August 12, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
Baltimore, MD 21244-1850

Dear Administrator Verma:

On behalf of the Healthcare Information and Management Systems Society (HIMSS) and the Association of Medical Directors of Information Systems (AMDIS), we are pleased to provide written comments to the Centers for Medicare & Medicaid Services (CMS) in response to the Request for Information (RFI) on Reducing Administrative Burden To Put Patients Over Paperwork. We appreciate the opportunity to leverage our members' expertise in offering feedback on this RFI and its focus on ideas to help reduce the burdens placed on clinicians—as time and attention clinicians spend on burdensome activities is time and attention diverted from patient care. We look forward to continued dialogue with CMS on policies and programs focused on alleviating clinician burden issues as well as other relevant provisions of the 21st Century Cures Act (Public Law 114 -255).

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 companies, 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.

As an association, HIMSS encompasses more than 78,000 individual members and 650 corporate members. We partner with hundreds of providers, academic institutions, and health services organizations on strategic initiatives that leverage innovative information and technology. Together, we work to improve health access, and the quality and cost-effectiveness of health care. Headquartered in Chicago, Illinois, HIMSS serves the global health information and technology communities with focused operations across North America, Europe, United Kingdom, the Middle East, and Asia Pacific.

Founded in 1997, AMDIS is the premier professional organization for physicians interested in and responsible for healthcare information technology. AMDIS Members are the thought leaders, decision makers and opinion influencers dedicated to advancing the field of Applied Medical Informatics and thereby improving the practice of medicine. With our symposia, blogs, on-line forum, journal, presentations, sponsored and co-sponsored programs, and networking

opportunities, AMDIS truly is the home for the "connected" Chief Medical Information Officer (CMIO).

HIMSS and AMDIS appreciate that healthcare is complex and often requires hard work and extraordinary effort on the part of clinicians to arrive at the right diagnoses as well as to provide appropriate treatment. We believe this level of effort defines our members' clinical work as professionals. That said, we share the belief of CMS that much of the work that clinicians face today is unnecessarily burdensome, where burden is defined as clinician activity that does not serve patient interests, does not improve quality or safety, or regardless of intent, is a barrier to clinical workflow and limits the ability of clinicians to appropriately engage with patients.

Our organizations want to work with the Department of Health and Human Services (HHS) to eliminate the unnecessary actions that occur in the course of clinical practice. Ultimately, HIMSS and AMDIS want clinicians to be able to focus their time on actions that make sense, such as caring for patients and delivering better outcomes. We want to help CMS reduce burden so that our members and other clinicians can deliver better and more efficient care.

HIMSS and AMDIS appreciate the work undertaken thus far across HHS to begin to address clinician burden issues. For our public comment, we offer the following overarching thematic thoughts and recommendations for creating an environment where the burden on clinicians is minimized, while prioritizing the ultimate goals of delivering better outcomes, higher quality, and more cost-effective care:

- **Advance the Shift to Value-Based Care Delivery and Expand the Use of Alternative Payment Models (APMs) to Help Reduce Burden**

HIMSS and AMDIS continue to be encouraged that CMS, and HHS more broadly, endeavor to push healthcare delivery in the direction of value-based care, not only to produce better outcomes for patients, but also to minimize the burden issues that are inherent in a fee-for-service care environment. CMS should push for the continued development of demonstration and pilot programs to test different value-based service delivery and APMs in order to study the most prominent factors that mitigate clinician burden as well as how additional care settings and clinicians can emulate those advances.

Overall, value-based care can promote more useful documentation processes if the program is structured to focus on clinical outcomes that can be measured from the record without a requirement that turns clinicians into clerks. Managing patients in a value-based system can provide greater opportunities to deliver care differently so clinicians can provide more value-added services.

However, it is important to note that burdensome fee-for-service requirements cannot be replaced by other equally-burdensome reporting requirements from different care models. Any action to shift toward value-based care should be made with the goal of avoiding new and different types of burden being imposed on clinicians.

HIMSS and AMDIS encourage CMS to continue to forcefully push healthcare delivery in the direction of value-based care, not only to deliver better outcomes to patients, but also to minimize the burden issues that are inherent in the historical paper-based models of a fee-for-service care environment. Value-based care and APMs continue to proliferate across the healthcare enterprise, and burden reduction efforts should remain a priority when pushing forward and testing these new care delivery models.

- **Health Information Technology (IT) Tools are Part of Any Solution to Resolve Clinician Burden**

HIMSS and AMDIS understand that this RFI is intended to align with 21st Century Cures Act requirements to reduce regulatory and administrative burden related to the use of health IT and electronic health records (EHRs). However, we want to assert the importance of health IT tools in resolving any burden-related issues in our healthcare system. When properly designed and utilized, health IT can reduce the burden associated with documentation, administrative functions, and regulatory compliance.

EHRs and other health technologies are designed to serve as documentation records, to improve care and overall health as well as streamline the added layer of requirements that regulatory compliance often demands. Current regulatory requirements interfere with this longer-term strategic role that EHRs play in the healthcare ecosystem, to collect and aggregate the very data that will be used to enable value-based care delivery. These requirements have shifted focus from the delivery of clinical care to the transactions that support the payment of care.

The future state of health information and technology builds on our work thus far and advances an end-game where a more advanced information and technology infrastructure can help deliver better and safer care. It should also incorporate the constructs of increasing focus on the patient and supporting better decisions and shared decision-making, thus improving the efficiency of normal healthcare operations, which includes reducing or eliminating burden.

In addition, there will be greater demands placed on technology to help make the right information more accessible at the right place and time so it is more meaningful and impactful to patients and providers. As burden reduction efforts at CMS continue to move forward, it is important to recognize that information and technology are essential components of any solution to alleviate clinician burden.

- **CMS Should Work with the Entire Stakeholder Community to Map All of the Regulatory Requirements Placed on Clinicians in the Course of Care Delivery and Determine Areas of Convergence and Contradiction**

The current healthcare regulatory structure often places additional requirements on clinicians that contribute to burden challenges. In some cases, two or more regulations conflict, leaving provider organizations to make their best guess about how to proceed. CMS, along with its colleagues across HHS, should work with the entire stakeholder community to map all the regulatory requirements placed on clinicians in the course of care delivery and determine areas of convergence and

contradiction. The ultimate goal of this exercise would be to catalog and summarize every regulation that influences clinical practice and determine the objectives of each included provision. This effort would allow HHS to answer the question about which goals should be prioritized in each regulation as well as to ensure that goals do not significantly overlap with the goals inherent in another regulatory measure. Stakeholder groups like HIMSS and AMDIS stand ready to provide input on whether a regulation supports its stated goal, and if not, how it might be adjusted to meet it.

The root cause analysis we describe is necessary to determine the regulatory provisions that are most burdensome and how they should be modified to meet each intended goal. A regulatory map that describes how regulations are related and interact would help CMS determine how it could best issue regulations and policies as well as simplify or modify rules and policies for the benefit of beneficiaries, clinicians, and providers.

HIMSS and AMDIS recognize that this regulatory mapping exercise could take some time to address and receive the necessary input from the community, so we suggest that CMS take several interim steps to reduce burden while it is underway. Ultimately, CMS should grant more physicians the ability to focus their energy on treating patients, not on documenting specific data elements that regulators and payers want included in EHRs. Many of the concerns related to clinician burden emanate from the need to document information in a patient's clinical note that justify billing and reimbursement. This often requires repeating the same information that already exists in other parts of the EHR. This redundancy is unnecessary, and adds to the volume of existing tasks already placed on the clinician, re-directing their energy away from treating the patient, as well as diluting the value of the documentation.

HIMSS and AMDIS want to move away from the perception that if a physician did not document specific required elements of a service in a patient's EHR, that physician did not perform those services. CMS has made significant strides in this kind of recognition over the last two years, and we want to ensure that the agency continues to move deliberately in this direction.

Moreover, until unnecessary documentation requirements can be eliminated, CMS should also create more robust resources to help demystify documentation requirements and show how they relate to coverage and reimbursement decisions. It would be extremely helpful for CMS to lead the development of a minimum data set requirement that payers—including both internally within the agency as well as with Medicare Administrative Contractors (MACs)—would use to determine the level of service delivered during a patient encounter and confirm reimbursement decisions.

In addition, we advocate for the creation of a resource guide that hospital and provider compliance departments could use for improved clarity on the documentation requirements for different clinical services. Given that compliance departments often hyper-interpret regulatory or documentation requirements for fear of potential risks associated with improper documentation, such a resource would be invaluable—it would offer assistance to these departments so they have the rules that they need to properly communicate documentation requirements to clinical staff.

- **CMS Must Shift the Paradigm from Requiring Clinicians to Submit Documentation to Payers for Coverage and Reimbursement Decisions to a Scenario where Health IT Tools and Approved Devices Send the Structured Data Elements that Payers Need to Make these Decisions Directly from EHRs**

The US healthcare delivery infrastructure has failed to adapt reimbursement processes to the digital health paradigm, as our current paper-based practices have yet to take advantage of the billions of dollars spent to move to a digital health universe. Currently our healthcare system requires that clinicians submit documentation to payers for coverage and reimbursement decisions, adding further burden in the course of treatment of a patient. HIMSS and AMDIS suggest that this burden could be removed by allowing health IT tools and approved devices to send structured data elements that a payer needs to make these decisions directly from the EHR and not require any additional steps or specified documentation from clinicians. In doing so, this path would explore the use of a structured dataset to abstract content for payers to obtain necessary information, and would focus on the automated push-out of the specific information that a payer needs directly from the EHR or other health IT tool. Overall, this broader approach would allow the entire healthcare system to utilize EHRs as effective tools for capturing and reporting the various discrete data elements that contribute to figuring out what work a clinician does in the course of treating a patient.

Under this shift, HIMSS and AMDIS envision that clinicians would submit patient demographic information, date of service, and request payment for the services delivered. At that point, Medicare or Medicaid (as well as other payers) would have their own internal processes to determine what constitutes a valid billable service. The payer would send a data pull request to the clinician's EHR to validate the service and make payment. For this process to work properly, further development would be needed around standardized data transmission for this specific purpose, using Fast Healthcare Interoperability Resources (FHIR) application programming interfaces (APIs). In addition, such a redesign would require health plans to rethink how to pay for each service. Certain safeguards will have to be built into the definitions of the pull process and query language utilizing existing (and planned) FHIR APIs, including: valid authorization for payers to access data through contractual relationships; specifications about how this process is completed; establishing audit trails; additional privacy and security protections; and, the opportunity for explainability with a feedback loop that allows providers to appeal and contribute to the algorithms that determine reimbursement.

- **CMS Should Move to Finalize its Interoperability and Patient Access Proposed Regulation and Empower Patients with Greater Control of Their Data**

CMS must focus on facilitating broader efforts around greater data sharing capacity and interoperability, as the lack of both of these end-states contributes to significant sources of clinician burden. HIMSS and AMDIS have historically recommended leveraging existing reporting data to avoid undue burden on the end user. However, we continue to highlight the important roles that interoperability and the transmission of data play in the functionalities of health IT products, and encourage HHS's continued promotion in improving interoperability functionality when discussing burden issues.

Unfortunately, the current ability of one EHR to exploit information shared by another EHR or health IT tool is often not seamless or without barriers, but rather a constant work in a progress. For example, challenges consistently remain when attempting to incorporate or utilize clinical data found in state and regional health information exchanges (HIEs) into a facility's EHR. Ideally, the process should be straightforward for clinicians to navigate from their EHR to the state/regional HIE portal, authenticate to the state/regional HIE portal, search, match, and select the correct patient, and filter to the relevant clinical data to review as well as utilize for the purposes of making real-time clinical judgments. These processes are very time-consuming, and the patient is ultimately the one who suffers as these administrative activities have the tendency to detract from and delay direct patient care.

The inability to send and receive data is not limited to the clinician, as it extends to the patient. HIMSS and AMDIS encourage HHS to fully implement the broader policy goals on information blocking from the 21st Century Cures Act in order to aid in appropriately addressing these overarching issues. Ultimately, we would emphasize that empowered patients make better-informed healthcare decisions that contribute to the delivery of improved outcomes, and patients can only truly act on information that is present and available at the time healthcare decisions are to be made.

Moreover, the greater data sharing that more readily occurs in a value-based payment structure, integrated network, or APM framework supports the importance of both interoperability and patient empowerment. Historically it has not been effortless for providers outside of Accountable Care Organizations to get data as easily from CMS and other providers as it was for providers within one of these arrangements. If the healthcare community is to be held accountable, even within a fee-for-service (FFS) framework, access to all claims on a specific patient should require fewer obstacles than there are today. Claims data is not as comprehensive as clinical data, but we acknowledge and support all steps that CMS is making to facilitate greater interoperability and make claims data more accessible to those providers who are not in fully integrated networks. This step would reinforce greater data sharing models across the healthcare ecosystem as well as foster the availability of more information with which to engage patients.

- **Quality Reporting Must be Prioritized When Seeking to Reduce Clinician Burden**

HIMSS and AMDIS acknowledge the benefit and the need for good quality reporting that promotes better health outcomes. However, with this recognition, we support a more holistic approach in terms of the professionals who can and do contribute to the reporting process as part of the care team. At this time, we emphasize the importance of approaching the strategies and recommendations for reducing documentation burden from a team-based healthcare perspective. Clinical care, more than ever before, includes additional professionals and disciplines working together toward the common goal of promoting health for patients, families, and communities. With this in mind, we urge the use of inclusive language and consideration of all members of the healthcare team and how they contribute to care provision, as well as the documentation and reporting processes, including quality reporting.

Under the "pull" paradigm introduced earlier, open APIs can enable the practice of pulling information from EHRs for the purpose of billing as well as quality assessment. CMS should also look at the further development and operationalization of bulk FHIR data access, as it is also very relevant to quality reporting. Overall, it is critically important that quality reporting leverage data already present in the EHR or other health IT tools to seek the information for a quality assessment, rather than to task clinical staff to abstract the data and create a report. Software can be very successful at this task. We should create the policies, standards, and infrastructure to migrate this clerical job from humans to computers.

In addition, HIMSS and AMDIS have long supported robust field testing of new electronic clinical quality measures (eCQMs) prior to their release by CMS, and we would like to note that this field testing would reduce the burdens of workarounds and modifications that are sometimes needed in eCQM implementation.

Moreover, CMS should be commended for its work to create the Electronic Clinical Quality Improvement (eCQI) Resource Center as it promotes the accessibility as well as the presentation of CMS quality requirements. HIMSS and AMDIS ask that CMS expand the resource center beyond simply eCQM-related material, to encompass a linkage with the National Library of Medicine Value Set Authority Center as well as more descriptive information on the appropriate creation of value sets.

Earlier in this letter, we asked CMS to create more robust resources to demystify documentation requirements; the same principle applies around resource formation to better explain quality reporting. There is still an information gap about how CMS Regulations connect with various federal/CMS quality initiatives and the measures that are required for reporting. There would be a significant reduction in burden if CMS were to better coordinate its multiple websites and communication/education channels that currently house various quality reporting-related material to make it easier for clinicians and their staff to interpret federal quality reporting information.

- **Reducing Clinician Burden May Help to Address Health Care Cost Challenges**

Given the HHS focus on controlling health care costs, HIMSS and AMDIS would like to emphasize the importance of addressing clinician burden in any plans to tackle health care cost challenges. Recent research from Shasha Han, MS, et al, in the *Annals of Internal Medicine* from June 4, 2019, estimated annual burnout-attributable costs ranged from $2.2 billion to $6.7 billion to the US health system, with their analysis also estimating the annual cost at $7,600 per physician. Studies have found that overly-burdened clinicians have lower productivity and deliver poorer outcomes to patients, among other issues like earlier retirement exacerbating physician shortages. As HHS works through plans to address health care costs, it is imperative that solutions to address burden are part of the discussion.

In this response, HIMSS and AMDIS echoed many of the comments that we collaborated on in our January 2019 letter to CMS and the Office of the National Coordinator for Health IT on the Strategy on Reducing Burden Relating to the Use of Health IT and EHRs. We encourage HHS to take a holistic approach to address clinician burden to ensure that all policies are evaluated to help

reduce the burdens placed on clinicians—as time and attention clinicians spend on burdensome activities is time and attention diverted from patient care. As emphasized in this response letter, we want clinicians to be able to focus their time on actions that make sense, such as caring for patients and delivering better outcomes. Ultimately, we want to help HHS reduce burden so that practitioners can deliver better and more efficient care.

Moreover, HIMSS and AMDIS are committed to be being a valuable resources to CMS as the agency moves forward to address this RFI, implement the Patients over Paperwork Initiative, and alleviate clinician burden issues. We welcome the opportunity to meet with you and your team to discuss our comments in more depth. Please do not hesitate to contact Jeff Coughlin, HIMSS Senior Director, Federal & State Affairs, at 703.562.8824, or Eli Fleet, HIMSS Director, Federal Affairs, at 703.562.8834, with questions or for more information.

Thank you for your consideration.

Sincerely,

Harold F. Wolf III, FHIMSS
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