STATE OF WASHINGTON
HEALTH CARE AUTHORITY
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June 3, 2019

Donald Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, Floor 7
Washington, D.C. 20201

Re: Request for comments, ONC notice of proposed Rulemaking

Dear Dr. Rucker,

On March 4th, ONC published a notice of proposed rulemaking (NPRM) entitled "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program." On the same date, the Center for Medicare and Medicaid Services (CMS) published a companion NPRM entitled "Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers Advancing Interoperability in Innovative Models."

Washington State Health Care Authority (HCA) reviewed the ONC notice of proposed rulemaking and its potential impacts to the Medicaid program. Washington is very interested in supporting ONC and our community partners with creating, implementing, and sustaining innovative ways to securely share health information. Overall, HCA is pleased to see ONC approach dismantling many of the barriers that have impeded the true interoperability of healthcare information that was envisioned with the Health Information Technology for Economic and Clinical Health (HITECH) Act. HCA is pleased to see ONC leverage this rulemaking to ensure that vendors of Certified Electronic Health Record Technology (CEHRT) modules and systems, health information exchanges and networks, and community providers better coordinate and share information to support patient health. HCA does have general concerns with how the proposed rules will impact existing systems, particularly for smaller or rural providers who have already expended the funds they received under the HITECH Act. We welcome the opportunity to partner with ONC on how to design thoughtful upgrades to the health information exchange (HIE) and Electronic Health Record (EHR) network to accomplish federal goals while ensuring our providers can continue to serve the vulnerable Medicaid population in Washington.

Comments from HCA, the Washington State Medicaid Agency

Section III. Deregulatory Actions for Previous Rulemaking

In section III, ONC proposes changes and reductions in current regulations to streamline provider requirements for participation on the Promoting Interoperability Program.

HCA Comments:

- HCA believes in administrative burden reduction, and applauds ONC at working towards trimming unnecessary requirements from the 2015 CEHRT criteria. However, we believe that the removal of the medication list should not be implemented as described in this rule. While this criteria may seem ubiquitous with modern EHRs, it feels premature to eliminate this requirement while attempting to strengthen the ability for both clinicians and State agencies in addressing the opioid crisis. This rule may support the underpinnings of a health information sharing infrastructure that could address a centralized medication management protocol through a non-EHR solution, but eliminating the medication list criteria before that solution is widely adopted could lead to significant difficulty with accurate and complete medication management.

- HCA has similar concerns regarding the changes to smoking status, which is another key function for population health, particular for public health and the Medicaid population. Significant investment is being made to address health factors related to smoking and nicotine usage, and the ability for State actors to access clinical information from provider EHRs is still at an early stage. Changing the collection and usage of smoking status information in EHRs would damage State and public health ability to collect and utilize this information to support public and population health.

Section IV. Updates to the 2015 Edition Certification Criteria
Section V. Modifications to the ONC Health IT Certification Program

In section IV and V, ONC provides updates and guidelines regarding the 2015 Edition of the Certification Criteria for EHRs. Key standards identified include Application Programming Interfaces (APIs), Fast Healthcare Interoperability Resources (FHIR), and the United States Core Data for Interoperability (USCDI).

HCA Comments:

- We agree that APIs, FHIR, and USCDI have the potential to solve key problems with interoperability. However, they may prove logistically complex to administer as they become more widespread. In addition, APIs and the USCDI are not consensus-driven standards, and we do not agree with the requested exemption to the National Technology Transfer and Advancement Act.

- FHIR is extremely promising, but is a relatively new transaction format. The accelerated timeframe creates a concern that there will not be enough FHIR experts available to meet requirements, and not enough time or funding to effectively train state staff to gain the technical understanding of these new formats.

- FHIR also has not previously been a requirement as part of the Promoting Interoperability, formerly Meaningful Use, Program, and a significant amount of infrastructure has been developed by state government entities to leverage the systems that providers and vendors created under those rules. Provider resources will be strained in developing, implementing, and maintaining interfaces to meet the rules outlined in the CMS and ONC NPRM, and many

previously developed systems will be neglected, if not abandoned entirely. HCA and other agencies would like guidance as to how funding can be leveraged to enhance these systems to ensure data flows appropriately to support our citizens.

- The EHR vendor market has already seen a significant rise in products which are no longer being maintained to current CEHRT standards. These rules as proposed have the potential to bring other EHR products out of compliance with CEHRT standards. We expect that the providers which would see the largest impact are small and rural providers who have previously invested in lower-featured and lower-cost EHR solutions, and no longer have Promoting Interoperability Program incentives available. ONC should consider funding and investments which support acquisition of new EHR products for small and rural providers whose EHR systems will not be certified to the new criteria.

- For small and rural providers, access and use to some of these standards will also require significant investment to update and modernize workflow related to these new data exchange procedures. ONC should consider funding and investments which support workflow and procedure modernization for small and rural providers consistent with the new technologies proposed.

- ONC should also consider funding and other resources to modernize investments by the States and provider communities related to this NPRM. Specific areas which would benefit from targeted modernization include electronic clinical quality measurement, registry reporting, population health and analytics, and query-based exchange.

Section VII. Conditions and Maintenance of Certification

In section VII, ONC provides an approach for the condition and maintenance of certification by developers of Health IT Modules.

HCA Comments:

- We applaud ONC on addressing information blocking, and including provisions related to information blocking as a condition of certification. Specifically, the provisions related to real world and production environment capabilities to support appropriate access and sharing of electronic health information (EHI) will provide a significant boost to interoperability and meeting the goals of the HITECH Act.

- We support ONC in ensuring that contracts between providers and EHR vendors are strengthened to support honest and transparent communication regarding the user experience with CEHRT.

- We support ONC in requiring real-world testing of APIs of ensuring that CEHRT meets the capabilities providers will use to provide care to their patients. HCA believes that API testing should be expanded to explicit support the inclusion of automated testing of API endpoints and automated API resource validation as part of maintenance of certification.

- We request that ONC consider that failure to report to public health and other state-mandated registries to be explicitly identified as information blocking. As noted in the NPRM, failure to report this information is a significant public health concern.

Section VIII. Information Blocking

In section VIII, ONC lays a significant groundwork for how information should be shared by covered entities. This includes an extremely detailed explanation of when information blocking may apply and when it may not apply to specific prohibitions on exchange.

HCA Comments:

- We applaud ONC on addressing information blocking for health information networks (HIN), HIE, and health IT developers. Significant impediments to the sharing of health information have prevented the vision of the HITECH Act from improving care in our communities. Specifically, HCA appreciates the protections awarded to providers to ensure that data moves as expected from the investment into CEHRT, and lowering the amount that providers can be charged for basic information interoperability.

- HCA requests that State agencies and state institutions are specifically excluded from the definitions of healthcare provider, HIN, HIE, and health IT developer. HCA and other state agencies perform work that is similar to these functions, but operate in a legal and regulatory environment that contains external complications compared to other entities contemplated by the NPRM.

- In addition, HCA would like ONC to address the additional provider and other entity burden regarding the documentation around information blocking in approved cases. If State entities are not specifically excluded from these definitions, this will create a significant administrative burden that will consume additional public resources.

- HCA requests that the sub-exception for information blocking regarding not providing access pursuant to an individual request should tie back to the established process for requesting a restriction of uses and disclosures as documented in HIPAA at 45 CFR 164.522. HCA and other State agencies have significant concern that this exception, as written, will become the new blockage for information exchange.

Section X. Patient Matching Request for Information

In section X, ONC solicits comments regarding an approach for patient matching. We agree that patient matching is a significant concern and support ONC in taking a broad-view federal approach on this topic in conjunction with the request from CMS. We appreciate the opportunity to provide comment.

HCA comments:

- A consistent patient matching strategy is foundational to the goals outlined in this rule. We urge ONC to accelerate and resolve the patient matching strategy prior to establishing rules regarding volume and speed of data exchange.

- We support ONC in considering and exploring modern patient matching algorithms. We consider this to be a superior approach to creating a Universal Patient Identifier (UPI). While there could be potential in a UPI, a UPI does not support more advanced matching procedures that can incorporate sparse historical data and additional data points where available.

- There is a significant lack of information available on the success rates and accuracy of patient matching. We support creating a transparent and consistent measurement strategy that allows for improving patient matching software and algorithms without enforcing specific software or algorithms. This should include a use-case driven repository of evaluation results such as accuracy, automation vs. manual effort, and time performance.

ONC discusses issues related to the overall quality of data at the point of data capture causing significant downstream issues with patient matching.

HCA comments:

- There is a potential for improving data capture by using automatic queries against validating data sources or using consistent patient matching algorithms against other known sources of patient data. This would include services that verify and authenticate demographic data such as address, but also provide potential matches which could be validated and linked at the initial encounter.

ONC discusses the possibility for improving patient matching through access to their own clinical information.

HCA Comments:

- This could support improved patient matching through validation and the acquisition of patient-generated data, but many state data sources are not equipped to incorporate this type of data, and could require an extensive investment in both human and technical processes to accommodate.
- States will vary in their ability to implement this, but we would support efforts allowing states to approach involving patients in patient matching processes
- There is a significant administrative cost to managing the support infrastructure for patient access of this scale, such as supporting identity verification and authentication processes.

ONC asks for input on performance evaluation of available patient matching algorithms.

HCA Comments:

- We support creating a transparent and consistent measurement strategy that allows for improving patient matching software and algorithms without enforcing specific software or algorithms. This should include a use-case driven repository of evaluation results such as accuracy, automation vs. manual effort, and time performance.

- We support an ONC role in ongoing development of best practices on patient matching algorithms, publishing the criteria, method, rules, accuracy and other attributes related to the algorithm, and encouraging the use of these algorithms.

- We support an ONC role in maintaining a list of software that meets the best practices through a transparent approach such as that used by the Certified Health IT Product List. ONC could enhance or encourage certain algorithms or software by creating a comprehensive testing platform that shows how software vendors have met specified criteria, publishing results in a standardized, public, and understandable fashion

- This could also be utilized to increase the transparency of patient matching indicators contemplated in the proposed rule such as database duplicate rate, duplicate creation rate, and true match rate based on tested and verified data sets and real-world implementations.

HCA wants to thank ONC for taking our comments into consideration for the implementation of these important measures to support the sharing of health information. HCA looks forward to partnering with HHS to further the nation's ability to establish, maintain, and support electronic health record technology and secure health information sharing.

Sincerely,

MaryAnne Lindeblad

Medicaid Director