



A Passionate Voice for Compassionate Care

June 3, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

REF: CMS-9115-P

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

Dear Ms. Verma:

The Catholic Health Association of the United States (CHA), the national leadership organization of more than 2,200 Catholic health care systems, hospitals, long-term care facilities, sponsors, and related organizations, is pleased to submit these comments on the Centers for Medicare & Medicaid (CMS) proposed rule on interoperability and patient access to health data.

CHA supports the goals of improving patient access to their health information and to increasing the interoperability of electronic health across providers and care settings, and appreciates the efforts of CMS to advance this agenda. As CMS moves forward, it is essential to prioritize patient privacy and data security, establish reasonable standards, minimize unnecessary burdens on providers and improve data flows across the care continuum.

- **Application Programming Interface: Privacy and Security of Patient Data**

The proposed rule would require Medicare Advantage (MA) organizations, state Medicaid and CHIP agencies, Medicaid and CHIP managed care organizations and issuers of Qualified Health Plans in the federally-facilitated exchanges to establish an open Application Programming Interface (API) that would allow plan enrollees to obtain certain information, including personal health information, from the plan through third-party application software (an “app”) of their choice. CHA supports the advancement of health information technology to promote easy electronic patient access to the type of information contemplated in the proposal. However, the privacy and security of patient information is critical.

Since 1995 the Health Insurance Portability and Accountability Act (HIPAA) privacy and security provisions have protected patient health information and patients are accustomed to assuming that the privacy of their data is secure. These privacy protections could be rendered meaningless if covered entities such as hospitals, providers and health plans must provide electronic access to protected health information to third-party apps that are not subject to HIPAA requirements. The apps may have limited competency in protecting patient information and may include consent language that allows for greater use of personal data than patients realize.

To protect patients **we urge CMS to work with ONC to develop an appropriate process for evaluating apps that interact with patient health information and consider a formal vetting or certification requirement.** All patients would benefit from having access to apps that have been evaluated using objective standards. Those who are not English proficient, have lower health literacy, or are less perceptive consumers generally are more vulnerable to loss of personal health information through an app that does not provide appropriate privacy and security protections. CMS and ONC should also work together to develop a robust program of consumer education and outreach about the privacy and security of health data and the potential risks involved in giving third-party apps access to personal health information. CMS should also further clarify that HIPAA-covered entities would not be responsible for the security of personal health information once it has been received by an individual's chosen third-party app.

We are also concerned that the timeline CMS proposes is too aggressive. The 2020 compliance deadline is unreasonable given the operational and technical challenges of meeting the API requirements. CMS should delay the implementation dates to allow for the development and testing of APIs with sufficient data privacy and security elements.

- **Revisions to the Conditions of Participation for Hospitals and Critical Access Hospitals (CAHs)**

CMS proposes to modify the Conditions of Participation (CoP) for hospitals and CAHs to require electronic patient event notification of a patient's admission, discharge or transfer (ADT) to another provider of care setting. While CHA agrees interoperable ADT notification would advance clinically appropriate information exchange, **the CoPs are not the appropriate way to advance interoperability or data exchange and we oppose including this requirement in the CoPs.**

As CMS acknowledges, the Office of the National Coordinator has not set a specific standard for patient event notifications as part of its health information technology certification program. There are also significant challenges associated with ADT notification, including the issues of patient matching and identifying which providers have appropriate and existing relationships with a patient. Post-acute and other providers that were not included in EHR-adoption incentive programs would not be able to receive the notifications. For this reason, hospitals should only be held responsible for the transmission, not the receipt, of the information.

Given these challenges, the burdens that would be imposed on hospitals and the severe penalty for non-compliance with the CoPs (potential exclusion from the Medicare program) we urge CMS to withdraw the proposal and look instead to other means to increase interoperable electronic exchange of ADT notifications. The best way for CMS to promote the exchange of patient event notification would be to continue to build toward the type of health information exchange envisioned under existing mechanisms, such as the draft Trusted Exchange Framework and Common Agreement (TEFCA) or the Medicare Promoting Interoperability Program.

- **Request for Information on Advancing Interoperability Across the Care Continuum**

CMS seeks comments on strategies for advancing interoperability across the care continuum. CHA agrees that the success of interoperability depends on achieving electronic health information exchange across the spectrum of health care providers and payers. As noted in the proposed rule, electronic health information exchange among hospitals and post-acute care and behavioral health providers would facilitate improved coordination among providers at care transitions.

As CMS notes, post-acute care, behavioral health and home and community-based services providers have not been able to participate in Medicare and Medicaid EHR adoption incentives created by the HITECH Act. CMS should create incentives for EHR development and provide health IT investment resources in these settings in order to make interoperability across the care continuum possible.

CMS invites comments on whether hospitals and physicians should have the ability to collect and exchange some of the PAC standardized patient assessment data elements developed under the IMPACT Act. Rather than applying standards developed specifically for one care setting to other providers, CMS should pursue a more holistic approach to developing appropriate cross-continuum standards. CMS should work with stakeholders as it develops USCDI and data standards to address how best to collect and exchange data across care settings.

CHA believes that 42 CFR Part 2 substance abuse regulations should be brought into alignment with HIPAA requirements to allow the use and disclosure of patient information for treatment, payment and health care operations. Access to a patient's entire medical record, including addiction records, ensures that certain providers and organizations, when medically necessary, have all the information necessary for safe, effective, high quality treatment and care coordination that addresses patients' health needs. Alignment between the two laws is also needed to maximize interoperability and care coordination with behavioral health providers.

- **Public Reporting of Information Blocking Attestation**

CMS proposes to publicly report those hospitals and CAHs that submit a "no" response to any of the three attestation statements regarding information blocking that are currently required under the Promoting Interoperability Program. These attestations were developed to implement provisions of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. CHA supports the promotion of interoperability and does not oppose the public display of this information in principal. However, ONC has proposed new rules, including penalties, on information blocking.

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CMS should delay the effective date to consider how the current attestation interacts with the new information blocking rules as finalized by ONC and to give stakeholders time to gain experience with new rules.

- **Request for Information on Advancing Interoperability in Innovative Models**

The proposed rule indicates CMS plans to use the Center for Medicare & Medicaid Innovation (CMMI) to test ways to promote interoperability and is seeking comments on general principles around interoperability within Innovation Center models. CHA agrees CMMI could play an important role in expanding interoperability and supports including interoperability principles and piloting data standards as part of care redesign in payment innovation models.

CMS should proceed with caution, however. Given that alternative payment models involve multiple providers, CMS should avoid imposing interoperability requirements on APMs that could create unintentional burdens or result in duplicative penalties. As CMS notes and should consider when applying interoperability principles to APMs, providers of post-acute, behavioral health and home and community based care have lower rates of health IT use and were excluded from EHR adoption incentive programs. CMS should develop strategies and incentives to support investment in health IT by these providers.

Thank you for the opportunity to provide comments on the proposed rule on interoperability and patient access to health data. If you should have any questions about these comments or would like additional information, please do not hesitate to contact Kathy Curran, Senior Director, Public Policy, at 202-296-3993.

Sincerely,



Lisa A. Smith
Vice President
Public Policy and Advocacy