College of Healthcare Information Management Executives

January 28, 2018

Don Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Rucker:

The College of Healthcare Information Management Executives (CHIME) is pleased to submit comments on the *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*, as called for under Section 4001, "Assisting Doctors and Hospitals in Improving Quality of Care for Patients, in the 21st Century Cures Act.

CHIME is an executive organization dedicated to serving chief information officers, chief medical information officers, chief nursing information officers, chief innovation officers, and other senior healthcare IT leaders. With more than 2,800 members, CHIME provides a highly interactive, trusted environment enabling senior professional and industry leaders to collaborate; exchange best practices; address professional development needs; and advocate the effective use of technology to improve the health and healthcare in the communities they serve. Our mission is, "To advance and serve healthcare leaders and the industry improving health and care globally through the utilization of knowledge and technology."

Section 4001 of the Cures Act contains an extensive list of items the U.S. Department of Health & Human Services (HHS) is required to address in order to help review and take action to reduce the burdens on providers. Those burdens include reducing challenges associated with the use of electronic health records (EHRs), EHR incentive programs, value-based care, EHR certification, improving patient access to records, simplifying quality report, among other areas. Our members support efforts to reduce regulatory burdens that stand in the way of fostering better health and care for patients, particularly barriers that impede technological innovation.

ONC's report, which acts as a blueprint for ways to reduce burdens on providers, is broken down into four broad areas: 1) clinical documentation; 2) health IT usability and the user experience; 3) EHR reporting; and 4) public health reporting. And, the report is broken down into three burden reduction goals: 1) reducing the effort and time required to record information in EHRs during care delivery; 2) reducing the effort and time required to meet regulatory reporting requirements for providers; and 3) improving the ease of use of EHRs. Our comments focus on burden topics 3 (EHR reporting) and 4 (public health reporting).

Top-level Feedback

1. **Certification**: ONC should ensure certified EHRs are capable of ingesting and interrogating external data and co-mingling native data with external data, as well as ensuring data provenance.

2. **Patient identification:**

    a. HHS should support innovation that targets ways to uniquely and accurately identify patients (including leveraging the Deputy Secretary's Innovation and Investment Summit (DSIIS)); and

    b. The Centers for Medicare and Medicaid Services' (CMS) Center for Medicare and Medicaid Innovation (CMMI) should promote private sector-led solutions in patient identification.

3. **Claims data access:** We support the recommendation to implement an open application programming interface (API) approach to HHS electronic administrative systems to promote integration with existing health IT products.

4. **Promoting Interoperability (PI):** Further simplification efforts should ensure continued program alignment and simplification including for Medicaid providers. Our comparison chart depicts the current variety in measure requirements.

5. **Stark and Antikick back safe harbors:** The EHR donation exemption should be extended past 2021 and the types of technology permitted to be donated should be expanded (i.e. to include hardware), as well as permitting donation of services.

6. **Quality measurement:** CMS should review the Department of Defense's (DOD's) data dictionary and determine whether this could be recycled for the purposes of reporting Medicare quality data.

7. **Prescription Drug Monitoring Programs (PDMPs):**

    a. CMS should require as a condition of receiving the full federal financial match as permitted under the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), that states require interoperability between EHRs, other systems, and PDMPs such that the data received by a provider is able to be consumed into the EHR.

    b. CHIME strongly supports the SUPPORT Act's provisions calling for HHS to name PDMP standards.

8. **Sharing substance abuse information:** The policies to share substance abuse data as established under 42 CFR, Part 2 should be aligned with the consent policies in the Health Insurance Portability and Accountability Act (HIPAA).

9. **Da Vinci:** Standardizing medication information and lab data, as well as, streamlining prior authorization and incorporating payor rules and requirements into documentation templates are priority use cases.

Topic 1: Clinical Documentation

Da Vinci (Strategy #3, Recommendation #5)

The administrative costs in our healthcare system have been well-chronicled and contribute greatly to the cost of delivery, yet little in the way of value or improved outcomes. For instance, according to Change Healthcare (now McKesson,) 9% of hospital claims representing $262 billion out of $3 trillion are denied annually. We appreciate the work CMS is undertaking to reduce waste and return precious healthcare dollars to patient care.

Included among the ways to reduce the administrative burden examined by ONC in their report are efforts underway by the Da Vinci project which include a series of use cases. The use cases being tackled by Da Vinci include: 30-day medication reconciliation; locating payor coverage requirements; payor specific documentation requirements and templates; electronic health record exchange (HEDIS/Stars & Clinician Exchange); notification (ADT) (transitions in care, ER admit/discharge); risk-based contract member identification; authorization support; quality measure reporting; and laboratory results. We recognize the burdens faced by clinicians in navigating the maze of payor requirements and appreciate the efforts to streamline them.

Medication adherence and reconciliation are persisting challenges for our members. Standardizing medication information – which ONC addresses as Health IT usability - will bring benefits not only to providers in the form of improved workflow and simplification, but also in fewer readmissions and improvements in patient care. Today in some settings this happens manually on paper. For instance, post-acute providers typically get a long paper print-out of medications patients are taking once transferred from an acute care setting. Having a way to port this electronically in a systematic way would bring much value. As one of our members in a (PAC) setting noted, he has an easier time locating opioid drugs a patient is taking than non-opioid drugs. Better technology can certainly help identify and avert situations such as duplicate drugs for an individual patient and avoid hospital readmissions.

Labs are another area our members have identified as a priority. Today not all EHRs are able to receive discrete lab data and are not able to include lab reference ranges; some are only capable of noting a "high" or "low" result. One member noted that with his 2015 CEHRT upgrade he is now able to see lab results displayed and merged which he didn't have under the previous version. However, his 2015 CEHRT version still does not depict lab reference ranges. It is also worth mentioning that while most of our members have received their 2015 CEHRT, some are still in the midst of deploying it. CMS and ONC should continue to realize the impact upgrades have on clinical workflow. For instance, many (if not all) of our members will need to take another upgrade this year to accommodate the new opioid measures under the Promoting Interoperability program. ONC discusses the need to standardize clinical content like prescription drug information under the Health IT Usability and User Experience priority area of the report and we agree with this

Finally, we believe there is merit to focusing on streamlining prior authorization and incorporating payor rules and requirements into documentation templates, taking into account that payor rules would only be effective with harmonized/standardized rules. One member noted, "Dealing with the diverse rules among the several players in a provider's market was the source of confusion in my experience." Another member noted, "We have a cloud service provider that handles our surgical auths, we have difficulty placing our rehab patients and incorporating requirements for each receiving facility into our EMR, and we've discussed tighter integration of interqual criteria into our EMR. This project would be highly beneficial to providers and payors. We spend a lot of time, and employ A LOT of people, to comb through patient records, review criteria manually, code accounts and ask providers for clarifications, prepare for claim submission, manage denials, and perform insurance follow up. As a lean organization we've had discussions with our payors in the past about how to make this a more efficient process."

Social Determinants of Health Data

While not addressed in this report, another topic called out by members centers around social determinants of health. As one member reflected, "We worked very closely with three organizations in our community to align our documentation set so we are comparing apples to apples and reporting the same information out of our EMRs (and we can aggregate it easily in a warehouse)." **We appreciate that ONC has called out social determinants of health in the draft Common Agreement as being an emerging data class.**

Topic 2: Health IT Usability and the User Experience

Continuity of Care Documents (Strategy #4, Recommendation #4)

We recognize that improving usability of health IT can help reduce clinician burden. We agree with ONC's recommendation to continue promoting nationwide strategies that further the exchange of electronic health information to improve interoperability, usability, and reduce burden.

Among the areas discussed in the ONC report are information overload, something our members continue to hear from clinicians, remains a frustration point. Specifically, we continue to hear from our members that clinicians must navigate a vast amount of data and that unless well-organized, presents a sea of information clinicians are constantly wading through. Clinicians are often faced with a practical scavenger hunt as they attempt to locate the information needed at that point in time. As ONC notes, "If not properly organized and managed by the EHR system, a clinician may have to spend time searching through large amounts of information for the piece that is needed to perform a clinical task." ONC goes on to discuss the lengthy Continuity of Care Documents (CCD) clinicians must wade through. These are all issues and challenges familiar to our members. **We believe a place where ONC could help that would reduce burdens on clinicians is working with vendors to better ingest and interrogate external data; co-mingling native data with external data; and maintaining data provenance.**

Budget (Strategy #4, Recommendation 2)

We agree with ONC's assessment that EHR developers can help institutions plan for this by being transparent with projected costs (and associated benefits) over the anticipated lifespan of EHR implementation. For a complete discussion of our ideas around greater transparency associated with vendor costs and needed standards (including the current state of APIs), please see our letter to ONC on the EHR reporting program.

Patient Identification

Consistently identifying patients across health systems and different EHR platforms and other systems is a significant challenge. While not substantively discussed, patient identification is routinely identified as a significant barrier (if not the biggest) impeding interoperability. And, without a single system for accurately identifying patients, it creates enormous burdens on providers and presents risks to patient safety. As one member noted, he has one vendor for their hospital and another for the ambulatory side plus some other systems and they still need interfaces. Matching patient data is fraught with errors because of the lack of a defined unique identifier and our members continue to assert the ability to accurately match patients to their records will foster better interoperability and improve patient safety.

Given the Congressional ban in place since 1998 that prohibits HHS from spending any funds to establish or deploy a unique patient identifier, innovation in the private sector is needed to overcome this hurdle to improved patient care. CHIME has long been a supporter of developing a national patient identifier to accurately and efficiently match patients with the correct record. This is integral to CMS' goal to achieve the free-flowing exchange of patient records and true interoperability, as well as, reduce regulatory burdens for providers.

We recommend HHS: 1) Support innovation that targets ways to uniquely and accurately identify patients (including leveraging the Deputy Secretary's Innovation and Investment Summit); and 2) utilize the Centers for Medicare and Medicaid Services' (CMS) Center for Medicare and Medicaid Innovation (CMMI) to promote private sector-led solutions in patient identification.

Security (Strategy #4, Recommendation #4)

ONC discusses how the Cures Act defines interoperability as, "enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user." Ensuring patient data remains secure is paramount. We did not, however, see a discussion of security in this document.

The current regulatory framework governing breaches presumes a breach has occurred unless a provider can demonstrate otherwise. This framework is problematic because it lacks clear and practical guidelines for providers, and in practice results in substantial overreporting due to providers' confusion and their fear of repercussions. The extent of reporting has become so voluminous under the current framework that the regulation arguably renders the notification and reporting meaningless for patients, providers, government, and other stakeholders. Patients are likely unable to discern the instances breaches of information could result in personal harm. The information reported is also so

voluminous as to render it meaningless for patients and others interested in addressing real problems to protecting the privacy of patient records. The current Office for Civil Rights (OCR) policy imposes a stigma on entities reporting a breach in perpetuity. The proposed changes seek a fair mechanism to relieve an entity of being listed as a "violator" once the entity takes action to correct its vulnerabilities. Therefore, we believe changes to current rules are needed to strike a better balance between the protection of PHI, continuous and rapid evolution in technology including health technologies, and the practical realities of implementing privacy protections and practices.

We also believe a way to promote better cyber hygiene while reducing substantial regulatory burdens is to incent this. We recommend incenting the use of best practices like those developed under the public-private effort as part of the 405(d) work stemming from the Cybersecurity Sharing Act of 2015 . In addition to creating Stark and Anti-kickback safe harbors for the donation of other technology and services, we also believe a new safe harbor is needed that permits cybersecurity technology and services. We discuss our ideas on this in more depth in our letter to CMS on Stark here and our letter to OIG on AKS here.

Topic 3: EHR Reporting

Promoting Interoperability (Strategy #1, Recommendations #1 and #3)

We applaud CMS for making further policy changes that better align the measure requirements for Medicare hospitals and Medicare clinicians under Promoting Interoperability. While CMS has reduced some of the requirements for Medicaid providers, these measures remain unaligned with the Medicare ones. And, tracking the requirements for each set of providers is a daunting task. Appended to our letter is a table we have developed that providers an overview of the measures required under each provider type (Medicare hospital, Medicare clinician under MIPS, and Medicaid providers). Keeping track of the measures and annual changes still requires navigating a patchwork of rules and thousands of pages regulation. Also, the CMS measure specification sheets were just released – well into the new year – making it challenging for providers to understand what is required of them.

Our members continue to believe the Promoting Interoperability program relies too heavily on counting actions and too little on outcomes. **While we appreciate ONC's recommendation to further simplify the MIPS Promoting Interoperability performance category scoring, we want to be sure that any further changes under MIPS PI are aligned with Medicare hospital requirements.** Additionally, we worry that continuing to focus on measures that "focus on interoperability" while well intended, could continue to present barriers to providers if root cause issues like clunky CCDs or the lack of patient identity are resolved.

Access to CMS Claim Data (Strategy #2, Recommendation #3)

We agree with ONC's recommendation to CMS that the agency should, "Implement an open API approach to HHS electronic administrative systems to promote integration with existing health IT products." Having recommended this to CMS and in speaking with them we understand work is underway to building an API approach to exchanging data with their partners. Our members have long bemoaned the lack of timely

access to CMS data; this takes on new urgency as providers move increasingly into value-based arrangements. Therefore, offering this access to data will provide great utility to our members. As one member remarked, “CMS needs to do this in real time. This is how we will improve. If I’m a patient and seeing the claim came...(it) takes 6-12 months to get.”

Stark & Antikick back Flexibilities

ONC notes under the EHR at the inception of the report that the statute, among other things, calls for identifying burdens associated with value-based payment models. And, under section 2 of ONC’s report the agency makes the recommendation to, “Incentivize innovative uses of health IT and interoperability that reduce reporting burdens and provide greater value to physicians.” ONC says, **“**To spur clinicians and health care organizations to use health IT in impactful ways, HHS should continue to explore opportunities within existing reporting programs such as the Quality Payment Program, the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, and the Hospital IQR Program to reward both innovative uses of health IT and advancements in interoperability that improve care for patients.” However, there is no discussion of Stark or the AKS, rules which are widely perceived by providers as burdensome and impeding the transition to value-based care.

Supporting clinicians’ ability to meet the PI Program or engage in programs that require the exchange of health information and quality reporting, have relied heavily on the EHR donation permissions established under Stark and the AKS rules. **The EHR donation exemption has been pivotal is spurring greater EHR adoption among clinicians and with the drive to exchange more data and foster better patient access to their data, not only should the rules be extended beyond 2021, CHIME believes they should be expanded to better support these needs.**

Today providers such as hospitals are permitted to make donations of software or information technology and training services used predominantly to create, maintain, transmit, or receive EHRs and the EHRs must be interoperable. Hardware, however, is not allowed to be donated under this exception. Providers (i.e., hospitals) may make permissible donations (up to 85% of the costs) to other providers (i.e., independent clinicians). The exceptions governing EHR donation exemptions were extended to December 31, 2021 in rules published in 2013. While there has been a substantial growth in hospital-employed physicians, there are still many independent practices with whom our members do business and who continue to benefit from the ability to receive a donated EHR.

Several of our members have taken advantage of this exception to donate EHRs and many feel the EHR donation exception has been pivotal in spurring adoption among smaller providers. They believe that the exception is still warranted but they also feel it should be expanded. It is widely recognized that a properly interconnected healthcare system, where data flow freely to authorized parties (and patients) in a uniform manner and is integrated seamlessly into the clinical workflow, is needed. Better data exchange is also needed to manage risk, which is heavily dependent on information sharing around clinician performance, administration and clinical information. The expectation is data exchange can help foster better outcomes and lower costs and thus is critical to moving the nation toward

a healthcare system that is rooted in value rather than volume. Therefore, regulatory flexibility that allows expanding the Stark and AKS EHR donation exemptions could help facilitate better data exchange, help providers better manage risk and help interoperability flourish.

Additionally, today, it is no longer enough to just reimburse for the cost of an EHR; financial support is needed to support data exchange. The myriad interfaces clinicians need to facilitate data exchange are frequently cost prohibitive and these costs are growing as more providers establish digital connections. Unfortunately, even with the move to application programming interfaces (APIs), providers will still face the need to pay for interfaces that will introduce a whole new wave of costs (both new, upfront and on-going support and maintenance) in addition to those needed to connect disparate EHRs. The costs to support this interconnectedness are growing as the policy and clinical expectations around data sharing grow. The use of medical devices connected to EHRs is growing; the use of mobile applications is exploding, especially as consumer become more engaged in their care; and technology is fostering remote care and the ability of patients to share patient-generated data. Further, as providers grapple with the opioid epidemic that has swept the nation, the need to access PDMPs also requires costly interfaces.

Contributing further to these issues is that some providers are further along their data exchange journey. While the Health Information Technology for Economic and Clinical Health (HITECH) Act incentives were aimed at hospitals and clinicians and spurred substantial uptake of EHRs among these providers, there is a need to exchange data across the care continuum such as long-term, post-acute and behavioral health providers. Some of these providers are further behind in their ability to exchange data and establishing interfaces for these providers can be a costly endeavor. Additionally, providers who may have more advanced data exchange capabilities still need to connect with these providers to thrive in risk-based and traditional fee-for-service models of care to control costs, coordinate care, and of course, improve patient outcomes.

Further, by our estimations, using the voluntary Trusted Exchange Framework, once finalized, will not be without costs. It remains unclear where the funding the Qualified Health Information Networks (QHINs) (i.e. health information exchanges) will come from, but we do not expect this to be free. The Recognized Coordinating Entity (RCE) could pass costs off to the QHINs who could then pass them off to the providers. While the costs for providers to participate in CommonWell and Carequality are absorbed today by the vendors, it is conceivable that at some point they will be passed onto providers, if they aren't already shifted to system support fees.

Last, as ONC notes, the Cures Act also calls for HHS to prioritize certification to reduce regulatory burdens. For a complete discussion of our ideas around greater transparency associated with vendor costs and needed standards (including the current state of APIs), please see our letter to ONC on the EHR reporting program.

Electronic Clinical Quality Measure (eCQM) Reporting Requirements (Strategy #3)

ONC's report calls out the burdens associated eCQMs. Our members continue to report ongoing frustration with quality measure data reporting and that pulling data still requires a

lot of "massaging" before it can be submitted. One way this may be able to be addressed is though the DOD's data dictionary. Our typical member has relationships with 20 payors resulting in a complex set of requirements they must meet around quality reporting that varies not only by payor but also across federal and state agencies. Many of the measures they are required to submit are similar but sufficiently different creating unnecessary burdens and duplication of effort. We appreciate CMS's efforts to drive down burdens with their Meaningful Measures initiative, and by reducing the number of eCQMs which must be reported. Unfortunately, even with these efforts there remains a significant amount of complexity for providers. Contributing to an already complex environment is the lack of standardized way to uniquely identify patients. As we have recommended previously to ONC, **we recommend the agency review the DOD's data dictionary and determine whether this could be recycled for the purposes of reporting Medicare quality data and whether this could be leveraged as a best practice.**

There has been discussion around reducing burdens on providers but facilitating direct payor access to provider data via an EHR. We appreciate HHS exploring how this could reduce the burden associated with collecting and submitting data. In order to facilitate this the data would need to highly standardized otherwise providers are looking at additional programming.

Topic 4: Public Health Reporting

PDMPs (Strategy #1, Recommendation #1)

ONC calls for federal agencies, in partnership with states, to 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. ONC also recommends states 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. CHIME strongly agrees with both recommendations.

Our members are committed to helping address the opioid epidemic and taking measurable steps to bend the addiction curve. CHIME's Opioid Task Force is working collaboratively with our members, the private sector including private companies affiliated with our Foundation, and other stakeholders to use technology and data-driven solutions to address this national public health crisis. For many of our members and Foundation firms, this issue is not only a priority, it is personal.

Since many states preclude providers from ingesting the data from the PDMP into the EHR, clinicians are forced to interact with two different system leading to degradation of clinical workflow. The automated ability for clinicians to query PDMPs directly from their EHR varies across clinicians and vendors and some of these issues are rooted in state laws as far as what is permitted. According to Pew Charitable Trusts, 24 states have no access to an integration solution[1]. A more recent study by the Electronic Health Records Association

[1] http://www.pdmpassist.org/pdf/PDMP_Integration_Status_20171205.pdf

(EHRA) asserts there are 28 states without integration.[2] For example, our members in Texas report their PDMP has said they are prohibited from integrating with the EHR due to state law. In states where integration is not permitted, this amounts to clinicians first needing to query a PDMP database, creating a screen shot or print of the PDMP record, and scanning the copy and inserting it into the EHR; in total, a process that is cumbersome and time consuming. **CHIME recommends that CMS require as a condition of receiving the full federal financial match as permitted under the SUPPORT Act, that states require interoperability between EHRs and PDMPs such that the data received by a provider can be consumed into the EHR. Doing so will reduce regulatory burdens on clinicians; prevent the added cost and burden to providers to build an extra connection; and provide the much needed data for analysis at both the health system and public health levels.**

ePrescribing of Controlled Substances (Strategy #1, Recommendation #2)

ONC calls for HHS to increase adoption of electronic prescribing of controlled substances (EPCS) with access to medication history to better inform appropriate prescribing of controlled substances. CHIME supports the mandate which requires providers to use EPCS beginning in 2021.

The SUPPORT Act also requires DEA to update multifactor authentication requirements that will permit biometrics and modern approaches to authentication that can be more easily integrated into provider workflows. A limited number of providers integrate EPCS into their EHRs. Some clinician groups have said the current DEA two-factor authentication requirements are burdensome. The SUPPORT Act calls for the DEA to update multifactor authentication requirements. **While we have not received complaints from our members with clinicians complaining about burdensome DEA requirements, we are aware of some open source software that could help; we recommend ONC consider this as a possible solution.**

Convening Stakeholders & Harmonizing Requirements (Strategy 2, Recommendations #1 & #2)

ONC calls for HHS to convene key stakeholders, including state public health departments and community health centers, to inventory reporting requirements from federally funded public health programs that rely on EHR data. ONC furthermore calls for HHS – based on the inventory - for relevant federal agencies to work together to identify common data reported to relevant state health departments and federal program-specific reporting platforms. CHIME strongly supports this. **The law also calls for the Government Accountability Office (GAO) to issue a report on PDMPs administered by states. We encourage ONC to work with GAO to connect them to providers like CHIME members who have experience interfacing with PDMPs.**

Further, the SUPPORT Act calls for HHS to name PDMP standards and to work with the Centers for Disease Control to improve the interstate interoperability of PDMPs

[2] https://www.ehra.org/sites/ehra.org/files/EHRA%20PDMP%20-%20EPCS%20-%20State%20Landscape%20June%202018.pdf

and improving their ability to integrate with EHRs. CHIME strongly supports these objectives and is pleased to offer any assistance we can in furthering these goals.

Sharing Substance Abuse Information (Strategy #2, Recommendation #3)

ONC calls on HHS to 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. CHIME has been a vocal supporter of the need to align Part 2 rules with the Health Insurance Portability and Accountability Act (HIPAA) rules such that sharing substance abuse information governed by 42 CFR, Part 2 rules would follow the HIPAA rules. While there have been several attempts to require this in law, unfortunately this was not included in the SUPPORT Act. **It is our understanding that Substance Abuse and Mental Health Agency (SAMSHA) is planning on releasing some new guidance and we urge ONC to work with their agency partner to encourage the greatest alignment possible with HIPAA.**

I. Conclusion

CHIME appreciates the opportunity to comment on ONC's regulatory burden reduction plan and welcome the opportunity to forward discuss our ideas with ONC. Should you have any questions please reach out to Mari Savickis, vice president, federal affairs at mari.savickis@chimecentral.org.

Sincerely,

Russell P. Branzell, FCHIME, CHCIO
President and CEO
CHIME