Quality & Regulatory

Regulatory Changes to Information Blocking and Patient Access to Medical Records

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Scrolling through social media in late June, I came across an oncologist who described a disheartening interaction with their patient brought upon by recent regulatory changes that allow patients access to their medical records. The pathology report indicated cancer, was uploaded into the accessible medical file, and then accessed by the patient who, at the time, was alone at home. The oncologist worried about what their patient was thinking between the time the patient read the report and received the oncologist's call confirming the results.

Interoperability of electronic health records (EHRs), along with patient access to their medical records, has been seen by many policymakers as a significant game changer that has the potential to improve patient engagement, care coordination, efficiency, and the delivery of patient-centered care. Moreover, use of Certified Electronic Health Record Technology (CEHRT) is one criteria of joining an Advanced Alternative Payment Model (APM), and health experts have also emphasized clinical and information integration as key to building team-based models. Access to medical records by patients is viewed as granting patients greater agency in understanding their diagnoses and making effective decisions on treatment options with their physicians. On the flip side, access to medical records for patients with low health literacy or a lack of understanding regarding what is significant within their medical record may present barriers to a patient fully realizing the potential benefits of such access.

Anesthesiologist participation in and reaction from interoperability initiatives and data sharing have been limited by a number of factors and contingencies. Anesthesiologist workflows, limited control of hospital and facility EHRs, and documentation procedures have made the specialty unique with regard to federal interoperability policy and EHR implementation prerogatives. Anesthesiologists provide care to patients in a variety of facilities and care settings that include hospitals, ambulatory surgery centers (ASCs), and office-based locations. They interact with a number of technology, facility administrations, and patient populations that carry their own facility-specific workflow challenges. And, as most anesthesiologists are apt to say, anesthesia is typically one of the last locations where a hospital's IT department engages on software and technology updates.

In 2019, in response to several sweeping proposals released by the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health IT (ONC), ASA requested CMS and ONC establish policies that reflected greater inclusion and consideration of the technology-related challenges anesthesiologists face. ASA encouraged both CMS and ONC to assess their proposals in relation to burden-reduction objectives, including both regulatory and workflow burdens that EHRs and health IT have placed on physician anesthesiologists and pain medicine physicians.

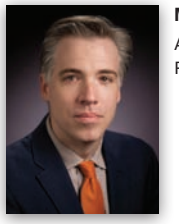
As the COVID-19 pandemic emerged in the US, CMS and ONC published their complementary rules on interoperability and patient access. CMS sought to remove the "siloed nature of health care [that] prevents physicians, pharmaceutical companies, manufacturers, and payers from accessing and interpreting important data sets." Allowing patients access to and have their patient record travel seamlessly from physician to physician and across different care settings could "empower patients to make better decisions and inform providers to support better health outcomes." Complementary to the CMS rule, the ONC regulation implements provisions of the 21st Century Cures Act and focuses on establishing and updating common data sets to facilitate data exchange, requirements for certified health IT vendors, and efforts to limit information blocking among various stakeholders. While anesthesiologists are likely aware of patients having been granted expanded access to their electronic health information under the new regulations, undoubtably, many questions around the requirements still remain.

CMS and ONC initially laid out an aggressive timeline for hospitals and other stakeholders to implement interoperability and patient access regulations. However, the timing of the rules in relation to the onset of the COVID-19 public health emergency resulted in delays in implementing many of its provisions. In particular, information blocking compliance deadlines found in the ONC Final Rule were extended through 2020 and again into 2021, resulting in increased confusion.

Most recently, several information blocking requirements took effect on April 5, 2021, for health care professionals (including anesthesiologists), health IT developers of CEHRT, Health Information Exchanges, and Health Information Networks. ONC's rule requires all physicians to make their office notes, lab results, and other diagnostic reports available to patients as soon as an electronic copy or information is available. Such a rule led to the unintended consequence, as described earlier, that the patient received a significant finding before a physician or other health professional could contact them. To dispel with some of the confusion, ONC has posted a series of FAQs online to assist in answering specific questions regarding the applicability of the information blocking and patient assess regulations on health care professionals.

Although many physicians already have well-established protocols for the release of information, the new requirements have introduced some complexities to existing policies. Analyzing how the exchange of electronic health information is handled in your facility, group, or practice will assist in identifying where potential obstacles exist in complying with the new requirements. Furthermore, the acts, and acts of omission, deemed "reasonable and necessary" and which do not constitute information blocking are also laid out in regulation. The exceptions cover issues related to the prevention of harm to a patient or other person, allowing for health IT upgrades and downtime, certain feasibility issues, and other factors that should be closely reviewed.

Given the complexities involved with the new information blocking requirements, it is important to remember that information blocking may not necessarily be viewed as approaching a clear compliance line. In fact, there are several grey areas in law and regulation that result in the need for a case-by-case approach in determining what constitutes information blocking. ONC has also indicated that failure to meet an identified exception will not immediately mean that the physician or other stakeholder engaged in information blocking. Anesthesiologists and their groups should engage their local counsel and/or hospital legal and compliance departments as well as any medical staff leadership and medical informatics officers on their responsibility to comply with information blocking rules during this regulatory rollout.



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In recent years, ASA and several physician committees and leaders have emphasized the need to engage further with policymakers and other stakeholders on interoperability and patient access to records. There are several avenues for consideration, including how best to nominate anesthesia elements for the United States Core Data for Interoperability (USCDI) standard, identifying common data sets that are useful to anesthesiologists prior to and during a surgical procedure as well as sharing relevant patient notes to surgeons and primary care physicians after the procedure, and in determining how best to inform patients who request their anesthesia record on the different elements or significance of those elements within the record.

ASA will continue to support meaningful information blocking regulations and advocate for advancements in interoperability to improve patient care through information exchange. ASA is encouraged by ONC's dedication to ensuring that medical specialty societies and other stakeholders have an appropriate voice in prioritizing data classes and data elements to be included in future USCDI rulemaking and in other features used to support greater interoperability and reduced barriers to care. Many physicians and other stakeholders see the benefit both of interoperability initiatives and patient access to their medical records, yet additional clarity would help all contributors and participants in our health care system navigate these changes.

The ASA Department of Quality and Regulatory Affairs continues to monitor regulations and engage with policy issues on these topics. We welcome member feedback and contributions on any experiences you wish to share that could help ASA staff and physician leaders constructively engage with CMS and ONC on these issues.

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