



January 24, 2019

Don Rucker, M.D.
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

Dear Dr. Rucker:

I am pleased to submit Allscripts' comments to the Office of the National Coordinator for Health Information Technology on the draft *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*. With a platform of clinical and business solutions for ambulatory, acute and post-acute settings, we are relied upon by the largest network of providers – over 330,000 physicians in more than 70,000 different practice locations and 2,300 hospitals. It is through our three decades of experience partnering with and deploying software to this vast network of providers that we can submit informed comments today on this important topic.

General Comments

We applaud the effort ONC is putting forth to reduce clinician burden. It is vital to create a strategy that appropriately balances the need for increased access to data about health delivery while doing as much as possible to not increase burden on those delivering care. Given our close partnership with clients who are using our software in the process of caring for patients, we do not find it surprising that the availability of more information at the point of care has not resulted in a less frustrating or demanding experience for clinicians.

Health IT solutions today are required to serve as the delivery mechanism for an unprecedented number of new regulations imposed on health care organizations and professionals, most of which were issued without fully considering the impacts on all corners of the health care system. We applaud the acknowledgement of the burden that has been created across system stakeholders and recommend that HHS embrace a systems-wide approach to current and future concerns about that burden. As is widely understood, a systems approach takes the view that most problems reflect predictable issues in the context of poorly designed systems. Instead of focusing corrective efforts or remediation in a single area or on a single stakeholder, a systems approach seeks to identify situations or factors which may give rise to burden and change the underlying systems to reduce burden or minimize the impact on clinicians. For example, proposing physicians work on how to reduce burden by joining task forces or workgroups will potentially have the opposite effect because it takes time and effort to participate.

It is important to clarify the definition of EHR-related burden vs EHR burden. EHR-related burden is defined as regulatory and administrative burden imposed on clinicians and HCOs through the use of health IT. Sources of EHR-related burden include federal programs such as the Quality Payment Program (QPP), Promoting Interoperability, and reporting-intensive alternative payment models, such as Accountable Care Organizations (ACOs). Other sources include quality initiatives, certification standards and data use, and administrative reporting, including public health reporting and clinical research.

On the other hand, EHR burden is defined as burden imposed upon clinicians by poorly designed and developed health IT products. Sources of EHR burden include poorly designed user interface, functionality gaps, and time to market.

Clinical Documentation

Clinical documentation burden can be reduced by taking a systems approach. For example, stating the use of EHRs "may impose administrative burdens" unnecessarily discounts the degree of burden imposed by billing and audit requirements. Allscripts recommends taking a systems approach to eliminating or reducing the sources of billing and audit requirements. Regarding "EHRs may add additional burden, particularly where health IT systems have failed to address clinical/administrative processes," this statement fails to take a systems approach and to fully understand that health IT implementation is a shared responsibility between health IT suppliers and health care organizations. The solution(s) to addressing this burden will come from continued and expanded collaboration of HCOs and health IT suppliers.

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

Recommendation 2: Leverage data already present in the EHR to reduce re-documentation in the clinical note.

We applaud the strategy to reduce regulatory burden on documentation requirements for patient visits. The introduction of a single payment rate for several levels of office based/outpatient E/M visit codes and the establishment of minimum documentation, thus reducing or eliminating unnecessary documentation, would be welcome by providers. These changes, along with eliminating the need to re-document existing information in the medication record, is also a gain for providers. However, we note the broad industry concern that consolidation of the payment rates could serve as a disincentive for healthcare professionals to taking the most complex patients, even with the payment bonuses available for that care. This needs to be very carefully considered to avoid that unintended consequence.

Recommendation 3: Obtain ongoing stakeholder input about updates to documentation requirements.

Stakeholder input is valuable and should be a continuous process as recommended changes are implemented. The process needs to be defined and planned because the effort it takes to implement changes is not agile.

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

Allscripts agrees with the recommendation to waive documentation requirements for purposes of testing or administering APMs. The reduction of medical review burden and additional reporting requirements will contribute to overall burden reduction. We note, however, that allowing the pendulum to swing too far in the focus on burden reduction could inadvertently move us away from the goal of moving to value-based payment. Such value-driven healthcare is dependent on the capture of extensive information about the patient and the care delivered to him or her, and moving too extensively away from documentation requirements will compromise the ability for the country to do that effectively.

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

Recommendation 1: Partner with clinical stakeholders to promote clinical documentation best practices.

Allscripts supports the recommendation to partner with clinical stakeholders to promote clinical documentation best practices. For example, the U.S. Core Data for Interoperability (USCDI) is appropriate; however, forcing the standards to be applied in all patient cases and extracted by document type in every instance regardless of clinical relevance would be a real burden. Additionally, forcing all standards to be present in each document will drive a long list of data elements charted and shared that may not be appropriate for all patients or relevant to all clinicians. Defining the content standard adds real industry value; forcing unnecessary use of such a standard where not clinically valuable does not.

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

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

Allscripts supports data standardization of templates, data elements, and real-time standards-based electronic transactions between providers, supplier and payers. There is an opportunity for innovation to move from an electronic system that mimics the current manual process to one that can recognize what an order requires prior authorization, automatically collects the required by a prior authorization rules engine, and automatically invokes a request to the payer's prior authorization engine via an API to arrive to an immediate approval or denial.

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

Allscripts recommends the use of CDS Hooks at the point of care as a new standard approach to support prior authorization.

Health IT Usability and the User Experience

Allscripts agrees usability and the user experience is important and is an opportunity to reduce clinician burden. Balance is needed to make systems user-friendly and consistent while understanding EHRs are proprietary, unique, and operating in a competitive market.

Standards should enable industry success, not hinder it. For example, HL7 has been accepting comments for their HL7 EHRs-FM Release 2: Usability Conformance Criteria, Release 1 (PI ID: 995) guide for over a year. Using a standard design format depending on the definition of format may be controversial when it impacts vendor systems where the interface design is part of their product marketing.

Allscripts agrees with the assessment that, "Usability challenges within EHR and health care IT products can increase clinician burden", and accordingly, we continue to employ human factors experts, usability standards, and best practices to improve the user experience across the Allscripts portfolio. Understanding that HCOs customize health IT to varying degrees for use in their practices, hospitals, and medical centers, it is essential to include HCO IT leadership as a key stakeholder with shared responsibility in delivering the best user experience possible.

Within each application, user options should be consistent such that the end user is able to navigate with ease. At the same time, EHRs should not be blamed for organizations failing to put in the time, effort, and/or resources to implement and utilize the systems to their full capabilities. No EHR system is going to be able to eliminate the need for assiduity on the part of the clinician.

The report outlines three goals to reduce provider burden:

- (1) Reduce the effort and time required to record information in 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.
- (3) Improve the functionality and intuitiveness (ease of use) of EHRs.

Despite the initial focus on a systems-approach, as described, these burden reduction goals as listed are focused entirely on health technology. They fail to address potential steps to eliminate or mitigate regulatory and administrative burden imposed on clinicians and HCOs which require the use of health IT. Acknowledging that health IT has an opportunity to improve usability and add new functionality, it is not reasonable to expect it can eliminate or satisfactorily mitigate the effects of regulatory and administrative burden on its own. In addition, health IT management is not solely the responsibility of suppliers. HCOs must also share in the responsibility in managing how technology is deployed, configured, and upgraded and how clinicians are trained and supported. The recommendations above are absent of any recognition of that.

Allscripts seeks additional information regarding the following statement, “Another challenge with EHR GUI design is that products have typically been designed with user interfaces that support a linear and logic-based thought process, rather than the complex clinical pattern recognition that occurs during the diagnostic and treatment process.” Allscripts agrees with the statement but requests ONC provide concrete examples of linear versus pattern recognition; including images would be greatly appreciated.

We end this section by noting that overly prescriptive policies could result in a de facto forced redesign of products across the industry, which would adversely affect Allscripts and its clients. Developing specialized or standardized solutions for small subsets of the market would be done only at an enormous development cost and prevent the company from delivering new functionality and necessary enhancements to the larger market, such as prior authorization and PDMP integration. Furthermore, there would be a cost to clients to retrain their employees (clinical and non-) to use significantly revised products, and it could also adversely affect customized workflows they have built within their organizations. We recommend against this.

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

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

Allscripts recommends leveraging the results from the ONC Easy EHR Issue Reporting Challenge and strongly encourage EHR systems to consider implementing the functionality.

Allscripts does not agree with the following statement: "A priority for workflow optimization should be the reduction of required clicks to complete necessary actions." While we should remove all unnecessary clicks, this "PRIORITY" focus has actually led directly to a lot of the cognitive burden that exists in EHRs. To reduce clicks, most health IT companies (often in collaboration with their users) have made other design decisions that have created greater burden on their users. Click reduction should be one of many efforts; the priority focus should be a shift to efficiency, effectiveness and satisfaction. ONC should not tell developers how to achieve that but rather set out the goals.

Recommendation 2: Improve clinical decision support usability.

Conceptually incorporating providers in to the design of health IT solutions is a simple step in the right direction and health IT vendors are already doing this currently. Areas where there are additional challenges are in the accounting for the different styles or preferences in clinical workflows, as well as addressing the various needs of specialty practices. Allscripts recommends ONC encourage the adoption of predictive capability. ONC should identify specific high-risk conditions and situations with requirements to monitor a number of high frequency and high-risk clinical issues that systems should monitor for. Toward that suggestion, ONC should issue a recommendation for vendor capability and systems implementation and make it publicly available.

Recommendation 3: Improve clinical documentation functionality.

In addition to speech recognition, Allscripts supports the use of EHR logging functionality. It can be used to gather end user data and gauge the cognitive tax score the EHR is putting on the end user. The vendor is then empowered to make functional design decisions to improve the user experience. It is also important to acknowledge that the burden EHRs present stems from a variety of sources, such as billing and organizational requirements. Burden reduction is broader than just the EHR and should be addressed from all angles.

Recommendation 4: Improve presentation of clinical data within EHRs.

Allscripts agrees EHRs can and should work to improve the presentation of clinical data. Meaningful Use Stage 2 originally had a cross document search requirement; the requirement was decreased to include a single document search. Allscripts recommends a required search function within the patient record to allow providers to find specific information. This would make data retrieval less burdensome.

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.

Allscripts is concerned with the ability to harmonize user actions for basic clinical operations and still maintain uniqueness within the market. It will take a significant amount of time and cost for vendors and clinicians to agree on specific basic actions.

Recommendation 2: Promote and improve user interface design standards specific to health care delivery.

Allscripts is strongly opposed to any requirement that would require sharing our intellectual property with our competition. There is a risk of diluting the marketplace if all EHRs are required to roll out the same designs and workflows. Furthermore, if all EHR systems must abide by a narrow, prescriptive set of usability standards, it would significantly impact innovation in the market, ultimately negatively affecting clinicians and patients alike.

Recommendation 3: Improve internal consistency within health IT products.

Allscripts agrees health IT products should improve internal consistency; it will contribute to burden reduction.

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

Allscripts promotes design patterns that enhance patient safety. Standardization needs to include the set of data that needs to be displayed based upon the action or workflow that the clinician is attempting to do. For example, reconciling a medication or renewing one may require the display of different information compared to just briefly viewing the medication list.

Recommendation 2: Standardize order entry content within health IT.

Standardizing order entry content within health IT will require a systems approach to be successful. For instance, to fulfill this recommendation, the organizations who supply medication information must make improvements to their order codes, such that the health IT vendors can consume and display them in a more user-friendly manner.

Recommendation 3: Standardize results display conventions within health IT.

Allscripts expresses caution around the concept of standardizing the results display. We reiterate that ONC's role should be to give the industry a goal to achieve with guardrails, if necessary, but any prescriptive approach dictating a look or specific user interface would be overreach and burdensome to developers. If it's deemed to be necessary to work towards any such alignment across products, we recommend it be kept at a high level to still allow for innovation and variation among the health IT vendors.

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.

Allscripts acknowledges that end user engagement and training is important and bears a cost. Costs can be viewed as a burden to our clients. The patient is important to consider, as well; with increased access to their data, they will also need intuitive applications to access and store their data. Education about the application they are using is also vital to their successful engagement.

Recommendation 4: Continue to promote nationwide strategies that further the exchange of electronic health information to improve interoperability, usability, and reduce burden.

Allscripts supports efforts to promote nationwide strategies that further the exchange of electronic health information and believes it should be done without special effort on the part of the user. Standards should be promulgated more widely to ease data exchange.

EHR Reporting

We applaud the efforts taken by CMS to make it easier for providers to participate in programs that require reporting. We appreciate and applaud HHS in evaluating the system effects of federal programs that require clinicians and HCOs to report performance data using health IT. For example, the removal of the patient-dependent measures in the 2019 Promoting Interoperability program is a positive step. We encourage more of this type of action. Accordingly, the EP/EH requirements should be carried out across various clinical environments, and the certification process should be more encompassing than EP/EH systems if we desire broad interoperability. Furthermore, the MU2015 requirement for a provider engaging with a new patient to retrieve or attempt to retrieve a transition of care document, track and report it is incredibly disruptive to providers. This requirement should be reviewed and revised to allow more flexibility in meeting the spirit of the requirement which is to evaluate available patient information. The source could be C-CDA, or FHIR request and the information needed may be more concise than a full document. Finally, long timelines and lack of transparency hinder a systems-approach, allowing stakeholders to contribute to measure development, and absolutely leads to

a climate of uncertainty for physicians, hospitals, and the health IT developers that support them. Even more concerning, it directly inhibits innovation.

Again, we also note in discussing programs that require documentation and reporting that swinging too far in reaction to concerns about provider burden will adversely affect the pace and efficiency with which we move toward value-based payment models. It is our opinion that this has already started to be a tradeoff, and we caution against making decisions about burden reduction while blind to other implications that would stem from a major shift in policy direction.

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 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.

Allscripts agrees the differences between federal and state program requirements result in considerable workflow burden for clinicians. To reduce this burden, Allscripts recommends there be a common baseline, as well as a mechanism for federal and state programs to achieve a common standard.

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

Recommendation 2: Adopt additional data standards to makes access to data, extraction of data from health IT systems, integration of data across multiple health IT systems, and analysis of data easier and less costly for physicians and hospitals.

Allscripts agrees data exchange is critical to patient care. While there should be data exchange standards, requirements should be judicious such that they do not promote bloat and unusable documents that place more burden on the physician as they try to decipher relevant information. Additionally, Allscripts agrees there is value in the use of APIs, given our leadership in this space for a decade. However, within our client population, the feedback we've received is that clinicians and patients find the workflows using APIs confusing and are not using them as much as they could (or should) be, even where they are available. If API use is to be seen as a huge improvement in exchanging information, more and better educational efforts need to be implemented.

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.

Allscripts supports the idea of testing newly developed electronic clinical quality measures, however we also express caution that this is likely to put additional burden on both vendors and clinicians, at least in the short-term. It is costly for vendors to develop and deploy new measures, and it takes time and effort for the clinicians to be trained.

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

Allscripts supports the idea of electronic quality measurement through pilot programs and reporting incentives, however we again want to express caution this should be done in a way that does not increase the cost to both vendors and providers.

Public Health Reporting

Allscripts acknowledges the importance of federal and state requirements associated with providing clinical information to public health entities across the United States of America. Allscripts is committed to working with all stakeholders to identify methods for achieving improvements in U.S. public health while concomitantly decreasing the burden on clinicians and health care organizations. Although the associated burden related to these public health programs may not be eliminated entirely (e.g. dual authentication for EPCS), a collaborative approach must be undertaken by stakeholders to mitigate associated burden as much as possible.

Allscripts supports the standardization and certification of public health agencies; these programs are essential to improving U.S. public health. All entities involved in the provision of care and sending or receiving data should be certified to ensure consistent standards are being used. We propose it initially be voluntary and eventually be required. For example, there are variations between state PDMPs, which could be eliminated through ONC published standards. Allscripts strongly encourages a level of PDMP workflow integration using usability standards and API solutions where parties in the workflow are supporting them. Data Segmentation for Privacy (DS4P), currently optional in the 2015 Edition Final Rule, should to be mandatory to move this forward safely and effectively. The lack of standards in the laboratory space is also a problem which could be addressed to greatly simplify and make more affordable exchange of such data.

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

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

Allscripts agrees standardization of PDMPs is needed. There should be a central system to link them together; preferably the system should not cost clinicians more money to adopt.

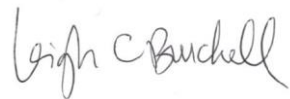
Closing

Allscripts recommends expanding the work ONC does in this area to include the patient view. With the emphasis on patients being in control of their data, it is important for regulatory agencies and vendors to understand the issues they face in accessing and understanding information about their care. In addition to patient representation, impacts to all identified entities, vendors, system owners, and regulatory bodies should be represented in future reports.

Additional recommended embellishments include the development of a defined system to measure clinician burden, which would help all interested parties to more accurately understand if the industry is succeeding in reducing frustration and its related effects. The assessment mechanism should include measuring over time to accurately judge the effectiveness of implemented strategies. The measures and results should be ranked and publicized to ensure transparency after being developed through a robust stakeholder-inclusive process.

In closing, Allscripts appreciates the opportunity to provide input on this very important topic, and we welcome the opportunity to engage further where it might be helpful.

With respect,



Leigh Burchell

Vice President, Policy & Government Affairs

Allscripts

(919) 247-1144

leigh.burchell@allscripts.com