EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

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January 4, 2021

Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Donald Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health IT
U.S. Department of Health and Human Services
330 C Street, SW
Washington, DC 20201

Dear Secretary Azar, Administrator Verma, and Dr. Rucker:

The EHR Association's nearly 30 member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our focus is on collaborative efforts to accelerate health information and technology adoption, assist member companies with regulatory compliance, advance information exchange between interoperable systems, and improve the quality and efficiency of patient care through the use of technology.

We have reviewed as carefully as possible within the allowed timeframe the proposed rule entitled Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information (CMS-9123-P). While most of the requirements are focused on payers, our member companies have extensive experience in supporting interoperability

needs across the healthcare community and expect that many of our clients will turn to us to create innovative tools that leverage the technology CMS proposes to require. It is in this capacity that we respond today.

We applaud CMS' effort to ease the flow of information held by payers to other relevant individuals and organizations. There are benefits to be attained by smoothing the transition for patients from one payer to another as their insurance changes. And healthcare providers will benefit from the automation of burdensome and time-consuming prior authorization processes. Continuing to build on FHIR-based standards and USCDI will enable a more consistent approach to sharing the same data across different use cases and stakeholders.

Provider Adoption

We appreciate that the proposed rule does not create prescriptive requirements for how provider organizations must interact with the proposed APIs for impacted payers. Updates to current programs that are in progress, such as requirements to adopt updates to Certified EHR Technology, will make it challenging to require use of additional novel capabilities across the majority of providers, especially given that some of the proposed standards have low maturity and adoption in the industry today. We appreciate the opportunity the proposed rule gives providers to partner with their health IT developers to create innovative new tools that leverage the capabilities of the proposed APIs to improve data exchange and streamline administrative processes. We believe that CMS' approach will promote the adoption of technologies that reduce burden without creating rigid regulatory requirements. Because developers of technology other than EHRs will also take advantage of the APIs, (e.g., SMART on FHIR Apps, Population Health solutions, or mixed solutions that span across the clinical and payer contexts), such flexibility is appropriate to enable the adoption of desired workflows across clinicians, administrative users, and financial users.

Timelines for Standards Adoption

ONC adopted the underlying standards and implementation specifications (HL7® FHIR® R4.0.1 and HL7 FHIR US Core R3.1.1) to the implementation specifications described in this CMS regulation at 45 CFR 170.215 — Application Programming Interfaces Standards — as the fundamental standards and implementation specifications for healthcare operations for APIs. There is again a disconnect between ONC's Interim Final Rule in late October 2020 on the Interoperability, Information Blocking and Certification regulation and associated applicability dates. In that ONC rule, software developers have until December 31, 2022 to deliver 170.215 as their certified API standard, while none of the implementation guides identified by CMS in this NPRM are included in ONC's Certification Program. However, this proposed rule by CMS seems to suggest that healthcare providers would begin using the functionality associated with that standard only one day later (by January 1, 2023). We strongly suggest that CMS recognize the likelihood that adoption of this new functionality will likely take significantly more time than available by January 1, 2023, particularly given that such adoption is voluntary on the part of providers.

Maturity of Named Standards

We appreciate CMS' utilization of standards-based APIs to establish the requirements described in this proposed regulation. Standards-based technologies reduce ambiguity and can lead to faster and more consistent implementations across the healthcare community. However, we note that the implementation guides named in this proposed rule were developed quickly, and have not been deployed for use in production. Indeed, only the HL7 FHIR US Core Implementation Guide and the CARIN Implementation Guide were formally published before the NPRM became available in the Federal Register. Without more experience in practice, it is likely that such standards may not be fit for adoption at scale without further updates. Therefore, we recommend that CMS acknowledges that wide adoption of some of the implementation guides might not be realistic until they have been reviewed and updated in the context of actual implementations on a wider scale. Specifically, the provider community should not be required to widely adopt new capabilities until the interoperability use cases have been clearly identified, and timelines reconciled with other provider-focused initiatives.

Prior Authorization

In response to a request for comment on the inclusion of prior authorization into Conditions of Participation, we urge CMS to delay creation of such a requirement until the standards have been sufficiently exercised and deployed, in order to be confident that they should be required for the industry at large. The current standards are not sufficiently mature, and it would be most appropriate to delay any such requirement until there is sufficient implementation experience across the industry. Instead, we suggest pursuing initial voluntary adoption, followed by inclusion in the ONC Certification Program using optional certification criteria and related CMS measures with positive incentives, before consideration of a punitive approach that is more appropriate when the standards and capabilities are sufficiently mature and well understood.

We support opportunities to explore additional approaches to minimize the need for prior authorizations, particularly in risk-sharing programs, and appreciate the interest in standardizing data sets to support prior authorization. With the variety of health plans and rules, we realize that may not be fully attainable. However, we encourage CMS to have payers align the data elements required by prior authorization requests to help streamline requests. We would also support sharing previous prior authorization decisions by payers to eliminate potential repetitive work by providers in making requests.

If the focus is on clear data requirements based on FHIR-based APIs supporting USCDI and its vocabulary as it expands, we believe that the necessary level of consistency can be achieved without requiring one common set of questionnaires. We would welcome the opportunity to collaborate with CMS and other stakeholders to pursue this goal.

Prior Authorization Decisions

We note that the relevant standards to enable status updates on prior authorization decisions are not referenced in the Payer Patient Access API requirements. Either the Prior Authorization Support (PAS) implementation guide should be referenced that has such capabilities, or an update to the PDex guide is

required to provide a more suitable, lightweight approach. We recommend CMS defer adopting this requirement until the implementation guides support it.

Multiple Patient Data Sharing

The Da Vinci PDex and CARIN Blue Button implementation guides provide specifications for single patient claims, encounter, and clinical data sharing from a payer to a provider. The FHIR Bulk Data implementation guide provides specifications on how to generally share multi-patient data in bulk. However, guidance on how to share the data scope of PDex and Blue Button using FHIR Bulk Data has not yet been established.

We also seek clarification on when the CMS BCDA and DPC specifications will be fully aligned with the Da Vinci PDex, CARIN Blue Button, and FHIR Bulk Data guidance to avoid unnecessarily variant implementations across payers of any kind. We suggest that until this alignment occurs, that providers not be required to support guidance that still needs to be aligned.

Requests for Information

While we commend the administration's commitment to reducing regulatory burdens and improving patient care, the proposed rule includes several requests for information (RFIs), which will be critical to informing future rulemaking. We believe those RFIs do not have the same urgency for response as the regulatory language in the earlier part of the NPRM, and because the holiday season meant that EHR Association volunteers and staff were unavailable for part or all of the last two weeks, we did not have confidence in our ability to draft thoughtful and thorough responses to the questions posed. Accordingly, we note here that we intend to submit a separate letter by the end of January to provide input on the important topics put out for feedback in the RFIs. We trust that such input can always be useful to the agency.

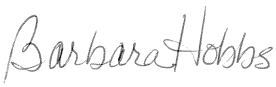
We appreciate your consideration of our comments.

Sincerely,

Hans J. Buitendijk
Chair, EHR Association
Cerner Corporation

David J. Bucciferro
Vice Chair, EHR Association
Foothold Technology

HIMSS EHR Association Executive Committee



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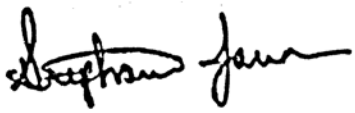

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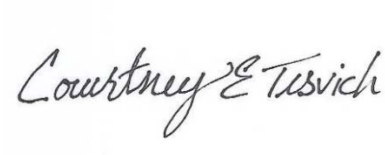

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About the HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS.

For more information, visit www.ehra.org.

Cc:

Alexandra Mugge
Director and Deputy Chief Health Informatics Officer
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