules also require hospitals to make public a separate file detailing standard charges for certain common "shoppable" services.

For both requirements within the final rule, CMS adopts a definition of "standard charges" that includes:

1. Gross charges
2. Discounted cash prices
3. Payer-specific negotiated charges
4. De-identified minimum negotiated charges
5. De-identified maximum negotiated charges

Importantly, for the comprehensive file detailing standard charges for all items and services, CMS specifies that standard charges (as listed above) must be included for each item or service (including both individual items and services and service packages). For each standard charge element, CMS will require hospitals to provide the standard charge element that applies when an item or service is provided in an inpatient setting, as well as the corresponding standard charge that applies when the item of service is provided in an outpatient department setting.

In addition, the comprehensive file detailing standard charges for all items and services will be required to include:

- A description of each item or service
- Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the CPT code, HCPCS code, DRG, NDC, or other common payer identifier

Separately, the final rule requires hospitals to post payer-specific negotiated rates online in a searchable and consumer friendly format for 300 common "shoppable" services. Seventy of the services are stipulated in the rule, while hospitals can choose the other 230 services they wish to post.

Applicability
This final rule applies to all hospitals, defined as institutions licensed as hospitals by state law, including:

- Inpatient psychiatric facilities (IPFs)
- Inpatient rehabilitation facilities (IRFs)
- Long-term care hospitals (LTCHs)
- Critical access hospitals (CAHs)
- Rural hospitals
- Sole community hospitals (SCHs)

Notably, the rule does not apply to ambulatory surgery centers.

Important compliance dates
This rule's requirements on hospitals is set to go into effect January 1, 2021, and hospitals would have to update the files at least annually. Hospital organizations have filed a lawsuit seeking to block the final rule.

Transparency in coverage: health care payers

Basics of the rule
This proposed rule would require health payers to disclose price and cost-sharing information to participants, beneficiaries, and enrollees up front.

Specifically, the proposed rule would require health payers to give consumers real-time, personalized access to cost-sharing information, including an estimate of their cost-sharing liability for all covered health care items and services through an online tool (and make available in paper form upon a consumer's request). The proposed rule also would require health payers to disclose, on a public website, their negotiated rates for in-network providers and allowed amount paid for out-of-network providers

Applicability
The proposed rule would apply to employer-based group health plans and health insurance issuers offering group and individual coverage in the private insurance market. The proposed rule also would apply to employers offering self-funded coverage.

Important compliance dates
CMS proposed for the provisions of the proposed rule to apply for plan years beginning on or after 1 year of the finalization of the rule.

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Endnotes

1. Patient Protection and Affordable Care Act (ACA), Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), 21st Century Cures Act of 2016.
2. Timing for the enforcement of information blocking civil monetary penalties will be established by future notice and comment rulemaking by the Office of Inspector General (OIG).