

HITRD RFI Responses, March 15, 2019

ACTION ON INTEROPERABILITY OF MEDICAL DEVICES, DATA, AND PLATFORMS TO ENHANCE PATIENT CARE

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March 15, 2019

Mr. Alex Thai
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Re: Comments of the Connected Health Initiative to the National Science Foundation's Networking and Information Technology Research and Development National Coordination Office Regarding New Approaches to Solve the Interoperability Issues between Medical Devices, Data, and Platforms

Mr. Thai:

ACT | The App Association's Connected Health Initiative¹ (CHI) writes to provide comments to the National Science Foundation's Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO) in response to its request for information (RFI) on new approaches to solve the interoperability issues between medical devices, data, and platforms.²

CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of remote monitoring (RM), and support an environment in which patients and consumers can see improvement in their health. This coalition of leading mobile health companies and stakeholders urges Congress, Office of the National Coordinator for Health Information Technology (ONC), the Food and Drug Administration (FDA), the Center for Medicare & Medicaid Services (CMS), and other regulators, policymakers, and researchers to adopt frameworks that encourage mobile health innovation and keep sensitive health data private and secure.

¹ <http://connectedhi.com>.

² <https://www.federalregister.gov/documents/2019/02/15/2019-02519/request-for-information-action-on-interoperability-of-medical-devices-data-and-platforms-to-enhance>.

CHI's members are significantly affected by health data interoperability issues and as such work to advance policy solutions that will enable a connected and interoperable continuum of care. A truly interoperable connected healthcare system includes patient engagement facilitated by asynchronous (also called "store-and-forward") technologies (ranging from medical device remote monitoring products to general wellness products) with open application programming interfaces (APIs) that allow the integration of patient-generated health data (PGHD) into electronic health records (EHRs). Data stored in standardized, interoperable formats facilitated by APIs provides analytics as well as near real-time alerting capabilities. The use of platforms to manage data streams from multiple and diverse sources will improve the healthcare sector and help eliminate information silos, data blocking, and barriers to patient engagement.

Interoperability must not only happen between providers, but also between RM products, medical devices, and EHRs. We have consistently urged policymakers, including ONC, to encouraging the voluntary implementation of industry standards to ensure interoperability between EHR systems, medical devices, and healthcare products. This same practice could also be used to measure the interoperability of EHR products.

The success of value-based care models depends heavily on bi-directional interoperability of healthcare data. To reward better outcomes and cost-effective approaches to care, providers must be able to utilize two-way APIs to access, share, and make meaningful use of data about their patients. True interoperability involves not just the ability to access data, but also the ability to use and manipulate it for the user's purposes and the patient's benefit. Knowing the whole story is important for providers and payers to understand the best treatment plan or prevention measures for patients, as well as for patients who seek greater engagement in their own care. Data from previous care settings becomes more important in value-based care because the viability of the provider depends on outcomes. The process to arrive at these outcomes becomes more efficient with care plans tailored to patients' medical history, genetics, and other factors.

This is especially true for providers in rural areas, where there are fewer physicians serving people who live further away from care. Because of these geographic challenges, rural providers need data that shows which care plans or prevention and treatment measures are likely to work—and which are not—for the patients they see as well as to make adjustments to those care plans based on PGHD without requiring the patient to travel to the clinic. Physicians spend about half their time doing paperwork and grappling with EHRs that create friction in their workflow. With fewer caregivers per capita and greater distances between patients and caregivers in the less urban parts of the country, a system that traps physicians in endless stretches of administrative busywork is even more costly for rural patients. Value-based care models enable providers in rural areas to divert resources to where and when they are needed most. The ability to access and analyze data on patients and populations is central to the ability to deliver cost-effective, high-quality care.

The private sector is making strides to assist with the interoperability of data across EHRs and other platforms, and a diversity of APIs are emerging to assist in bringing PGHD into the continuum of care. For example, Health Level Seven International (HL7) is a standards-setting organization comprised of stakeholders from across the healthcare spectrum that has developed the Fast Healthcare Interoperability Resources (FHIR) standard. This is a “light, thin” standard that attempts to homogenize a relatively small subset of data formats and elements across different data users in the healthcare system. The FHIR standard also comes with an API to facilitate the exchange of EHRs. To effectuate the adoption of FHIR, HL7 launched the Argonaut Project, which is also working on standardizing more granular aspects of data formatting and field entries.

Incentives must be aligned in such a way that they encourage the adoption of data field and format standards like FHIR without strict mandates that could lock in standards that fail to keep pace with innovation. Data field and format standardization is likely to change as better data set management develops. Eventually, EHRs and other vendors should provide for two-way APIs that allow software developers to both download data from large sets held by the EHR *and* upload that data into the system. This two-way capability will be central to ensuring that 1) patients will benefit from newer innovations as quickly as possible, and 2) interoperability will evolve more naturally with developments in software and hardware.

Furthermore, as information access and exchange increases, so should efforts to ensure patient data is secure and private. Patients should have meaningful knowledge on the use or reuse of their data, along with commonsense controls over its use. Information moves at the speed of trust; EHRs and other vendors must strengthen patients’ and providers’ trust placed on the security and privacy of our most sensitive data. Healthcare providers usually work with a wide variety of vendors, from device makers to software companies, and ensuring they all work together to paint an accurate and seamless picture for caregivers is critical, especially for value-based care models.

We also note that interoperability solutions should provide useable data from various sources, not just from certified EHR technology (CEHRT) and CEHRT systems. There must also be positive incentives to communicate and pass information from one party to another. We also note that the Medicare Access and CHIP Reauthorization Act³ (MACRA) provides that incentive in a value-based healthcare environment—one which engages patients, reduces costs, and documents quality metrics. We believe positive incentives should include the use of CEHRT, non-CEHRT, or technology that is built on CEHRT. Those incentives should also be calibrated to the need of physician-patient engagement and not directly linked to federal reporting requirements.

³ Pub. L. 114-10 (2015).

CHI has developed a number of detailed written positions that we believe will assist the NCO in its efforts to solve health data interoperability issues between medical devices, data, and platforms; and which address the specific questions posed in the NOC's RFI. They are as follows, and are appended to this comment letter:

- CHI comments to ONC on its Draft Trusted Exchange Framework and Common Agreement (submitted February 20, 2018)
- CHI comments to ONC on its Draft U.S. Core Data for Interoperability (USCDI) and Proposed Expansion Process (submitted February 20, 2018)
- CHI comments to the Department of Health and Human Services (HHS) on its Request for Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program (submitted October 17, 2018)
- CHI comments to ONC on its Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs (submitted January 28, 2019)

Further comments of CHI that address digital healthcare policy issues, including health data interoperability, can be accessed at www.connectedhi.com.

We appreciate the opportunity to submit comments to the NCO on this matter and look forward to the opportunity to meet with you and your team to discuss these issues in more depth. Thank you for your consideration.

Sincerely,



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Connected Health Initiative



The American Medical Association (AMA) appreciates the opportunity to comment on the Office of the National Coordinator for Health Information Technology (ONC) proposed draft of the Trusted Exchange Framework and Common Agreement (TEFCA, Common Agreement, or Framework). Overall, the AMA supports ONC's goals for the TEFCA, including the ability to (1) provide physicians access to health information about their patients, regardless of where the patient received care; (2) provide patients and their caregivers to access their health information electronically without any special effort; and (3) ensure that organizations accountable for managing benefits and the health of populations can receive necessary and appropriate information on a group of individuals. We also appreciate ONC's desire to create a single "on-ramp" for physicians and patients and recognize the overarching need to simplify and clarify the process and governance required for nationwide health information exchange (HIE).

While the draft TEFCA lays out the principles, terms, and conditions for trusted exchange, there are a number of critical questions and concerns that ONC must address prior to releasing a final draft. We also highlight that the scope and pace of the draft initiatives are very ambitious, and it is not clear if the proposed TEFCA process will ultimately achieve ONC's goals. Through that lens, the AMA is providing specific feedback and suggestions, and requests that ONC provide further information on the questions included in these comments.

Principles to achieve health care goals

The AMA provided comments to ONC during its first public comment period on the TEFCA. Our comments highlighted the importance of recognizing ongoing efforts by private sector stakeholders, and we appreciate ONC's efforts in the draft TEFCA to survey the HIE landscape and identify areas where greater harmony could lower exchange cost, complexity, confusion, or other friction points.

We also recommended that ONC consider realistic and achievable goals for the TEFCA, that the agency derive these goals from provisions within the 21st Century Cures Act (Cures), and use the goals as a metric for measuring success. Furthermore, we recommended avoiding duplication of existing agreements and additional complexity and burden on physicians. Our major goals for a successful Framework include the following:

- The Framework should address, at a national level, the business, technical, and governance components of interoperability to achieve patient-centered care;
- The Framework should incorporate Cures provisions around vendor information blocking and access to longitudinal patient health records while also limiting administrative burden; and
- The Framework should empower physicians and patients with clear and up-to-date information about the value proposition, structure, and limitations of health information exchange networks.

Health information exchange principles—technical

With respect to the first goal, ONC has acknowledged the importance of technical standards in interoperability.

TEFCA language:

The 2015 Edition certification criteria (2015 Edition) help facilitate greater interoperability for several purposes and enables Electronic Health Information exchange through new and enhanced certification criteria, standards, implementation specifications, and Certification Program policies.

Certification enables End Users to have confidence that their health IT will support interoperability for the appropriate use cases and helps enable the exchange of Electronic Health Information in a structured way.

If the Certification Program or the ISA [Interoperability Standards Advisory] do not have applicable standards, Qualified HINs [Health Information Networks] should then consider voluntary consensus or industry standards that are readily available to all stakeholders, thereby supporting robust and widespread adoption.

At a minimum, Qualified HINs connecting to other Qualified HINs should adopt and use standards and implementation specifications that are referenced in the 2015 Edition final rule and the ISA. Further, Qualified HINs should actively engage with ONC to improve and update the ISA's detail, in order to inform the content of the ISA and ensure that the appropriate and best standards are referenced for needed use cases.

Finally, Qualified HINs and their participants should work collaboratively with standards development organizations (SDOs), health systems, and providers to ensure that standards, such as the C-CDA, are implemented in such a way that when Electronic Health Information is exchanged it can be received and accurately rendered by the receiving healthcare organization.

The AMA appreciates ONC's attempt to leverage the uniformity health IT certification brings to the industry, and agrees with ONC that, beyond 2015 Edition, the ISA is the next logical collection of standards to assist with meeting interoperability needs. However, while we recognize the need to anchor technical methods of interoperability to a common set of requirements, AMA seeks clarification as to how ONC intends to ensure conformance to these standards and how certification criteria or ISA standards are the right fit for interoperability at this scale.

TEFCA language:

Qualified HINs should ensure that the data exchanged within their own network and with other Qualified HINs meets minimum quality standards by using testing and onboarding programs to verify minimum quality levels. Qualified HINs may consider using open source tools, such as ONC's C-CDA scorecard tool for testing the quality of C-CDAs. They may also consider developing tools to test the quality of data exchange using Fast Healthcare Interoperability Resources (FHIR) APIs. These types of testing programs can help ensure that high quality data is exchanged both within and across HINs.

The AMA agrees that Qualified HINs (QHINs) should ensure Participants (that is, persons or entities participating in QHINs) conform their own networks to the appropriate minimum quality standards' implementation guides, and that testing tools are available to support this need. However, while the draft TEFCA identifies 2015 Edition as the bases for interoperability, ONC has downplayed the utility of robust, continuous, and transparent testing to achieving national interoperability.

The AMA has regularly highlighted the importance of health IT testing and has urged ONC to focus its efforts on the validation of system interoperability, usability, and safety. Since 2015 Edition criteria will play a major role in underpinning interoperability in the TEFCA, the Framework's draft language leads to the assumption that products certified by the 2015 Edition process will have already performed the testing necessary to ensure system-to-system interoperability. There seems to be a further assumption that this level of testing will be sufficient to ensure the complex interactions between disparate health IT products, HIEs, QHINs, Participants, and End Users (that is, individuals or organizations using the services of a Participant to send and/or receive electronic health information), and the ability of these technologies to consistently and seamlessly facilitate the permitted purposes, goals, and use cases identified in the draft TEFCA. **We do not believe this to be the case and are concerned with these assumptions.** In addition, the importance of testing is only briefly mentioned near the beginning of the draft TEFCA, while the concept of "burdensome testing" is mentioned at least four times. The AMA questions as to why ONC positioned testing in a negative connotation instead of addressing the pros and cons of testing principles.

ONC has made efforts to improve conformance testing in its certification program, and has extended its oversight of health IT to in-the-field product surveillance. While we acknowledge that ONC has made some attempts to address our concerns, ONC's certification program, and therefore 2015 Edition, is tooled for compliance to Centers for Medicare & Medicaid Services (CMS) programmatic requirements. Clearly, testing an electronic health record (EHR) for Meaningful Use (MU) or Advancing Care Information (ACI) programs is not the same as validating a system's ability to empower individuals to use their electronic health information to the fullest extent; enable providers and communities to deliver smarter, safer, and more efficient care; and promote innovation at all levels—all of which are explicitly listed in the draft TEFCA as components of an interoperable health system.

The AMA strongly urges ONC to clarify and identify the discrepancies between 2015 Edition and the gaps that must be bridged to align health IT development, design, and testing with ONC's stated TEFCA goals.

Again, the AMA supports a nationwide trusted exchange framework; however, we are concerned with the assumptions outlined above as they relate to standards use and conformance testing. As stated earlier, ONC has extended its oversight into certified health IT, particularly those products used in production environments. Would ONC then leverage its in-the-field surveillance capability if concerns were raised about the conformance of health IT's certified criteria as it relates to TEFCA? **The AMA seeks clarity from ONC on where it believes its oversight role intersects with a QHIN's oversight and/or that of a Recognized Coordinating Entity (RCE).**

TEFCA language:

A. Adhere to standards for Electronic Health Information and interoperability that have been adopted by the Secretary of the U.S. Department of Health & Human Services (HHS) or identified by ONC in the Interoperability Standards Advisory (ISA).

The AMA believes the description of this principle discourages the use of standards with patented technologies or other intellectual property. We disagree with this as an overarching concept and recommend that any standards need to be considered for inclusion if they are embedded and widely used in current health care exchanges, as replacing them would cause a larger burden on the health care system.

Health information exchange principles—governance

ONC has proposed a multi-layered approach to governance. This approach suggests a hierarchical structure, positioning a single entity—the RCE—to manage the oversight and day-to-day operations of the TEFCA. Additionally, ONC states the RCE will be charged with onboarding organizations to the final TEFCA; ensuring QHINs comply with the terms and conditions of the TEFCA; addressing non-conformities with QHINs; developing additional use cases; updating the TEFCA over time; and working collaboratively with stakeholders.

The AMA recognizes the need for an RCE and supports ONC's proposed approach.

TEFCA language:

To operationalize the Trusted Exchange Framework, the RCE will incorporate additional, necessary provisions into the Common Agreement as long as such provisions do not conflict with the Trusted Exchange Framework, as approved by ONC. The RCE will be expected to monitor Qualified HINs compliance with the Common Agreement and take actions to address any non-conformity with the Common Agreement—including the removal of a Qualified HIN from the Common Agreement and subsequent reporting of its removal to ONC. The RCE will also be expected to work collaboratively with stakeholders from across the industry to build and implement new use cases that can use the TEFCA as their foundation, and appropriately update the TEFCA over time to account for new technologies, policies, and use cases.

ONC believes that a private-sector organization would be best positioned to serve as the RCE and, to that end, we intend to release an open and competitive Funding Opportunity Announcement (FOA) in spring 2018 to award a single, multi-year Cooperative Agreement to an RCE. The multi-year Cooperative Agreement will allow ONC to closely collaborate with the RCE to help ensure that the final TEFCA supports all stakeholders and that interoperability continues to advance. In general, we believe the RCE will need to have experience with building multi-stakeholder collaborations and implementing governance principles. The FOA announcement will provide additional specificity on the eligibility criteria that an applicant would have to meet to be chosen as the RCE.

The AMA looks forward to further clarification from the ONC on what the RCE is and what its unique role will be in the health care interoperability ecosystem. Based on the description above, and other language in the draft TEFCA, we believe ONC envisions the RCE playing a number of different roles, including convener; arbitrator; contracts administrator; trainer; enforcer; overseer; and the standards developing organization (SDO)/technical compliance entity.

The development of additional use cases is a major factor in the success of the TEFCA, and therefore, use case development must be a priority for the RCE. While a broadcast query for treatment purposes is an important aspect of nationwide interoperability, we also foresee the need to replicate high-impact use cases. For instance, many new Alternative Payment Models (APM) utilize a combination of Certified EHR Technology (CEHRT) and custom-developed software to engage patients or manage populations. Results have decreased hospitalizations and emergency room visits, reduced spending, and improved patient satisfaction.¹ Still, it is extremely difficult for health care providers to receive timely and actionable data from payers. Replicating these results across the nation will require exposing health IT developers to successful APM health IT frameworks. **To that end, we recommend that the RCE also act as a “use case clearinghouse” to help ensure that health IT developers, QHINs, and Participants accommodate the needs of new care models.**

Representing and accommodating the needs of the End Users should be a major factor in the governance of the RCE. **The AMA recommends that the RCE be overseen by a regularly-meeting governing board that includes representation from the provider community, patient/non-covered entity community, and public health community. The AMA emphasizes that the RCE should have independence from ONC with transparent accountability and governance.**

Information blocking

Information blocking constitutes activities that prevent, interfere with, or discourage electronic transmission and sharing of electronic health information across the medical community. The AMA has long prioritized the reduction of vendor-driven information blocking, and to this end, we suggested that the TEFCA establish a “floor” for limiting information blocking. Unfortunately, while CMS has implemented requirements around provider information blocking, ONC has yet to operationalize Cures information blocking requirements for health IT vendors.

With the release of the draft TEFCA, we are perplexed as to why ONC has decided to seek feedback on a national interoperability framework without first promulgating a notice of proposed rulemaking on vendor information blocking. **Guidance relating to what does and does not constitute information blocking is a critical component missing from the draft TEFCA.** While the draft Framework contemplates actions that may limit access to electronic health information, not enough information is available to sufficiently inform comments in this area. **The AMA strongly urges ONC to reopen a public comment period on the draft TEFCA once information blocking regulations are in place.**

¹Illinois Gastroenterology Group. Proposal to the Physician Focused Payment Model Technical Advisory Committee (PTAC) on *Project Sonar*. <https://aspe.hhs.gov/system/files/pdf/253406/ProjectSonarSonarMD.pdf>



The AMA also seeks clarity as to ONC's intent on leveraging the TEFCA as a component in information blocking considerations. For instance, would participation in the TEFCA constitute not preventing, interfering with, or discouraging electronic transmission and sharing of patient health information? What roles will QHINs or the RCE play in determining failure to abide by the terms and conditions of the Common Agreement as it relates to information blocking? If an entity reports a failure by another Participant or End User to incorporate or to abide by the terms and conditions of the Common Agreement, how would an appeals process be managed?

TEFCA transparency and physician burden

TEFCA language:

All parties desiring to participate in Electronic Health Information exchange should know, prior to engaging with a Qualified HIN, the responsibilities of being a participant in a Qualified HIN, the responsibilities of acting as a Qualified HIN, and the protections that have been put in place to ensure that all privacy and security requirements are followed. Qualified HINs should voluntarily make these and other terms and conditions for participating in their network easily and publicly available via their website; meaning they are not accessible only to members but also to the general public.

The AMA applauds the draft TEFCA's principles promoting transparency and cooperation/non-discrimination. However, we encourage ONC to more explicitly address issues of stakeholder choice and voluntary participation in QHINs in the final TEFCA principles. Due to the sensitive nature of electronic health information and the potential disruption to physician practices involved in implementing the required technology, **the AMA underscores the importance of ensuring that Participants understand and can willingly elect to participate in information sharing via QHINs.** Some of the potential users and use cases outlined in the draft TEFCA raise questions as to physicians' ability to willingly participate (or not participate) in QHINs. Specifically, in many states and cities, physicians' financial viability is entirely dependent on participation in particular health insurer networks.

For example, 43 percent of US metropolitan areas have a single health insurer with at least half of the commercial insurance market share. In locations such as these, physicians would face potentially insurmountable financial disadvantages if they were to choose not to participate in the dominant insurer's network. In turn, this would force physicians to agree to the dominant insurer's terms of participation for a QHIN that they might otherwise oppose, including participation in a QHIN about which they have technological or security concerns. Physicians could also be forced to join multiple QHINs based on different health plans' requirements for network providers, which could impose significant financial burdens upon practices—particularly smaller practices with already strained resources. **As a result, we recommend that ONC add language to the TEFCA that protects physicians' ability to voluntarily join a QHIN and prevents insurers from requiring QHIN participation as a term of network contracts.**

Improved accessibility to health information has the potential to transform care delivery and improve patient outcomes, particularly as the US health system transitions from a fee-for-service model to value-based payment. However, earlier efforts in improving data accessibility through HIEs have faced obstacles in funding and long-term stability and viability. As such, we urge ONC to analyze the challenges that have undermined and curtailed past efforts to improve the exchange of health information so that learnings from those endeavors can be applied to the TEFCA. **Specifically, we encourage ONC to audit current/operational and past/failed HIEs to identify key factors that have played a role in the success or failure of other data exchange initiatives. This evaluation should examine ways to ensure that funding and viability issues will not threaten the success of this new initiative to build QHINs.**

TEFCA value proposition, structure, and limitations

TEFCA language:

Payers and health plans, including employer sponsored group health plans may wish to work with Qualified HINs to connect to Electronic Health Information that would better support payment and operations, including using analytics for services such as assessing individuals' risk, population health analysis, and quality and cost analysis. These Population Level requests are fundamental to providing institutional accountability for healthcare systems across the country.

Supporting these types of use cases necessitates the ability to exchange multiple patient records at one time (i.e. population level or "bulk transfer"), rather than potentially performing hundreds of data pulls or pushes for a panel of patients. Qualified HINs should provide the ability for participants to both pull and push population level records in a single transaction. This decreases the amount of time a clinician's resources are devoted to such activity and makes more time available for actual patient care.

End Users should have access only to the information they need for a given purpose, consistent with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule's minimum necessary standard. The AMA agrees that reducing the difficulties inherent in accessing medical information at the individual or population health level is an important goal; however, we have concerns with the potential pitfalls of stakeholders having unprecedented access to information across the health care system. Current data request processes, while limiting, are narrowly scoped for specific use cases and involve some level of "gating" that helps prevent improper use and disclosure, and helps enforce compliance on both ends of the transaction (collection (query) and disclosure). The TEFCA must ultimately include mechanisms to limit data exchange in response to both broadcast and directed queries to the minimum amount of information necessary.

We strongly recommend that ONC consider all ramifications of bulk data access, including privacy and security of an individual's electronic health information, and situations that may inadvertently result in "select all & copy". Clearly, increasing ease of access to data is an imperative; however, ONC must also consider the need to hold entities accountable, including assuring that covered entity End Users can comply with HIPAA's minimum necessary

obligations in both launching and responding to queries. **We recommend ONC explore mechanisms such as: 1) requiring QHINs to monitor query and response logs and take action against Participants and End Users who abuse the openness of the system through overly broad queries (for example, suspending or revoking query rights); and 2) establishing a mechanism—by way of a QHIN or RCE—for receiving and promptly resolving complaints about abuse of the system.**

The AMA appreciates that a Participant or End User's failure to comply *may* result in terminating access to data (as oppose to automatically resulting in termination). It may be beneficial to lay out remedial steps such as a corrective action plan prior to resulting in termination so that all parties have knowledge of the noncompliance and what steps need to be taken to remedy.

TEFCA language:

6.2.4 Identity Proofing. Each Qualified HIN's security policy shall include the following elements to ensure appropriate identity proofing: (i) End Users/Participants. Each Qualified HIN shall identity proof Participants and participating End Users at a minimum of IAL2 prior to issuance of credentials;

9.1.4 Identity Proofing. Each Participant shall identity proof participating End Users and individuals in accordance with the following requirements: (i) End Users. Each Participant shall identity proof participating End Users at Identity Assurance Level 2 (IAL2) prior to issuance of access credentials;

The AMA seeks clarification on the specific identify proofing process envisioned by ONC as the draft TEFCA describes two separate identify proofing processes. It is not clear if ONC intends for each QHIN to provide identify proofing services for its Participants and End Users, i.e., top down, or if QHINs will provide a one identity proofing service while Participants provide yet another, i.e., distributed and non-centralized. In discussing the draft TEFCA's approach with other stakeholders, the AMA has encountered different perceptions as to the actual process.

The AMA supports the ultimate goal of reducing the friction and cost associated with identify proofing. However, given the confusion around ONC's approach, the AMA requests further clarity. For instance, if a QHIN provides an identify proofing service for all of its Participants and End Users, how would this service be managed, distributed, and funded? Would all physician offices be required to implement new software and services for identify proofing patients? Furthermore, what educational process will be developed to ensure all individuals, End Users, and Participants are clear on the use and security of the identities? Overall, AMA is concerned about the additional burden of and potential cost to physicians participating in the TEFCA that are going to be required to identity proof individuals.

The AMA also notes that ONC has not addressed an important component of the Cures language as it relates to the TEFCA. Cures requires ONC to work with the National Institute for Standards and Technology (NIST) around interoperability pilot tests:

“(iii) PILOT TESTING.—The National Coordinator, in consultation with the National Institute of Standards and Technology, shall provide for the pilot testing of the trusted exchange framework and common agreement established or supported under this subsection (as authorized under section 13201 of the Health Information Technology for Economic and Clinical Health Act). The National Coordinator, in consultation with the National Institute of Standards and Technology, may delegate pilot testing activities under this clause to independent entities with appropriate expertise.”

Given the complexities, interdependencies, costs, and potential burdens of establishing, managing, and deploying a nationwide identity proofing process, the AMA strongly urges ONC to pilot test, in consultation with NIST, any and all identity proofing methods considered for use in a national trusted exchange framework prior to finalizing the TEFCA. Considering the importance of managing access, authorization, and authentication at this scale, ONC would be remiss to not leverage appropriate pilot testing to bolster confidence and trust in the privacy and security of patient health information.

TEFCA language:

9.1.1 Permitted Purposes. Each Participant shall support all of the Permitted Purposes by providing all of the data classes the then current USCDI when and to the extent available when requested and permitted by Applicable Law. Each Participant shall respond to Queries/Pulls for the Permitted Purposes.

10.1 Each Participant shall be responsible for ensuring that the obligations described in this Section 10 shall be incorporated into all existing and future End User Agreements.

Some state and federal laws do require patient consent for exchange of Electronic Health Information. For example, for some health conditions such as HIV, mental health, or genetic testing, state laws generally impose a higher privacy standard (e.g., requiring patient consent from the individual) than HIPAA. Additionally, under 42 C.F.R. Part 2, subject to certain exceptions, federally assisted “Part 2 programs” are required to obtain consent to disclose or re-disclose health information related to substance use disorder information, such as treatment for addiction. When required by federal or state law, a Qualified HIN’s ability to appropriately and electronically capture a patients’ permission to exchange or use their Electronic Health Information will engender trust amongst other Qualified HINs seeking to exchange with that network.

The AMA seeks clarification as to the parties, purposes, and differences of the Common Agreement, Standard Agreement, Participant Agreement, and End User Agreement. Understanding these agreements and the relationships among them and their signing parties is critical due to the contractual enforceability mechanisms; unlike EHR certification and information blocking, ONC will have limited ability to oversee the TEFCA. Specifically, Section 10 of the draft Framework discusses an “End User Agreement” as a term of art; however, it is not a defined term in Section 1. Thus, it would be beneficial for ONC to describe this agreement and how it differs from a Participant Agreement.

In explaining the different types of agreements, clarification is needed with respect to each agreement is meant to act as a business associate agreement, how a business associate agreement interacts with the agreement, or if the business associate agreement is meant to be a separate agreement. For example, could a Participant enter into a business associate agreement with a QHIN that limits the permitted purposes for which the QHIN can use the data to treatment and public health or does Section 9.1.1 trump all existing business associate agreements that Participant may have with the QHIN?

Ethical Obligation of Confidentiality

The AMA is concerned about the breach of trust with patients and potential liability against physicians and other health care providers of unauthorized disclosure of a patient's information especially (1) if the sharing or pulling of information from a Participant is automatic without any human confirmation or interaction and (2) if Section 9.1.1 will trump any business associate agreement a Participant may have with a HIN or QHIN, which means the Participant must share any data that is requested and permitted under law.

Physicians take patient privacy and confidentiality seriously. In keeping with the professional responsibility to safeguard the confidentiality of patients' personal information, physicians have an ethical obligation to manage medical records appropriately.² Information gathered and recorded in association with the care of a patient is confidential. Patients are entitled to expect that the sensitive personal information they divulge will be used solely to enable their physician to most effectively provide needed services. Disclosing information to third parties for commercial purposes without consent undermines trust, violates principles of informed consent and confidentiality, and may harm the integrity of the patient-physician relationship.³ Thus, physicians may face severe sanctions and liabilities when they breach this trust, as well as the loss of their patients' confidence.

The AMA is concerned that a physician may be liable for unauthorized disclosures when the query/pull is automatic and outside the control of the physician or physician staff. In addition, we have concerns as to whether a physician would be found to be non-compliant with the Common Agreement when he or she reasonably withholds information because its release would damage the physician-patient relationship. ONC should consider whether it is appropriate to have indemnification of Participants or End Users in certain situations when the decision to disclose data is outside the control of the Participant or End User. Relatedly, the AMA also seeks clarification to Section 9.1.1 as to what safeguards will exist to ensure that the permitted purposes are "permitted by Applicable Law"?

Specifically, due to the lack of data segmentation capabilities of many EHRs, some physicians are unable to send data electronically at a granular level. In the event that a physician has sensitive data subject to a higher privacy standard (e.g., imposed by state law or by 42 CFR Part 2), physicians may be unable to send electronic health information while still complying with applicable law, even if the data requested is not subject to a higher privacy standard. **The**

² AMA, Medical Code of Ethics. <https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-3.pdf>

³ Id.

TEFCA must specifically incorporate protections for those who cannot share queried data as a result of their EHR design, such that those physicians are not in violation of the Common Agreement.

TEFCA language:

9.2 Participant Compliance. Each Qualified HIN shall be responsible for taking reasonable steps to ensure that all Participants are abiding by the obligations stated in this Section. Each Qualified HIN further shall require that each Participant provide written documentation evidencing compliance with these obligations on at least an annual basis. In the event that a Qualified HIN becomes aware of a Participant's non-compliance with any of the obligations stated in this Section, then the Qualified HIN immediately shall notify the Participant in writing and such notice shall inform the Participant that its failure to correct any deficiencies may result in the Participant's removal from the Health Information Network.

Section 9.2 of the draft Common Agreement requires that Participants must provide written documentation evidencing compliance on at least an annual basis for each Qualified HIN. While the AMA appreciates the importance of demonstrating compliance, this requirement will add more administrative burden upon physicians that will add unnecessary costs to the health care system. Reducing administrative burden is an important goal to the AMA because it diverts time and focus away from patient care and leads to additional stress and burnout among physicians. **At the very least, ONC should create a standardized compliance form for Participants rather than potentially having Participants fill out multiple forms from each QHIN they interact with. ONC should also explore with the RCE and QHINs how data for compliance can be pulled automatically from the Participant's clinical flow and EHR.**

The American Medical Association (AMA) appreciates the opportunity to comment on the Office of the National Coordinator for Health Information Technology (ONC) proposed draft of the U.S. Core Data for Interoperability (USCDI) and proposed expansion process. The AMA supports ONC's efforts to improve the exchange and use of patient data. Physicians and patients have an expectation that all of a patient's health information stored electronically should be able to be exchanged in a trusted and safe manner. Expanding data classes, at the appropriate pace, is a necessary step in bolstering the availability of information to provide better, more effective patient care.

USCDI Principles

As outlined in separate comments, the AMA supports the advancement of the Trusted Exchange Framework and Common Agreement (TEFCA) to build more efficient and effective infrastructure for health information exchange built on existing efforts. Equally important to reducing the burden associated with health information exchange is the development of a process to identify the data that, when available, are required to be exchanged. The USCDI would redefine the health data required to be electronically exchanged 12 months after the new data classes have been officially added, establish a process by which data are considered ready for exchange in future years, and generally set a yearly timeframe for increasing data exchange requirements.

However, systems today are unable to reliably and completely exchange clinically meaningful and essential information. Despite the large amounts of health data being gathered, data are not always meaningful, organized, or structured in a way that can easily be used, accessed, or shared by people and systems. ONC proposes to revise the common clinical data set (CCDS) managed by 2015 Edition certified electronic health records (EHR) and primarily used to participate in the Centers for Medicare and Medicaid Services' (CMS) Merit-based Incentive Payment System (MIPS) and Meaningful Use (MU) programs.

As a set of guiding principles, the AMA recommends that ONC include additional criteria to assess whether a data class is ready for USCDI inclusion; provide flexibility in determining the prioritization and advancement of data classes; consider the physician burden for capturing new data elements; and eliminate the automatic link between annual data class updates and requirements for data classes to be included in the TEFCA.

Review of industry readiness

The primary model for health information technology (health IT) today is regulatory-centric, deployed around narrow federal reporting program requirements, rather than the promotion and maintenance of patient health and wellness. This is a result of a confluence of well-intended actions based on assumption, rather than evidence. MU program design decisions, for instance, were driven by aspirations and haste without first establishing need. The AMA recognizes that

ONC has, however, created a USCDI Task Force as part of the newly-formed Health Information Technology Advisory Committee (HITAC). We strongly agree with this decision. Ensuring a successful phased-in approach for new health data classes will require a concerted effort by a wide-range of stakeholders. It will also be crucial that ONC collect real-world evidence on the issues, gaps, and utility of current CCDS implementation to inform a robust USCDI process.

The AMA recommends that ONC appoint to its USCDI Task Force individuals that have data system implementation, clinical, quality measure development, and informatics experience. The initial charge of the Task Force should be to survey the use of CCDS data elements and generate a status report addressing the collection, exchange, and use of these data elements, as well as to explore whether there is industry consensus on the representation of these data.

Health IT testing

The ability of physicians to exchange data classes easily and efficiently must be assessed before the exchange is required by the USCDI—a step that is missing in the current proposal. The ONC certification program incorporates a set of standards in EHRs. Since the launch of the certification criteria in 2011, new standards and draft standards for trial use have been included in EHRs that physicians have been required to use in order to meet regulatory requirements. Experience with the current program indicates that the lack of adherence to constrained interpretations of standards has resulted in variation among EHR vendors and difficulties for physicians attempting to exchange health information. To address this challenge, the USCDI proposal states that multi-stakeholder agreement on technical specifications is necessary to make possible the exchange of a data class. It also states that data classes that are next in line for inclusion in the USCDI must be clearly defined and have proven real-world applicability across a broad and diverse array of use cases.

However, the USCDI process outlined by ONC does not reference any change in the testing of certified EHR technology (CEHRT) commensurate with the increased data that is expected to be exchanged. Greater testing under real-world conditions will be needed to provide confidence that certified EHRs adhere to the agreed-upon interpretation of the standards and support the increased information exchange required by the USCDI. This concern is also mirrored in our TEFCA comments. Furthermore, testing should ensure that physician practices are capable of adopting the USCDI standards and that administrative burden is minimal for the day-to-day operations of a physician practice.

The AMA recommends that ONC closely monitor the development of the standards underlying the proposed data classes. Additionally, we recommend ONC test the exchange of the data classes in widespread pilots. ONC also should revise the test criteria for CEHRT to include testing that explicitly validates their readiness to support the exchange of the USCDI.

Reevaluate expansion process

ONC proposes that the USCDI expand on an annual basis through an open and transparent process for consideration of new data classes. ONC generally expects a rolling two- to three-year period for multi-stakeholder development of technical specifications will be sufficient to move a data class from being under consideration to being ready for inclusion in the USCDI. Furthermore, the draft TEFCA proposes that Qualified Health Information Networks (QHIN) must update their data format and/or Application Programming Interfaces (API) to include new USCDI data classes not less than 12 months after being officially added to the USCID. Together, these timelines suggests an eventual lifecycle where physicians must add technology functionality to meet annually updated requirements. Yet, in reality, as standards are developed, tested, evaluated, and then implemented, the technology that supports the standards also has a life cycle. Experience to date indicates that it takes 18-24 months for vendors to develop new technology and for physicians to safely update, switch, and implement products. As a result, the concept of an annual technology process that includes only additions and does not consider testing, evaluation, and removal of technology is unrealistic.

In addition, not all data classes will require equal time for development. It is possible that two years will be sufficient time for some data classes but too little for others. For example, the newly designated clinical notes data class may require agreement on factors other than the simple identification of data types in order to support the ability of the sender and receiver to have the same understanding of the information shared (semantic interoperability). The same challenge of ensuring that the meaning is conveyed also may apply to data classes currently included in the CCDS but not supported by standards, such as laboratory value(s)/result(s) and care team members.

The AMA recommends that ONC revise the proposed timeline to permit organizations to undertake the work needed to develop standards and technology—with a focus on testing—to support accurate and useful information exchange, while also allowing for implementation considerations that are unique to physician practices.

Most health systems and physicians are exchanging the 2014 Edition standard to support health information exchange pending the widespread availability of 2015 Edition EHRs. While the 2015 Edition EHRs are being implemented by physicians, the AMA recommends that ONC reconsider the data classes in the context of their clinical priority and expected difficulty. ONC should develop a maturity scorecard for data classes that includes a metric for physician burden on capturing new data elements. The AMA also recommends that any **requirement that physicians exchange the USCDI be suspended until the overwhelming majority of physicians have adopted 2015 Edition EHRs and the results of the pilot tests are shared broadly, and in no event earlier than 2019.**

Furthermore, accurate patient identification is a high priority to ensure that the health information exchanged also supports safe patient care. While the proposed USCDI references the connection between data classes, data standards, and the TEFCA, the proposed USCDI does not reference a solution, framework, and principles for accurate patient identification that must accompany the proposed increase in health information exchange.

Prescription drug monitoring programs (PDMP)

The AMA applauds ONC for raising the issue of information exchange readiness to provide insights and assistance in the opioid crisis. State PDMPs, EHRs, and pharmacy systems contain important health data located in disparate technology systems. Currently, standards-enabled integration among these systems varies. In some instances, state health information exchanges (HIEs) provide the connection between the state PDMPs and the EHR within the clinical workflow, but this functionality is not widely available. Where this is not available, clinicians may be able to access the state PDMP from their EHR or they may be required to log into a PDMP portal for query or reporting of opioid prescriptions in a screen separate from the clinical workflow in their EHR.

Additionally, the AMA is aware of issues related to the bidirectional flow of information back from PDMPs into EHRs. For example, physicians querying prescription drug information from multiple PDMPs cannot easily reconcile prescription information back into their EHRs. PDMP data is often provided in an unstructured format—limiting physicians' use of their EHR's clinical decision support (CDS) functionality, drug-drug / drug-allergy checking capabilities, or incorporating codified medication information in Continuity of Care Documents (CCD).

The AMA recommends that ONC work with the state PDMPs and HIEs to utilize agreed upon standards to facilitate effective and efficient bidirectional information exchange. The AMA also recommends that ONC work with pharmacy networks, state HIEs, EHR vendors and the Drug Enforcement Administration (DEA) to continue efforts to overcome barriers to information exchange.

October 17, 2018

Donald Rucker, MD
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

RE: *Request for Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program* (83 FR 42913)

Dear National Coordinator Rucker:

The Connected Health Initiative (CHI) writes to respond to the Office of the National Coordinator for Health Information Technology's (ONC) request for information on the Electronic Health Record (EHR) Reporting Program.¹ We appreciate the opportunity to assist ONC as it develops revised reporting criteria under the EHR Reporting Program consistent with the 21st Century Cures Act (21CC Act).

I. Introduction & Statement of Interest

The Connected Health Initiative (CHI) is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their health. We seek policy changes that will enable all Americans to realize the benefits of an information and communications technology-enabled American healthcare system. For more information, see www.connectedhi.com.

¹ HHS Office of the National Coordinator for Health Information Technology (ONC), *Request for Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program*, 83 FR 42913 (August 24, 2018) ("RFI").

CHI is a long-time active advocate for the increased use of innovative technology in the delivery of healthcare and engages with a broad and diverse cross-section of industry stakeholders focused on advancing clinically validated digital medicine solutions. For example, Morgan Reed, executive director of CHI and president of its convening organization ACT | The App Association, is an appointed member of the American Medical Association's (AMA) [Digital Medicine Payment Advisory Group](#). The DMPAG is an initiative bringing together a diverse cross-section of 15 nationally recognized experts to identify barriers to digital medicine adoption and propose comprehensive solutions regarding coding, payment, coverage and more.² CHI is also a board member of Xcertia, a collaborative effort develop and disseminate mHealth app guidelines that can drive the value these products bring to the market. These guidelines also seek to increase the confidence that physicians and consumers can have in these apps and their ability to help people achieve their health and wellness goals.³

II. Certified EHR Technology and the Future Connected Care Continuum

Data and clinical evidence from a variety of use cases continue to demonstrate how the connected health technologies available today – whether called “telehealth,” “mHealth,” “store and forward,” “remote patient monitoring,” or other similar terms – improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement, particularly for the chronically ill. Connected health tools, including wireless health products, mobile medical device data systems, telemonitoring-converged medical devices, and cloud-based patient portals, can fundamentally improve and transform American healthcare by securely enabling the exchange of health information and incorporating patient-generated health data (PGHD) into the continuum of care and render meaningful and actionable. We urge ONC's review of CHI's aggregation of numerous studies that demonstrate the improved outcomes and reduced costs associated with greater use of connected health innovations.⁴

² <https://www.ama-assn.org/delivering-care/digital-medicine-payment-advisory-group>

³ <http://www.xcertia.org/>

⁴ This CHI resource is publicly accessible at <https://bit.ly/2MblRou>.

Despite the proven benefits of connected health technology to the American healthcare system, these solutions are constrained by several U.S. government policies. For example, statutory restrictions codified by Congress in 2000⁵ limit the Medicare telehealth services beneficiaries eligibility for coverage to geographically rural locations and several facilities that serve as the only originating sites. Moreover, Medicare coverage of remote monitoring was relatively anemic until last year. However, over time, CMS began to take important steps to better utilize connected health technology in several components of Medicare, such as through the expansion of the PFS' Telehealth Services List, as well as in key Medicare programs like the Medicare Shared Savings Program (MSSP). However, the pace of wider adoption of connected health innovations by CMS lagged behind the efficiencies offered by cutting-edge technology.

In 2017, CMS took several major steps to advance the uptake of connected health innovations across its programs. For example, CMS took crucial steps in 2017 to promote flexible use of remote monitoring innovations in the QPP. As part of the QPP's merit-based incentive payment system (MIPS) rules, CMS adopted an Improvement Activity (IA) that CHI proposed – titled *Engage Patients and Families to Guide Improvement in the System of Care* (IA_BE_14) – which incentivizes providers to leverage digital tools for patient care and assessment outside of the four walls of the doctor's office. The IA encourages providers to ensure that any devices they use to collect PGHD do so as part of an active feedback loop. CHI is especially encouraged that CMS assigned high weight and linkage to an Advancing Care Information bonus to this IA, signaling to providers that CMS acknowledges the important role connected health tools can play in improving health outcomes and controlling costs.

The range of innovative connected health tools available today (and those in development), across patient conditions, offer key health IT functionalities that enable greater engagement in prevention and treatment as well as improved outcomes envisioned by the 21CC Act. Further, a diversity of application program interfaces (APIs) are emerging to assist in bringing PGHD into the continuum of care. CHI stresses that not all of these are necessarily well integrated with EHRs. While CEHRT will be required to support APIs, many vendors will enable “read only” access, allowing for data to only flow out of the EHR rather than both in and out. Additionally, we are aware that CEHRT vendors have not implemented a common approach to API development and lack a consistent implementation of API technical standards—creating “special effort” to develop applications and undue burden and costs for our members.

⁵ See Section 223, Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 <https://www.congress.gov/106/bills/hr5661/BILLS-106hr5661ih.pdf>

Many CHI members develop unique applications that benefit both providers and patients. However, misplaced CEHRT incentives drive EHR development to focus on measurement and reporting, rather than patient and clinician needs. Similarly, providers are not rewarded for health IT use consistently (e.g., across all Quality Payment Program [QPP] components). For instance, the QPP MIPS Promoting Interoperability (PI) component is solely focused on CEHRT use, while the IA category rewards for the use of both CEHRT and non-CEHRT. ONC's EHR Reporting Program should provide providers, third-party application developers, and other CEHRT users information on EHRs' ability to capture, incorporate, and leverage PGHD. For instance, providers and our members would both benefit from understanding if and how an EHR can be utilized PGHD in clinical decision support (CDS) systems. CEHRT developers could report on their products' ability to capture structured PGHD and incorporate into their systems' CDS logic; the ability of CEHRT to consume PGHD via an API (along with any applicable API costs); and precautions taken to secure interoperability with the API.

Furthermore, we urge ONC, along with all of HHS, to consider shifting away from rigidly requiring the use of CEHRT to an outcomes-based approach permitting the use of non-CEHRT across the entire MIPS program. ONC and CMS should also seek to minimize administrative burdens (e.g., lengthy documentation and reporting program requirements) on Medicare caregivers. As such, ONC should work with CMS to leverage EHR data generated as a byproduct of PI participation. EHR vendors already track and record many data points used for PI reporting, so there is no need to continue to use physicians as reporting intermediaries. For instance, CMS' "Support Electronic Referral Loops by Receiving and Incorporating Health Information" measure lumps summary of care records received and the reconciliation of clinical information into one process. Providers are required to manage and report both the acceptance of summary documents and the reconciliation process. This tasks providers with juggling the technical aspect of interoperability, *i.e.*, digital document capture and incorporation, and the laborious process of reconciliation.

Instead, more clarity is needed on whether the EHR was able to use the summary of care document without burdening the provider, whether the EHR was able to provide the provider with usable and actionable clinical information in a format that supports clinical decision making, and if the EHR enabled a closed-loop referral. This type and level of information is far more meaningful and valuable to providers, CMS, and ONC, and should be supplied by the EHR developer. ONC should work with CMS to implement a "record once, reuse multiple times" approach, leveraging EHR-captured data for both ONC's EHR Reporting Program and CMS' EHR Reporting Programs (e.g., PI). To be clear, the intent is to reduce the reporting requirements on providers by using EHR-captured data—provided by the EHR vendor—as an alternative, supplement, or direct replacement for provider reporting in programs like PI. This data would contribute to EHR performance measurement needs of both agencies.

Such steps must serve as a cornerstone of CMS' effort to provide flexibility for MIPS eligible clinicians to effectively demonstrate improvement through health IT usage. Changes to the EHR reporting program are inherently linked to other important rules, including the Physician Fee Schedule, which recently began incentivizing the use of asynchronous tools that will bring PGHD into care. CHI continues to support efforts to revise healthcare frameworks and programs (e.g., MIPS measures and objectives) to facilitate CEHRT program alignment with non-CEHRT use (e.g., remote monitoring technology, which can greatly improve patients' care and wellness). CHI strongly supports ONC's EHR Reporting Program as a method to enable competition and innovation to drive the development and flexible use of both CEHRT and non-CEHRT. CHI stresses that more must be done to reduce the over regulation of CHERT to allow natural market forces to inform health IT development.

As a community, we continue to support ONC's efforts to utilize advanced technology to augment care for every patient. With the congressionally-mandated shift from fee-for-service to value-based care in Medicare approaching, ONC's efforts in continuing to advance the range of connected health innovations that will help American healthcare the improve outcomes and cost savings are essential.

In the 21CC Act, Congress directed HHS to develop required categories for measurement of CEHRT performance in the areas of security; interoperability; usability and user-centered design; conformance to certification testing; and others. CHI supports ONC's efforts to develop such categories consistent with the 21CC Act, building on its existing framework.

As ONC builds its new EHR compliance program, we urge for a prioritization of technology developer awareness to encourage market participation by innovators. ONC should develop clear and easily accessible guidance on reporting requirements, and reinforce that CEHRT certification is a floor, rather than a ceiling, to ingenuity of the products and services offered to caregivers. As noted above, ONC's new CEHRT program reporting framework will be developed alongside the creation of the PI framework by CMS; we strongly encourage for coordination and alignment across both programs; the communication of a clear relationship between both programs; and the utilization of data reported for one program to be used for another in all ways practicable in order to streamline compliance for all entities reporting into programs as well as for analysis by HHS of programmatic success.

III. Conclusion

CHI appreciates the opportunity to submit comments to ONC and urges its thoughtful consideration of the above input. We look forward to the opportunity to further work with CMS and other stakeholders towards realizing the the successful implementation of the EHR Reporting Program.

Sincerely,



Brian Scarpelli
Senior Global Policy Counsel

Connected Health Initiative



January 28, 2019

Don Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services

RE: *Comments of the Connected Health Initiative on the Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*

Dear National Coordinator Rucker:

The Connected Health Initiative (CHI) writes to provide input on the Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC) draft *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs* (Draft Plan), issued for public comment on November 28, 2018.¹

CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their health. We seek policy changes that will enable all Americans to realize the benefits of an information and communications technology-enabled American healthcare system. For more information, see www.connectedhi.com.

CHI is a long-time active advocate for the increased use of innovative technology in the delivery of healthcare and engages with a broad and diverse cross-section of industry stakeholders focused on advancing clinically validated digital medicine solutions. For example, Morgan Reed, executive director of CHI and president of its convening organization ACT | The App Association, is an appointed member of the American Medical Association's (AMA) [Digital Medicine Payment Advisory Group](#). The DMPAG is an initiative bringing together a 15 nationally recognized experts to identify barriers to digital medicine adoption and propose comprehensive solutions regarding coding, payment, coverage, and more.²

¹ <https://www.healthit.gov/buzz-blog/health-it/strategy-on-reducing-regulatory-and-administrative-burden-relating-to-the-use-of-health-it-and-ehrs-released-for-public-comment>.

² <https://www.ama-assn.org/delivering-care/digital-medicine-payment-advisory-group>.

CHI is also a board member of Xcertia, a collaborative effort to develop and disseminate mHealth app guidelines that can drive the value mHealth apps bring to the market. These guidelines also seek to increase the confidence that physicians and consumers can have in mHealth apps and their ability to help people achieve their health and wellness goals.³

CHI supports ONC's efforts to reduce administrative burdens in healthcare by (1) reducing the effort and time required to record health information in electronic health records (EHRs) for clinicians; (2) reducing the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and healthcare organizations; and (3) improving the functionality and intuitiveness (ease of use) of EHRs.

We are pleased that ONC shares our view that unnecessary documentation requirements are a widespread challenge to caregivers and, ultimately, patients. CHI members develop and use digital health products with improved user interfaces (UIs) that can vastly improve the physician's experience with the technology they use to collect, review, manage, and share important health data. In addition to reducing unneeded documentation requirements, we urge ONC to take all steps practicable to unlock the ability of caregivers to use new and innovative technologies in their health data management practices.

CHI also appreciates ONC's linkage in the Draft Plan to the important steps recently taken by the Centers for Medicare and Medicaid Services (CMS) in the calendar year (CY) 2019 Physician Fee Schedule (PFS) to reduce documentation and administrative burdens on caregivers—particularly in connection with digital health reimbursement and increased flexibility in CMS' EHR reporting programs. CHI supported such measures while working with CMS in the leadup to the CY2019 PFS final rule being released, and any steps ONC takes to reduce administrative burdens related to using health IT and EHRs must build on the important steps CMS has taken. CHI notes that there are further related CMS policy changes that represent several major steps to advance the uptake of connected health innovations across beneficiary programs which ONC should be sure to complement through this effort. Such policies include unbundled support for the use of remote patient monitoring in the CY2019 PFS; putting an Improvement Activity in place to use of remote monitoring innovations in the Quality Payment Program's Merit-based Incentive Payment System (MIPS) rules which incent providers to leverage digital tools for patient care and assessment outside of the four walls of the doctor's office; and many others.

³ <http://www.xcertia.org/>

The range of innovative connected health tools available today (and those in development), across patient conditions, offer key health IT functionalities that enable greater engagement in prevention and treatment as well as improved outcomes. Further, a diversity of application program interfaces (APIs) are emerging to assist in bringing patient-generated health data (PGHD) into the continuum of care. CHI stresses that not all of these are necessarily well integrated with EHRs. While certified EHR technology (CEHRT) will be required to support APIs, many vendors will enable “read only” access, allowing for data to only flow out of the EHR rather than both in and out, reducing the utility of the EHR technology. Additionally, we are aware that CEHRT vendors have not implemented a common approach to API development and lack a consistent implementation of API technical standards—creating “special effort” to develop applications and undue burden and costs for our members.

Many CHI members develop unique applications that benefit both providers and patients. However, misplaced CEHRT incentives drive EHR development to focus on measurement and reporting, rather than patient and clinician needs. Similarly, providers are not rewarded for health IT use consistently (e.g., across all Quality Payment Program [QPP] components). For instance, the QPP MIPS Promoting Interoperability (PI) component is solely focused on CEHRT use, while the IA category rewards for the use of both CEHRT and non-CEHRT. ONC’s EHR Reporting Program should provide providers, third-party application developers, and other CEHRT users information on EHRs’ ability to capture, incorporate, and leverage PGHD. For instance, providers and our members would both benefit from understanding if and how an EHR can be utilized to bring PGHD into clinical decision support (CDS) systems. CEHRT developers could report on their products’ ability to capture structured PGHD and incorporate it into their systems’ CDS logic; the ability of CEHRT to consume PGHD via an API (along with any applicable API costs); and precautions taken to secure interoperability with the API.

Furthermore, we urge ONC, along with all of HHS, to consider shifting away from rigidly requiring the use of CEHRT to an outcomes-based approach permitting the use of non-CEHRT across the entire MIPS program. ONC and CMS should also seek to minimize administrative burdens (e.g., lengthy documentation and reporting program requirements) on Medicare caregivers. As such, ONC should work with CMS to leverage EHR data generated as a byproduct of Performing Interoperability (PI) participation. EHR vendors already track and record many data points used for PI reporting, so there is no need to continue to use physicians as reporting intermediaries. For instance, CMS’ “Support Electronic Referral Loops by Receiving and Incorporating Health Information” measure lumps summary of care records received and the reconciliation of clinical information into one process. Providers are required to manage and report both the acceptance of summary documents and the reconciliation process. This tasks providers with juggling the technical aspect of interoperability (i.e., digital document capture and incorporation) and the laborious process of reconciliation.

Instead, more clarity is needed on whether the EHR was able to use the summary of care document without burdening the provider, whether the EHR was able to provide the provider with usable and actionable clinical information in a format that supports clinical decision making, and if the EHR enabled a closed-loop referral. This type and level of information is far more meaningful and valuable to providers, CMS, and ONC, and should be supplied by the EHR developer. As part of its strategy, ONC should work with CMS to implement a “record once, reuse multiple times” approach, leveraging EHR-captured data for both ONC’s EHR Reporting Program and CMS’ EHR Reporting Programs (e.g., PI). To be clear, the intent is to reduce the reporting requirements on providers by using EHR-captured data—provided by the EHR vendor—as an alternative, supplement, or direct replacement for provider reporting in programs like PI. This data would contribute to EHR performance measurement needs of both agencies.

CHI continues to support efforts to revise healthcare frameworks and programs (e.g., MIPS measures and objectives) to facilitate CEHRT program alignment with non-CEHRT use (e.g., remote monitoring technology, which can greatly improve patients’ care and wellness). CHI strongly supports ONC’s EHR Reporting Program as a method to enable competition and innovation to drive the development and flexible use of both CEHRT and non-CEHRT. CHI stresses that more must be done to reduce the over regulation of CEHRT to allow natural market forces to inform health IT development.

As a community, we continue to support ONC’s efforts to utilize advanced technology to augment care for every patient. With the congressionally-mandated shift from fee-for-service to value-based care in Medicare approaching, ONC’s efforts in continuing to advance the range of connected health innovations that will help American healthcare the improve outcomes and cost savings are essential.

Finally, as ONC builds its new EHR compliance program, we urge for a prioritization of technology developer awareness to encourage market participation by innovators. ONC should develop clear and easily accessible guidance on reporting requirements, and reinforce that CEHRT certification is a floor, rather than a ceiling, to ingenuity of the products and services offered to caregivers. As noted above, ONC’s new CEHRT program reporting framework will be developed alongside the creation of the PI framework by CMS; we strongly encourage for coordination and alignment across both programs; the communication of a clear relationship between both programs; and the utilization of data reported for one program to be used for another in all ways practicable in order to streamline compliance for all entities reporting into programs as well as for analysis by HHS of programmatic success.

Based on the above, we offer the following on certain Strategies and Recommendations in the Draft Strategy:

- CLINICAL DOCUMENTATION, Strategy 3: Leverage health IT to standardize data and processes around ordering services and related prior authorization (PA) processes.

CHI notes its support for this Strategy and its Recommendations. Digital health innovations offer the ability to reduce burdens associated with prior authorization, as opposed to the legacy approaches unfortunately still in use today (mail or fax). CHI specifically notes its support for the 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.

CHI supports efforts to evaluate and address factors that lead to PA burden. It is important to note that process automation cannot fully relieve current practice burdens associated with PA. Broader policy reforms are needed to achieve meaningful reductions in the administrative hassles associated with PA. HHS' recommendations focus on how to make the actual PA process more efficient and less burdensome for the stakeholders involved, which is an admirable and essential component to PA reform. We believe that the industry should leverage technological advancements to reduce the overall volume of PAs by selectively targeting services and providers for PA and clinical documentation processes and eliminating low-value or problematic PA requirements. Examples of such efforts could include exploration of gold carding programs, clinical decision support mechanisms, regular review and adjustment of payers' PA lists, and other programs.

While prior authorization processes can be made more efficient through automation, they inherently can require patients and practices to take additional steps as compared to services without prior authorization. Refining the process and reducing the volume of PA is critical because even a fully automated process will result in administrative costs for providers and plans and can negatively impact care delivery. For example, a seamless electronic prior authorization process does not help a patient who suddenly cannot get a chronic medication they've taken successfully for years due to PA requirements under a new plan. As a result, prior authorization processes should only be applied to appropriate services, patients and clinicians.

- HEALTH IT USABILITY AND THE USER EXPERIENCE, Strategy 1: Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation tools.

CHI strongly supports this Strategy and each of the Recommendations included in it. We are committed to better aligning EHR system design with real-world clinical workflow; improving clinical decision support usability; improving clinical documentation functionality; and improving the presentation of clinical data within EHRs. As discussed above, many of the products we develop and use increasingly utilize rapidly-improving APIs which should be fostered to develop further to advance this Strategy and its Recommendations. We further support ONC's policies advancing testing of criteria that maps to real-world utility for caregivers to ensure that U.S. federal policy advances this Strategy.

However, federal policy is a major driver in EHR system design. CHI continues to highlight that federal reporting requirements (e.g., the Quality Payment Program's Promoting Interoperability measures) are significant determinations in how EHRs look and feel to physicians. Program requirements are too focused on physicians reporting use of EHRs as opposed to whether EHRs are useful to physicians and the care they provide to their patients. Given the frequency with which HHS cites CMS program requirements as the major driver for EHR adoption, it is perplexing that HHS chose to ignore federal policy's role in EHR system development. HHS neglected to provide recommendations on federal program (e.g., Quality Payment Program and Health IT Certification) changes necessary to improve EHR system design, usability, and safety. CHI strongly urges HHS to review the nature of its own programs and include practical recommendations to improve patient care, safety, and reduce physician burden associated with EHRs. For instance, HHS should recommend charting a path away from prescriptive EHR measures and simply measure whether clinicians are using EHRs—but not score them based on how often they are using certain functionalities.

- HEALTH IT USABILITY AND THE USER EXPERIENCE, Strategy 2: Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction.

As we discuss above, the UI of today's EHR systems presents a challenge to many caregivers, and our members actively compete in the marketplace to address this issue. While competition and transparency in the marketplace will drive the development of better UIs, CHI urges for ONC to enable improved UIs and other innovations by encouraging the development and flexible use of both CEHRT and non-CEHRT.

CHI supports HHS' acknowledgment that health IT user interface design and configuration is a major contributor to physician cognitive burden. We agree with HHS' recommendations and have worked with many health IT stakeholders to develop and advance principles and best practices around health IT usability. However, until product comparison improves, a disconnect will continue to exist between health IT development and health IT vendor adherence to usability recommendations and best practices. Health IT vendor assertion to health IT design principle and best practice adherence must be balanced with transparency and accountability. Verifying conformance to these principles will help build trust. CHI continues to stress that physicians need more tools to become well-informed consumers of technology. Congress recognized this and directed HHS to develop an EHR reporting program. CHI has recently provided extensive recommendations to increase health IT transparency and inform end-users.⁴ HHS should recommend its own EHR Reporting Program ideas to assist in this strategy. We further stress that HHS should identify additional methods to increase health IT transparency within the ONC Health IT Certification Program's Principles of Proper Conduct.

- HEALTH IT USABILITY AND THE USER EXPERIENCE, Strategy 3: Promote harmonization surrounding clinical content contained in health IT to reduce burden.

CHI agrees that greater harmonization of health IT clinical content is needed to further reduce burdens on caregivers, and we support this recommendation.

⁴ The CHI's comments regarding the 21st Century Cures Act Electronic Health Record Reporting Program are accessible at <https://www.regulations.gov/document?D=HHS-ONC-2018-0022-0074>.

- HEALTH IT USABILITY AND THE USER EXPERIENCE, Strategy 4: Improve health IT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden.

CHI agrees with this Strategy and each of its Recommendations. CHI members work today to develop their products by incorporating end user caregiver viewpoints and needs at the earliest stages, and believe the normalization of this practice will most helpfully enhance clinician efficiency and satisfaction while reducing clinician burdens.

CHI appreciates the opportunity to submit comments to ONC and its Draft Strategy, and we look forward to the opportunity to further work with ONC and other stakeholders to realize a digital health innovation-enabled care continuum that minimizes burdens on caregivers.

Sincerely,

*/*signed*/*

Brian Scarpelli
Senior Global Policy Counsel

Connected Health Initiative

