January 28, 2019

Don Rucker, M.D.

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 S.W.

Washington, D.C 20201

Re: Strategy for Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and Electronic Health Records

Dear Dr. Rucker:

On behalf of the 25,000 physician, resident and medical student members of the Massachusetts Medical Society I am pleased to offer our comments to the Office of the National Coordinator for Health Information Technology (ONC) on the Strategy for Reducing Regulatory and Administrative Burden relating to the Use of Health IT and Electronic Health Records, (EHRs).

At the outset, I want to thank the Administration for its interest in reducing administrative burden and acknowledging its role as the leading cause of physician burnout. Simply stated, there is no greater problem impacting our profession at this time. The level of physician burnout has reached crisis levels – impacting physicians and their patients. Recent evidence indicates that nearly half of all physicians’ experience burnout in some form. And it appears the problem is getting worse. The 2018 Survey of America’s Physician Practice Patterns and Perspectives, conducted by Merritt Hawkins on behalf of the Physicians Foundation, finds that 78% of physicians’ experience feelings of professional burnout at least sometimes, a dramatic increase from 4% in the 2016 survey. Of perhaps even greater concern, surveys show that young physicians, medical students and residents are suffering from burnout rates comparable to their senior colleagues. The potential impact on the physicians, patients, families and our health care workforce are demonstrable. The Department of Health and Health Services predicts a workforce shortage of up to 90,000 physicians by the year 2025, noting burnout as one of the key drivers for the shortage.

This year, the MMS convened a task force with the Massachusetts Hospital Association (MHA), and working with the Harvard T.H. Chan School of Public Health and the Harvard Global Institute summarized the literature on the magnitude of the problem and identified short, medium- and long-term recommendations that would have a significant impact on relieving the problem. The MMS, MHA and Harvard recently issued the attached report “A Crisis in Health Care: A Call to Action on Physician Burnout.” The report indicates that a major contributor to physician burnout is dissatisfaction and frustration with EHRs. The 2018 Physician Foundation Survey identified EHRs as the single most important “pain point” confronting physicians in their practices.

The Task Force made several recommendations relative to ONCs responsibilities and federal mandates which I would like to highlight.

1. Require that certification compliance ensures that data for quality measurement purposes as required by CMS, NCQA, and health plans/payers and states is easily extractible and readily available within the EHR and that duplicative documentation requirements are eliminated**.**

As you know, the Office of the National Coordinator for Health Information Technology (ONC) is responsible for setting standards for certification of EHRs. To receive certification, EHRs are required to have easily extractable measures as mandated by payers, government, and other measurement organizations. Yet, progress on this front has stalled. ONC last issued certification criteria in 2015. This three-year interval is the longest since ONC was given this mandate in 2009, with standards previously issued in 2011, 2014, and 2015. New standards that address the usability and workflow concerns of physicians are long overdue. To date, ONC has devoted relatively little attention to usability (defined as “the extent to which… users achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use”) in its criteria despite ongoing research, consultations, and a set of use cases and guidelines issued in 2015. It is unacceptable that EHRs which fail to readily meet federal and state requirements for reporting on quality mandates and other measurements are passing certification. It is critical that ONC resume its responsibility to insure usability.

1. Permit software developers to develop a range of apps that can operate with most, if not all, certified EHR systems and encourage their use

The concept is similar to how Apple and Google apps stores deliver an immense array of functionality on millions of different mobile devices according to the user’s preferences. The problem is the “one size fits all model” approach for EHRs – where physicians are forced to use a small number of certified EHR systems across a wide range of medical specialties, practices and patient populations. Application Programming Interface (API) was required by the 21st Century Cures Act. Greater availability of API would allow physicians, clinicians and hospitals to customize their workflow and interfaces according to their needs and allow for rapid implementation of innovations. Epic’s Apple Orchard is a first step in this approach – but clearly much more needs to be done to make APIs more universally available and useful.

1. Increase development of Artificial Intelligence (AI) to support clinical documentation and quality measurement.

A new and promising, but less developed approach to reducing the burden on physicians and other clinicians is in the development of AI technologies. AI applications could for example analyze physician text narratives and extract clinical problems. It could also be developed to review clinical documents and extract information for quality or other reporting requirements.

The remainder of our comments focus on the proposed changes to E&M documentation guidelines and the ONC proposal to reduce Administrative Burden. Many of our specific recommendations are adopted from the AMA’s comments which we strongly support. We have highlighted several of key concern.

1. **E&M Coding proposals**

The MMS strongly supports the intent of proposals to simplify E/M guidelines and to reduce burdensome click requirements. This year the Society joined with the AMA and the vast majority of state and national medical associations in opposing the proposed collapsing of E&M payment as part of the proposed changes to the 2019 Medicare Physician Payment Rulemaking. As our comments detailed, we believed the proposal would have caused serious harm to patients with the most complex and serious illness. By delinking payment from medical decision making and patient complexity, the proposal would have undervalued the care provided to these patients and the physicians who care for them. We are pleased CMS chose to delay a number of these changes. We also agree that several of the final policies in the physician Medicare fee schedule are positive and will help reduce unnecessary documentation. These include:

* Removing the requirements to document medical necessity for a home visit,
* Requiring a patient history only for new information between patient visits,
* Eliminating the requirement for physicians to redocument information in the medical record.

The MMS is also pleased that CMS is working with the AMA-CPT Workgroup on recommendations for changes to E&M coding for 2021. The 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 to improve the health of the patient. To achieve these goals, the 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.

To date the workgroup has made three primary recommendations for office-outpatient visits.

1. Elimination of history and physical exam as elements for code selection.
2. Establish two primary E/M code selection criteria – MDM or Total Time.
3. Modifications to the Criteria for MDM

The AMA’s comments review these initial recommendations in more detail. Acknowledging the significant overlap between HHS’ burden reduction strategies and the workgroup’s recommendations to improve E/M clinical documentation, they also studied the impact of these changes on physician workflow. For example, the work group estimates the changes to the history and physical exam will reduce the amount of time spent on documentation by 15%. They also calculated that the newly proposed time measurement– vastly simplified from the CMS proposal – will also save time.

The workgroup and its recommendations evidence a demonstrable commitment from the physician community to work with HHS, CMS and ONC to reduce unnecessary administrative burdens while at the same time finding the appropriate basis to calculate the value of physician’s work.

**ONC Strategies to Reduce Regulatory and Administrative Burden Relating to the Use of Health IT and Electronic Health Records (EHRs)**

1. **Clinical Documentation**

The document’s problem framing statements and strategies indicate a clear understanding of the concerns and burdens experienced by physicians and clinicians. Overall, we are grateful for continued efforts to reduce the documentation requirements for reimbursement, simplify quality reporting requirements and improve EHR workflow. Cluttering of the electronic record with extraneous and duplicative data further burdens our providers with time spent reviewing the chart to deduce the essential patient narrative. Our comments to the Medicare Physician Schedule Proposed rules for 2019 and the QPP programs noted above contain detailed recommendations with respect to changes to Clinical documentation guidelines and changes to the QPP reporting requirements. Other recommendations specific to the ONC draft follow.

Strategy 3 – Leverage health IT to standardize data and process around ordering services and related PA processes

We strongly support the focus on reducing the documentation burdens of prior authorization and utilization review. The variability of the data requirements from payor-to-payor, the variability of duration or number of interventions authorized, as well as the volume of data required have rendered automation of this data acquisition and submission process daunting for providers, support staff, and vendors alike. We support advancing the electronic submission process and recommend additional attention be paid to reducing the volume and variability of clinical necessity guidelines for required data to reduce this burden

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

The MMS supports efforts to evaluate and address factors that lead to prior authorization (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.

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.

The MMS joins the AMA in urging ONC to require 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 health plan with which they do business. As they note, such an attachment has been developed by the National Committee for Vital and Health Statistics and is under review by CMS. However, industry wide adoption of a uniform attachment is critical to improve efficiency and reduce burden.

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

The MMS 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 MMS supports the need to pilot standardized electronic ordering services. Pilots 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.

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

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.[[1]](#footnote-1) The electronic transmission shall comply with technical standards adopted by the Secretary. We strongly believe 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.

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

While we support efforts to use technology to make the prior authorization process more efficient, overall our goal is to reduce the number of prior authorizations that are required. By definition prior authorizations take time and cost money – no matter how seamless the process. Designed as a tool to control costs and utilizations by insurers, PA should only be used if at all, in select cases. In many ways prior authorizations are the perfect example of a misguided cost containment tool. The amount of time and money its takes physicians to obtain PA merely adds to the cost of care and administrative burden. As physicians and health care move towards assuming more risk, through ACO and APM and value-based models, we believe the reliance on prior authorizations will be obfuscated appropriately by the physician and health care team’s assessment of the appropriate care. In the meantime, we support efforts to standardize the process and to restrict its use to selected procedures which meet carefully defined criteria

1. **Health IT Usability and the User Experience**

The MMS strongly supports strategies and recommendations to improve EHR usability and alignment with clinical workflow, standardization of the canonical workflows for chart review, as well as ordering and documentation processes to improve the intuitiveness of use across various EHR platforms.

We realize that members of the EHR vendor community believe they employ user-centered design experts and provide configuration tools to make it possible to deliver a high degree of organization-specific and specialty-specific usability to their clinicians. Many of these vendor configuration tools are highly complex and do not contain the basic functions required to manage user context, dependency tracking, transparency, human readability, auditing, and provenance. These deficiencies increase the expense to support these systems as well as further complicate a healthcare system’s ability to be timely and agile in optimizing the platform’s usability.

EHR vendors should be encouraged to invest in improving their configuration tools on behalf of implementation teams as well as personalization strategies for end-users. These investments would contribute greatly to improvements in data presentation, documentation and order entry. Further, while EHR systems may offer many tools for user personalization, very few, if any, have invested in developing the capabilities of their systems to learn from past user behavior. Rather than burdening the user with having to learn and continuously curate the level of personalization required to achieve his or her satisfaction, EHR developers could essentially build platforms leveraging the user profile, such that the system learns from past user behavior and anticipates the user’s needs. These kinds of approaches can potentially be undertaken by EHR vendors within their native application architectures as well as via 3rd party solution integration.

We strongly support the recommendations to prioritize investments that improve clinician efficiency. These investments are typically shared across three key domains: vendor investments, implementation and configuration investments, and operational investments. Underestimation of the budgetary requirements to drive clinician efficiency is a common problem. While we wait for EHR vendors to improve their configuration and personalization functionality as outlined above, it will be important to point out that health systems should be encouraged to both invest in the necessary implementation resources to optimize user experience as well as invest in support staff who can unburden clinicians of administrative and data entry tasks within their scope of practice. Workforce composition is highly varied in health systems and practices, nationwide, and, it would be helpful to develop national benchmarks for the necessary complement of implementation and operational support staff.

*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 MMS agrees there is a desperate need to align EHR system design with real-world clinical workflows. As we noted earlier in this document, health IT is a major factor in physician burden and burnout, which takes away valuable time from providing care to patients. We agree with the AMA’s assessment that there are two major drivers of EHR design that need to be addressed– federal policy and health IT development and lack of user centered design. With respect to the federal government we strongly support the AMA recommendation that HHS review 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 also support testing EHRs in a real world setting to better support clinical workflow and to reduce the burden on the practicing physicians. 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.

* Recommendation 2: Improve clinical decision support usability.

The MMS 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. Further, we agree the appropriate application of data standards is essential to providing high-quality health care.

* Recommendation 3: Improve clinical documentation functionality

The MMS agrees there is a tremendous need and opportunity to improve EHRs to help with clinical decision-making. The AMA has established the Integrated Health Model Imitative (IHMI) which leverages collaborative communities, a physician -led validation and review process and advanced data modeling to support improvement in clinical decision support and data standardization. The IHMI works with over 30 stakeholders in this effort – including technology developers, consumer groups, professional associations and standards development organizations. We urge ONC to support the IHMI as a body to support cross stakeholder agreements related to standardization/modeling, medical knowledge representation and efforts around data portability and liquidity

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

The. MMS 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. As we noted earlier in our comments, physicians should have access to a wide range of apps similar to smartphone for EHRs. ONC’s Testing and Certification Programs play an important role in supporting this effort.

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

The MMS supports HHS’ acknowledgment that health IT user interface design and configuration is a major contributor to physician cognitive burden. At a minimum, physicians need more tools to become well-informed consumers of technology. 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 MMS agrees there needs to be a concerted effort across health IT developers to harmonize clinical content in their products. As noted at the outset of our comments, we believe ONC should require as part of certification that all EHR products can comply easily with federal mandates. ONC should consider developing standards for all EHRs to meet this goal. 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.

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

The MMS 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.

Additionally, we note physicians are required to continuously invest significant funds into ever changing 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.

Regarding the financing of EHRs in physicians’ offices we recommend that Medicare and other payors should be required to include the cost of the investing in and maintaining EHRs as part of practice expenses calculations. In addition, physicians who are a required to purchase new EMR systems because they are affiliated with a hospital or health system should be reimbursed for the cost of the new EMR as well as implementation costs (education, downtime, etc.). Anecdotally we are hearing that hospitals are not willing to help with these costs because of concerns regarding potential Stark violations. HHS should issue guidance on this issue. As federal and state mandates continue to change, as health systems choose to change EHRs, non-employed physicians are forced to bear the burden of these costs which can be overwhelming for a practice. If we are sincere in our goal of reducing administrative burden and burnout, we must address the financial pressures that are associated with ever changing mandates for an imperfect but necessary product.

1. **EHR Reporting**

The MMS strongly supports the simplification of all the QPP reporting requirements as well as improved interoperability. It is important to note, however, that the focus on data exchange for transitions of care and clinical data reconciliation have created a significant data curation burden for physicians and other clinicians. The lack of standards and efficient tools is resulting in a continuous “boomerang effect” of data exchange such that clinicians are being sent vast amounts of redundant and unnecessary data. Some of the information is generated by their own EHRs, other information is curated by other sources and is duplicative of or only slightly different from what is already in the receiving clinician’s EHR. The EHR vendor community should be encouraged to invest in advancing the capabilities of data reconciliation tools to reduce this burdensome volume of duplicate data curation

*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 MMS strongly 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. The current program is system is unnecessarily complicated, confusing and time consuming. The AMA has worked with a number of national medical special groups on a proposal which would require yes/no attestation, focus on clinical care, promote higher-value EHR functionality, align measures with workflows, and increase access to health information. We urge HHS to 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 MMS 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.

* 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 MMS appreciates CMS’ engagement with physicians in burden reduction efforts. We will continue to work with CMS in support of this effort, however, we continue to believe our overall goal should be transition away from detailed meaningless EHR measurement. Information generated as a byproduct of physician-patient engagement and clinical care is far more insightful. Further, 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.

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. Feedback reports 18 months after the performance year are not useful in helping physicians learn from their previous work experience.

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

MMS fully supports this goal.

*Data Standards*

Coordinated data management is critical to interoperability. The MMS strongly supports the AMA recommendation 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*

As more data becomes widely available, the MMS urges HHS to carefully review privacy and confidentiality policies to prevent any potential harm to an individual’s privacy as a result of this unprecedented access to information. We urge HHS to take a methodical approach and to insure physician and patient communities are well-informed and support with efforts to advance data access at this scale. Access must be provided for a given purpose and consistent with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule’s minimum necessary standard.

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

The MMS supports efforts to improve the value and usability of electronic clinical quality measures while decreasing health care provider burden.

1. **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 MMS strongly 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). We are currently reviewing the HHS interagency Pain Management for Best Practices proposal which includes many important recommendations in this area. For example, the draft recommends that EHR vendors to work to integrate PDMPs in their system design at minimal to no additional cost to providers – which we strongly support. The MMS will be providing separate comment on the Pain Management Best Practices Document.

It should also be noted that we have concerns about information that is currently not being included in the PMP. At present in MA, Mass Pat, the Ma prescription monitoring program displays all controlled substances dispensed in Massachusetts over the past 12 months, this includes buprenorphine/suboxone prescribed for OUD, and it includes methadone when prescribed for pain and dispensed at a pharmacy. It does not include methadone dispensed at an Opioid Treatment Program (a methadone clinic). As the PMP has become more user friendly and more accurate, many physicians also use the PMP as a medication reconciliation tool. They generally presume Mass PAT is an accurate list of all controlled substances prescribed. Most do not know about the gap in the PMP for methadone from an OTP. Proponents of including Methadone argue that this is a patient safety issue because there can be significant negative drug interaction that could occur because of this gap. Opponents are supporters of maintaining the current 42 CFR part ii protections. Their concerns are that until we make real progress in addressing stigma we must retain all privacy protections for persons seeking OUD.

At issue are the 42 CFR regulations which prohibit the sharing of disclosable data. We also understand that they are a series of conversations taking place over 42 CFR Part 2 overall and its protections. At a minimum we believe it is important the physicians are clearly advised about the limitations of the PMP absent a resolution to these issues.

* 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 MMS appreciates HHS’ acknowledgment of the barriers to implement electronic prescribing for controlled substances (EPCS). We have joined with the AMA in urging the DEA to update the current EPCS regulations, which have been unchanged since 2010. These regulations are woefully out of date and 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 outlines specific changes needed in the regulations for biometric devices to improve 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.

The importance of updating these regulations promptly cannot be overstated. The Opioid crisis continues to be a major public health care. Less than 10% of physician’s offices nationally use EPSC for controlled substances; equally notable are the large health systems which do not use EPCS for controlled substances. Barriers include cost and work flow challenges. Widespread use of EPCS for controlled substance will significantly help reduce the number of drugs that are stolen or diverted. Physicians want to use this technology as they know it safer and more efficient. For these reasons, both Congress and our state legislature have mandated that physicians use EPCS for controlled substances. (Ma mandates is for 2020; federal mandate is for 2021). If the DEA fails to issue new regulations promptly, physicians will once again find themselves being penalized for their failure to comply with a mandate for circumstances beyond their control. Buying and implementing the new systems to EPCS controlled substances will take time and money – both necessary for appropriate implementation. But a physician’s office cannot be expected to do this overnight. This issue is yet another example of what can go so horribly wrong with EHRs and Health IT. The technology exists to improve patient safety and care and physicians are eager to use it. Because the federal government has failed in its responsibility to help implement these mandates, the vendor community will continue to benefit from existing and costly archaic systems. Making EPCS of controlled substances fit into the physicians work flow, cost efficient and easy to implement is very doable and a specific action HHS can take to directly address unnecessary administrative burden. While we understand the DEA is a separate agency, we understand the goal of reducing administrative burden to be shared across the Administration and its agencies.

*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.*

* Recommendation 3: HHS should provide guidance about HIPAA privacy requirements and federal confidentiality requirements governing substance use disorder health information 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. As our comments to the previous section notes, we understand there is an ongoing conversation about some of these provisions. 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. Physicians need and want guidance that helps them navigate the 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 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 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. Further, 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.

In closing, I want to thank you for the opportunity to comment on this draft. It is our understanding that several other rulemakings regarding interoperability and other seminal issues impacting EHRs, HIT and patient care are forthcoming. We look forward to commenting on those as well, The Society is hopeful that this rulemaking is an indication that the agency is committed to making EHRs effective clinical tools. We urge HHS to implement specific, actionable, measurable steps with defined timelines. For too long the physician community has been held accountable for the failure of the EHR and HIT systems despite reasons that were beyond well beyond our control. Health systems continue to block information sharing, vendors develop EMRs that are difficult to use, and federal and state mandates, rather than help improve the quality of care, create a series of meaningless tasks that only take more time away from patient care. It’s no wonder physicians are burned out.

As always, the Massachusetts Medical Society looks forward to working with you on this and other initiatives to help improve the quality of our health care and to support the physicians and other professionals who provide that care.

Sincerely



Alain Chaoui, MD,

1. Section 1860D-4(e)(2)(E) of the Social Security Act (42 USC § 1395w-104(e)(2)(E)(ii)(II)). [↑](#footnote-ref-1)