HIMSS™

January 4, 2021

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Washington, DC  20201

Dear Administrator Verma:

On behalf of the Healthcare Information and Management Systems Society (HIMSS), I am pleased to provide written comments on the Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information Proposed Regulation**.** HIMSS appreciates the opportunity to leverage our members' expertise in offering feedback on this regulation and describe our perspective on further improving the electronic exchange of health care data, continuing to support the Centers for Medicare & Medicaid Services (CMS) drive toward interoperability, and reducing burden in the health care market. Overall, we look forward to working with CMS to realize these goals and improve patient access to health information.

HIMSS is a global advisor and thought leader supporting the transformation of the health ecosystem through information and technology. As a mission-driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research and analytics to advise global leaders, stakeholders and influencers on best practices in health information and technology. Through our innovation engine, HIMSS delivers key insights, education and engaging events to healthcare providers, governments and market suppliers, ensuring they have the right information at the point of decision. Headquartered in Chicago, Illinois, HIMSS serves the global health information and technology communities with focused operations across North America, Europe, the United Kingdom, the Middle East, and Asia Pacific. Our members include more than 83,000 individuals, 480 provider organizations and 650 health services organizations.

We are supportive of the work completed thus far across the Department of Health and Human Services (HHS) to provide patients with more access to and control over their data. We endorse the emphasis in this regulation to achieve appropriate and necessary access to complete health records for patients, providers, and payers, while at the same time, reducing burden across the healthcare ecosystem. HIMSS believes that patients should be at the center of their own care, and the thrust in this regulation, as well as in the CMS Interoperability and Patient Access Final Regulation, affirms that goal. By placing patients at the center of their own care, the regulation leads to greater patient empowerment and improved outcomes.

Changes to the prior authorization process included in this regulation also help improve the patient experience and access to care. HIMSS, in conjunction with the Association of Medical Directors of Information Systems (AMDIS), highlighted clinician burden issues associated with prior authorization processes in a 2019 response to the Strategy on

Reducing Burden Relating to the Use of Health IT and EHRs. We strive to ensure that health IT tools are leveraged appropriately to make prior authorization processes more efficient for patients and providers.

In the regulation, CMS proposed to require that information about prior authorization decisions be made available to patients through the Patient Access Application Programming Interface (API). In addition, CMS proposed to require impacted payers to share the same information about prior authorization decisions with a patient's provider via the Provider Access API upon a provider's request, and, the same information about prior authorization decisions be made available via the Payer-to-Payer API.

We emphasize the importance of the clinical relevance of this prior authorization-related information throughout this sharing and exchange between patients, providers, as well as payers and CMS should prioritize how this information benefits patients. As stated in the regulation, appropriate data exchange would include information about pending and active prior authorizations, if such information were applicable. We support the premise that CMS did not include information about denied or expired prior authorization decisions as part of the proposed requirement because it could result in a significant amount of information being shared that may not be clinically relevant at the moment in time the data are exchanged.

We recommend CMS proceed cautiously with directing the sharing of any prior authorization information that could adversely impact a patient's treatment plan. As per this regulation, the patient should always be able to access all prior authorization decisions and documentation via an API, but providers and payers should have a more limited view of prior authorization decisions as directed by the patient. We emphasize that pending and active prior authorizations are much more likely to be clinically relevant and important for patients, providers, and payers to know in order to support treatment and care coordination, as well as efficient and effective payer operation that can lead to the best possible outcomes for patients.

With these factors in mind, HIMSS offers the following thoughts and additional recommendations as this regulation becomes final:

**Create Additional Educational Resources on the Benefits of Greater Patient Control of Information**

As CMS continues to advance patient-directed decision making and formal shared decision making as a broader construct across all its programs, the agency should work to create more resources for patients on the benefits of and positive outcomes that result from an individual's greater control of their health information. These resources should also include information on the potential risks such patient control poses and steps that an individual can take to mitigate those risks and safeguard their personal health information.

CMS's proposed regulation includes information about how educational resources must be created in non-technical, simple, and easy-to-understand language explaining general information. The agency also notes that the Office of the National Coordinator for Health

Information Technology's (ONC's) 21st Century Cures Act Final Regulation makes clear that it is not information blocking to provide information that is factually accurate, objective, unbiased, fair, and non-discriminatory to inform a patient about the advantages and disadvantages and any associated risks of sharing their health information with a third party. The CMS Interoperability and Patient Access Final Regulation required that impacted payers share educational resources with patients to help them be informed stewards of their own health information and understand the possible risk of sharing data with third-party applications.

The proposed regulation takes the safeguard a step further and proposes to require that impacted payers request a privacy policy attestation from third party application developers when the third party app requests to connect to the payer's Patient Access API. Furthermore, CMS proposing the quarterly reporting of Patient Access API metrics to the agency will help it understand the impact this API is having on individuals and inform how CMS could improve access or use through additional consumer education.

Overall, much of the proposed regulation focuses on the educational resources that payers and providers should create to inform patients, enrollees, and beneficiaries on these topics. However, there is a real foundational opportunity for CMS to build on its partnership with ONC and create additional resources to develop direct-to-patient education that advises patients on the parameters around patient control of information and appropriate data sharing. The additional resources that CMS (with ONC) creates would complement the work that payers and providers develop and serve to support the broader principles underlying this regulation.

**Reexamine the Implementation Timeline Requirements in this Proposal**
HIMSS supports the steps that CMS is offering in the proposed regulation to provide patients with more access to and control of their data. However, the requirements and implementation timelines in the proposed regulation, combined with the requirements in ONC's 21st Century Cures Act Final Regulation, the CMS Interoperability and Patient Access Final Regulation, and the 2015 Edition Cures Update, is stretching the health information and technology development, deployment, and training resources of all healthcare stakeholders.

Moreover, it is important to note the devastating impact COVID-19 is having across the health ecosystem, upending technology implementation plans and timelines. As many payers and providers focus their attention on managing growing demands for care, and ensuring they have the products, equipment, and supplies to support clinicians to deliver quality care, CMS should consider these factors when finalizing timelines for this Regulation. We recommend that CMS wait until more information is available about the near-term trajectory of COVID-19 before finalizing any effective dates. CMS should ensure it is considering COVID-19-related challenges when finalizing any implementation dates, as well as the other pending regulatory changes required over the next 18-24 months.

## Provide Clarity around the Payers Impacted and Implementation Guides (IGs) Specified in this Proposal

In the CMS Interoperability and Patient Access Final Regulation, the impacted payers included Medicare Advantage Organizations, in addition to the payers covered in this Regulation, which include Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges.

Between these two regulations, and the fact that some requirements are slated to impact different payers, CMS should create a compendium tool to help payers navigate what is required of each payer as well as the required implementation dates as they currently exist. CMS speaks in this proposed regulation about the importance of aligning policies across all these programs to benefit patients, and how patients enrolled in these programs may churn from payer to payer within a given program, as well as between programs. We believe the benefits of better leveraging API technology across these payers will help patients immensely, but the community needs to better understand what is expected of each payer.

In addition, CMS is proposing the adoption of certain IGs needed to support the proposed API policies included in the Regulation. The community is seeking clarity on whether this proposal is putting forth updated IGs for the current versions of the three standards identified, or if CMS is allowing for later versions of these standards to be accompanied by their own IGs. We also encourage CMS to consider whether an adaptation of ONC's voluntary Standards Version Advancement Process (SVAP) is warranted here, which could better enable health IT developers' ability to incorporate newer versions of HHS Secretary-adopted standards and implementation specifications.

In terms of the Requests for Information (RFIs) included in the Proposed Regulation, HIMSS expresses the following brief considerations, with the offer to provide more extensive follow-up with CMS on these topics at a future date:

- ***Methods for Enabling Patients and Providers to Control Sharing of Health Information***
  Patients and providers both play critical roles in data segmentation decisions. With the Department seeking public comments on proposed changes to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Regulation, we expect to address many of these questions in that public comment letter.

- ***Electronic Exchange of Behavioral Health Information***
  HIMSS applauds discussions around the inclusion of behavioral health providers in the adoption and use of EHRs and API technologies, but we ask for similar considerations of post-acute care providers and their heath information and technology uptake, given the importance of those care settings in the broader ecosystem.

- ***Reducing the Use of Fax Machines***
  HIMSS supports broader interoperability and exchange of data, and recognizes the utility of faxes for many heath care interactions and transactions, but we emphasize that CMS could better align its program policies and requirements to reduce the number of instances where a fax is mandated in addition to electronic validation. There are also federal regulatory policies in place where a fax machine is utilized in order to ensure program compliance and avoid any potential waste, fraud, and abuse issues. Greater compliance clarity from CMS would be helpful in alleviating these issues and minimizing the use of fax machines as a back-up or secondary compliance mechanism.

- ***Accelerating the Adoption of Standards Related to Social Risk Data***
  HIMSS believes that Social Determinants of Health (SDOH) information should be incorporated and utilized for healthcare delivery services to treat patients in a more holistic way. It is difficult to overestimate the importance and impact that SDOH information has on overall health outcomes. Where people live, work, go to school, and socialize as well as the social services that they receive affect a wide range of health risks and factors making it even more important to include these data in health IT tools along with other care information to allow clinicians to appropriately treat patients. HIMSS members that provide direct and indirect patient care services experience the impact of SDOH every day as they try to deliver care and work within a system that enables better outcomes to their patients. We are committed to helping CMS find the best way to standardize this information and ensure that it is interoperable for the benefit of patients and their caregivers. As the US health system continues its push toward value-based care delivery, more data sources must integrate data into health information and technology tools, including but not limited to, SDOH information.

  A current focus for the HIMSS membership is on how best to use information and technology tools to collect, standardize, and present SDOH information in the development of treatment plans at the point of care. SDOH information would likely provide the underlying context for clinicians as to whether a treatment plan can be adhered to or whether follow-up care and referrals will be utilized. However, the first step is ensuring the federal government and state agencies can collect the information, provide it in a shareable format across programs, and use the data to the benefit of people availing themselves of these social services. The true value of SDOH information to the healthcare community is in improving care delivery and uncovering new obstacles that need to be addressed for the betterment of patients as well as the broader social safety net community.

Overall, HIMSS wants to facilitate greater nationwide interoperability that leads to information exchange and to provide patients with more access to and control of their data. We support the steps included in the Proposed Regulation to achieve appropriate and necessary access to complete health records for patients, providers, and payers, while reducing burden across the healthcare ecosystem. HIMSS believes that patients should be at the center of their own care, and the work by CMS in this Proposed

Regulation, as well as in the Interoperability and Patient Access Final Regulation, supports that premise.

We welcome the opportunity to further discuss these issues in more depth. Please feel free to contact me at 703.562.8814 or Jeff Coughlin, Senior Director of Government Relations, at 703.562.8824, with questions or for more information.

Thank you for your consideration.

Sincerely,

Thomas M. Leary

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Senior Vice President for Government Relations