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Submitted Electronically and by Hand

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National Coordinator for Heath Information Technology
Office of the National Coordinator (ONC)
Department of Health and Human Services
Attn: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule
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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attn: CMS-9115-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: ONC and CMS Proposed "Interoperability Rules": ONC "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" (RIN 0955-AA01) and CMS "Interoperability and Patient Access" (RIN 0938-AT79 / CMS-9115-P)

Dear Dr. Rucker and Administrator Verma,

As former public servants who have each had the honor of serving as National Coordinator over the past 15 years, under both Republican- and Democrat-led administrations, we appreciate the opportunity to submit comments on the proposed rules entitled "Interoperability and Patient Access" (CMS-9115-P) and "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" (RIN 0955-AA01), together the "proposed interoperability rules." We offer enthusiastic support for the proposed rules.

These rules, coupled with the Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2, represent a crucial opportunity to advance interoperability across key sectors of our nation's healthcare system and, perhaps most importantly, to empower patients and their caregivers with easy access to their personal health information. Once implemented, these regulations have the potential to foster a cultural transformation in U.S. healthcare, support innovation in care delivery, and offer a welcome paradigm shift toward more engaged and empowered consumers.

While we are proud of the accomplishments in advancing health information technology over the past 15 years - particularly the forward leaps in technology standardization and specifications; the more widespread adoption, implementation and use of electronic health records (EHRs); and the availability of actionable electronic information - we recognize that significant challenges remain to achieve the vision of interoperable health information technology.

We view the 21st Century Cures Act (Cures Act) as path-breaking legislation and believe its implementation is critical to improving our healthcare system. Never has it been more important to come together in the interest of patient and consumer empowerment and act swiftly to break down

remaining barriers and data silos. Our industry is at a tipping point as technological capability, policy, and industry readiness align, poised to capitalize on the many years of foundation-building. If these rules are rapidly adopted and effectuated, tremendous progress can be made over a relatively short period of time to deliver on the promises of interoperability, a reduction of administrative burden and improved care delivery.

The advancement of application programming interfaces (APIs) holds new promise as a powerful and positive disrupter to enable clinical data liquidity and convenient patient access to personal data, as witnessed in other major consumer-focused industries where APIs are safely and effectively employed, such as banking, energy and web-based retail services. The extension of data sharing requirements, including APIs, to health plans offers an unprecedented opportunity for clinicians and patients to have a longitudinal view of medical histories and for patients to have easier, comprehensive access to cost, service and payment information. Access to more complete medical information can improve clinical decision-making tools and enhance patient safety.

In the spirit of strong bipartisan collaboration to advance interoperability through the decade ahead, we are pleased to offer the following observations and high-level comments on the proposed rules:

1. Rapid Advancement of APIs Enabled by Data Standards Is Critical.

The proposed rules take an important step in requiring the implementation of HL7 Fast Healthcare Interoperability Resource (FHIR®) as the foundational standard for open APIs. **We strongly support the rapid advancement of the FHIR standard and the use of APIs.** The use of FHIR coupled with the transition to the United States Core Data for Interoperability (USCDI) standard, with both its expanded elements for data sharing beyond the Common Clinical Data Set (CCDS) and its structured process to expand data elements over time based on stakeholder consensus, will dramatically improve health data interoperability. In addition, the USCDI standard will add two new important data classes to exchange - clinical notes and an audit trail of the data, including its origin(s) - enhancing the value of data sharing.

We also strongly support the requirement for real-world testing as mandated by the Cures Act and generally as proposed by ONC for 2015 Edition Certified EHR Technology (CEHRT). We think broad and comprehensive testing for API responsiveness across both provider and health plan applications is a critical implementation step.

2. Expansion of the Interoperability and API Framework to Health Plans Is Game-Changing.

We agree with CMS that "patients should have the ability to move from health plan to health plan, provider to provider, and have both their clinical and administrative information travel with them throughout their journey."

We believe the use of FHIR-based APIs to make patient claims and other health information available to patients and payer participation in trusted exchange networks will result in the creation of a more complete and longitudinal picture of a person's healthcare history and represents a huge step forward. Providing clear guidance on a shared set of standards across industry stakeholders is critical, as APIs hold the promise of bringing together a patient's claims, encounters and clinical data, in many cases for the first time. The participation of health plans in trusted exchange networks also has the potential to bolster current alternative payment models (APMs), and lay the foundation for new and expanded APMs by making needed data available in a timely manner to manage care, risk and cost, and for providers and plans to improve significantly care coordination, continuity efforts and consumer experiences.

We recognize there is not an equivalent to the CEHRT process currently for payers and that this will represent a significant transition for some health plans; we encourage CMS and ONC to work with plans to ensure a feasible but timely implementation schedule.

3. Medicare's Conditions of Participation Are a Powerful Tool to Help Drive Interoperability and Exchange.

CMS has authority to impose certain requirements on hospitals that participate in the Medicare program to ensure the health and safety of beneficiaries receiving services in those hospitals. We fundamentally believe interoperable patient data has enormous implications for patient care and safety and **applaud CMS' proposal to revise the Conditions of Participation (CoPs) to advance interoperability.** This represents an enormous step forward in advancing the goals of the Cures Act and sets the expectation that, as the largest purchaser of healthcare services on behalf of its beneficiaries, CMS will require a foundational exchange of health information from its contracted providers.

Electronic patient notifications are a useful tool for improving transitions of care between settings as well as for promoting patient safety. We agree with CMS' assessment that most eligible hospitals can generate automated electronic patient event notifications and an initial focus on admission, discharge and transfer (ADT) messages is a realistic starting point. However, while the technical capabilities exist today, many organizations will need to update their business and operational practices to comply. We recommend a moderate degree of flexibility to support successful, timely implementation. Not all hospitals use CEHRT to generate ADT notifications; and hospital registration and admission systems may appropriately be separate from the CEHRT. In addition, as we have witnessed through efforts to exchange electronic summary of care records under the EHR Incentive and Promoting Interoperability programs, notable gaps still exist across the continuum of care related to qualified ambulatory and post-acute care providers' ability to directly receive information. As such, we recommend CMS remove the express requirement to use CEHRT for ADT messages and suggest instead hospitals send direct notifications where feasible and/or use a trusted exchange network to make notifications available to all eligible receiving providers. In response to CMS's request for feedback, we also agree that event notification alert requirements should be extended to emergency department and "observational" stays.

However, importantly, electronic notifications are a fairly narrow "use case" that we believe should be viewed as a starting point, not the end point. **We urge CMS and ONC to view implementation of this requirement as a learning experience to inform the logical outgrowth of applying the CoPs to a broader set of requirements focused on interoperability (beyond basic data exchange) and facilitating access to actionable data at the point of care to advance patient health and safety goals.**

4. Information Blocking Provisions and Strong Compliance Mechanisms Are Essential.

We support ONC's thoughtful consideration of the operational, technical and patient-related circumstances under which data may be temporarily or necessarily withheld. The categories, as outlined, are pragmatic and practical. We believe the seven categories of "reasonable and necessary" exceptions are the right ones and, from a policy perspective, offer solid guardrails for defining and deterring information blocking.

We believe strong enforcement of information blocking should be of the highest priority in order to realize the goals of interoperability. We recognize the implementation of some of these provisions will be complex and some will be more straightforward. In order to be able to meaningfully enforce

information blocking restrictions, ONC will need to provide additional guidance around all seven provisions to ensure those acting in "good faith" do not unwittingly engage in information blocking activities. We suggest ONC consider a mechanism whereby actors can seek advisory opinions as to certain practices as they seek to navigate this new area of regulation, oversight and enforcement.

Among the most challenging for the industry to navigate will be provisions related to API pricing parameters and transparency. Price has unacceptably been used in the past to ration electronic exchange of information or to block it outright, and **we strongly support ONC's proposal that API pricing should not be a barrier in allowing patients access to their health information**.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) authorizes information to be exchanged amongst providers for limited treatment, payment and operations purposes and requires patient access to their data in a patient-preferred format with strict limits around charging marginal costs to patients (such as for copying or postage). **We agree the requirement of cost limitations should be extended to data sharing with patients and providers via APIs.**

That said, we realize that a new marketplace will be growing, focused on using healthcare related data to create value for providers and consumers. Business cases for new and innovative applications will need to develop in a competitive system that needs time and flexibility to mature. Currently, there is much unknown and untested related to the development and service costs of these new applications. As such, **we support the recent Health Information Technology Advisory Committee (HITAC) recommendations related to distinguishing "basic" and "value-add" information access and, at a minimum, ensuring free or near-free access to information contained in the USCDI data set exchanged via APIs.**

5. A New Privacy Framework Should Be Developed in Parallel With Implementation of the Proposed Interoperability Rules to Protect Consumers.

The proposed interoperability rules and the ONC Health IT Certification Program further federal efforts to ensure that electronic health information is available and can be securely and safely shared to improve the health and care of the American public. **We believe it is of utmost importance to implement these proposed interoperability rules as quickly as possible to propel the healthcare industry forward by finally enabling the meaningful flow of data.** In and of themselves, these rules do not, however, fully address patient and consumer privacy protections. **In parallel, we recommend that CMS and ONC, together with other relevant agencies and departments (such as the HHS Office of Civil Rights and the Federal Trade Commission) and private-sector colleagues, develop a companion consumer privacy framework.**

Consumers should clearly understand how their data is being used by third-party APIs and how to exercise their consent options. **A process should be put in place to ensure appropriate privacy protections are in place for consumers as the API market develops**. As previously noted, standards-based APIs are widely used in a myriad of other industries, including those that foster the exchange of sensitive personal information. The development of a privacy framework should not be allowed to become another obstacle to revolutionizing how health information is shared and to empowering consumers; rather it should be developed and matured in concert with the modernization of our nation's health IT infrastructure. There are private sector and public-private examples of models that ONC and CMS can look to from both healthcare and other industries.

6. Ensure Resources for Robust Stakeholder Education and Continue to Foster Alignment With Related Regulations

Investment in efforts to educate stakeholders - including payers, providers, health tech firms, consumer advocacy organizations, patients and others - to understand the implications and opportunities of these regulations will be critical to their successful implementation. We encourage both agencies to carefully plan for and adequately resource education and outreach.

We also note that important efforts beyond the provisions laid out in these rules will have material impact on their success. We advise ONC and CMS to ensure broader stakeholder representation in trusted exchange governance in order to foster achievable participation from more sectors in the industry. Further, we wish to note our support of continued efforts to develop enhanced and accurate patient-matching solutions, starting with CMS's proposal to develop a cross-CMS patient identifier while not limiting more ambitious private-sector efforts.

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In summary, we congratulate ONC and CMS on a thorough set of proposals that consider the multitude of factors and requirements to advance an interoperable future as envisioned under the Cures Act. Interoperable data will allow us to unlock the value long-sought from our EHRs - as opposed to the just internal enterprise data many organizations can access today - to achieve key cost, quality and health improvement goals. We appreciate the opportunity to submit comments to ONC, CMS, and other federal agencies that will be implicated by these proposed interoperability rules, and enthusiastically share our support and endorsement for this important work to move the U.S. healthcare system into the 21st century.

Respectfully,

Dr. David Blumenthal | Dr. David Brailer | Dr. Karen DeSalvo

Dr. Robert Kolodner | Dr. Farzad Mostashari | Dr. Vindell Washington

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