Summary of the CMS and ONC
Interoperability and Patient Access Proposed Rules

On Monday February 11, 2019, the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator (ONC) for Health Information Technology released a long-awaited set of proposed rules to address interoperability, information blocking, and patient access to data and electronic health record (EHR) certification criteria.

The CMS Interoperability and Patient Access Proposed Rule outlines opportunities to make patient data transparent, useful, and transferable through secure and standardized formats. In this 251-page rule, CMS includes several major proposals that have significant implications for Health IT stakeholders, including emergency physicians and the patients we serve.

The ONC proposed Interoperability, Information Blocking and ONC Health IT Certification Program Proposed Rule details proposals that further advance interoperability and patient access to health information. This 724-page rule implements certain provisions of the 21st Century Cures Act, including definitions for activities that do not constitute information blocking.

Below is a summary of key proposals outlined in the CMS and ONC rules. It is important to note that these are proposed rules, and therefore none of the policies included in them are final. Over the next several weeks, ACEP will submit comprehensive responses on both rules to CMS and ONC.

CMS Interoperability and Patient Access Proposed Rule

New Proposed COP for Hospitals

- **One of the most significant proposals included in the rule is a new Medicare Condition of Participation (COP) that would require hospitals, including psychiatric and critical access hospitals, to send an electronic notification when a patient is admitted, discharged, or transferred (ADT).**

- Under the proposal, providers working in facilities with EHRs would be required to send ADT notifications with basic patient information to other facilities following an ADT event.

- CMS states that notifications regarding patient events will lead to improved coordination of care, as recipient providers would be aware of any urgent care and ED visits for their patients. This would also allow the recipient an opportunity to arrange appropriate patient follow-up, modify treatment plans, and update records.

Network for Exchange of Secure Health Information

- CMS proposes to require other private and public payers beyond traditional Medicare (Medicaid, the Children's Health Insurance Program [CHIP], Medicare Advantage [MA] plans, and Qualified Health Plans [QHP] in the Federally-facilitated Exchanges [FFEs]) to participate in a trusted exchange network. This network would include the capacity for patients, providers, and insurers to access secure patient records,

transmit protected health information (PHI) across EHRs, and provide a messaging and notification platform for providers. The network platform would also require secure verification of identity for all participants.

 o CMS cites evidence-based research in Emergency Medicine[1] (Lammers et al, 2014) to support the notion that Health Information Exchange (HIE) can improve quality of care (testing, diagnosis, and treatment) by reducing redundant medical services such as radiology imaging and contribute to overall cost savings.

Secure Mobile App for Health Information

- CMS also includes proposals related to the use of standardized Application Programming Interfaces (APIs). APIs are intended to allow patients and health care providers the opportunity to use third-party software (like a mobile app) to access secure information in a standardized format.

- CMS proposes that APIs meet criteria for (1) standardization; (2) technical transparency; and (3) implementation in a pro-competitive way.
 o Any documentation associated with the API must be publicly accessible, without requiring special technology or additional burdensome requirements.

- In the event that a patient would like to send a copy of their health information to a provider, the patient could request transmission of their medical record through the API application.

- CMS anticipates that payers and providers may also improve coordination of care, reduce duplication, arrange follow-up care, and provide appropriate notification of changes to treatment plans through access to the totality of the patient's managed care.

- CMS is proposing that by 2020, enrollees in private and public insurance programs (MA, CHIP, QHP issuers in FFEs) must be provided with immediate electronic access to their personal health information and medical claims.
 o CMS states that access to a utilization history could help to prevent unnecessary ED visits, lapses in medication adherence, communication of new coverage rules, and changes to the enrollee's network.

Patient Identification within the Network (Unique Patient Identifiers)

- To identify records for a single patient, CMS believes health information from multiple sources must be compared to identify common elements.

- Previously, a unique patient identifier (UPI) was proposed as the most efficient way to accomplish accurate patient record linkage. However, there were Health Insurance Portability and Accountability Act (HIPAA)-related concerns over privacy and security of information outweighed the benefits of a UPI. CMS is currently prohibited from using funds to adopt a UPI standard.

- In lieu of a UPI, CMS is proposing a "***patient matching process***" by which health information is sourced from multiple demographic fields (name, DOB, gender, and address).

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[1] Lammers, et al., "Does Health Information Exchange Reduce Redundant Imaging? Evidence from Emergency Departments", *Medical Care.* Volume 52, Number 3. March 2014.

Provider Information Directory

- CMS is proposing updates to the National Plan and Provider Enumeration System (NPPES) to include the ability to capture digital contact information for all clinicians.

- Medicaid, CHIP, MA and managed care organizations would also be required to create a provider directory for their network of contracted providers that is publicly accessible on an API.
    - Clinicians who do not submit digital contact information through NPPES will be identified and asked to complete their contact and plan coverage information, which will in turn be readily available on the API provider directory.
    - Listed information on the API is the same data that MA organizations currently require clinicians to disclose to enrollees. This data includes the names of providers, addresses, phone numbers, and specialty.
    - The provider directory must be updated through the API within 30 calendar days if any changes are made.

Information Blocking

- CMS defines "information blocking" as the practice of withholding data or intentionally limiting compatibility or interoperability of health information. To address information blocking, CMS proposes to publish the names of clinicians and hospitals that answered "no" to attestation statements committing them to data sharing, as well as those that failed to submit digital contact information to CMS.

Request for Information (RFI)

- CMS includes a Request for Information (RFI) on 1) Interoperability and health IT adoption in post-acute care (PAC) settings, and 2) the role of patient matching in interoperability and improved patient care.

ONC 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Proposed Rule

Patient Access to Data

- ONC recommends that the healthcare industry adopt standardized APIs based on the well-known Fast Healthcare Interoperability Resources (FHIR) standards and calls for health IT developers to publish APIs and allow health information to be accessed, exchanged, and used without special effort through the use of APIs.

Information Blocking

- ONC implements the information blocking provisions of the 21st Century Cures Act. ONC proposes seven exceptions to the definition of information blocking: (1) preventing harm; (2) promoting the privacy of EHI; (3) promoting the security of EHI; (4) recovering costs reasonably incurred; (5) responding to requests that are infeasible; (6) licensing of interoperability elements on reasonable and non-discriminatory terms; and (7) maintaining and improving health IT performance.

Price Transparency

- ONC states that transparency in the price and cost of health care empowers patients to make more informed health care decisions by improving anticipation and planning for health care costs.

- ONC seeks comment on parameters and implications of including price information specifically related to:
    - (1) "Emergency care, including how and when transparent prices should be disclosed to patients and what sort of exceptions might be appropriate, such as for patients in need of immediate stabilization; (2) Ambulance services, including air ambulance services; (3) Unscheduled inpatient care, such as admissions subsequent to an emergency visit."
    - Additionally, the ONC seeks comment on the "technical, operational, legal, cultural and environmental challenges to creating price transparency" within health care.

Updates to 2015 Edition Certification Criteria

- ONC is responsible for establishing standardized criteria for EHRs. In the rule, ONC proposes a number of changes to the 2015 Edition Certified EHR Technology (CEHRT) criteria, including:
    - The removal of the Common Clinical Data Set (CCDS) definition and its references and replacing it with the US Core Data for Interoperability (USCDI) standard. If finalized, this proposal would establish a set of data classes and elements that would be required to be exchanged in support of interoperability nationwide.
    - The modification of the current the electronic prescribing (e-prescribing) standard to NCPDC SCRIPT 20170701.
    - The removal the Health Level 7 (HL7) Quality Reporting Document Architecture (QRDA) standard. As a replacement, ONC proposes to require Health IT modules to support the CMS QRDA Implementation Guide.
    - The adoption of two new privacy and security transparency attestation certification criteria.

Health IT in Pediatric Care Settings

- ONC proposes recommendations for the voluntary certification of health IT for pediatric practice settings that does not necessitate a separate certification program.