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January 28, 2019

The Hon. Alex M. Azar II
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar,

On behalf of the Electronic Health Record (EHR) Association, we are pleased to submit comments on the draft report, "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs," which was published jointly by the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS) on November 28, 2018. These comments are based on the collective perspectives and experiences of the Association's 35 member companies who serve the majority of hospitals and ambulatory care providers using EHRs across the U.S.

As HHS takes important steps toward reducing clinician burden, it is important to recognize that a key contributor to the frustration of providers with EHR documentation requirements has been compliance with outdated guidelines which are geared to billing and policy requirements rather than patient care. The current proposed Strategy and CMS's "Patients Over Paperwork" initiatives are welcome steps toward more focused documentation requirements.

Below, the Association provides additional comments related to the proposed strategies and recommendations in the four key areas outlined in the report.

Clinical Documentation

Strategy 1: Reduce regulatory burden around documentation requirements for patient visits.

Overall, the EHR Association supports strategies and recommendations aimed at reducing regulatory burden related to patient visit documentation requirements, including the recommendation to continue gathering stakeholder input about updates

to documentation requirements and the recommendation to leverage data already present in the EHR to reduce re-documentation in the clinical note, where that is feasible.

As HHS moves toward proposals to change billing requirements, we believe a measured pace of introducing changes will be critical to successfully updating the systems and workflows which have been used for many years. Most EHR clinical documentation capabilities for visit services are embedded in documentation elements and visit acuity scoring algorithms of E/M services. As with all changes that are introduced to health information and technology, especially those that impact clinical workflows, clinicians and clinical support staff need time to learn about the changes and adapt to using new, less prescriptive approaches.

Providing sufficient details well in advance of an effective date will be critical for the successful rollout of these changes, as the implementation details are often critical when it comes to ensuring health information and technology system development can be completed in advance of when providers must implement the changes.

The EHR Association is strongly supportive of policy directions which use information already present and relevant in the patient's medical record, representing a historical record of the patient to be used in this context.

Strategy 2: Continue to partner with clinical stakeholders to encourage adoption of best practices related to documentation requirements

The EHR Association strongly endorses the recommendation to partner with clinical stakeholders to promote clinical documentation best practices as documentation requirements are developed.

We are supportive of efforts to engage all stakeholders across the industry, including health IT developers, health plans and other organizations that may be impacted by changes to Medicare documentation requirements. For example, maintaining alignment with non-federal payers will be key as changes go into effect which directly impact payment so that acceptable documentation and billing approaches are not driven based on payer source, such as the way E/M services are now documented.

In addition, requirements for Promoting Interoperability (PI) should be the same for eligible clinicians (ECs), Eligible Providers (EPs), and Eligible Hospitals (EHs) -- regardless of the payer driving the program. Managing different quality programs based on payer classification is difficult, expensive and confusing for all stakeholders.

The EHR Association supports strategies that encourage best practices related to clinical documentation, because it is important to recognize the potential for unintended consequences of these proposed changes on other, equally important, HHS goals. For example, quality measurement, standards-based interoperability, and clinical decision support are typically driven by the structured documentation captured in an EHR by the provider. We encourage HHS to identify ways to explore potential

ramifications of documentation changes on the wide range of clinician workflows before broadening them in ways that may negatively impact other initiatives.

Strategy 3: Leverage health IT to standardize data and processes around ordering services and related prior authorization processes.

Health information and technology will play a critical role in modifying the data and processes around ordering and prior authorization. Changes in this area will require collaboration across multiple stakeholders, including payers. Therefore, we strongly support the recommendation to coordinate efforts and to evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization. In particular, we see value in greater transparency and consistency on the part of payers regarding prior authorization or documentation requirements necessary to justify a service or procedure. Varied authorization requirements across payers are challenging to resolve into a consistent, easy to understand provider flow that would build on data already available from essential clinical documentation.

The EHR Association supports a prior authorization pilot, potentially in a disease area where standard regimens have been published and where there is an opportunity for a consistent approach to authorization.

We support development of interoperability standards and specifications to advance the use of electronic prior authorization of electronic submission of medical documentation as well as identifying incentives to encourage providers to adopt technology that can leverage these standards. We also caution against the use of prescriptive regulatory mandates that lock in use of a specific standard that can only be replaced by further regulation, and support the focus CMS is demonstrating through the Da Vinci project to identify opportunities to streamline the authorization process building on data already available through the expanding set of FHIR-based service APIs being deployed through EHRs, thus reducing administrative overhead and reducing re-documentation requirements.

A pilot will be most successful if it permits an onboarding approach that continues a progression toward the use of standards and specifications to avoid burden on healthcare providers as they transition towards new technologies. From our experience, new standards and approaches are more likely to be adopted by healthcare providers if the approach supports the clinical workflow instead of requiring an offshoot of additional documentation requirements.

Health IT Usability and the User Experience

Strategy 1: Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation tools.

Strategy 2: Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction.

Strategy 3: Promote harmonization surrounding clinical content contained in health IT to reduce burden.

EHR Association members are heavily invested in the usability of EHR technology. EHR developers follow widely recognized user-centered design (UCD) processes and continuously optimize the usability of their systems, and this should be recognized and encouraged. However, detailed, prescriptive design and formatting standards should be left to best practice sharing, as standards are too rigid and slow moving to rapidly adjust to the latest learnings in this particular space.

The recommendation in Strategy 1 to “better align EHR design with real-world clinical workflow” is in conflict with the recommendations under Strategy 3 related to standardizing clinical content in health IT. “Real-world clinical workflow” varies across settings of care and clinical providers, and may not be a measurable recommendation. In the same way that driving a car differs in the user experience from driving a motorcycle, EHR systems may have different user experiences designed to be as optimal as possible for the users, clinical workflows, and settings for which it was designed. This tradeoff between consistency and fit is one that we as developers are well-positioned to understand because of our intense investment in user research and understanding of the context of use.

In the EHR Association white paper, "[EHR Design Patterns for Patient Safety](#)," which was created through a collaborative effort of EHR Association member companies’ software designers and engineers, human factors experts, clinicians, and other staff who bring decades of experience in the development and deployment of EHRs in healthcare organizations of varying sizes and specialties. In the white paper, we provide examples of areas where harmonization may be beneficial with regard to patient safety, such as the use of tall man lettering when displaying medications and ensuring that normal and abnormal lab results are displayed clearly and consistently.

The “EHR Design Patterns for Patient Safety” white paper also addresses alert fatigue and provides recommendations for addressing this in EHR technology. These recommendations are not overly prescriptive in order to allow for differences in design and intended user. For example, while most EHR developers in the U.S. use red exclamation points or the letter X to indicate errors, the size and placement of the alert varies depending on context.

The EHR Association appreciates the recommendation to promote proper integration of the physical environment with EHR use because this is something that EHR developers work on with customers across various clinical settings. This intersection between the physical environment and EHR software is another reason why we caution against prescriptive regulations related to EHR user interface, as it is another area prime for innovation and for market differentiation across products.

Strategy 4: Improve health IT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden

The Association agrees that engaging key stakeholders early in acquisition and implementation processes is imperative to successful EHR implementation. We add that it is important to include

clinicians in defining value and implementation success. Providers should consider their options fully and understand how many variables directly affect them before deciding to 'customize' system options which then localizes their implementation. Customizations can present challenges that may also impact usability.

Software currency is important to enable the latest usability enhancements. EHR Association members work on strategies to ensure that updates to our software--including updates to usability--are easy to deploy and widely adopted so that as many clinicians as possible can benefit. We recommend this proposed Strategy document address the importance of staying current with software updates.

EHR Reporting

Strategy 1: Address program reporting and participation burdens by simplifying program requirements and incentivizing new approaches that are both easier and provide better value to clinicians.

EHRA supports simplifying incentive program requirements. However, recent simplification initiatives have not successfully incorporated industry feedback, and have had the unintended consequence of actually adding complexity to the programs. Recent new measures (e.g. the combined HIE measure and new opioid measures in Promoting Interoperability) have been rolled out without incorporation of stakeholder input, and are specified in ways that have caused significant waste for developers and are likely to have negative impacts on clinician experience.

We see a process improvement opportunity for more detailed input and feasibility on new potential measures. We suggest a review, feedback, and public feasibility assessment of new measure specifications by a diverse set of stakeholders prior to their incorporation into CMS programs. EHR developer feedback could have helped CMS reshape the combined HIE and new opioid measures to better achieve intended goals and to mitigate the negative impact on clinician experience.

When regulatory programs are announced without sufficient detail to support software development and program implementation, this increases the development burden on health information and technology developers, and leads to a lack of standardization across providers using different systems. One example of where standardization would be helpful is in the new opioid-related Promoting Interoperability measures added for program year 2019. The measures do not identify a standardized approach for defining opioids or calculating the number of opioid days, which means there is a high chance of variability across products and participating providers.

Strategy 2: Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.

The EHR Association is supportive of efforts to leverage health information and technology functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs. Many of the burdens felt by EHR developers and healthcare providers that are related to these

programs stem from regulatory drivers such as program requirements that do not align with clinician workflows or finalizing policy changes with insufficient time for the changes to be developed and implemented in health IT systems.

Strategy 3: Improve the value and usability of electronic clinical quality measures while decreasing health care provider burden.

EHRA strongly supports improving the value and usability of electronic clinical quality measures. There are already good, recently developed quality measures available for care. Before new measures are developed, it would be beneficial to revisit some of the more troublesome existing measures and improve them where possible, or potentially retire them if providers are consistently giving feedback that a measure does not align with current clinical workflows.

We support the idea of field testing new measures before consideration, with the aim that providers can assess how well the new measures can be incorporated into the workflow and “seamless” to the user. The fitness of the measure should be reviewed before it is ever proposed. We suggest adoption of a "burden ratio" to determine what percentage of data required for measurement is captured from the clinical workflow, based on what is recorded sufficient for patient care, taken against the total set of data that is being collected. A ratio should be developed that determines whether the measure can be considered "non-burdensome."

Public Health Reporting

Strategy 1: Increase adoption of electronic prescribing of controlled substances and retrieval of medication history from state PDMP through improved integration of health IT into health care provider workflow.

The EHR Association supports this recommendation. We find there is a lack of meaningful integration of PDMP data within clinical workflows; current requirements force users to break out of their workflow to perform an inquiry. We encourage more discussion on how to solve this problem.

For example, CMS has stated that PDMPs provide view-only access (no data element level access or exchange enabling deeper workflow integration). However, not every state offers that access, data may not cross state lines, or a state may disallow data element level integration to enhance CDS within clinical workflows. Substantial work should be done at the federal level to break down barriers that exist within and among states to allow meaningful use of data, not only within an individual state but also across state lines. We encourage advancement of truly interoperable PDMPs to enable a holistic view of a patient's medication history.

Strategy 2: Inventory reporting requirements for federal health care and public health programs that rely on EHR data to reduce collection and reporting burden on clinicians. Focus on harmonizing requirements across federally funded programs that impact a critical mass of health care providers.

The EHR Association supports these recommendations. Specifically, with regard to the third recommendation found in Strategy 2, we find that discrepancies between the 42 CFR and HIPAA requirements confuse providers when they try to determine if sharing of data is allowable. This confusion leads providers to err on the side of caution and contributes to the problem of non-sharing of data. We continue to encourage development of guidance to harmonize these requirements and promote usability of data across providers.

We appreciate HHS' focus on clinician burden reduction. Thank you for this opportunity to provide our input. We welcome additional opportunities to share our expertise as this initiative moves forward.

Sincerely,



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Sasha TerMaat
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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 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.