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June 3, 2019

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-9115-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: 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,

On behalf of our over 135 member hospitals and integrated health systems located in Wisconsin, the Wisconsin Hospital Association ("WHA") appreciates the opportunity to comment on CMS-9115-P, a proposed rule regarding healthcare interoperability issued by the U.S. Department of Health and Human Services ("HHS"), Centers for Medicare & Medicaid Services ("CMS").

Our Wisconsin member organizations—both large and small and urban and rural—provide services well beyond the four walls of a hospital, and those services are provided by physicians, advanced care providers, and other non-physician practitioners. WHA's member organizations operate a full continuum of care, including hospitals, clinics, outpatient surgery, rehab, long-term care, home health, and other healthcare services.

Our members' embrace of coordinated care delivery models and provision of care across a continuum of services inside and outside of the hospital has been a key driver in Wisconsin regularly being recognized for high-quality healthcare. With that comprehensive approach to care delivery, our members bring a perspective that often is unique compared to other parts of the country.

WHA supports healthcare interoperability—*i.e.*, the capacity to send and receive a patient's health information from multiple sources between different systems and locations—as a way to improve healthcare coordination, safety, and quality, to empower patients, and to increase efficiency.[1] WHA likewise supports CMS's commitment, expressed in the proposed rule, "to solving the issue of interoperability and achieving complete access to health information for patients."[2] As CMS works with the healthcare industry to advance our mutual goals of interoperability, WHA urges CMS to do so in a way that reduces the burden on providers of using EHRs and that aligns mandated EHR use with provider workflow and patient need.

Because regulatory burden creates additional healthcare costs and limits provider productivity, reducing EHR-related burden on physicians and hospitals is a priority for WHA. We believe that CMS should minimize EHR-related regulatory burdens and ensure that any additional EHR investments, additional time spent using EHR

[1] Am. Hosp. Ass'n, Sharing Data, Saving Lives: The Hosp. Agenda for Interoperability (2019) 3-4, available at: https://www.aha.org/system/files/2019-01/Report01_18_19-Sharing-Data-Saving-Lives_FINAL.pdf.
[2] 84 Fed. Reg. 7,610, 7,611.

technology, or adjustments to workflow that are necessary to comply with regulatory requirements are outweighed by healthcare cost-savings and improvements in patient outcomes.

In our comments on the Office of the National Coordinator for Health Information Technology's ("ONC") recent draft "Strategy on Reducing Regulatory & Administrative Burden Relating to the Use of Health IT & EHRs" ("Strategy"), WHA encouraged HHS to identify additional regulatory reforms to reduce EHR-related provider regulatory burden when such regulations do not meaningfully improve healthcare quality, safety, and efficiency. And in our comments on the 2019 Inpatient Prospective Payment System and Physician Fees Schedule proposed rules, WHA supported CMS's decision to reduce regulatory burden by simplifying EHR reporting requirements in the Promoting Interoperability performance category of the Merit-Based Incentive Payment System and in the Medicare Promoting Interoperability Program.

We understand that HHS likewise has committed publicly to reducing EHR-related provider burden. On March 5, 2018, in remarks to the Federation of American Hospitals, Secretary Azar identified the following as a "key engine for transformation" of healthcare: "addressing any government burdens that may be getting in the way of integrated, collaborative, and holistic care for the patient, and of structures that may create new value more generally."[3] Further, in ONC's draft Strategy, ONC acknowledges that while EHRs have the potential to support high-quality healthcare delivery, regulatory and administrative burdens associated with the use of EHRs can decrease productivity, increase healthcare costs, and detract from patient-centered care.[4] ONC identifies as significant source of EHR-related burden the misalignment between EHR and clinical workflows and says that "[a]s EHRs continue to evolve, it is imperative that they support the workflows that have been established in clinical practice so as not to add to clinician burden."[5]

Also in ONC's draft Strategy, CMS Administrator Verma said that "we believe that providers should be able to focus on delivering care to patients instead of spending far too much time on burdensome and often mindless administrative tasks."[6] Finally, in this proposed rule, CMS says that "[w]e are committed to solving the issue of interoperability and patient access in the U.S. health care system while reducing administrative burdens on providers."[7]

As is explained in more detail below, WHA offers the following recommendations with respect to this proposed rule:

- **WHA urges CMS not to finalize its proposal to amend the Conditions of Participation to require hospitals, psychiatric hospitals, and critical access hospitals to send patient event notifications for admission, discharge, and transfer. This proposed mandate would create significant burden for hospitals without meaningfully improving healthcare quality, safety, and efficiency. In addition, the relationship between the proposed mandate and federal healthcare data privacy laws is unclear.**
- **While WHA supports CMS's intention to promote adequate pathways for sharing administrative payer data, the proposed 2020 effective date for CMS's proposals related to payer interoperability may be too aggressive to ensure that payers have sufficient time to be able to share such data safely and securely.**

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[3] Azar, Alex, Remarks on Value-Based Transformation to the Fed'n of Am. Hosps. (March 5, 2018), https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-value-based-transformation-to-the-federation-of-american-hospitals.html.

[4] Office of the Nat'l Coordinator for Health Info. Tech., Strategy on Reducing Regulatory & Admin. Burden Relating to the Use of Health IT & EHRs (2018) 9-10, available at: https://www.healthit.gov/sites/default/files/page/2018-11/Draft%20Strategy%20on%20Reducing%20Regulatory%20and%20Administrative%20Burden%20Relating.pdf.

[5] *Id.* at 31.

[6] *Id.* at 7.

[7] 84 Fed. Reg. at 7,611 (emphasis added).

WHA believes that our recommendations will advance the goals of interoperability in a way that aligns with WHA's and HHS's mutual goals of reducing EHR-related regulatory burden on hospitals and physicians.

Hospital Patient Event Notifications for Admission, Discharge & Transfer

CMS proposes amending the hospital, psychiatric hospital, and critical access hospital ("CAH") Conditions of Participation ("CoPs") to require such hospitals to use their EHR systems to send patient event notifications at the time of the patient's admission to the hospital and either immediately prior to or at the time of the patient's discharge or transfer from the hospital. The notifications would have to be sent to practitioners, other patient care team members, and post-acute care service providers if all of the following circumstances are met:

- The recipient receives the notification for treatment, care coordination, or quality improvement purposes;
- The recipient has an established care relationship with the patient relevant to his or her care; and
- The hospital has a reasonable certainty of receipt of notifications.

According to CMS, "hospitals and their partners may identify appropriate recipients through various methods," including requesting the information from patients, obtaining it through the patient's medical record, or working with an intermediary that maintains such information.[8] In addition, CMS proposes that hospitals, psychiatric hospitals, and CAHs must demonstrate that their EHR system's notification capacity is fully operational and operates in accordance with all laws regarding the exchange of patient health information.

WHA urges CMS not to finalize this proposed mandate because it would create significant burden for hospitals without meaningfully improving healthcare quality, safety, and efficiency. In addition, the relationship between the proposal and federal healthcare data privacy laws is unclear.

Because hospitals implementing the proposal would have to expend significant time and resources making workflow adjustments and policy changes, we disagree with CMS's assessment that "this proposal would impose a minimal burden on hospitals."[9] WHA agrees with U.S. Senator Alexander, Chairman of the U.S. Senate Committee on Health, Education, Labor & Pensions ("HELP"), who at a May 7 hearing of the HELP Committee talked about the importance of making sure that new regulatory requirements for interoperability do not add to administrative burdens faced by hospitals and physicians.

In addition, the workflows prescribed by the proposal do not align with the workflows that have been established in clinical practice, which ONC identified in its recent draft Strategy as a significant source of EHR-related burden.[10] In the proposal, the regulatory language for admission notification is similar to the regulatory language for discharge and transfer notification, whereas admission is clinically distinct from discharge and transfer, and workflow processes for admission notification would differ from workflow processes for discharge and transfer notification.

Further, certain aspects of the proposal are duplicative of discharge requirements for hospitals under 42 C.F.R. § 482.43(d) and for psychiatric hospitals under 42 C.F.R. § 482.61(e). Likewise, under the Medicare Promoting Interoperability Program, if a hospital or CAH transitions or refers a patient to another setting or provider of care, the hospital or CAH must create a summary of care record using certified EHR technology and electronically exchange the summary of care record.[11] In the proposal rule, CMS acknowledges this duplication but defers

[8] *Id.* at 7,652.
[9] *Id.* at 7,669.
[10] *See* note 4, *supra*, at 31.
[11] 42 C.F.R. § 495.24(e)(6)(ii)(A).

responsibility to hospitals "to consider ways to fulfill these requirements in ways that reduce redundancy while still remaining compliant with existing requirements."[12]

WHA believes that CMS instead should heed Administrator Verma's statement, expressed in ONC's draft Strategy, that "providers should be able to focus on delivering care to patients instead of spending far too much time on burdensome and often mindless administrative tasks,"[13] such as the burdensome task of reducing the redundancy of duplicative CMS regulatory requirements. This is especially important for this proposal because of the stark consequences of failing to comply with the CoPs, *i.e.*, exclusion from Medicare.

The proposed rule is also unclear about the relationship between the proposal and federal healthcare data privacy law. While CMS does state that "[t]he patient event notifications and other exchanges of patient information would be permitted as disclosures for treatment purposes" under the HIPAA Privacy Rule,[14] CMS does not address whether the hospital must ensure that the notification recipient is compliant with such federal privacy laws as HIPAA and 42 C.F.R. Pt. 2 ("Part 2"). For example, if a hospital does not have an agreement in place with a notification recipient for the sharing of protected healthcare information, such as a HIPAA business associate agreement or a Part 2 qualified service organization agreement, the hospital presumably would have to choose between complying with the CoPs or with federal privacy laws that require such an agreement.

Payer Data Exchange Through APIs & Payer-to-Payer Data Exchange

CMS's rule contains a variety of proposals for the sharing of payer data, including (1) a proposal to require certain payers to implement and maintain an open application-programming interface ("API") that permits third-party applications to retrieve certain data at the direction of an enrollee and (2) a proposal to require certain payers to maintain a process for the electronic exchange of the U.S. Core Data for Interoperability ("USCDI") data set with other payers at the request of an enrollee.

Specifically, CMS is proposing that by 2020, Medicare Advantage ("MA") organizations, Medicaid and CHIP fee-for-service and managed care programs, and qualified health plan ("QHP") issuers in federally facilitated exchanges ("FFEs") must make the following data accessible to third-party applications through open APIs:

- Standardized data concerning adjudicated claims, including appeals, provider remittances, and enrollee cost-sharing;
- Standardized encounter data;
- Payer-managed clinical data, including laboratory results; and
- Except for QHP issuers in FFEs, provider directory data on the insurer's network of contracted providers and drug benefit data.

CMS also is proposing that by 2020, MA organizations, Medicaid and CHIP managed care programs, and QHP issuers in FFEs:

- Must accept and incorporate into its records about the enrollee the USCDI data set from any other plan that has provided coverage to the enrollee within the previous five years; and
- At any time during the enrollee's enrollment and up to five years after disenrollment, must send the USCDI data set to any other plan that currently covers the enrollee or to any other recipient identified by the enrollee.

[12] 84 Fed. Reg. at 7,652.
[13] Note 4, *supra*, at 7.
[14] 84 Fed. Reg. at 7,652.

While WHA supports CMS's intention to promote adequate pathways for sharing administrative payer data, the proposed 2020 effective date for both proposals may be too aggressive to ensure that payers have sufficient time to be able to share such data safely and securely.

As stated above, WHA supports healthcare interoperability as a way to improve healthcare coordination, safety, and quality, to empower patients, and to increase efficiency, and we support robust sharing of health information by and between payers. In particular, we agree with CMS's assessment that the proposal for payers to exchange the USCDI data set with other payers may reduce burden on providers by streamlining prior authorization processes, limiting the need for providers to write letters of medical necessity, and otherwise limiting the need for providers to intervene with payers to ensure that a patient receives necessary and appropriate care.

While WHA supports payer interoperability, we believe that the proposed 2020 effective date for both proposals may be too aggressive to ensure that payers have sufficient time to be able to share such data safely and securely. At a May 7 hearing of the U.S. Senate HELP Committee, Chairman Alexander suggested that HHS phase in the proposed 2020 deadline. Further, while we appreciate that CMS in the proposed rule clarified that "covered entities are not responsible under the HIPAA Rules for the security of PHI once it has been received by a third-party application chosen by an individual," we also note that ONC conceded at the May 7 Senate HELP Committee that HHS had not yet resolved privacy issues related to handling of health information by third parties who are not HIPAA covered entities.

Thank you again for the opportunity to comment. If you have any questions, please contact Andrew Brenton at (608) 274-1820 or abrenton@wha.org.

Sincerely,

Eric Borgerding

President