January 28, 2019

Donald Rucker, MD, National Coordinator for Health IT  
Department of Health and Human Services  
Office of the National Coordinator for Health Information Technology  
Mary E. Switzer Building  
Mail Stop: 7033A  
330 C Street SW  
Washington, DC 20201

Dear Dr. Rucker:

On behalf of the American Academy of Family Physicians (AAFP), which represents 131,400 family physicians and medical students across the country, I write in response to the draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs made available for public comment by the Office of the National Coordinator for Health Information Technology (ONC) on November 28, 2018.

The AAFP appreciates that ONC seeks feedback on this draft report required by the 21st Century Cures Act. We agree with the primary goals listed in the report’s introduction and stand ready to work with ONC to implement policies that:

• Reduce the effort and time required to record information in electronic health records (EHRs) for health care providers during care delivery.
• Reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and health care organizations.
• Improve the functionality and intuitiveness (ease of use) of EHRs.

Achieving these goals is imperative because family physicians continue to experience significant EHR documentation burdens and hassles complying with regulatory reporting requirements. Physicians are not satisfied with the current functionality and usability of EHRs. Improvements in the core functionality of EHRs is needed, especially to support value-based care. The AAFP is concerned that gaps in EHR functionality to support primary care practices are widening with the additional requirements of value-based payment models, particularly in regard to the timely aggregation of data from multiple sites, the ability to access, analyze, and interpret an overwhelming amount of data, and the actionability of the data.

The AAFP is pleased with the draft report’s in-depth discussion on administrative burdens related to health IT. Of those addressed by the report, the discussion does a very good job describing the burden and some of the challenges and opportunities to reduce the burdens. The AAFP encourages HHS to perform a thorough root cause analysis of these burdens to gain an
understanding of what led to the them and to prevent occurrence of unintended additional burden.

However, there are some fundamental issues not addressed in the draft report findings. The AAFP is concerned that the clinical work that physicians and other clinicians perform (or need to perform under value-based care) is not addressed in-depth. First, current health IT solutions are not yet designed to support that work. Second, the need to articulate the clinical work performed is different than ensuring that health IT matches optimal clinical workflow. Third, workflow is the process through which the clinical work is completed, and it is not true that that workflow can be standardized.

An example of medication reconciliation will help describe “clinical work.” When looked at from a process or workflow standpoint, medication reconciliation requires two separate medication lists which are then integrated to a single list. From a clinical work standpoint, medication reconciliation requires:

• understanding what medication the patient should be taking (given clinical state, insurance, social determinates, patient preferences, etc.),
• ensuring that the patient understands what they are to be taking,
• making sure the appropriate orders are in place, and
• documenting the new “reconciled medication list” in the patient chart.

In clinical work, issues like medication cost and medication adherence are represented. Medication reconciliation entails taking two lists, determining differences, and harmonizing the lists. Thus, in addition to ONC working to insure optimal workflows, HHS should work to support the physician community in better articulating “clinical work” so that developers better understand the higher-level cognitive processes physicians go through so that health IT design can best support this work.

The draft report lays out a set of strategies and recommendations and the AAFP is largely supportive of them. Overall, the AAFP strongly urges ONC to convert the “could”, “should”, and “encourage” language in the report into required actions. Compliance with these mandates by vendors will significantly decrease the administrative burdens of physicians. It is time for them to be mandates and not suggestions.

The AAFP offers the following responses to the italicized recommendations in the draft report.

Health IT Usability and the User Experience - Strategy 1: Improve usability through better alignment of EHRs with clinical workflow; improved decision making and documentation tools.

Recommendation 1: Better align EHR system design with real-world clinical workflow. First, the AAFP is pleased ONC recognizes “real-world” needs in the recommendation on aligning clinical workflow. There is no standardized workflow in primary care at the level of a visit. In the primary care practice, when a patient presents with a focus on a single, specific disease state, patient visits are still variable even with the same physician. Trying to standardize an office visit is akin to attempts to standardize driving an automobile. While it is impractical to create a single standardized process to drive, it is possible to standardize sub-processes such as navigating a four-way stop. So, ONC should look at smaller units of work than the visit as areas for potential standardized workflow. For purposes of EHR alignment, for instance, ONC
could define the workflow for administrating a vaccination or for performing a diabetic foot exam. If such smaller tasks were standardized with identified indications and contraindications, an EHR system could be designed that sets forth these tasks as a palette for selection with prioritization given to those indicated.

The AAFP encourages ONC to focus on EHR system design for small tasks. This will support a more dynamic, real-time, data-driven creation of workflows that are patient, physician, and encounter specific. A focus on large clinical tasks is counter-productive for primary care.

**Recommendation 2: Improve clinical decision support usability.**
We agree with the need to semantically model clinical concepts and knowledge so that health IT systems can be smarter. Health IT systems need to support clinical decision making. In addition to the semantic data standards, there is the potential of new machine learning (ML) algorithms to support and accelerate semantic modeling. HHS should support the advancement of ML applications to support improved clinical decision support usability. The AAFP is undertaking an effort to engage the artificial intelligence (AI) and ML community to address these issues and looks forward to partnering with HHS in these efforts.

**Recommendation 3: Improve clinical documentation functionality.**
In addition to removing the need to document non-clinically relevant information to support billing and other regulatory requirements, the AAFP agrees that the functionality to document clinically relevant information must improve. The AAFP has embarked on a robust effort to drive proven technology innovation into family medicine to reduce administrative burden, especially EHR documentation strains. New innovations in the realm of ML (speech recognition, natural language processing, computer vision, etc.) that could be leveraged within a practice’s health IT stack to significantly reduce burden and improve care delivery should be promoted. The AAFP will be working with industry leaders to pilot solutions within practices. We will be validating the efficacy and adoptability of these solutions and working to learn best practices that will be shared widely. In addition to testing the technical solutions arising from this effort, the AAFP recognizes the need to test new models of oversight (documentation requirements, auditing, quality measurement, etc.) and payment to further accelerate the scalability of these solutions. We encourage HHS to explore opportunities to support such pilots.

**Recommendation 4: Improve presentation of clinical data within EHRs.**
Current EHRs are cluttered with non-clinically relevant information causing burdens on physicians to mine for relevant information. Additionally, most EHRs do not contain the intelligence to filter, aggregate, and integrate data based on their semantic meaning. Clinician-led informatics work is needed to provide semantic data models to enable development of health IT systems that can analyze clinical data. These semantic data models must also support the proper filtering and aggregation needed to present the appropriate, clinically relevant data to the physician. The AAFP is working with the new combined Health Services Platform Consortium (HSPC) and Clinical Information Interoperability Council (CIIC) to establish nationally recognized semantic data models to support care delivery. We encourage HHS and other federal agencies to continue and/or start engaging with this new combined entity to further its efforts. While there is some promise in ML advances to accelerate the work of semantic modeling, this work demands significant national support.
Health IT Usability and the User Experience - Strategy 2: Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction.

**Recommendation 1: Harmonize user actions for basic clinical operations across EHRs.**
We agree that work is needed to ensure that health IT user interfaces leverage best practices to improve patient safety and user experience.

**Recommendation 2: Promote and improve user interface design standards specific to health care delivery.**
We support work to discover best practices for user interface design and to support health IT developers in implementing best practices. However, the AAFP believes that mandating use, such as through certification, should not be part of federal policy. Instead private sector competition will more efficiently lead to adoption of best practices.

**Recommendation 3: Improve internal consistency within health IT products.**
The AAFP encourages HHS to change the focus of this recommendation. We recommend that HHS focus on the development of frameworks and design best practices to enable modular system design. Adoption of these frameworks would also address the issue of consistency within a product. Additionally, by focusing at a higher framework level, HHS can best support a modular or service-oriented approach to health IT system design. We are concerned that the complexity and rapid advancements in technology and medical practice place unrealistic burdens on individual vendors to meet the broad and diverse needs of family physicians. Instead, the health IT enterprise should promote a service-oriented framework that allows for solutions from multiple vendors to work together as a larger system. Service-oriented systems and application-focused platforms have worked well in other industries and the AAFP calls for such innovation within health care.

**Recommendation 4: Promote proper integration of the physical environment with EHR use.**
The AAFP agrees with the need to focus beyond software. The EHR and physical environment are individual parts of a work system. We use the Systems Engineering Initiative for Patient Safety (SEIPS) model. Policies must recognize the entire work system when trying to improve and optimize health care. We are encouraged to see that many aspects of this work system model are addressed in different areas of this report.

Health IT Usability and the User Experience - Strategy 3: Promote harmonization surrounding clinical content contained in health IT to reduce burden.

**Recommendation 1: Standardize medication information within health IT.**
We agree with standardization to support and promote patient safety.

**Recommendation 2: Standardize order entry content within health IT.**
We support improvement in the order entry process. We believe that standardization alone will not decrease the burden of order entry. Potentially, a single order entry process to accommodate the many exceptions in orders could lead to less efficient data entry and increased burden on ordering clinicians.

In addition to working to standardize order entry content, work is needed to semantically model orders including indication and appropriate uses. Intelligent health IT systems could then use this semantic modeling to identify the most probable orders and potential erroneous orders. This should decrease the likelihood of mistaken entry and decrease the burden of ordering.
Recommendation 3: Standardize results display conventions within health IT.  
We agree with standardization to support and promote patient safety.

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

Recommendation 1: Increase end user engagement and training.  
We agree that end-user engagement is critical for the success of an EHR implementation. Engagement from purchasing, customization, implementation, and training is needed.

Recommendation 3: Optimize system log-on for end users to reduce burden.  
This optimization should be prioritized. It is a real opportunity that is easily achievable. The issue of system log-in will grow as the need for 2-factor authentication proliferates to support appropriate security.

Recommendation 4: Continue to promote nationwide strategies that further the exchange of electronic health information to improve interoperability, usability, and reduce burden.  
We agree that nationwide strategies are critical. True interoperability will not be achieved until there is a nationally recognized standard semantic models of clinical data and medical knowledge.

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 AAFP strongly urges ONC to eliminate Health IT utilization measures as part of the Quality Payment Program (QPP). Within QPP, the measures for quality and cost should be the focus of QPP. Per ONC data, over 80% of family physicians have adopted EHRs. Higher adoption rates exist in hospital-based care. It is time to move completely beyond the policies of the Meaningful Use program. Simplification in scoring has not decreased the burden on physicians.

Recommendation 2: Incentivize innovative uses of health IT and interoperability that reduce reporting burdens and provide greater value to physicians.  
Providing bonus points to physicians that are using health IT in innovative ways is appropriate. Ultimately, however, health IT utilization measures should be eliminated from base QPP scoring.

Reducing reporting efforts by automating the extraction of data from EHRs by CMS or other payers must be completely voluntary, meaning penalties must be eliminated for denying such access. Bonus points for physicians that do not allow access should also be eliminated. Additionally, systems should reflect who is accessing data and when it is accessed. Finally, participation by physicians should be graduated, not binary. Physicians should have the opportunity to participate in an a la cart menu of reporting programs to address their individual needs and practices.
Recommendation 4: To the extent permitted by law, continue to provide states with federal Medicaid funding for health IT systems and to promote interoperability among Medicaid health care providers.

CMS should identify geographic areas where health IT gaps exist and funnel new resources to those areas to improve equity and access. This would create a greater benefit than penalizing areas that struggle with health IT.

Recommendation 5: Revise program feedback reports to better support clinician needs and improve care.

We are pleased to see the report recommends that HHS explore an open application programming interfaces (API) approach. We recommend that HHS explore a bi-directional open API approach to not only allow physicians to report with their EHR via an API, but also to request real-time feedback via the API.

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

Recommendation 1: Consider the feasibility of adopting a first-year test reporting approach for newly developed electronic clinical quality measures.

We agree that implementation of new electronic clinical quality measures (eCQMs) is burdensome. While a first-year test reporting approach is better, it would have the disadvantage of delaying responses to issues and burdens. HHS should look to decrease the impact of adding new eCQMs into practice through implementation of data standards. Clinical data must be captured during the course of business for use in any new measures of interest, without the need to “map” data or upgrade systems. The prior discussion (Health IT Usability and the User Experience - Strategy 1) suggesting a focus on small units of work applies here.

Recommendation 2: Continue to evaluate the current landscape and future directions of electronic quality measurement and provide a roadmap toward increased electronic reporting through the eCQM Strategy Project.

As ONC seeks to improve electronic quality measurement, the AAFP strongly encourages careful consultation with our Vision and Principles of a Quality Measurement Strategy for Primary Care. It calls for a principled redesign of health information technology that enables affordable, expansive, accessible aggregation of data, powerful analytics, and meaningful interpretation. Health IT should automate data collection and quality measurement, eliminating the need to self-report. Information should be pushed to clinicians and patients at a point in time when it is most useful for decision-making and action.

EHRs were not designed to support quality measurement and improvement. We encourage ONC to share the AAFP’s vision, one in which future, automated quality measurement will generate evidence from every patient encounter to reveal patterns, predict outcomes of various treatment options, inform new standards of care, and drive large-scale, rapid improvement. Once achieved, data would prompt clinical decision support at the initial action point, informing quality as it happens. Doing so would also effectively move improvement away from reviewing measures and allow immediate action to close treatment gaps. Just-in-time information will equalize the partnership between clinicians and patients, empowering patients to knowledgeably participate in care decisions. The AAFP encourages ONC to promote policies that allow technology to connect patients and caregivers to social networks and community services that are equipped to address socioeconomic factors that impact health, strengthening the role that
patients have in managing their own health. The AAFP stands ready to work with ONC to achieve this continual learning, self-improving environment. We believe it will change the face of quality measurement and improvement.

Furthermore, the AAFP reminds ONC that technological capacity can already achieve much of this future state, but its high cost limits widescale adoption, especially by independent physicians. The benefits of investing in technology must outweigh its costs in a business environment, such as a physician office, in which financial viability can be threatened by drastic shifts in payment policies and practice costs. Unfortunately, the disappointing experience with health IT to date and a lack of trust in “black box” algorithms have made it difficult for physicians to risk investment based on promises of improved efficiency, better care, and lower costs. Physicians have been expected to fill current technology gaps by expending their own time, effort, and resources for quality measurement and reporting, with little, if any, return on investment.

**Recommendation 3: Explore alternate, less burdensome approaches to electronic quality measurement through pilot programs and reporting program incentives.**

Alternative, less burdensome approaches are desperately needed. Efforts to achieve a state where eCQMS can be deployed in an EHR to produce accurate measurements without special effort by the physician or practice must be prioritized. Reporting eCQMs should require no special effort outside of care delivery by the physician or their practice. AI and ML offers promise in this area.

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

Pharmacies should be accountable for verifying whether controlled substances were ordered by other clinicians and/or filled by other pharmacies. Pharmacies should also be responsible for communicating with the ordering physician prior to filling a prescription—one example of a small unit of work that could greatly benefit by innovation in APIs.

**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 2: HHS should continue to work to harmonize reporting requirements across federally funded programs requiring the same or similar EHR data from health care providers to streamline the reporting process across state and federal agencies using common standards.**

HHS must work to harmonize reporting requirements across federal and private programs.

**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.**

Issues of data ownership, interoperability, and data exchange must be resolved to catalyze the flow of information across disparate health information networks.
We appreciate the opportunity to provide these comments. Please contact Steven E. Waldren, MD, MS, Vice President and Chief Medical Informatics Officer, at 913-906-6000 or swaldren@aafp.org with any questions or concerns.

Sincerely,

Michael L. Munger, MD, FAAFP
Board Chair

About Family Medicine
Family physicians conduct approximately one in five of the total medical office visits in the United States per year—more than any other specialty. Family physicians provide comprehensive, evidence-based, and cost-effective care dedicated to improving the health of patients, families, and communities. Family medicine’s cornerstone is an ongoing and personal patient-physician relationship where the family physician serves as the hub of each patient’s integrated care team. More Americans depend on family physicians than on any other medical specialty.