



January 28, 2019

Ms. Seema Verma Administrator Centers for Medicare & Medicaid Services US Department of Health and Human Services Baltimore, MD 21244-1850

Donald Rucker, MD National Coordinator for Health Information Technology US Department of Health and Human Services Washington, DC 20201

Dear Administrator Verma and Dr. Rucker:

On behalf of the Healthcare Information and Management Systems Society (<u>HIMSS</u>) and the Association of Medical Directors of Information Systems (<u>AMDIS</u>), we are pleased to provide written comments to the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) in response to the <u>Strategy on Reducing Burden Relating to the Use of Health IT and EHRs</u>. We appreciate the opportunity to leverage our members' expertise in offering feedback on this strategy document and its focus on ideas to help reduce the burdens placed on clinicians—as time and attention clinicians spend on burden resolution is time and attention diverted from patient care. We look forward to continued dialogue with CMS and ONC on this topic as well as other and programs included in provisions of the 21st Century Cures Act (Public Law 114 -255).

As a mission driven charitable organization, HIMSS offers a unique perspective with deep expertise in health innovation, public policy, workforce development, research, and analytics to advise global leaders, stakeholders, and influencers on best practices in health information and technology. Through our innovation companies, HIMSS delivers key insights, education, and engaging events to healthcare providers, governments, and market suppliers, ensuring they have the right information at the point of decision.

As an association, HIMSS encompasses more than 76,000 individual members and 660 corporate members. We partner with hundreds of providers, academic institutions, and health services organizations on strategic initiatives that leverage innovative information and technology. Together, we work to improve health, access, as well as the quality and cost-effectiveness of healthcare. Headquartered in Chicago, Illinois, HIMSS serves the global health information and technology communities with focused operations across North America, Europe, United Kingdom, the Middle East, and Asia Pacific.

Founded in 1997, AMDIS is the premier professional organization for physicians interested in and responsible for healthcare information technology. AMDIS Members are the thought leaders, decision makers and opinion influencers dedicated to advancing the field of Applied Medical Informatics and thereby improving the practice of medicine. With our symposia, blogs, on-line forum, journal, presentations, sponsored and co-sponsored programs, and networking opportunities, AMDIS truly is the home for the "connected" CMIO.

HIMSS and AMDIS appreciate that healthcare is complex and often requires hard work and extraordinary effort on the part of clinicians to arrive at the right diagnoses as well as to provide appropriate treatment. We believe this level of effort defines us as professionals. That said, we share the belief of CMS and ONC that much of the work that clinicians face today is unnecessarily burdensome, where burden is defined as clinician activity that does not serve patient interests, does not improve quality or safety, or regardless of intent, is highly inefficient.

Our organizations want to work with the Department of Health and Human Services (HHS) to eliminate these unnecessary actions that occur in the course of clinical practice. Ultimately, HIMSS and AMDIS want clinicians to be able to focus their time on actions that make sense, such as caring for patients and delivering better outcomes. We want to help CMS and ONC reduce burden so that our members and other practitioners can deliver better and more efficient care.

HIMSS and AMDIS appreciate the work undertaken thus far across HHS to address clinician burden issues. For our public comment, we offer the following overarching thematic thoughts and recommendations for creating an environment where the burden on clinicians is minimized, while prioritizing the ultimate goals of delivering better outcomes, higher quality, and more cost-effective care:

• Accelerate the Shift to Value-Based Care Delivery and Expand the Use of Alternative Payment Models (APMs) to Help Reduce Burden.

The implementation of value-based care delivery models make minimizing burdens on clinicians more possible, as many of the documentation and re-documentation requirements in a fee-for-service environment are minimized. CMS and ONC should push for the continued development of demonstration and pilot programs to test different value-based service delivery and APMs in order to study the most prominent factors that mitigate clinician burden as well as how other care settings and clinicians can emulate those advances.

Overall, value-based care naturally promotes more efficient documentation processes and medical billing and coding is different with an identified value-based care component, so non-value add services are reduced. Managing patients in a value-based system provides greater opportunities to deliver care differently so clinicians can provide more value-add services.

However, it is important to note that burdensome fee-for-service requirements cannot be replaced by other equally-burdensome reporting requirements from different care models. Any action to shift toward value-base care should be made with the goal of avoiding new and different types of burden.

HIMSS and AMDIS encourage CMS and ONC to continue to push healthcare delivery in the direction of value-based care, not only to deliver better outcomes to patients, but also to minimize the burden issues that are inherent in a fee-for-service care environment. Value-based care and APMs are proliferating across healthcare, and burden reduction efforts remain a priority when pushing forward these new care delivery models.

• Health Information Technology (IT) Tools are Part of Any Solution to Resolve Clinician Burden.

HIMSS and AMDIS understand that the strategy document's intent is to be consistent with 21st Century Cures Act requirements to reduce regulatory and administrative burden related to the use of health IT and electronic health records (EHRs). However, we want to assert the importance of health IT tools in resolving any burden-related issues in our healthcare system. When properly designed and utilized, health IT can reduce the burden associated with documentation, administrative functions, and regulatory compliance.

EHRs and other health technologies are designed to serve as documentation records, to improve care and overall health as well as streamline the added layer of requirements that regulatory compliance often demands. Burden interferes with this longer-term strategic role that EHRs play in the healthcare ecosystem, to collect and aggregate the very data that will be used to enable value-based care delivery.

The future state of health information and technology builds on our work thus far and advances an end-game where a more advanced information and technology infrastructure can help deliver better and safer care. It should also incorporate the constructs of increasing focus on the patient and supporting better decisions and shared decision-making, thus improving the efficiency of normal healthcare operations, which includes reducing or eliminating burden.

In addition, there will be greater demands placed on technology to help make the right information more accessible at the right place and time so it is more meaningful and impactful to patients and providers. As this initiative moves forward, it is important to recognize that information and technology are an essential part of any solution to alleviate clinician burden.

o Documentation and Workflow Requirements Must be Fully Aligned with Burden Reduction Efforts.

Many of the concerns related to clinician burden emanate from justification for billing and reimbursement purposes and the need to document information in a patient's clinical note and then often re-document that same information, even though those data elements already exist in other parts of the EHR. HIMSS and AMDIS want to move away from the perception that if a physician did not document specific services in a patient's EHR, that physician did not perform those services.

The steps that CMS has taken to allow physicians the option to re-document or simply verify information in the EHR on the services performed by other clinical staff help to address burden, and allow physicians to focus their energy on documenting and accessing other key components of clinical information that should be in the EHR which could help improve patient outcomes and meaningfully contribute to a learning health care system.

Full alignment of documentation and workflow requirements centers on burden reduction, and value improvement—for the patient, the clinician, as well as the healthcare delivery system as a whole. Our organizations want the healthcare community to evolve toward a system where clinicians can focus on documenting information and constructing workflows around delivering better care and more positive patient outcomes, rather than superior Current Procedures Terminology (CPT) or Evaluation/Management (E/M) coding.

To implement such a system, HIMSS and AMDIS recommend the creation of several resources to help demystify documentation requirements and how they relate to coverage and reimbursement decisions. We are advocating for consensus around the creation of a minimum data set that payers—including CMS and Medicare Administrative Contractors (MACs)—would use to determine the level of service delivered during a patient encounter and confirm reimbursement decisions. If there is clarity around the specific data elements that a payer requires, much of the documentation and re-documentation burden is lifted. HIMSS and AMDIS want to minimize low-value documentation requirements in a system that seeks to deliver high-value care.

Another resource that we would like to see created is geared toward hospital and provider compliance departments so they have improved clarity on what the documentation requirements are for different clinical services. Often, compliance departments hyper-interpret regulatory or documentation requirements for fear of potential risks associated with improper documentation. In turn, clinical staff is required to document and re-document information for the services they deliver. HIMSS and AMDIS encourage CMS to work with stakeholders to create a reference document with clear and comprehensive documentation instructions as well as related use cases, so that compliance departments have the rules that they need to properly communicate documentation requirements to clinical staff. This resource document should provide compliance departments with the roadmap to allow for minimal burden on clinicians.

In the longer term, HIMSS and AMDIS encourage HHS to think more broadly about how to shift the paradigm from requiring clinicians to submit documentation to payers for coverage and reimbursement decisions to a scenario where health IT tools and approved devices send the structured data elements that payers need to make these decisions directly from an EHR. This idea may explore the use of a structured dataset to abstract content for payers to obtain the necessary information, or could focus on the automatic push out of the specific information that a payer needs directly from the EHR or other health IT tool. There are patient privacy and security issues as well as broader access restrictions that need to be addressed under such a paradigm shift, but HIMSS and AMDIS are interested in further exploration and refinement of this concept with HHS and other stakeholders from across the community to help address burden issues.

Leverage Artificial Intelligence (AI) as Burden Reduction Tool.

HIMSS and AMDIS recommend that HHS make a strategic research investment to study how AI can help relieve clinician burden issues. The healthcare enterprise is primed for greater use of AI technologies to improve care processes and deliver more effective care to patients resulting in optimal outcomes, all while reducing the burden that many current documentation requirements place on clinicians.

As previously discussed, much of the work that clinicians face today is unnecessarily burdensome, and HIMSS and AMDIS want to work with HHS to eliminate these unnecessary actions that occur in the course of clinical practice. In so doing, this will allow clinicians to be able to focus their time on caring for patients and delivering better outcomes.

Given all the demands placed on clinicians, we envision that the use of AI technologies can contribute to address many of these issues. With additional research and evaluation, AI can be incorporated into the clinical practice workflow to help clinicians better manage all of the information available to them surrounding a patient visit.

There are significant unintended consequences that documentation requirements have had on EHR usability with what should be digestible information about a patient encapsulated in a clinical note. These notes often provide only minimal value to collaborating clinicians given the extreme length of some notes that are used to justify payment or the medical necessity of a service instead of being used to derive benefit for other practitioners or to improve the patient experience. For example, researchers are currently testing the use of AI to parse the voluminous data in a clinical note to bring the right, succinct information directly to the patient's bedside for help in determining the most relevant data necessary to treat a patient during a specific encounter.

In addition, AI can help address clinician burden in several other ways, from assessing risk to the development of more extensive clinical decision support and radiology tools to aid in diagnosing patients. HIMSS and AMDIS want HHS to facilitate more research and development on what is needed to create effective interactions between humans and AI systems to advance further study and refinement of AI technologies.

Based on the strategies and recommendations included in the strategy document, we also offer the following comments:

Clinical Documentation Strategies

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

HIMSS and AMDIS are supportive of the recommendations under this strategy, focusing on the reduction of overall regulatory burden around documentation, leveraging data already present in the EHR to reduce re-documentation in clinical notes, and waiving documentation requirements in the testing or administering of APMs.

HIMSS supported the documentation reduction actions in the 2019 Physician Fee Schedule, specifically related to reducing the burden on clinicians by expanding the current policy on recording patient history and previous exam details in clinical notes. This provision allows providers to focus their documentation on what has changed since a patient's last visit, rather than re-documenting information that has remained the same between visits. HIMSS and AMDIS encourage CMS to look for other opportunities to reduce documentation burden as a part of Evaluation and Management (E/M) documentation requirements. As HIMSS and AMDIS noted in our joint letter in June 2018, it is critical to include E/M documentation requirements as part of any discussion around minimizing clinician burden.

In addition, as previously discussed, there is a significant amount of structured data in EHRs that can be used for coverage and reimbursement decisions in lieu of clinicians re-documenting the information in a clinical note. HIMSS and AMDIS are supportive of CMS leveraging that information. Also, given the amount of patient-level data that CMS already collects from providers, we encourage CMS to repurpose collected information to replace documentation requirements and eliminate additional reporting. Moreover, CMS and ONC should look to the evolving field of patient-generated health data (PGHD) as an additional opportunity to reduce clinician burden. The PGHD future state includes a greater usefulness for this kind of data and fully integrating it into clinical practice can contribute to replacing additional documentation burden and serve to further engage patients in shared decision-making about preventive and chronic care management.

There are also several private sector efforts underway across the community to reduce clinician documentation requirements that CMS and ONC should call on for help in addressing this issue. For example, HIMSS participates as a sponsor of the Nursing Knowledge: Big Data Conference effort with the University Of Minnesota School Of Nursing that is focused on establishing an Admission History & Current State Screening Task Force.

The Task Force is charged with defining a model for nursing admission history for an adult patient admitted to an acute care facility. The ideal content for a nursing admission history is not clearly defined across the profession, and the variability creates confusion in roles as well as responsibilities within the care team and inhibits reuse of data for clinical decision support and research. The nursing admission history effort will help provide important data for delivering and coordinating patient care, patient population management, and research while minimizing documentation burden for the nurse. These outputs should provide the foundation for continued work in defining nursing admission history for other patient populations and care settings and should be championed by CMS and ONC.

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

HIMSS and AMDIS fully support CMS and ONC expanding partnerships with community stakeholder groups, industry, other federal agencies, and state government agencies that can collaborate on developing model practices around clinical documentation. The development of

these practices should be included in a community-wide partnership to ensure that there are multiple opportunities to participate and buy-in from each sector. HIMSS prides itself on its role as a convener and would be willing to help CMS and ONC bring all these stakeholders together to develop model practices and highlight lessons learned from the development and implementation of new documentation requirements.

In addition, we emphasize the importance of approaching the strategies and recommendations for reducing documentation burden from a team-based healthcare perspective. Nurses are on the frontlines of care and should be considered stakeholders in most healthcare use cases as they contribute a significant amount of the clinical assessment data used for reporting quality measures. Clinical care also includes additional professions and disciplines working together toward the common goal of promoting health for patients, families, and communities. With this in mind, we urge the use of inclusive language and consideration of all members of the healthcare team and how they contribute to care provision, as well as documentation and reporting.

We also encourage CMS and ONC to create learning curricula for these new practices that will ensure each part of the community is fully informed and has the resources to succeed with implementing these potential documentation changes.

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

HIMSS and AMDIS support the strategy and seek relief from the burdens associated with prior authorization processes. Health IT tools can play a significant role here, but greater information transparency is critical for determining coverage ahead of time, rather than relying on technology to try to fix inconsistent or incomplete documentation requirements after a coverage issue arises.

The idea of improving automation processes is intriguing and we also support the recommendation around providing incentives to adopt technology to generate and exchange standardized data elements to aid prior authorization processes. We do caution that clinicians' ordering patterns and prior authorization processes can differ significantly by specialty and care setting, so there needs to be a degree of flexibility when recommending standards. There is also an opportunity to examine whether AI can help facilitate this flexibility and simplify these processes for the end user.

One promising effort that we fully support is CMS's work to develop a prototype Medicare feefor-service Documentation Requirement Lookup Service. CMS is collaborating with industry and other stakeholders to streamline workflow access to coverage requirements, starting with allowing providers to determine Medicare prior authorization and documentation requirements at the time of service and within their EHR or integrated practice management system.

This collaboration around a Lookup Service should be amplified and built upon across the entire community to try to alleviate the burden issues inherent in prior authorization processes.

Health IT Usability Strategies

• Strategy 1: Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation tools.

HIMSS and AMDIS are supportive of this strategy and we want to work with HHS to ensure that the principles underlying usability and user-centered design continue to be prioritized in the development and use of health IT tools to treat patients, improve patient safety, and realize better outcomes. HHS agencies have created several resources that the community should leverage when addressing these issues. For example, ONC's 2015 Edition Health IT Certification Criteria (2015 Edition) includes functionalities and testing protocols focused on safety-enhanced design that the community should capitalize on—the agency should look at how it can ensure all stakeholders are sharing their best practices related to 2015 Edition implementation and how this information is being used to help alleviate clinician burden.

As our organizations highly prioritize patient safety, it is critically important to also consider the safety of health IT implementations. In recent years, we have learned more about some of the unintended consequences of health IT, causing not only additional burden to clinicians, but most importantly, causing actual patient harm attributed to usability, functionality, and programming concerns. Some of these events can be attributed to aspects of any health IT infrastructure which could include errors of commission or omission, caused by technical (hardware/software) issues, human-machine interface, inadequate testing, or ineffective organizational processes and activities.

To appropriately address safety, HIMSS urged ONC in its October 2018 letter on the EHR Reporting Program to further refine the program to address health IT safety factors, particularly in the usability aspects of the program. There are existing efforts that focus on the safety components of health IT implementation that shed light on the safety of EHRs and have promoted measures that address these issues. There is an opportunity to adopt these tools in the broader health IT community and allow EHR developers, along with other healthcare stakeholders, to have a common understanding of the safety opportunities as a means to further ensure that the deployment and optimization of these health IT tools focus on safety as part of the socio-technical aspects of the health IT project.

Moreover, the research underway at the Agency for Healthcare Research and Quality (AHRQ) on usability and clinician burden should be amplified and strengthened. For example, in an AHRQ-funded project, Thomas H. Payne, MD, and his team at the University of Washington Medical Center and Harborview Medical Center, Seattle, developed and implemented a voice-generated enhanced electronic note system, or <u>VGEENS</u>, to translate clinical notes into usable, actionable information in EHRs. The system was designed to match the workflow of physicians when doing inpatient rounds in order to improve accuracy and timely availability of inpatient progress notes. Innovative ideas like Dr. Payne's work need to be fully supported by AHRQ (as well as on an

HHS-wide basis) and the advances shared across the community to help inform and improve clinician burden issues.

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

HIMSS and AMDIS are supportive of harmonizing user actions for basic clinical operations across EHRs and encourages HHS to help facilitate the sharing of best practices around user-centered design so that clinicians encounter common interface and workflow design elements as they transition between different care settings and use varying EHR technologies.

We are also supportive of the creation of a collaborative and shareable repository of EHR usability practices that the entire community can leverage. We would encourage additional focus on the user interface elements of how best to design and support clinical workflows and reference potential stylistic changes for presentation of information. These practices may also be helpful when considering the redesign of exam rooms and how to maximize face-to-face interactions between clinicians and patients as well as the rest of the care team.

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

HIMSS and AMDIS affirm their support for efforts to harmonize clinical content, especially related to how prescription drug information is displayed in health IT products, as well as how order entry for laboratory orders, imaging orders, and procedure orders are performed in these products. A level of platform-agnostic consistency across this clinical content is important for all clinicians. Consistency in how results are displayed to the clinician is also critical, but there may be more variation in results display conventions based on specialty, care setting, or how a specific user interfaces with technology. This is an area that intersects with functional design principles and needs to be further explored as more research is conducted on how different people digest data and internalize information.

Standardized data elements, electronic clinical quality measures (eCQMs), and the use of built-in standard terminology in clinical documentation systems, will contribute to data comparability across providers and settings, and help address data exchange and interoperability, care coordination, payment analysis, and longitudinal outcome analysis, in addition to reducing burden.

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

CMS and ONC should help promote the sharing of best practices on how facilities can make sound health IT acquisition decisions as well as what steps they should take to get clinician involvement and buy-in in those processes. Log-in issues for clinicians can contribute to burden and should be further investigated to include approaches such as single sign-on capabilities.

Concerns around interoperability and data sharing as well as how to send and receive information are also significant sources of clinician burden. HIMSS and AMDIS encourage HHS to fully implement the broader policy goals on information blocking from the 21st Century Cures Act that will help to appropriately address these issues.

It is also important for CMS and ONC to focus on community-wide data sharing issues when seeking to address clinician burden. The confluence of interoperability and usability challenges greatly impacts burden and must be addressed through the upcoming work of your agencies. The ability of one EHR to exploit information shared by another EHR or health IT tool is often a work in progress. For example, challenges remain when trying to incorporate or utilize clinical data found in state and regional health information exchanges (HIEs) in a facility's EHR. The process should be straightforward for a clinician to navigate from their EHR to the state/regional HIE portal, authenticate to the state/regional HIE portal, search, match, and select the correct patient, and sort through and find the relevant clinical data to review. Often, this process is burdensome and very time-consuming, and, as a result, detracts from direct patient care.

When thinking about health IT usability and the presentation of clinical data within EHRs, HIMSS and AMDIS suggest that HHS think more broadly about this issue and not simply focus on usability and a single health IT product, but also the usability associated with the handshake between collaborative health IT products. Given the desire for clinicians to leverage more aggregated clinical data from outside of their facilities, this usability and design issue becomes critically important. With development of the second iteration of the Trusted Exchange Framework and Common Agreement underway, we encourage CMS and ONC to utilize this voluntary framework to help alleviate clinician burden issues related to data sharing.

EHR Reporting Strategies

• 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.

HIMSS and AMDIS are supportive of the work undertaken by CMS to simplify and streamline the reporting requirements in the Promoting Interoperability performance category under the Merit-based Incentive Payment System (MIPS) for clinicians as well as the Inpatient Prospective Payment System (IPPS) for hospitals. The refocused programs are built on a smaller set of measures that require the exchange of health information between providers and patients and incentivize providers to make it easier for patients to obtain their medical records electronically from both clinicians and hospitals. These regulations also reduce burden in other ways, such as significantly simplifying the scoring structure for the MIPS Promoting Interoperability performance category. Moreover, we are also in favor of providing additional incentives to spur innovative uses of health IT to support greater data sharing, reduce burden, and provide more value to clinicians as well as patients.

An even greater focus on interoperability and data sharing is also a positive step forward when discussing burden reduction. HIMSS and AMDIS appreciate the focus of the strategy document

on how burden hinders the achievement of the HHS vision of interoperability, and we firmly believe that addressing interoperability challenges will help alleviate clinician burden and help to improve the practice of medicine and clinical care. The ability to offer clinicians greater access to information about patients relieves burden, but also provides opportunities to increase overall efficiency, deliver better outcomes, and improve the patient experience.

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

In October 2018, HIMSS shared its <u>recommendations</u> around the creation of the EHR Reporting Program in a way that leverages existing reporting data to avoid undue burden on the end user. HIMSS continues to promote the important role that interoperability and the transmission of data play in the functionalities of health IT products, and encourage HHS's continued promotion of improving interoperability functionality.

In addition, as highlighted in the <u>HIMSS Interoperability Call to Action</u>, HIMSS and AMDIS support the adoption and harmonization of data standards to support the exchange, access and use of data across health IT systems. Currently the work to achieve ubiquitous, interoperable health information exchange has led to the creation and use of numerous standards, data formats, and use cases.

These vary greatly in their scope of implementation and use. Community-wide understanding of the adoption and use of these standards is limited at best, and inconsistency in the implementation of these standards has created challenges in producing interoperable exchange. We encourage HHS to focus on harmonization across current standards and education to promote the appropriate adoption of these standards to improve access, extraction, integration and use of the data for care and reporting.

While standards-based interoperability is critical to improving care, it also plays a role in reducing burden associated with quality reporting. The <u>work of HIMSS members</u> has highlighted that the role standards-based exchange places in the aggregation of data for measures and identifying gaps in data quality. With focus on improving data quality, increasing the level of consistency around standard use, and harmonizing versioning across standards, HHS can decrease the burden of sharing and using data as well as reporting criteria related to this exchanged data.

Especially as the healthcare industry continues to shift toward value-based care, new non-traditional stakeholders and data sources should be considered in any strategy to reduce burden. For example, HIMSS recently provided feedback to HHS's Administration for Children and Families regarding the development of standards for data exchange in their human services programs. These data represent a subset of the social determinants of health (SDoH), an emerging data set that is critical to a more holistic care delivery plan. HIMSS encourages CMS and ONC to include organizations such as ACF in any broader strategy development to ensure data from these social programs are incorporated and standardized in a manner that does not increase provider burden.

Moreover, HIMSS and AMDIS are supportive of implementing an open application programming interface (API) approach to HHS electronic administrative systems to promote integration with existing health IT products. API interfaces continue to show promise as an approach to compile and collect data from multiple disparate sources into one application. HIMSS has previously stated its support of API interfaces as a component of an EHR Reporting Program. However, it is important to keep in mind the capabilities of rural, underserved, and small practice-based providers and health systems. HHS must assess the learning curve and workforce requirements for these practices among providers to ensure appropriate implementation of the necessary applications to integrate with the HHS systems.

Input from existing interoperability initiatives and state-based HIEs would be helpful in the implementation of this approach as these organizations have been developing API-based solutions to promote integration across their member products. Also, coordination with existing efforts in the standards development space could influence any implementation strategies outlined by this recommendation. For example, the DaVinci Project has a number of use cases leveraging Health Level Seven International (HL7) Fast Healthcare Interoperability Resources (FHIR) based APIs to streamline administrative processes related to the exchange of payer information. Lessons from those projects can inform HHS in the creation of additional interfaces that complement existing approaches.

• Strategy 3: Improve the value and usability of eCQMs while decreasing health care provider burden.

Core to the missions of HIMSS and AMDIS is promoting the use of health information and technology to improve the quality of healthcare delivery through effective performance measurement and clinical decision support. We appreciate CMS efforts to reduce clinician burden through improving the value and usability of eCQMs.

The primary source of administrative and provider burden associated with quality reporting stems from the need to document in a structured manner in order to properly populate current eCQMs with quality data. eCQMs require capture of structured clinical data to enable accurate and repeatable calculation of measures. Structured data is disruptive to normal provider workflow, particularly the need to document through the use of extensive drop down menus with large numbers of options for clinical exclusion criteria. Workflows also vary widely by different EHRs and configurations, and measure logic changes during the annual eCQM update require analysis and redesign of workflows with brief time windows.

The first critical step for CMS to achieve its goals is to ensure required data elements for selected eCQMs be gathered accurately and efficiently in the healthcare provider workflow, using data elements already collected as part of the care process and stored in the EHR or other interoperable clinical and financial health information technology. Re-using these data elements for eCQMs as a byproduct of care delivery would significantly reduce provider burden as data used in eCQMs should be easily extractable for reporting purposes. As we move into a more interconnected healthcare environment, we need to be thoughtful about assuring data quality as it is gathered and reported from multiple data sources outside of the typical clinical workflow.

In the strategy document, HHS proposed to consider the feasibility of adopting a first-year test reporting approach for newly-developed eCQMs. While this is a practical method of testing new eCQMs, the possibility of a provider collecting data on a measure which may not produce accurate or actionable results, creates burden without necessarily enhancing the value proposition, which focuses on the ability to leverage the quality data to initiate rapid cycle clinical quality improvement projects.

In order to ensure that eCQMs collect data accurately, HIMSS and AMDIS recommend that CMS focus on ensuring each eCQM be thoroughly tested for validity, reliability, and feasibility prior to inclusion in any eCQM set tied to an HHS quality reporting program. Field-testing prior to general release would improve the quality of the specifications and endorsement by the National Quality Forum (NQF) would ensure that the measures produce comparable and consistent results against the intent of the measure in all care settings. The eCQM testing process should include a testing site with a set of sample data, testing examples, and an Implementation Guide that can be used by vendors during their implementation and testing. HIMSS continues to strongly support the concept of a National Testing Collaborative, fully-funded and supported by HHS.

Providers and vendors have incorporated the ability to capture many structured data elements mapped to various codes into their workflows, and systems are often only able to electronically capture a limited set of codes from coding systems directly into EHRs. HIMSS and AMDIS would like to see eCQMs field tested in all relevant care settings using all available vendors. There is great variation between EHR vendor system workflows for documenting, and back-end builds, and there is also variation in providers who use one comprehensive health IT system, and providers who integrate "best of breed" systems. EHR variation can lead to challenges in a hospital's or provider's ability to electronically abstract data elements and provide accurate eCQM quality reports.

In order to make field testing robust, providers should be incentivized to participate. This incentive should provide both small hospitals who lack resources, and large hospitals who have resources allocated to other priorities, the ability to participate in extensive field testing programs. eCQM standards and value sets should also be harmonized across all measures used in CMS and other reporting programs. Providers have expressed frustration with variation in value sets developed for the same or very similar concepts. In addition, some of the measure specifications for very similar measure intents are not fully aligned across these different programs.

HIMSS and AMDIS fully support the movement of quality and clinical decision support to embrace the HL7 FHIR standard but recommend harmonization with existing standards and profiles to fully achieve interoperability and facilitate a smoother transition for providers, hospitals, EHR vendors, and implementers. As with eCQMs, FHIR-enabled data element reporting must fully undergo feasibility and field testing in all care settings to ensure measures populated via data element reporting are accurate reflections of the care delivered against the intent of the measure. HIMSS and AMDIS also encourage CMS to incentivize providers and hospitals to participate in that feasibility testing and field testing process.

HIMSS members have noted that there appears to be multiple initiatives surrounding FHIR and data element reporting occurring in the HHS ecosystem. Overall, data element reporting must align with the CMS Long Term Support Service (LTSS) Data Element Library, ONC Common Clinical Data Element Set, US Core Data Initiative (USCDI), and the CMS Common Clinical Data Elements (CCDE) Pilot. HIMSS would like CMS to clarify with stakeholders how these initiatives strategically fit together and drive data element reporting.

Public Health Reporting Strategies

• Strategy 1: Increase adoption of electronic prescribing of controlled substances (EPCS) and retrieval of medication history from state PDMP through improved integration of health IT into provider workflow.

HIMSS and AMDIS are fully supportive of efforts to improve interoperability between EHRs and state prescription drug monitoring programs (PDMPs) as well as increase adoption of EPCS. The focus of the National Health IT Week Virtual March on States in October 2018 highlighted both of these issues as critical toward addressing the opioid crisis. Each issue is also a key component toward alleviating clinician burden.

EPCS is a powerful solution to combating the opioid crisis by gaining better control of tracking opioid prescriptions and securely delivering them to pharmacies. A growing number of states have been enacting laws that mandate EPCS use—the further broadening of EPCS adoption would help prevent additional diversion of opioids, improve patient safety, and strengthen prescribing processes toward alleviating burden.

In addition, integrating PDMP data into EHRs would help minimize clinician burden by improving workflow and eliminating the necessity of clicking between two disparate IT systems. States have the ability to leverage enhanced federal funding to build a PDMP or enhance PDMP functionality and HIMSS and AMDIS encourage states to take advantage of these opportunities to improve patient safety while relieving burden.

• 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.

HIMSS and AMDIS offer to help HHS convene stakeholder organizations to inventory these reporting requirements as well as work together to identify commonly reported data for state and federal programs that could be leveraged from EHR data elements. In addition, there are significant strides that can be taken to harmonize and streamline provider reporting requirements across analogous federal and state programs using common standards in order to alleviate burden issues. Creating a system that uses the same EHR data to meet reporting requirements at both the federal and state levels simply makes sense, and HIMSS and AMDIS support HHS collaborating with states to accomplish these tasks.

Moreover, HIMSS and AMDIS support the creation of clear guidance from HHS on where the Health Insurance Portability and Accountability Act (HIPAA) of 1996 is aligned with 42 CFR Part 2 requirements on the confidentiality of certain substance use disorder patient records. With a lack of clarity around the intersection of HIPAA and Part 2, this issue places a significant burden on clinicians to interpret compliance with existing regulations. If clinicians could better understand these regulations, they could better coordinate care and minimize a substantial source of burden.

HIMSS and AMDIS are committed to be being valuable resources to CMS and ONC to help implement all the provisions of the 21st Century Cures Act as well as alleviate clinician burden issues. We welcome the opportunity to meet with you and your team to discuss our comments in more depth. Please do not hesitate to contact <u>Jeff Coughlin</u>, Senior Director, Federal & State Affairs, at 703.562.8824, or <u>Eli Fleet</u>, Director, Federal Affairs, at 703.562.8834, with questions or for more information.

Thank you for your consideration.

Sincerely,

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