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
330 C St. SW
Washington, District of Columbia 20201

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CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their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]

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[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.

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[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.

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[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.

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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,

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