January 28, 2019

Donald W. 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 St. SW
Floor 7
Washington, DC 20201

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

Dear Dr. Rucker:

The Physicians Advocacy Institute (PAI) appreciates the opportunity to provide comments on the Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs (Strategy), posted in November 2018.

PAI is a not-for-profit organization that was established to advance fair and transparent policies in the health care system to sustain the profession of medicine for the benefit of patients. As part of this mission, PAI seeks to better understand the challenges facing physicians and their patients and to also educate policymakers about these challenges. PAI also develops tools to help physicians prepare for and respond to policies and marketplace trends that impact their ability to practice medicine. PAI's Board of Directors is comprised of CEOs and former CEOs from nine state medical associations: California Medical Association, Connecticut State Medical Society, Medical Association of Georgia, Nebraska Medical Association, Medical Society of the State of New York, North Carolina Medical Society, South Carolina Medical Association, Tennessee Medical Association, and Texas Medical Association, and a physician member from Kentucky. As a physician-based organization, PAI is equipped to provide comments and insight into many of the challenges facing the medical profession.

PAI is committed to advancing policies that protect the ability of patients to receive high-quality care and is supportive of the goals Health and Human Services (HHS) Secretary Azar, Centers for Medicare and Medicaid (CMS) Administrator Verma, and Office of the National Coordinator (ONC) Coordinator Rucker have outlined in their respective messages included in the draft Strategy. PAI commends HHS, CMS, and ONC (hereinafter collectively referred to as "ONC") on outlining a strategy for addressing areas of clinician burden associated with health information exchange and electronic health records

(EHRs). Interoperability and the unimpeded flow of information, for both physicians and their patients, is critical to ensuring the delivery of coordinated, high-quality, and necessary health care.

Overview

The 21st Century Cures Act requires HHS to outline a plan for reducing regulatory and administrative burden related to the use of health IT and EHRs, specifically requiring HHS to: 1) establish a goal for burden reduction relating to the use of EHRs; 2) develop a strategy for meeting that goal; and 3) develop recommendations to meet the goal. In response, HHS and ONC (collectively ONC) have issued this report in which they outline three primary goals based on stakeholder engagement: 1) reduce the effort and time required to record information on EHRs for health care providers during care delivery; 2) reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and health care organizations; and 3) improve the functionality and intuitiveness/ease of use of EHRs. Through their stakeholder engagement, ONC also identified four key issue and challenge areas: 1) clinical documentation; 2) health IT usability and the user experience; 3) EHR reporting; and 4) public health reporting. Within each of these challenge areas, ONC identifies corresponding key strategies and recommendations. These are outlined below along with PAI's comments and suggestions.

Specifically, as the ONC proceeds with implementing the Strategy, we urge the ONC to take the following into consideration:

- Vendors should have accountability for ineffective exchange of information and their products and health care delivery systems should be accountable for delaying, withholding or limiting data from being displayed, provided, or shared across platforms. This will relieve undue pressure on physicians.

- Physicians and patients have little influence on the speed with which these exchanges are implemented and have minimal control on acceleration. Many vendors have delayed their updates and continue charging practices exorbitant fees for these updates, even when they are delayed or not completed.

- Physicians are often unjustly penalized for reliance on vendors and trusting that their vendors will become certified, maintain their certification, and appropriately submit their data to CMS on their behalf.

- Continuous stakeholder engagement should remain a key focus, specifically with state medical societies who hear directly from physician membership about the difficulties and burdens and can provide valuable insight into recommended updates and changes at the data collection, display, review and connectivity phases of medical record data usage.

Clinical Documentation

Clinical documentation challenges include those associated with actual E/M documentation guidelines and requirements, as well as the additional range of documentation tasks that must be satisfied for administrative and billing requirements (i.e., prior authorization). ONC proposes three key strategies for addressing this issue area: 1) Reduce regulatory burden around documentation

requirements for patient visits; 2) Continue to partner with stakeholders to encourage adoption of documentation requirement best practices; and 3) Leverage health IT to standardize data and processes around ordering services and related prior authorization processes.

Reduce regulatory burden around documentation requirements for patient visits.

Under this strategy, ONC proposes recommendations focused on continuing efforts to reduce overall burden, leveraging existing data in EHRs to reduce re-documentation notes, obtaining ongoing stakeholder input on updating documentation requirements, and waiving documentation requirements as necessary for testing and administering alternative payment models (APMs). Additional focus is placed on need for advancing best practices and considering the workflow processes, including data input, data output and flow, prior authorization, and standardized templates.

Physicians have reported that complying with the different documentation requirements (including the use of CPT coding nomenclature and ICD-10-CM) takes away personal and patient time and leads to physician burnout. Thus, PAI believes that these recommendations would help alleviate some of the clinician burden related to documentation. We believe it is important to continue to engage stakeholders, especially for understanding how existing EHR data and clinical documentation requirements can be changed going forward to improve connectivity and patient care delivery at the point of care. These conversations should include both physicians and health plans, as well as health systems, since all three are integral to clinical documentation of care and ensuring that patients continue to access necessary treatments without delays due to EHR challenges. The ONC should also consider incorporating the recommended changes these stakeholders put forth into the accreditation standards and criteria for certified EHR technology (CEHRT) which is required for APMs under the Quality Payment Program (QPP). However, the burden should be on vendors and any system or entity mandating or requiring the use of a particular software or hardware system for ensuring that they are meeting these standards and acquiring certification in a timely and effective manner.

Continue to partner with stakeholders to encourage adoption of documentation requirement best practices.

PAI is supportive of promoting and advancing best practices for reducing burden. One potential path for achieving these may be through the adoption of Choosing Wisely principles that have been developed and agreed upon by the respective stakeholder groups. A value of these best practices is that, unlike regulations or law which can often be complicated and require clarification, the Choosing Wisely principles are described in simple terms that can be understood by physicians and patients. PAI believes that such a straightforward and simple approach should be used for future best practices as well.

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

There is much variability across the board regarding workflow processes and data input (e.g., state, federal, vendor, setting) on how personal health information (PHI) is collected and shared. PAI supports the strategy and recommendations for standardizing not only data but the processes around ordering services. This is especially critical as patients may receive care across different

settings, as well as in different states, and standardization would help ensure that they continue to receive coordinated and informed care. We believe it would be valuable to streamline and automate the processes for prior authorization of services which can delay critical patient care. With the appropriate EHR infrastructure and data elements in place, physicians can ensure that patients receive necessary care faster without having to first go through a time-consuming prior authorization process. As part of this, the ONC should consider how health plan level information could be adopted into the EHR for instances when prior authorization is necessary. For example, a specific surgery, or even the post-operative care, such as medications, may require prior authorization by one health plan but not another and the EHR could include clinical decision support (CDS) type tools, which alert the physician that prior authorization is required in a specific case because of the patient's health plan.

Health IT Usability and the User Experience

Additional EHR-related burdens are centered around how well a user can learn and use the product to achieve their goals, whether the product is user-centered, and overall experience using the product within the clinical workflow framework. ONC proposes four key strategies for addressing this clinical burden area: 1) Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation tools; 2) Promote user interface optimization that will improve efficiency, experience, and end-user satisfaction; 3) Promote harmonization surrounding clinical content contained in health IT to reduce burden; and 4) Improve health IT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden.

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

PAI recognizes the value and importance of CDS tools, however, as noted in the draft Strategy, they can incumber EHR data entry. We believe that CDS tools should be developed and implemented in a way that supports patient care and physician decision-making as appropriate, and not required as a blanket policy that may not be necessary for every patient. CDS tools should also be aligned with health plan guidelines, at the health plan level (as described above). However, as noted in the draft Strategy, information overload can be a source of burden, and we agree it is essential that usability considers and improves EHRs organization, management, and search functionalities as well as connectivity and interoperability.

Promote user interface optimization that will improve efficiency, experience, and end-user satisfaction.

Promoting the user interface and harmonizing the actions for clinical operations across EHRs and improving internal consistencies within and across products would contribute significantly to reducing physician burden. PAI supports the ONC's strategy recommendations and encourages greater focus on bi-directional information exchange as part of its harmonization efforts. Lack of harmonization in how the information is displayed and presented can hinder patient care and efficiencies due to the lack of usability of the data.

A feature the ONC could consider would be requiring functionality that would automatically create a clinical summary of relevant information based on the type of provider requesting the summary (e.g., primary care physician, specialist, diagnostic provider, etc.). The different providers could work with

vendors to identify key data elements that would be helpful and valuable to them for the services they provide to the patient at that time.

Promote harmonization surrounding clinical content contained in health IT to reduce burden.
We also believe that standardization of medication information, entry content, and display conventions would be helpful, but could potentially be further burdensome for physicians if there is not correlating standardization by, for example, drug manufacturers, health plans, or hospitals. Standardization would only be as effective as its adopters, and PAI urges the ONC to ensure that it occurs across settings, vendors, and stakeholders.

Improve health IT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden.
Meaningful focus on the end-user, including training and budget constraints, is currently missing from the EHR landscape. However, it is important to note that a one-size-fits all approach is not helpful for these purposes. Different care settings, physician specialties, and patient characteristics and access needs should be factored in to enhance the usability and user experience for EHRs. One recommendation would be considering how vendors and academic centers could help provide early training and education on EHRs to medical students so they are already accustomed to the different functionalities and can work with vendors to further tailor the products to their needs. This will also provide ongoing and early feedback to vendors for product updates to keep pace with the medical advancements in treatments, therapies, and care models.

PAI strongly supports ONC's recommendation to continue promoting nationwide strategies that further exchange of electronic health information to improve interoperability, usability, and reduce burden. We believe that nationwide strategies and standards for EHRs are important and, once set, should be enforced. However, we stress the need to hold vendors, rather than physicians, responsible and accountable for satisfying any standards and to make sure that health systems also comply with these standards and do not unnecessarily restrict or limit access to critical and time sensitive patient care and treatment information.

EHR Reporting

EHR reporting for federal, state, and other value-based programs add to the existing regulatory and reporting burdens already existing within these programs. Stakeholders have identified the following key challenges with EHR reporting: electronic clinical quality measures (e-CQMs) infrastructure and implementation, technical challenges, and program requirements. The ONC proposes three strategies for addressing these burdens: 1) Address program reporting and participation burdens by simplifying program requirements and incentivizing new, easier and better value approaches; 2) Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs; and 3) Improve the value and usability of e-CQMs while decreasing health care provider burden.

Address program reporting and participation burdens by simplifying program requirements and incentivizing new, easier and better value approaches.

The ONC recommends focusing on simplification across programs, as well as aligning e-data collection with existing workflows to address program reporting and participation burdens instead of imposing new and burdensome data collection requirements. PAI supports simplification of reporting requirements across programs; however, we stress the need for stability and consistency to make programs more predictable. Continuity in the programs would allow physicians and practices to have a general idea of how they can make changes in their practices to increase their overall performance scores and payment adjustments.

Additionally, PAI supports providing states with funding to promote interoperability within Medicaid. This is especially important as the Medicaid beneficiary population is served by community providers, including small practices, who often lack resources and access to HIEs and interoperable systems. However, we believe this funding should be extended and be provided for promoting interoperability across payers and health systems and hospitals as well. Furthermore, funding should be allocated to help support existing efforts rather than "recreating the wheel." For example, in states where a "private" HIE or interoperability option and infrastructure is already in place (e.g., by a state medical society), focus should be on building upon and further expanding that existing infrastructure for interoperability purposes rather than trying to create something new from scratch.

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

As discussed above, bi-directional data exchange is critical for not only program reporting purposes, but also coordinated and more informed patient care. An open API approach could be utilized to help support bi-directional data exchange, but there are shortcomings of this option. PAI believes that this is only one solution and should not be considered the only solution. We urge against imposing the adoption costs of these solutions on physicians and practices. For smaller practices and individual physicians, costly solutions can be burdensome and an obstacle to their ability to contribute to greater health information exchange and care coordination for their patients.

Improve the value and usability of e-CQMs while decreasing health care provider burden.

PAI supports this strategy for improving the value and usability of e-CQMs. Adopting a first-year test reporting approach for newly developed e-CQMs is a helpful way to phase in these new measures; however, testing must include physicians of different practices types, specialties, and sizes to ensure that the e-CQMs are truly feasible. We also encourage the ONC to continue evaluating the current landscape and future directions of e-CQMs and provide a roadmap toward increased e-reporting through the e-CQM Strategy Project. As part of its efforts to explore alternate, less burdensome approaches to e-quality measurement through pilot programs and reporting program incentives, the ONC should leverage best practices from and alignment with existing program reporting and participation requirements, such as Medicare Advantage or Medicaid value-based payment arrangements as well as APMs.

Public Health Reporting

ONC has identified two key areas of burden for public health reporting: 1) lack of automated standards-based reporting requirements across federal programs; and 2) health IT integration challenged related to electronically prescribing of controlled substances (EPCS) and retrieval of medication history from prescription drug monitoring programs (PDMPS).

Increase adoption of e-prescribing of controlled substances and retrieval of medication history from state PDMP through improved integration of health IT into health care provider workflow.

PAI believes that efforts as part of this strategy should include a requirement that each state's PDMP be able to accommodate EHR integration. Industry standards should be adopted to ensure that EHR vendors include PDMP integration as a basic service. Additionally, the ONC may consider providing incentives, but not mandates, for EPCS, so that physicians would still have the flexibility to use paper prescriptions when and EHR or e-Rx may not be available or accessible. As well, the ONC should consider ways to ease the financial burden imposed upon physicians and other providers to access their own PDMP data.

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

The ONC recommends that HHS should: 1) convene key stakeholders to inventory reporting requirements, and work together to identify commonly reported data for state and federal programs; 2) continue to work to harmonize reporting requirements across federally funded programs requiring the same or similar EHR data from providers to streamline the reporting process across state and federal agencies using common standards; and 3) 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.

PAI believes that streamlining the reporting requirements and identifying common data elements for state, federal, and other programs would help reduce physician burden and contribute to the public health reporting goal. However, these efforts should be done with stakeholder input, especially those who must enter the data and who must rely on the data for care delivery, and not in isolation as the ONC recommends. The delivery of health care services is a cross-sector model and it is important that the different requirements from each of the sectors be incorporated and aligned within the EHR and health IT elements of the delivery model. PAI further agrees with ONC and urges further clarification and additional guidance on HIPAA privacy requirements. Additional guidance on what information can be exchanged, what information can be used for patient care services as opposed to just monitoring, and who certain exceptions apply to would be extremely valuable and help facilitate greater use of and comfort with using EHRs.

Conclusion

Overall, PAI supports CMS' efforts to streamline and reduce unnecessary burdens placed on physicians related to EHRs, interoperability, and health IT. These adjustments must benefit all physicians and providers equally and not be designed or structured simply for large health systems.

We welcome the opportunity to work with the ONC to further implement and advance strategies and efforts to reduce burden in a meaningful and impactful way. If you have any questions, please contact me at rseligson@ncmedsoc.org, or Kelly C. Kenney, PAI's Executive Vice President and CEO, at k2strategiesllc@gmail.com.

Sincerely,

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President, Physicians Advocacy Institute