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

Re: Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs

Dear Dr. Rucker:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments to the Office of the National Coordinator for Health Information Technology (ONC) on the Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and Electronic Health Records (EHRs).

The report's section on clinical documentation required for physician visits is particularly important to the AMA, and we appreciate the opportunity to offer our feedback. We have provided detailed comments below on ONC's discussion of the Centers for Medicare & Medicaid Services' (CMS) revisions to the Evaluation and Management (E/M) coding and guidelines used for physician office and outpatient visits. Following our comments on clinical documentation required for physician visits, we have provided responses to each of ONC's recommendations on the remaining topics.

Clinical Documentation Required for Physician Visits

The AMA is grateful that the Administration is focused on reducing physician's administrative burden and physician burnout. The AMA is closely aligned with the Administration's goal to remove unnecessary documentation burdens and enact policies that provide administrative simplification so physicians can spend more time with their patients, rather than on paperwork. We are grateful that the Administration has put this critical issue on the table.

As noted in the report, unnecessary clinical documentation is a common challenge faced by physicians. Excessive E/M documentation requirements can be particularly burdensome for

physicians, taking time away from patient care and making it more difficult to locate medical information in patients' records. Physicians and other health care professionals are extremely frustrated by "note bloat," with pages and pages of redundant information in the medical record that can make it difficult to quickly find important information about the patient's present illness or most recent test result.

The report lays out the documentation burden reduction initiatives finalized by CMS in the calendar year (CY) 2019 Medicare Physician Fee Schedule final rule (2019 final rule) as key to the Administration's efforts to address excessive clinical documentation. The AMA agrees that the policies finalized for CY 2019 are extremely positive and will reduce unnecessary documentation. We also appreciate that CMS has recognized the ongoing work of the AMA and medical specialty societies on E/M documentation burden and postponed the implementation of any coding and payment-related changes to E/M visit services until 2021. In the 2019 final rule, CMS noted that an AMA-convened workgroup comprised of practicing physicians with expertise in coding and documentation, as well as a commercial payer representative, has developed a comprehensive coding and documentation solution building on the burden reduction initiatives of CMS to address the problem at the foundation and improve patient care, while providing stability to physician practices.

Outline of the CMS 2019 Clinical Documentation Improvements

CMS finalized several clinical documentation policies that will streamline documentation requirements, reduce note bloat, and contribute to a better environment for health care professionals and their Medicare patients. These revisions, which were strongly supported by the AMA and more than 150 specialty and state medical societies, include:

- Removing the requirement to document medical necessity of furnishing visits in the home rather than the office;
- Changing the required documentation of the patient's history to focus on the interval history since the previous visit; and
- Eliminating the requirement for physicians to re-document information that has already been documented in the patient's record by practice staff or the patient.

Outline of the CMS 2021 E/M Office Visit Coding and Payment Policies

CMS also finalized a number of additional policies that are scheduled to go into effect in CY 2021. Among those additional initiatives are:

- Paying a single rate for E/M office/outpatient visit levels 2 through 4 for new and established patients.
- Allowing physicians to choose how to document E/M office and/or outpatient services using one of the following: the existing guidelines or medical decision making (MDM) or time.

- Requiring documentation equivalent to a level 2 office visit for payment of the collapsed code.
- Implementing an add-on code describing additional work inherent in primary care services.
- Implementing an add-on code describing additional work inherent in non-procedural specialty care.
- Implementing a new "extended visit" add-on code.

CMS asserts that documentation burden would be substantially reduced and time available for patient interaction increased by the streamlined visit level selection and minimal medical record entry incorporated into the office visit reporting process. The AMA strongly disagrees that the added documentation reduction from the code collapse-single payment proposal as envisioned by CMS will be realized for several reasons, including:

- Appropriate medical care of Medicare beneficiaries frequently requires more than the care described by a level 2 office visit; the most commonly billed office visits are those for level 4 (99204 and 99214). Medicare claims data confirm that patients receiving level 4 visits are more complex than those receiving level 2 or 3 visits as the mean number of diagnoses per patient increases with each level of office visit.
- The professional obligation to enter sufficient information into the medical record to support continuity of care for a typical Medicare patient will often result in more extensive documentation than is contained in the record of a level 2 visit.
- The complexity of an office visit is often unpredictable, so that physicians usually cannot pre-select the appropriate visit level, limiting the potential time and documentation efficiencies that might be achieved by the changes.
- Even with rapid access to multiple medical record templates designed to facilitate visit level documentation regardless of the basis for visit selection, time will be required to choose the proper template and this choice will not be possible until late in the visit.
- Maximizing burden reduction and time gained would require that every office visit be provided, documented, and billed at level 2, at least for Medicare patients. Accurate determination as to whether Medicare will be a patient's payer would be necessary prior to the beginning of the visit.
- It is unknown whether commercial payers would ever support these changes in documentation. Separate clinical workflows would then be required for patients depending upon whether they are Medicare beneficiaries. The inefficiencies for physicians and their staffs to continuously run parallel processes likely would be far more substantial than any efficiency gained through burden reduction flowing from the proposed payment collapse.

Furthermore, in the 2019 final rule, CMS noted that it expects that for record keeping, compliance with private payer requirements, and for clinical legal or other purposes, many physicians "would continue generally to seek to document medical record information that is consistent with the level of care furnished." The AMA concurs. There are many reasons for medical record documentation and CMS' payment collapse will not make them all go away.

Additionally, when discussing alternative E/M coding and payment proposals, CMS acknowledges the differences in patient complexity between levels and provides, "we were persuaded by public comments (detailed elsewhere in this final rule), indicating that Medicare should continue to recognize distinctions in visit complexity among the current levels 2 through 5 visits."

While CMS undertook the task of reducing physician burden with good intentions, the AMA is worried that implementing the payment collapse policy with its implicit delinking of payment from physician work and patient complexity is highly likely to be accompanied by multiple unintended negative consequences for Medicare beneficiaries, including:

- Avoidance of Medicare patients, especially those with complex diseases and multiple chronic conditions as they are likely to have more extensive health issues than beneficiaries of other payers. We appreciate CMS' decision to maintain a separate level 5 code and payment but remain concerned that paying the same rate for three office visit codes that involve patients who have very different needs and physician services of very different time and intensity is likely to create incentives to spend less time with patients.
- Shortening of office visits for Medicare patients and/or spreading their comprehensive care over multiple visits as physicians struggle to balance work and practice resources required with fixed payments regardless of visit level.
- Truncated medical record documentation that will impair continuity of their care, reflecting both the minimal documentation standard proposed by CMS and the reduced payment for higher level office visits.

In summary, the AMA appreciates the attempt to reduce practitioner burden represented by CMS' changes to E/M office visits; however, we find the centerpiece payment collapse policy to be inconsistent with delivery of high-quality, up-to-date care of today's often complex Medicare beneficiary. We sincerely appreciate CMS' indication in the 2019 final rule that the agency will work with the medical profession and the AMA-convened panel of experts in refining an E/M documentation and coding framework that will reduce burden on clinicians.

The CPT/RUC Workgroup Recommendations – Revisions to the E/M Office and/or Outpatient CPT Guidelines and Codes

It was for these reasons that the AMA and over 100 national medical specialty societies responded to the CMS proposal published in the CY 2019 Physician Fee Schedule proposed rule by developing a comprehensive, consensus-based solution that identified core documentation and Current Procedural Terminology® (CPT®) code requirements that have been leading to unnecessary documentation burdens for years. This solution incorporates CMS' burden reduction policies finalized in the 2019 final rule. The solution also includes several of the policies CMS finalized for CY 2021, such as allowing physicians to document patient office visits using MDM or time.

The CPT recommendations are also aligned with the strategies and recommendations detailed in the report, mainly that they will enable HHS to:

- Continue to reduce overall regulatory burden around documentation of patient encounters,
- Obtain ongoing stakeholder input about updates to documentation requirements, and
- Focus on partnership with clinical stakeholders to promote clinical documentation best practices.

Background and Process: Developing the CPT/RUC Workgroup Recommendations on E/M

Immediately following the publication of the CY 2019 Physician Fee Schedule proposed rule, the Chairs of the CPT Editorial Panel and the AMA/Specialty Society RBRVS Update Committee (RUC) responded to extensive concerns of the physician community by forming the CPT/RUC Workgroup on E/M (E/M Workgroup) to solicit suggestions and feedback on the best coding structure to foster documentation burden reduction, while ensuring appropriate valuation, and to craft a coding proposal that could be submitted and reviewed by the CPT Editorial Panel at their February 7-8, 2019 meeting. The E/M Workgroup spent countless hours trying to reach consensus around an alternative proposal that works for patients, physicians, CMS as well as other payers.

The CPT Editorial Panel Process – Open and Transparent

The CPT code set has been in existence for over 50 years, and the CPT Editorial Panel process is open and transparent, allowing any public stakeholder to both attend the meetings and submit code change applications for consideration. In addition to the clinical expertise of the 17 members who sit on the CPT Editorial Panel, the CPT editorial process is supported by a robust infrastructure of over 100 national medical specialty societies and over a dozen organizations representing non-MDs/DOs who appoint Advisors to provide clinical guidance to the Panel on the myriad applications that are submitted each year.

The CPT/RUC Workgroup on E/M (E/M Workgroup) Membership and Process

The E/M Workgroup's process supports the stated goals of the Administration to receive stakeholder input from a wide range of clinical specialties who provide input to define proper clinical standards for documentation and payers who provide input about the information necessary for claims payment.

The E/M Workgroup contains 12 members with six having primary expertise in the RUC and valuation process and six having primary expertise in the CPT Panel and coding process. The clinical expertise of the members was also taken into consideration, ensuring a mix of primary care, surgery and qualified health care professionals were included. Finally, a commercial payer, who is also a Panel member, served on the Workgroup.

The E/M Workgroup had seven open stakeholder calls with an average of nearly 300 participants. Stakeholders representing medical specialty societies, commercial and Medicare contractor payers, and CMS policy staff participated. Finally, the E/M Workgroup held one face-to-face meeting on September 29, 2018.

Each meeting gave time for the E/M Workgroup to both discuss amongst themselves and hear from individual stakeholders on each issue. Several surveys were also created to solicit more detailed feedback from the large community of interested parties and those results were compiled by AMA staff and presented to the E/M Workgroup and to all attendees during the relevant meetings. Importantly, many of the major decisions by the E/M Workgroup including the definition of time and key definitions of MDM criteria were based on these stakeholder survey results.

Arriving at a consensus and crafting the E/M Workgroup's recommendations were the first critical steps; however, feedback and refinements will continue. Physicians and other health care professionals and interested stakeholders, including CMS officials, will continue to have a platform to suggest further edits and improvements as the recommendations work through the CPT Editorial Panel review process. The CPT Editorial Panel will vote during its upcoming February meeting.

CPT/RUC Workgroup on E/M Recommendations

The E/M Workgroup is committed to changing the current coding and documentation requirements for office E/M visits to simplify the work of the health care provider and improve the health of the patient.

To achieve these goals, the E/M Workgroup established the following guiding principles related to the group's ongoing work product, which are in alignment with the stated CMS goals for their proposal:

1. To decrease administrative burden of documentation and coding,
2. To decrease the need for audits,
3. To decrease unnecessary documentation in the medical record that is not needed for patient care, and
4. To ensure that payment for E/M is resource-based and that there is no direct goal for payment redistribution between specialties.

The E/M Workgroup made three primary recommendations. Importantly, like the CMS proposal, these changes only affect office/outpatient E/M services.

1. **Elimination of history and physical exam as elements for code selection.**
   As is discussed in the report, the antiquated system of mandatory documentation of a patient's history and/or physical examination has been a continued burden on physicians for decades. As the report says:

> The medical field's efforts to automate this coding and documentation paradigm with the advent of EHRs led to a system of electronic templates and checkboxes that meets billing requirements that reflect a prior clinical era, but bloat the record with unnecessary and difficult-to-navigate information.

The E/M Workgroup's revisions to the CPT codes and guidelines eliminate the need to mandatorily document these elements. The E/M Workgroup revised the code descriptors to state providers should perform a "medically appropriate history and/or examination." However, these elements should no longer be a primary driver of appropriate code level selection. Physicians will now be able to document only what is clinically relevant.

2. Establish two primary E/M code selection criteria – MDM or Total Time.

We believe that CMS was correct in allowing physicians to document medical necessity combined with either time alone or MDM. This provides physicians with maximum flexibility and recognizes the differences in patients and specialties. CMS, ultimately, stated in the 2019 final rule that "time may be a good indicator of complexity of the visit and proposed that all practitioners have the option to use time as the single factor in selecting the visit level and documenting the E/M visit." The E/M Workgroup recommendations adopt this concept.

The E/M Workgroup's recommendation also improves the definitions of MDM and time. First, the Workgroup members meticulously went through the current definitions of MDM, listed in the CPT E/M guidelines, and suggested comprehensive revisions and additions to key terms. (See more discussion in element three.) A common complaint from physicians across the U.S. is the increased burden from ambiguous concepts that make proper documentation difficult. By clarifying ambiguous concepts, the root cause of the issue is addressed, thus creating sustainable burden reduction throughout the documentation process.

Second, the Workgroup modified the definition of time for office and/or outpatient E/M services to reflect minimum total time compared to the current system of typical time. The creation of a time threshold reduces the confusion around choosing ranges of appropriate times per level. Also, the concept of total time addressing patient care needs is easier to understand and aggregate from a documentation perspective. Given the advantages of using total time for clinical documentation and code selection, we foresee this recommendation resulting in fewer coding errors and improved program integrity. We also note that the CMS E/M coding and payment policy incentivizes multiple shorter visits instead of providing an appropriate length of visit to care for patients' needs. For example, a practice dedicated to walk-in acute episodes such as viral syndromes can see six return patients per hour and bill 99212, which is paid at $90/visit, totaling $540/hour. For practices seeing more complex patients, they see two return patients per hour and bill 99214, which is also paid at $90/visit totaling $180/hour. Clearly, there is a disincentive

to spend more time on visits. For the same scenario using the E/M Workgroup recommendation, six return patients at level 99212 are paid at $46/visit totaling $276/hour versus two complex return patients at level 99214 paid at $110/visit totaling $220/hour. In the Appendix, we include two tables outlining the differences in time and payment between the E/M Workgroup recommendations and CMS policies.

3. **Modifications to the Criteria for MDM**

The Workgroup used the current CMS Table of Risk as a foundation for designing revised required elements for MDM. Current CMS Contractor audit tools were also consulted to minimize disruption in MDM level criteria. The Workgroup revisions were primarily designed to provide clarity to key terms and definitions to elements that, for decades, have caused undue confusion for physicians.
For instance, the revisions remove ambiguous terms like "mild" and further define concepts like "acute or chronic illness with systemic symptoms" and "independent historian."

Also, due to the removal of history and physical exam from the required E/M code selection elements, the Workgroup was careful to ensure that revisions to the existing MDM sub-components moved away from simply counting data elements to achieve a code level. For instance, the MDM data sub-component was re-defined to focus on elements that affect the management of the patient (e.g., independent interpretation of a test performed by another provider and/or discussion of test interpretation with an external physician/QHP).

CPT/RUC Workgroup Recommendations and Burden Reduction Outcomes

As discussed throughout this section, there is significant overlap between HHS' burden reduction strategies and the CPT/RUC Workgroup's recommendations to improve E/M clinical documentation.

In the 2019 final rule, CMS states that the typical office visit requires 4.2 minutes to document. CMS predicts that for the policies it finalized for CY 2021 will reduce that time by 15 percent, a savings of .63 minutes per office visit. We believe that the E/M Workgroup recommendations will create the same level of efficiency. Consequently, physicians will see immediate reduction in administrative burden.

Physicians have long complained about the complex and burdensome documentation guidelines related to the history and physical exam. These elements of documentation led to the "copy and paste" and "note bloat" problems within EHRs. The E/M Workgroup recommendations eliminate this aspect of burdensome documentation, allowing physicians to document only what is truly clinically relevant. We believe this modification will result in a savings of at least 15 percent time spent on documentation. Good medical practice requires sufficient documentation to communicate the patient's condition, evaluation, and proposed management. This is imperative

regardless of coding structure. Both the CMS and the CPT frameworks eliminate "documentation for its own sake."

The E/M Workgroup recommendations related to time documentation and the use of an add-on code to report prolonged or extended time are more straightforward than the CMS policy and would not add any documentation burden. The CMS policy to implement several add-on codes for both intensity and time would increase the level of documentation burden. The CMS time methodology is counter-intuitive as demonstrated by the finalization of coding by typical time in one section of the rule, requiring clarification later that the code specific times are not relevant at 34 minutes for established and 38 for new patients, until the typical time for a level 5 service plus 30 minutes is attained. Furthermore, the highest-level service requires documentation not only about the time and medical necessity for the time, but also includes that rules still apply related to counseling and coordination of care. Moreover, it would be unreasonable to code 99215 using time if the GPRO service is implemented as it would be paid less than a 99212 and the GPRO service, $149 compared to $157.

In addition, the E/M Workgroup recommendations eliminate the need to add specialty add-on codes. CMS acknowledges that their own policies and definitions regarding these codes are not yet finalized. As written, the current CMS instructions for the add-on codes are confusing. Furthermore, in the 2019 final rule, CMS admits these add-on codes will require additional documentation, providing, "[w]e are also finalizing a policy to require minimal documentation to support reporting of the add-on codes that we are finalizing for use with the level 2 through 4 visit codes."

Responses to the additional strategies and recommendations in ONC's report are outlined below.

Clinical Documentation

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

- Recommendation 4: Waive documentation requirements as may be necessary for purposes of testing or administering APMs.

The AMA fully supports ONC and CMS exploring additional methods to reduce documentation requirements for APM participants. An overarching principle guiding the development of any new payment models should be avoiding unnecessary, burdensome requirements. Physicians participating in risk-based payment models already have incentives to control costs, making prior authorization (PA) and other payer documentation requirements unnecessary. Furthermore, before any administrative requirement is imposed, ONC should work with CMS to justify why it is needed and what other options were examined, and potential participants should be given the opportunity to suggest less burdensome approaches to achieving the same goal.

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

- Recommendations 1-2

Please see our comments in the E/M section of our letter.

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

The AMA supports ONC's goal to use health IT to reduce burden associated with PA. The current process of sending supporting clinical documentation by fax or mail is antiquated, costly, and administratively burdensome to both physicians and health plans, and can lead to significant delays in patient treatment. The AMA appreciates HHS' focus on the topic and the incorporation of our December 2016 PA survey results in its draft report; we note that updated survey is now available and recommend HHS incorporate the updated results in its Burden Strategy.

- Recommendation 1: Evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization.

The AMA supports efforts to evaluate and address factors that lead to PA burden. It is important to note that process automation cannot fully relieve current practice burdens associated with PA. Broader policy reforms are needed to achieve meaningful reductions in the administrative hassles associated with PA (see new AMA recommendation below). Furthermore, we agree "health IT enabled processes that leverage existing data within the record" may reduce the volume of PA requests from payers. However, explicit attention must be paid to ensure appropriate use of these processes. Without control mechanisms and monitoring for data access, we foresee the potential for unintended consequences or abuse. This issue is further explored under the EHR Reporting section of our comments.

- Recommendation 2: Support automation of ordering and PA processes for medical services and equipment through adoption of standardized templates, data elements, and real-time standards-based electronic transactions between providers, suppliers, and payers.

While the AMA is supportive of this recommendation, we find it concerning that it discusses the burden caused by a lack of a mandated attachment standard but does not mention the attachment standard recommended for adoption by the National Committee on Vital and Health Statistics (NCVHS) and currently under review by CMS. Industry-wide adoption of electronic clinical attachments has the potential to significantly improve process efficiencies, reduce time to treatment, and advance the Administration's and AMA's shared goal of improved interoperability. The AMA sees a particularly urgent need for an electronic attachment standard due to its integral connection to PA automation and its impact on patient care, as most PAs for medical services require additional supporting clinical documentation. We urge that this recommendation include an explicit call for the adoption a single format for clinical information and a single enveloping method in the attachment standard so that physicians are not required to accommodate the unique specifications of each particular health plan with which they do business. Additionally, we encourage greater enforcement of existing and future adopted

standards. There is currently very little enforcement of the Health Insurance Portability and Accountability Act (HIPAA) administrative standards, which undercuts their effectiveness in changing health plan behavior.

We support adoption of standardized templates and data elements for PA requests across payers. However, we note that past efforts to create standardized PA forms, including projects undertaken in several states, have been challenging and yielded mixed results as payers often insist on utilizing proprietary templates and question sets.[1,2] HHS could encourage and incentivize greater collaboration and cooperation across payers to standardize PA templates and data elements, as this 1) would support greater process automation through increased uniformity; and 2) reduce physician administrative burdens.

- Recommendation 3: Incentivize adoption of technology which can generate and exchange standardized data supporting documentation needs for ordering and prior authorization processes.

The AMA supports positive incentives to encourage provider usage of new standards. More importantly, there needs to be an industry commitment amongst payers to support the technology. If a technology is adopted and incentivized by CMS but is not also implemented across commercial payers, providers will be forced to utilize different methods of submitting documentation and prior authorizations throughout the industry. This variance would run counter to the goal of reduced provider burden.

- Recommendation 4: Work with payers and other intermediary entities to support pilots for standardized electronic ordering of services.

The AMA supports the need to pilot standardized electronic ordering services. We stress, however, that piloting cannot be done in a silo and must represent the unique environments of all entities that participate in the electronic ordering chain—including physicians. Piloting solely with payer and other intermediary entities could greatly detriment physician workflows. A successful pilot should address the concerns of all stakeholders, with particular attention to reducing physician burden and improving medical practice efficiency. Concurrently, HHS must work to ensure this process is voluntary and does not effectively become a mandate due to economic pressures (i.e., the unequal bargaining power of physicians in health plan contracting could force physicians into agreements that require pilot participation).

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[1] California (https://law.justia.com/codes/california/2011/hsc/division-2/1367-1374.195/1367.241) and Minnesota (http://www.health.state.mn.us/asa/rxpaform.html) each have insurance laws/regulations requiring the use of standard PA forms. As indicated, the results have been somewhat mixed. While there is standardization of the initial form, payers often simply require a supplemental questionnaire to be submitted that is effectively their specific, non-standardized questions. Some of the difficulties with the Minnesota law are expressed in a report by the Minnesota Department of Health (http://www.health.state.mn.us/asa/asadocs/epamedstandards.pdf – page 9).

[2] 2006 AHRQ report highlighting health plan resistance to standardizing questions: https://healthit.ahrq.gov/sites/default/files/docs/page/Findings%20from%20the%20Evaluation%20of%20E-Prescribing%20Pilot%20Sites.pdf#page=52

- Recommendation 5: Coordinate efforts to advance new standard approaches supporting PA.

The AMA eagerly awaits technological advancements in standards to reduce PA burdens.

Notably, section 6062 of the SUPPORT for Patients and Communities Act (P.L. 115-271) provides for the electronic transmission of PA requests for a covered Part D drug.[3] The electronic transmission shall comply with technical standards adopted by the Secretary. The AMA strongly believes that electronic PA should decrease the administrative burden on health care providers. Thus, when establishing technical standards, the PA request and response must be integrated into a health care provider's EHR or practice management system. Integrated means that the process is seamless to the health care provider, can be conducted completely within the EHR or practice management system, does not require the health care provider to log into separate payer portal(s), and does not require the health care provider to reenter or transfer data that is already in the EHR or practice management system.

We welcome the opportunity to provide input and perspective to help ensure that this and other solutions adequately meet the needs of the physician community. Again, participation in pilots of these new standards should be inclusive of physicians and voluntary, and health plans must still support mandated electronic standards while new technologies are being piloted.

- AMA Recommendation: Support advancements in health information technology and data analytics to refine PA policies and reduce the overall volume of PAs.

HHS' recommendations focus on how to make the actual PA process more efficient and less burdensome for the stakeholders involved, which is an admirable and essential component to PA reform. We believe that the industry should leverage technological advancements to reduce the overall volume of PAs by selectively targeting services and providers for PA and clinical documentation processes and eliminating low-value or problematic PA requirements. Examples of such efforts could include exploration of gold carding programs, clinical decision support mechanisms, regular review and adjustment of payers' PA lists, and other programs.

While prior authorization processes can be made more efficient through automation, they inherently can require patients and practices to take additional steps as compared to services without prior authorization. Refining the process and reducing the volume of PA is critical, because even a fully automated process will result in administrative costs for providers and plans and can negatively impact care delivery. For example, a seamless electronic prior authorization process does not help a patient who suddenly cannot get a chronic medication they have taken successfully for years due to PA requirements under a new plan. As a result, prior authorization processes should only be applied to appropriate services, patients and clinicians.

[3] Section 1860D-4(e)(2)(E) of the Social Security Act (42 USC § 1395w-104(e)(2)(E)(ii)(II)).

Implementing policy changes to reduce the overall volume of PAs aligns with industry-wide, cross-stakeholder efforts to achieve meaningful reform in utilization management programs. In 2017, the AMA, working with organizations representing physicians, hospitals, patients, and other health care stakeholders, released a set of 21 Prior Authorization and Utilization Management Reform Principles identifying problems with and recommending improvements to PA, step therapy, and other utilization management programs. Additionally, the AMA partnered with groups including the American Hospital Association, America's Health Insurance Plans, American Pharmacists Association, Blue Cross Blue Shield Association, and Medical Group Management Association to release the Consensus Statement on Improving the Prior Authorization Process in January 2018. Notably, both the reform principles and the consensus statement emphasize the need for programmatic policy changes in order to effectively reduce the burdens. Providers and health plans agree that making policy changes that eliminate prior authorization on services for which there is low variation in care, promote greater transparency regarding which services are subject to prior authorization, and protect patients to ensure prior authorizations do not impact continuity of ongoing care are essential.

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.

- Recommendation 1: Better align EHR system design with real-world clinical workflow.

The AMA agrees there is a desperate need to align EHR system design with real-world clinical workflows. Health IT use is a major factor in physician burden and burnout, which takes away valuable time from providing care to patients. The AMA has identified two major components that must be addressed—implications of federal policy and health IT development and user-centered design.

Federal policy is a major driver in EHR system design. The AMA continues to highlight that federal reporting requirements (e.g., the Quality Payment Program's Promoting Interoperability measures) are significant determinations in how EHRs look and feel to physicians. Program requirements are too focused on physicians reporting use of EHRs as opposed to whether EHRs are useful to physicians and the care they provide to their patients. Given the frequency with which HHS cites CMS program requirements as the major driver for EHR adoption, it is perplexing that HHS chose to ignore federal policy's role in EHR system development. HHS neglected to provide recommendations on federal program (e.g., Quality Payment Program and Health IT Certification) changes necessary to improve EHR system design, usability, and safety. The AMA strongly urges HHS to review the nature of its own programs and include practical recommendations to improve patient care, safety, and reduce physician burden associated with EHRs. For instance, HHS should recommend charting a path away from prescriptive EHR measures and simply measure whether clinicians are using EHRs—but not score them based on how often they are using certain functionalities.

We agree with ONC that adherence to proper human factor engineering principles can help developers better support the clinical workflow and reduce cognitive load on the end user. This process must include considerations around both product design and product testing. Just as testing a product's performance in real-world settings is critical, individuals involved in testing must accurately represent the end-user customer base. While some health IT vendors test products with medical doctors, there is a significant difference between using vendor-employed physicians/clinicians versus working with non-affiliated practicing physicians to understand workflows. Vendor-employed testers may have bias on product performance or curtail honest feedback. Furthermore, the experience (and level of frustration) with EHRs is very different between a part-time and full-time practicing physician. HHS should require vendors use full-time, non-EHR vendor-affiliated practicing physicians/clinicians to test products as part of federal health IT certification.

As identified in a joint project between the AMA, Pew Charitable Trusts, and MedStar Health's National Center for Human Factors in Healthcare, health IT testing should use rigorous testing requirements and use cases. This is necessary for both pre- and post-implementation of health IT. Research has shown that there is an absence of requirements and guidance on how to test clinician interactions with EHRs—specifically around safety issues. Clinical test cases, which are scenarios that reflect realistic patient conditions and how health care providers treat individuals, can help detect hazards. However, there are no clear criteria for what constitutes a rigorous test scenario. Similarly, some of the scenarios for federal certification, while testing that certain functions work, may not effectively evaluate the EHR for usability or safety. Federal regulations mandate the testing of certain safety-related features, such as medication-allergy checks; however, these requirements do not focus on whether those functions operate in a safe way. We urge HHS include in its recommendations concepts discussed under the "opportunities to improve usability certification test cases" and "criteria necessary to develop rigorous test cases" sections outlined in our joint project document.

- Recommendation 2: Improve clinical decision support usability.

The AMA agrees there is tremendous opportunity for clinical decision support (CDS) to be improved and augmented beyond alerts to include predictive care suggestions to help make decisions at the point of care. We also agree the appropriate application of data standards is essential to providing high-quality health care. We recognize HHS' reference to the National Academy of Medicine's (NAM) recent report, but it is unclear whether HHS is recommending that NAM's framework be used. We seek further clarity on this matter. In addition, the AMA has established an Integrated Health Model Initiative (IHMI) that leverages collaborative communities, a physician-led validation and review process, and advanced data modeling to support improvement in CDS and data standardization. IHMI is recognized by ONC's Interoperability Proving Ground and by the Health Information Technology Advisory Committee's Interoperability Standards Priorities Task Force. IHMI works with over 30 health care stakeholders, including major technology developers, consumer groups, professional associations, and standards development organizations. HHS should recommend IHMI as a body

to support cross-stakeholder agreement related to data standardization/modeling, medical knowledge representation, and efforts around data portability/liquidity.

- Recommendation 3: Improve clinical documentation functionality.

Please see our comments in the E/M section of our letter.

- Recommendation 4: Improve presentation of clinical data within EHRs.

The AMA agrees the presentation of clinical data is a critical component in the use of that data and the usability of EHRs. We emphasize the need for EHR functionality to integrate received electronic data into the EHR with a high level of usability and clinician-focused reconciliation functions. However, data should not be held in an EHR silo. We are encouraged by recent advancements in health IT design to utilize application programing interfaces (API) to support this need. Physicians and patients should benefit from an EHR application (app) ecosystem for EHRs just as users of smartphones have with the Apple App Store and Google Play. Similarly, physicians need access to a wide range of apps that are easy to install and use with their EHRs. HHS should consider how ONC's Health IT Testing and Certification Program can support this need. Furthermore, physicians and patients need support in choosing safe, effective, and usable products. Both the Food and Drug Administration (FDA) and ONC participate on the board of Xcertia, a multi-stakeholder effort to develop guidelines and recommendations for medical app development. HHS should recommend Xcertia as a coordinating body to help ensure medical apps are user-focused and developed utilizing industry best practices.

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

- Recommendations 1-4

The AMA supports HHS' acknowledgment that health IT user interface design and configuration is a major contributor to physician cognitive burden. We agree with HHS' recommendations and have worked with many health IT stakeholders to develop and advance principles and best practices around health IT usability. However, until product comparison improves, a disconnect will continue to exist between health IT development and health IT vendor adherence to usability recommendations and best practices until product comparison improves. Health IT vendor assertion to health IT design principle and best practice adherence must be balanced with transparency and accountability. Verifying conformance to these principles will help build trust. The AMA continues to stress that physicians need more tools to become well-informed consumers of technology. Congress recognized this and directed HHS to develop an EHR reporting program. The AMA provided extensive recommendations to increase health IT transparency and inform end-users. HHS should recommend its own EHR Reporting Program ideas to assist in this strategy. We further stress that HHS should identify additional methods to increase health IT transparency within the ONC Health IT Certification Program's Principles of Proper Conduct.

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

- Recommendation 1-3

The AMA agrees there needs to be a concerted effort across health IT developers to harmonize clinical content in their products. Health IT industry-wide standardized use and transmission of discrete data would allow for better end user functionality by potentially creating care and documentation efficiencies and preventing life-threatening transcription errors and patient adverse events. We agree that utilizing guidelines such as ONC's SAFER Guide and working with terminology organizations is an appropriate approach. These approaches, however, must be applied systematically across all health IT products and made available to clinicians ranging from solo practices to regional health care systems. While we appreciate HHS' attention on health IT vendor action, we recommend a framework be utilized to facilitate cross-stakeholder engagement and scalability. The primary focus should be to improve patient safety and health IT usability.

Beyond monitoring the effort, HHS should include the joint collaborative project between the AMA, Pew Charitable Trusts, and MedStar Health's National Center for Human Factors in Healthcare in its recommendations. Focus should be placed on Table 2 "Specific Criteria for Each Usability and Safety Component." The process of clinical content harmonization would benefit from an iterative approach. We recommend utilizing the EHR life cycle outline in Table 2. This process inherently requires the collaboration between health care providers and EHR vendors. Furthermore, this process enlists specific criteria and consensus metrics—ensuring everyone is "on the same page" and focused on patient safety. Adherence to these recommendations by EHR developers and health care providers can reduce the likelihood of patient harm.

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

- Recommendations 1-4

The AMA agrees that end user involvement is critical to the success of an EHR implementation in terms of both safety and usability. We further agree that clinical users should be involved from the very beginning of the acquisition process to ensure that the product purchased by an organization will meet the needs of its end users and their desired workflows. We agree that recommendations 1-4 broadly apply to all clinical users. The AMA participated in the development of ONC's Change Package for Improving EHR Usability and agrees it can help smaller practices optimize their EHR implementation. While we appreciate HHS' focus on health IT usability and the user experience, physicians should also have tools in place to monitor, track, and measure the impact of burden-reducing efforts. For instance, health IT vendors may incorporate SAFER guidelines in forthcoming products, but unless there is a process for

establishing the current level of physician burden, neither the physician nor the health IT vendor will know to what degree burden or burnout has been reduced—or increased for that matter. HHS should include the concept of a standardized burnout assessment as part of its overall burden reduction effort. The AMA has developed a STEPS Forward Module on preventing physician burnout as one potential resource. This includes a survey physicians can use to assist in assessing a base level of burnout.

Additionally, we note physicians continue to significantly invest in health IT resources. Practices are overwhelmed and overloaded. Too often health IT updates and upgrades are a condition of HHS program requirements. When products are upgraded to include "user-requested features" or improvements, physicians must balance EHR downtime and loss of access to records with training and workflow changes. HHS should include a recommendation to investigate the practical return on investment (ROI) for all future reporting programs requiring physicians to purchase, upgrade, install, or modify their EHRs. HHS should justify its proposals with quantitative and qualitative data. This ROI should be included in all future proposed rulemaking—allowing clinicians and provider groups to consider the impact and pros and cons of health IT modifications in their comments.

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.

- Recommendation 1: Simplify the scoring model for the Promoting Interoperability performance category.

The AMA supports HHS' efforts to simplify the scoring model for the Promoting Interoperability (PI) performance category of the Quality Payment Program (QPP). Reducing physician burden indeed requires further alignment between measurement and clinical workflows. In fact, the AMA has championed the concept of measure combinations to give clinicians a recommended set of related eCQMs, PI health IT measures, and Improvement Activities tied by a common thread so clinicians can maximize their participation in the program with reduced burden and a clinical focus. We strongly support HHS' recognition of this approach.

In conjunction with this approach, the AMA recommends that HHS also look to more immediate methods to address practical issues physicians face with the QPP when using EHRs. While we recognize that CMS has taken certain steps to reduce the burden of its reporting program on physicians, it must do more. As such, the AMA has identified a strategy to improve PI. This strategy simplifies PI and reduces burden through Yes/No physician measure attestation and leveraging health IT vendor reporting on utilization of Certified EHR Technology (CEHRT) functionality. The AMA has worked with medical specialty associations to develop this proposal; the proposal has buy-in from many specialty societies. The strategy also aligns with

HHS' stated goals of federal reporting programs being relevant to clinical care, promoting higher-value EHR functionality, aligning measures with workflows, and increasing access to health information. As such, HHS should include this approach in its recommendations, and CMS should include it in its proposed rule for the 2020 program year of the QPP.

- Recommendation 2: Incentivize innovative uses of health IT and interoperability that reduce reporting burdens and provide greater value to physicians.

The AMA supports HHS' recommendations to incentivize innovative uses of health IT and interoperability while also providing value to physicians and reducing burden. We recognize HHS' goal of thinking creatively to reduce burden while promoting health IT and interoperability. Put simply: non-traditional outcomes require non-traditional approaches.

The AMA is particularly interested in the concept of leveraging vendor-provided health IT utilization data to facilitate physician reporting. We explored this idea in our QPP CY 2019 comments and in our response to ONC's EHR Reporting Program Request for Information. EHRs track and record the process to meet measure requirements—making physicians feel they are just "going through the motions to check a box." The incentive is to use the EHR, and therefore EHR usage has become the focus. This is a major contributor to physician reporting burden. Rather than measuring a physician's ability to juggle the technical process of data access or interoperability, HHS' interest should be in which EHR functions best serve patients and physicians.

For instance, a physician could attest yes/no to a health information exchange (HIE) measure in PI. Their EHR vendor could provide the actual functionality the physician used to accomplish the HIE measure. Was Direct used (identifying the usefulness of that EHR function)? Did the physician's query find unique patient records (identifying patient matching/record completeness issues)? How many "places" did the system need to search (providing focus for HIE frameworks such as the TEFCA)? Was any information discoverable but "blocked"? EHR vendor-reported data could eventually expose health IT system efficiency, if the EHR accommodated the needs of the physician, whether the EHR contributed to or detracted from patient care, areas where federal policy could address gaps, and whether the EHR supported the *goal* of health information exchange. All of which is missing right now. We recognize reaching this level of analysis may take time to achieve. HHS should first leverage vendor-provided data to level set its understanding of current use and provide a metric for measurement.

Weaving physician attestation with vendor reporting is a powerful combination. This would reduce physician burden, facilitate ROI discussions, and more accurately represent the real-world use of technology. The Health Information Technology for Economic and Clinical Health (HITECH) Act permits a professional to satisfy the demonstration of meaningful use of CEHRT and information exchange through attestation. We also believe that HITECH would permit third party-supported physician attestation via "other means specified by the Secretary." Again, the AMA worked with medical specialty associations to generate support for this strategy.

- Recommendation 3: Reduce burden of health IT measurement by continuing to improve current health IT measures and developing new health IT measures that focus on interoperability, relevance of measure to clinical practice and patient improvement, and electronic data collection that aligns with clinical workflow.

The AMA appreciates CMS' engagement with physicians in burden reduction efforts. We will continue to interface with CMS by responding to its call for measures. However, while seeking stakeholder feedback for new measures is vital, we reiterate our comments on recommendations 1-2. HHS should strive to reduce physician reporting burden by transitioning away from EHR measurement. Information generated as a byproduct of physician-patient engagement and clinical care is far more insightful. Furthermore, all future physician measures should be "yes/no" attestation. Granular data on EHR use should be provided by the health IT vendor.

Interoperability measures should be specifically linked to or targeting improving patient outcomes. We agree new measure attributes should center on improving patient care, but physicians continue to shoulder most of the responsibility of implementing measures, which is not appropriate. This is traditionally very taxing on physician resources and provides inconsistent value in terms of care. As an analog, some structure and process quality measures are being retired since many were unable to demonstrate any linkages to driving improvements in patient outcomes. This linkage should be a core element of EHR measure development, established early in the process, and included in all newly proposed measures. HHS should recommend a process to develop an evidence base to demonstrate the linkages (and whether they are successful) and seek feedback from medical specialties. This process is consistent with the ONC Roadmap on Interoperability as well.

- Recommendation 4-5

The AMA supports HHS' attention on the need to revise program feedback reports to better support clinician needs and improve care. We reaffirm the user-suggested improvements mentioned in recommendation 5. Timely access to performance feedback data will help practices make necessary course corrections within a performance year and can help practices plan for consecutive year participation.

MIPS feedback reports in 2018 did not include the detailed patient level information that was available in the predecessor Quality and Resource Use Reports (QRUR). Physicians tell us that the QRURs were much more useful and that the QRUR drop down data should be restored in the feedback reports. It is our understanding that CMS intends to add this data in the future. HHS should include this in its recommended improvements.

CMS should also consider the timing of previous year MIPS feedback reports, which have been released in July after the close of the reporting period (for example, 2017 MIPS Feedback reports were released in July of 2018).

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

- Recommendations 1-2

Data Standards

The AMA views data standardization and mapping as a core component in access, extraction, integration and analysis. In 2015, we identified the need for a coordinated data management approach as a cornerstone of interoperability. We welcome HHS' recognition of this need and agree there are now a number of data initiatives underway—each addressing various issues. Just as the English language and subsequent exchange of information are based on vocabularies and grammar, the translation from medical data to knowledge can only occur if the meaning and structure of data is consistent and coordinated. We agree that ONC should *support* coordination, but stress that communities of private stakeholders, led by clinical experts, are best suited to establish goals, workplans, and priorities.

To address this issue, the AMA has launched the IHMI. As discussed above, the IHMI is a digital platform for stakeholder collaboration and clinical review to build a unified data model to organize data in an interoperable fashion. IHMI is recognized by ONC's Interoperability Proving Ground and by the Health Information Technology Advisory Committee's Interoperability Standards Priorities Task Force. Utilizing the IHMI, different computer systems will be able to exchange data with unambiguous, shared meaning and be fully comprehensive across systems and clinical environments—enabling a true longitudinal patient health record independent of the data's originating source. IHMI uses the best available science to define and model meaningful and clinically-valid data elements, including patient function, state, goals and social determinants of health in high burden disease areas.

The AMA strongly recommends that HHS establish a plan, in conjunction with stakeholders and other federal agencies, to focus interoperability efforts on promoting data consistency and access. This must include balancing policy goals with a sensible timeline.
HHS should leverage clinically-led efforts—like the IHMI—that aim to advance terminologies, data elements, coding, and common data models to promote interoperability.

Patient Data Access and Protection

The AMA recognizes the potential benefits of bulk data access for public and population health and quality improvement. Reducing the difficulties inherent in accessing medical information at the individual or population health level is an important goal; however, we have concerns with the potential pitfalls of entities having unprecedented access to patient information. We urge HHS to take a methodical approach and ensure the physician and patient communities are well-informed and copasetic with efforts to advance data access at this scale. Access must be provided for a given purpose and consistent with the HIPAA Privacy Rule's minimum necessary standard. Current data request processes, while limiting, are narrowly scoped for specific use cases and

involve some level of "gating" that helps prevent improper use and disclosure and helps enforce compliance on both ends of the transaction (collection [query] and disclosure).

While standards like Fast Healthcare Interoperability Resources (FHIR) may support data controls like segmentation, we are concerned those controls are an afterthought in FHIR-based API design and will become a "bolt-on" function—drastically increasing their costs and limiting their usefulness. The AMA has been told that FHIR developer efforts are first focused on "just making the technology work" and that "patient data protections and privacy controls are outside their scope." The downstream consequences of this approach will negatively impact physicians and patients. Mechanisms to monitor and control data access, patient consent and privacy, and ensure data provenance, governance, and enforce state and federal law must be inherent in FHIR development. Data flows at the speed of trust, and trust can only be established by actively seeking physician and patient input in this process.

We strongly recommend that HHS consider all ramifications of bulk data access, including privacy and security of an individual's electronic health information. Existing standards such as Consent2Share and Data Segmentation for Privacy (DS4P) are not being utilized due to cost, maturity, or lack of adoption.
Clearly, increasing ease of access to data is an imperative; however, HHS must also consider the need to hold entities accountable, including assuring that covered entities can comply with HIPAA's minimum necessary obligations.

- Recommendation 3: Implement an open API approach to HHS electronic administrative systems to promote integration with existing health IT products.

The AMA is in support of an open API approach to HHS electronic administrative systems as long as the data being shared via the open API is publicly available information. Information that physicians may provide as part of the enrollment or revalidation process, such as a social security number, should not be available via an open API because of the risk of identity theft.

The AMA also has concerns about the risk of HHS not having meaningful control over the exchange of data and around the privacy of physicians' data and the potential for fraudulent use of this data. Thus, HHS needs appropriate security and vetting systems for third parties.
For example, for traceability and auditing purposes, HHS should require an API key authorization or Open Authorization (OAuth) to automate the key exchange to access this information.

Strategy 3: Improving the value and usability of electronic clinical quality measures (eCQMs) while decreasing health care provider burden

- Recommendations 1-3

The AMA supports HHS' proposal to pilot eCQMs but cautions that one year may not be sufficient to draw meaningful conclusions. Additionally, due to the increased strain on resources,

HHS should develop positive incentives for those physicians and hospitals that take on additional work to participate. We recommend requiring more than a two-year testing for EHR systems. The broader the initial testing of health IT, the less likely there will be as many issues in implementation when rolled out. NQF and CMS require at least a two-year testing timeframe; however, limited testing information is ultimately generated which contributes to the challenges in eCQM implementation.

We also emphasize the need to incorporate EHR vendor feedback early into the eCQM development process. It is not sufficient that vendors are on a technical expert panel; both vendors and clinicians must be involved from the start. Furthermore, *implementation* of eCQMs cannot be the responsibility of physicians and hospitals alone. The feasibility of data availability and clinical workflows is vital during concept measure development. We stress the need for focused and targeted discussions with vendors and clinicians during measure development and specification. Tailoring a measure based on what is readily available in the EHR is critical. Too often, this work happens after the measure is initially specified—which is too late in the process. HHS should consider how to further promote early and often clinician involvement in measure development.

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.

- Recommendation 1: Federal agencies, in partnership with states, should improve interoperability between health IT and PDMPs through the adoption of common industry standards consistent with ONC and CMS policies and the HIPAA Privacy and Security Rules, to improve timely access to medication histories in PDMPs. States should also leverage funding sources, including but not limited to 100 percent federal Medicaid financing under the SUPPORT for Patients and Communities Act, to facilitate EHR integration with PDMPs using existing standards.

The AMA agrees with the HHS' recommendations to improve the integration of prescription drug monitoring programs (PDMPs) with EHRs and to facilitate electronic prescribing of controlled substances (EPCS). Additional burden reduction can be accomplished through adoption of the PDMP recommendations included on page 17 of the HHS Interagency Pain Management Best Practices Task Force draft report, which is currently available for public comment. For example, Recommendation 1b calls for clinicians to be trained on accessing and interpreting PDMP data, and 1c says physicians should engage patients to discuss their PDMP data rather than making a judgement that may result in the patient not receiving appropriate care. Regarding burden reduction specifically, Recommendation 1d states the health care provider team should determine when to use PDMP data, and that PDMP use should not be mandated without proper clinical indications to avoid unnecessary burden in the inpatient setting. Recommendation 1e calls for studies to identify where PDMP data is best used, with PDMP use

adjusted based on the study findings to minimize undue burdens and overutilization of resources. Recommendation 1f calls for EHR vendors to work to integrate PDMPs in their system design at minimal to no additional cost to providers. The AMA encourages HHS' to add the Pain Management Task Force recommendations to its report.

- Recommendation 2: HHS should increase adoption of electronic prescribing of controlled substances with access to medication history to better inform appropriate prescribing of controlled substances.

The AMA appreciates HHS' acknowledgment of the barriers to implement EPCS. As the AMA described in a March 2018 letter to the Drug Enforcement Administration (DEA), the current EPCS regulations, which have been unchanged since 2010, prevent user-friendly devices that are widely available in medical practices from being deployed to meet the multifactor authentication standards in the DEA rules. Current regulations have also driven down EPCS adoption. The AMA letter outlined specific changes needed in the regulations for biometric devices to improve and reduce physician burden. These requests are consistent with a recommendation from the President's Commission on Combating Drug Addiction and the Opioid Crisis that the DEA should increase EPCS uptake to prevent diversion and forgery and revise the EPCS regulations.

We appreciate HHS' recognition of Section 2003(c) of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (P.L. 115-271), which calls on the Attorney General/DEA to "update the requirements for the biometric component of multifactor authentication with respect to electronic prescriptions of controlled substances." Current regulations are impeding the implementation of EPCS. Removing these barriers will significantly reduce fraudulent prescriptions for opioid analgesics and increase the adoption of EPCS to combat the epidemic of opioid overdose deaths. HHS should coordinate with the DEA through the lens of reducing physician burden—with particular focus on cost, usability, interoperability, and effectiveness of EPCS system regulation.

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.

- Recommendations 1-2

The AMA supports HHS' efforts to reduce burden and streamline reporting requirements across federal and state agencies. We have heard concerns around state-mandated public health reporting requirements. For example, California recently enacted a law requiring health care providers diagnosing or treating patients with Parkinson's disease to report each case to the California Department of Public Health. This has raised questions as to whether this is a serious public health threat that warrants mandatory reporting given the burden it places on physicians. We note that, wherever possible, HHS should also consider encouraging practical reporting

needs in addition to streamlining. A balance should be struck between the volume and the value of information reported.

- Recommendation 3: HHS should provide guidance about HIPAA privacy requirements and federal confidentiality requirements governing substance use disorder health information in order to better facilitate electronic exchange of health information for patient care.

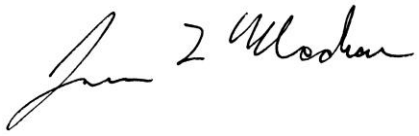
We agree with ONC's recommendation for HHS to provide guidance about federal privacy requirements, including HIPAA and 42 CFR Part 2. We also agree that doing so would help to advance the goal of promoting greater electronic information exchange, which has the potential to greatly improve care coordination while maintaining patient confidentiality. We note, however, that guidance developed to date does not seem to make its way to its intended audience. Many physicians contact the AMA months or even years after guidance is released asking questions about privacy laws. Furthermore, as the draft report notes, health care providers frequently report that privacy laws inhibit their ability to exchange information even when such laws, in fact, do permit information sharing. Indeed, we encounter many industry stakeholders beyond health care providers who misunderstand privacy laws and thus perpetuate confusion about how such laws permit information sharing. Finally, certain guidance focuses on overly simplistic use cases. Physicians need and want guidance that helps them navigate the "grey areas" of privacy law, such as whether text messaging is permitted under HIPAA, how to distinguish between patient-directed third-party access to protected health information and a third-party access request for information, and even distinctions between how mental health substance use disorder information can be shared. As such, we urge HHS to strategize around ways to ensure physicians, patients, and other health care industry stakeholders are alerted to new and existing guidance that contains answers to common clinical scenarios.

We wholeheartedly support ONC's recommendation that HHS monitor, test, and support development of technical standards for data segmentation, and strongly urge Congress to demonstrate its commitment to greater interoperability and privacy protections by prioritizing data segmentation in funding decisions, oversight, and legislation. We note that while technology exists to segregate data and software can help to electronically manage patient consent (e.g., Consent2Share), we have heard from physicians and health systems that such segregation functionality is costly to implement, and that open-source consent management software can be prohibitively expensive to incorporate into a customized EHR. We urge both Congress and the administration to recognize the pressing need for data segmentation to be made accessible and affordable to physicians. Such capabilities will enhance interoperability, strengthen the patient-physician relationship through a patient's increased confidence that a physician will not share data in a way that violates the patient's trust, and improve care coordination and patient outcomes resulting from a physician's ability to access sensitive information. Furthermore, such data segmentation capabilities would help to address issues related to many types of sensitive data—not only substance use disorder information, but also genetic information, behavioral health, sexual health, and minor health, among others—as well as easing the burden stemming from physicians' compliance with state privacy laws. Congress and HHS should reject the approach of legislating and regulating around these problems and instead focus on developing

data segmentation standards and software, while ensuring that such technology is widely available and affordable.

The AMA shares the Administration's continued focus on reducing burdens for physicians across the U.S. We are excited to continue to work with the Administration to secure long-lasting revisions to health IT policy and clinical documentation requirements for physician visits so that doctors may spend time on patient care rather than with paperwork. If you have any questions, please feel free to contact
Margaret Garikes, Vice President, Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



James L. Madara, MD

Attachments

APPENDIX

CPT/RUC Workgroup on E/M Proposal – Physician Time Reporting

CPT Code	Minimum Time on Date of Procedure	Range of Time to Report	2019 Medicare Payment	Payment Increment Between Levels
New Patient Office Visits				
99202	15	15-29	$77	-
99203	30	30-44	$110	$33
99204	45	45-59	$167	$57
99205	60	60-74	$210	$43
+99XXX	75	Report 99205 + 1 99XXX for each 15 minutes beyond 60 minutes	+$50 estimate	
Established Patient Office Visits				
99212	10	10-19	$46	-
99213	20	20-29	$75	$29
99214	30	30-39	$110	$35
99215	40	40-54	$148	$38
+99XXX	55	Report 99215 +1 99XXX for each 15 minutes beyond 40 minutes	+$50 estimate	

Incremental payment equates to $3 per minute and does not incentivize as a physician could generate more payment in seeing a different patient in that same time. Example, spending 10 minutes to move from 99212 to 99213 equates to $29 in additional payment versus at least $46 to see a different patient in that same amount of time.

CMS CY 2021 Proposal – Physician Time Reporting

CPT Code	Typical Face to Face Time	Range of Time to Report	2021 Proposed Payment	Payment Increment Between Levels
New Patient Office Visits				
99202	20		$130	-
99203	30			-
99204	45			-
99205	60		$212	$82
+GPRO1	38-89	Report 99202-99204 + GPRO1 if time was 38-89 minutes	+$67 (Total $197 – just $15 less than a 99205)	
+99354	90	Report 99205 +99354 if time is 90+ minutes	+$132	
Established Patient Office Visits				
99212	10		$90	-
99213	15			-
99214	25			-
99215	40		$149	$59
+GPRO1	34-69	Report 99202-99204 +GPRO1 if time was 34-69 minutes	+$67 (Total $157 - $8 less than a 99215)	
+99354	70	Report 99215 +99354 if time is 70+minutes	+$132	

Incremental payment is extreme, an established office visit that is 70 minutes is $124 more than a visit of 69 minutes, for example. Instructions regarding when to report 99202-99204 with GPRO1 versus 99205 alone are also confusing. A physician could report a 99212 + GPRO1 and be paid $8 more than a complex 99215. In what scenario would a 99215 be reported by time alone?