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August 12, 2019

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Verma,

On behalf of the Electronic Health Record (EHR) Association, we are pleased to provide comments in response to the Centers for Medicare & Medicaid Services' (CMS) *Request for Information; Reducing Administrative Burden To Put Patients Over Paperwork*. EHR Association members appreciate the opportunity to leverage our collective experience in support of CMS's efforts to transform Medicare, Medicaid, and the overall healthcare delivery system by focusing on patient-centered care, innovation, and outcomes.

The EHR Association's 32 member companies witness first-hand the critical role EHRs play in delivery system reform and the successful transition to value-based care. Our members serve the vast majority of hospitals and ambulatory care organizations that use EHRs and other health information and technology (IT) to deliver high quality, efficient care to their patients. Our customers look to us to interpret policy guidance and incorporate regulatory requirements into the EHR systems they use every day.

Our detailed responses to the RFI follows this letter. *We would like to stress that early engagement with EHR developing companies will greatly increase the impact and effectiveness of the CMS' efforts.* Our comments encourage CMS to consider the following:

- Evaluate the success of previous burden-reduction efforts before making new changes and recognize that frequent changes contribute to burden. Program changes should be the result of data and driven by outcomes versus change for the sake of change. Over time established processes will become more streamlined and thus reduce burden.
- Align programs across CMS. Healthcare stakeholders have long expressed frustration with a lack of alignment across programs; for example, patient electronic access is different across Medicare/Medicaid Promoting

Interoperability (PI). Additionally, CMS and ONC timelines should be coordinated.

- Ensure compliance reporting is clinically relevant. Compliance reporting should be a product of existing and relevant clinical documentation, rather than an additional documentation requirement that does not benefit patients but exists solely for the purpose of proving compliance.
- Work closely with payers and health plans—and their technology providers—prior to proposing major coding changes. Close collaboration will enable improved opportunities for those changes to be aligned across public and private payers.
- Engage technology providers prior to payers. EHR and other health IT developers have the expertise to help define timelines for development, testing, implementation, and rollout to avoid unforeseen challenges and unrealistic expectations.

The EHR Association believes that the rapid, widespread adoption of health IT has and will continue to help improve the quality of patient care as well as the productivity and sustainability of the healthcare system. The EHR Association is eager to support you as the Department moves forward on the President’s goal to make healthcare data more transparent and useful to patients.

We hope that insights from EHR developers and others with expertise in health IT will be incorporated into Patients Over Paperwork initiatives, and our members remain ready to assist. Please contact Sarah Willis-Garcia, EHR Association Program Manager, at swillis@ehra.org to let us know how we can best support CMS’ efforts.

Sincerely,



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Chair, EHR Association
NextGen Healthcare



Hans J. Buitendijk
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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.

EHR Association Comments
Centers for Medicare & Medicaid Services (CMS)
Request for Information; Reducing Administrative Burden to Put Patients Over Paperwork

Modification or streamlining of reporting requirements, documentation requirements, or processes to monitor compliance with CMS rules and regulations

CMS nearly exclusively focuses on ambulatory and acute care hospital providers to date, and the whole spectrum of healthcare providers should be considered for similar kinds of burden reduction. Both within a provider type as well as across provider types, which are often part of the same health system. CMS should consider that consistent, predictable processes allows for streamlining, while frequent program changes makes the process more burdensome for healthcare organizations as well as EHR developers. All changes must be deliberate, well thought out, address a real need, and have a positive impact on clinicians, patients, or both. Change for the sake of change has the potential to add burden or to even do harm.

For any proposal, it is critically important to evaluate whether the measure has had the intended outcome before making new changes. For example, identifying ways to systematically evaluate the success of the E/M coding changes that went into effect in PY 2019 and sharing those results. Further, changes that require software adoption, such as for the new Promoting Interoperability measures adopted for hospitals and eligible clinicians in 2019 IPPS and PFS rulemaking, should not be immediately applicable to the very next calendar year if they require development, certification, deployment, and workflow modification. In the case of the new measures CMS adopted in 2019, certification testing has not been possible until recently and only for the hospital measures. This has effectively curtailed the optionality providers should have for their reporting period; instead they are forced to wait until the certified reports are available for the new measures. This cannot continue to be the case and is unsustainable for future success of the program.

Alignment across programs is a key component to the goal of streamlining and ultimately reducing burden. For example, patient electronic access is different across the Medicare and Medicaid Promoting Interoperability (PI) programs. Specifically, the patient electronic access measure for EC Medicaid PI defines timely access as 48 hours, while in MIPS, timely is defined as four business days. This kind of needless fragmentation leads to clinician/administrative confusion and additional burden on developers who have to both educate customers about the distinction and maintain two separate sets of reporting tools with no added value. Additionally, consider the adoption of more “attestation-based” measurements for PI wherever possible to reduce burden brought on through attempts to build measurement evidence into clinical processes for complicated numerator and denominator definitions that do not comport with evidence being easily a byproduct of clinical workflow (see the Opioid measures adopted by 2019 rulemaking as an example).

Also, building awareness of the intentions of the payer community, particularly when it comes to documentation changes or measurement requirements that impact compliance (such as for the E/M documentation changes or for Appropriate Use Criteria implementation), would be helpful to reduce

burden. CMS looks to adopt a policy change that would require providers to consider who the payer is in order to know how to document or how to deliver care versus considering how care should be delivered for the sake of the whole of a provider's patient base. It is unclear why 'who the payer is' should impact the care delivered to the patient when it comes to documentation; establishing the medical necessity of a service; or in terms of the delivery of care. CMS should take more active steps in ensuring coordination of policy changes where payer distinction makes no substantive clinical difference to the care delivered.

The EHR Association recommends that CMS continuously challenge whether or not adoption of new documentation requirements or medical record requirements align with "telling the patient story" or simply satisfy a regulatory requirement that pertains to an audit need or a CMS data collection need. We commend CMS for good decisions made to ease admission documentation requirements. For example, members were pleased to see in the 2020 OPDS and PFS rules policies such as allowing for mid-level practitioners to sign their own documents versus having them re-transcribed by a supervising physician, which added no value to the delivery of care.

However, CMS should exhibit caution when such policy changes could undo long standing practices in a precipitous manner. This was true of the original E/M proposals put forth in 2019 PFS rulemaking and in the Condition of Participation related proposal for surgical providers related to easing the requirement of when a full prior History and Physical must be performed. While the proposal seemed like an improvement, the current practice is entrenched making it a heavy burden on surgical providers who would have to develop new, complicated policies that could be difficult to apply and follow due to situational variability. CMS should work first with professional societies and provider stakeholder groups to evaluate proposed changes to clinical documentation practices for acceptability before proposing any such changes in rulemaking. This should hold equal weight with seeking counsel of what other payers may be doing on the same policy topic.

CMS should always build in lead time for policy change adoption that accounts for health IT impact similar to the recommendations the EHR Association made for adoption of new certification criteria by ONC, which accounts for the time needed to build new capabilities, certification (if needed), rollout, and adoption. The restless cycle of software updates imposed within tight timeframes is itself an undue burden on providers.

CMS should seriously consider moving to a model where providers self-select measures as long as they are measures that meet policy requirements for validity, relevance, value and empiricism. The current 'top down' approach dictated by payment system regulations reinforces the payer specific fragmentation of measurement requirements of the same provider for the same patient base. In addition to alignment across CMS programs, CMS should champion provider ability to use the same basis of measurement for the sake of all of their patients across all of their payers as a strategy for alleviating burden.

Aligning of Medicare, Medicaid and other payer coding, payment and documentation requirements, and processes

The EHR Association has highlighted many concerns and recommendations in our response to the previous question, CMS should consider those comments for applicability to this question as well.

Furthermore, in order to avoid unrealistic requirements and processes, the EHR Association encourages CMS to reach out to technology providers even prior to engaging with payers. IT developers have the expertise to assist with determining timelines for development and testing, implementation, and rollout to ensure success. Also, we encourage CMS to work closely with payers, health plans, and their technology providers prior to proposing major coding changes. This collaboration will enable a better opportunity for those changes to be aligned from a timing perspective on both the public and private sides.

CMS should consider extending the Health Care Payment Learning and Action Network or make it a function of the CMMI to establish a collaborative to more formally align its requirements for documentation, for coding, for measurement, for care planning, for care management, and for other aspects of care delivery for Medicare with those of commercial, private, and state payers. To the extent this may need to be a more formal collaboration that is sanctioned by statutory authority, CMS should seek to do so.

We recommend that CMS be cognizant of the impact of their making policy changes for the sake of the Medicare program in isolation of other payers (even if leading the drive for change). Anytime distinguishing the payer becomes a factor in clinical practice, increased burden on the provider will be the result. While we understand isolated changes are inevitable, especially when CMS is leading on a policy matter, formal coordination, prior vetting of the need for change, and improved communication will prevent a counter effect of increasing burden when the goal is to reduce it.

Enabling of operational flexibility, feedback mechanisms, and data sharing that would enhance patient care, support the clinician-patient relationship, and facilitate individual preferences

The EHR Association recommends consideration of how CMS can support workflows for patient-provided data. Current regulations imply that patients cannot always provide their own data or that providers must re-enter it. CMS should consider working with ONC more on development of guidance on how providers may consider patient contributed data so as to increase its reliability, its veracity, its utility, and to address medico-legal concerns as to its acceptance into the medical record.

CMS should expand the understanding of the “visit documentation” as beyond the clinician note. The EHR Association is hopeful that CMS will reduce redundant documentation and address the problem of ‘note bloat’ in order to improve the medical record as a communication instrument for all providers. CMS should do more to affirm the usability of the longitude of the medical record beyond the visit context. For example, there are requirements of surgical providers for use of prior History and Physical (H&P) documents collected within the last 30 days that require it to be in the “medical record.” This is

often interpreted as “the visit record” by many providers (particularly HIM professionals), which leads to their taking steps to physically copy the prior H&P into the current visit in order to then use it for documenting concurrence and any new findings. Especially in cases of using integrated EHRs that make available the prior H&P where it originally resides, this kind of manual effort is wasteful and seems unnecessary as long as the concurrence and new findings are documented in the current service record and point clearly back to where the original H&P resides. CMS should err on the side of reducing requirements for what may contribute to “note bloat” or unnecessary copying of records just for the sake of their placement in the current visit to satisfy some literal construction of “the medical record” being confined solely to what is understood to be the visit record.

CMS should continue to work with HHS, the Office for Civil Rights, and State authorities to eliminate inconsistencies in privacy laws that are present for the same policy matter. For example, federal law under HIPAA permits patient access to lab results directly from the performing lab. However, many state laws place restrictions on that availability absent some action by the ordering provider to make them available. This creates inconsistencies in compliance requirements for Promoting Interoperability for clinical information availability to the patient when compared to the requirements of State law, and while PI does not trump state law, it does create burdens for providers operating a common EHR platform across multiple states for the use of the EHR in the same production usage.

CMS should use all available authorities to normalize clinical information sharing requirements across provider settings involved in common referral patterns or transitions of care when it comes to the semantic meaning of common data. This is not to say all referral summaries or discharge summaries contain the same content from all settings; but, where common data is included, regulatory requirements for the type of data, codification and structure, and how it is semantically represented should be at par.

Finally, EHR Association members seek clarification on the use of the phrase “individual preferences.” Does this term refer to provider preferences or patient preferences?

New recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, and providers.

The EHR Association strongly encourages CMS to stage new requirements, clearly giving the provider and developer community a timeline to plan, build, implement over the course of a typical software development timeline of two years. CMS should additionally coordinate deadlines with ONC. For example, ONC defined three measures for Medicare PI of the MIPS program, yet test specifications were not yet available at the halfway point of the year. CMS should set the timelines for these new measures after the specifications are available and have been validated by health IT developers. e.g., ONC testing specifications should be available a minimum of six months before CMS requires use of that particular functionality.

We request that CMS allow 12 months for software development supporting new requirements, to allow developers sufficient time and certainty to utilize the processes recommended in the ONC Burden

Reduction report, such as usability design and testing.

How can CMS improve the accessibility and presentation of CMS requirements for quality reporting, coverage, documentation, or prior-authorization?

EHR Association members have stated in prior responses the need for harmonization and consistency for measurement requirements where possible across CMS payment systems and programs.

While developers appreciate the opportunity to connect with CMS directly through the EHR Association, we have faced challenges related to receiving guidance on implementing regulations. Often the guidance provided to developers is fragmented and not publicly-available, e.g. when CMS provides guidance during a webinar or meeting but does not publish that guidance in an FAQ.

Also for the sake of coordination, given that many institutional providers seek accreditation from The Joint Commission and other accrediting bodies that require clinical quality measure reporting on their own merit, CMS should work to coordinate the timing of its specification publication in line with publication timelines of these accrediting bodies, particularly where the measure title and specifications are similar. Sufficient lead time -- at least six months for some measures, and 18-24 months for more complex requirements -- should be built into this publication cycle to allow for health IT developers to respond, and consideration given to minimize updates to once a year.

CMS should leverage its authority to lead and promote simplifying and making transparent clinical documentation requirements for Medicare, specifically for the authorization or payment of services. EHR Association members feel CMS has the opportunity to press for normalizing the requirements across payers to avoid unneeded variation, which leads to additional burden.

Additionally, CMS should incentivize adoption of innovative technologies to automate authorization processes including use of FHIR API-based services for discovery and evaluation of electronic clinical documentation; thus, reducing the need for claim attachment submissions and post payment audit record submission.

How can CMS address specific policies or requirements that are overly burdensome, not achievable, or cause unintended consequences in a rural setting?

When CMS publishes new policies or requirements in a final rule, but does not publish the necessary sub-regulatory guidance, this creates burden for health IT providers, clinicians, and healthcare organizations. Sub-regulatory guidance is needed forthwith in order to fully understand and implement those requirements. Months-long lags in provided critical guidance is a disservice to all impacted stakeholders. Additionally, implementation deadlines must be at least six months after the necessary sub-regulatory guidance is made available.

The EHR Association notes that CMS creates technical and cognitive burden for all healthcare stakeholders when it proposes or finalizes policies and/or requirements that were developed without

input from health IT providers and/or healthcare provider organizations; often, the requirements are not feasible within the current technical landscape and/or are not aligned with realistic clinician workflows.

To avoid this, we encourage CMS staff to schedule in-person visits to a variety of healthcare settings to understand their needs. Policy and procedure should not be drafted in a black box; when operating outside the framework of a formal RFI process, CMS should conduct onsite observations, and, where possible, engage with stakeholder groups including professional associations on the policies that will impact them. Inclusion of all stakeholders can provide necessary context for effective regulatory guidance.

At the ONC Annual meeting on November 30, 2018, Kate Goodrich spoke about how CMS had employed traditional user experience research techniques such as journey mapping, observational studies, and focus groups to understand providers. We encourage CMS staff to continue this work, especially through a focus on observing clinician behavior in diverse settings: community clinics, specialty clinics, hospital outpatient departments, and more. We recommend that CMS include practices from rural and urban settings; pediatrics, adult, and geriatric healthcare providers; large and small practices; employed and independent; charity care and concierge care; and more.

While CMS is likely focused on providers who take Medicare, EHR Association members urge you to understand how other providers in other payment arrangements (private payers, self-pay, etc.) might practice. In the development of our own software, EHR developers have found having an understanding of the breadth and variety of practice settings to be invaluable in meeting the needs, wants, goals, and challenges that providers face. Neither EHR software nor policy and procedure should be created without these important perspectives.

Finally, interoperability requirements are challenging for rural providers. An example of a particular challenge are requirements that focus on *receiving* transition of care documents from other facilities. In most cases, the hospitals and providers in rural settings are providing the initial care and then they transfer the patient to another facility. However, these rural providers typically are not *recipients* of a transfer, so they rarely receive transitions of care. Because of this, the rural provider population is significantly challenged by the “Support Electronic Referral Loops by Receiving and Incorporating Health Information” measure that is a part of the Promoting Interoperability program and MIPS.

A typical transfer to the rural hospital or ambulatory clinic may be from a nursing home, but nursing homes do not typically provide CDA documents, such as a CCD, so that transfer of care scenario would not count toward the measure. In many cases, the critical access hospital and ambulatory clinics in a common service area are already sharing an EHR solution, so they would have no need to transmit or receive a CCD; the information is already shared. Nevertheless, with no alternative facility or provider sending CDA documents, these providers are sending CCDs internally in order to meet the requirement for the Referral Loops measures. Therefore rural providers are subject to increased documentation burden, needlessly sending CCDs that waste time and ultimately clutter their EHR with extra documents, solely in order to meet a measure that does not align with the needs or realities of their care setting.