April 15, 2020

The Honorable Alex M. Azar II
Secretary, U.S. Department of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Re: Cures Act Final Rule (RIN 0955–AA01) and Interoperability and Patient Access Final Rule (CMS-9115-F)

Dear Secretary Azar, Administrator Verma and Dr. Rucker:

The Confidentiality Coalition (Coalition) appreciates the steps taken by the Office of the National Coordinator of Health Information Technology (ONC) in the Cures Act Final Rule, and by the Center for Medicare & Medicaid Services (CMS) in the Interoperability and Patient Access Final Rule (collectively, the Rules), to put patients front and center in making decisions about their healthcare, and break down barriers to health information sharing in the nation's health system. However, we write this letter in a time of unprecedented strain on our healthcare system, as our nation faces a public health crisis unlike any in its history. In light of this crisis, and as explained further below, we request that ONC and CMS extend the time period for implementation of the Rules.

The Coalition is composed of a broad group of hospitals, medical teaching colleges, health plans, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, employers, health product distributors,

pharmacies, pharmacy benefit managers, health information and research organizations, patient groups, and others founded to advance effective patient confidentiality protections. The Coalition's mission is to advocate policies and practices that safeguard the privacy of patients and healthcare consumers while, at the same time, enabling the essential flow of patient information that is critical to the timely and effective delivery of healthcare, improvements in quality and safety, and the development of new lifesaving and life-enhancing medical interventions.

The Coalition strongly supports the Administration's goal to provide patients with greater access to and control over their health information, and to promote the exchange of health information among patients, healthcare providers and payers. We also share the Administration's view that "where data flows freely and securely between payers, providers, and patients, we can achieve truly coordinated care, improved health outcomes, and reduced costs." However, at this time, healthcare workers and other resources are stretched to the limit in responding to the COVID-19 pandemic and cannot be allocated to the preparation that will be needed to implement these significant new regulatory requirements.

This preparation will require the involvement of staff from parts of the organization, including not only information technology (IT) specialists, but also operational, legal and compliance staff and clinicians. For example, clinicians serve as subject matter experts in clinical system and workflow configurations, and to develop and execute training for the workforce that interacts with patients as well as for the back-office staff in pharmacies, medical records, hospital operations, and clinical offices. These clinicians are currently devoting their time with a single-minded focused on the COVID-19 response and are not available to perform these regulatory implementation roles. Similarly, operations, legal and compliance staff are focused on addressing the many new legal directives, waivers, policies and procedures needed to address the public health emergency.

Finally, IT staff, who will bear the responsibility for implementing the many IT changes required by the Rules, are working around the clock to support the COVID-19 response. Not only are they providing health system operations support for direct patient- and member-facing services, but they are also supporting telemedicine and related telehealth services, such as ensuring that physicians maintain remote access privileges to patient monitoring system administration and patient telemetry data streams. In addition, as in other industries, healthcare organizations are heeding social distancing guidelines and public health orders to "shelter-in-place," with the result that IT staff are being called upon to support the exponential increase in the size of the remote workforce, in some cases by more than 500%. These IT workers form the backbone of the workforce needed to implement the Rules' requirements, but they are overwhelmed with COVID-19-related projects.

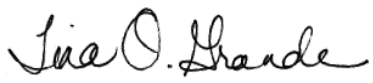
Quite apart from the resource limitations, many IT departments either have or will put a freeze on IT changes for the duration of the COVID-19 public health crisis because of

their potentially destabilizing effect. Where IT freezes are in place, application system changes needed to implement the Rules cannot begin to be developed, tested, or implemented in any IT system environment for the duration of the public health emergency, and vendor upgrades deferred, since even small routine maintenance patches can be destabilizing, with potentially catastrophic consequences. Even once the public health emergency is over, it will take many months for the IT environment to catch up with a backlog of maintenance before new regulatory work can be contemplated.

Based on the above considerations, we respectfully request that ONC consider delaying the publication of its Rule in the Federal Register until the COVID-19 health emergency is over. We also ask that ONC and CMS extend the time period for compliance with each requirement specified in the rules by a minimum of an additional 12 months, after the rules are published. Separately, we ask CMS to publish a notice exercising discretion of compliance enforcement for its rules with pending effective dates for the duration of the public health emergency plus at least 12 months and at least 18 months for state Medicaid programs and their respective agencies and health care partners. This will allow healthcare organizations to devote their resources to combatting COVID19 and dealing with the aftermath of this public health crisis without putting them at risk for being in non-compliance with the Rules. It will also allow them to commit the necessary time, effort and resources to implement these two important Rules properly, and to ensure a smooth and well-prepared rollout so that patients, providers and health plans are able to reap the benefits of the more connected and competitive healthcare system they promise to deliver. Additionally, we respectfully request that CMS provide communication regarding any delay in implementation and/or enforcement as soon as possible so that health plans can appropriately integrate the cost associated with developing Fast Healthcare Interoperability Resources (FHIR)-based APIs in upcoming bids.

Please contact me at tgrande@hlc.org or (202) 449-3433 if you have any questions or would like additional information.

Sincerely,



Tina O. Grande
Chair, Confidentiality Coalition and
Executive VP, Policy, Healthcare Leadership Council

cc: The Honorable Frank Pallone Jr., Chairman
The Honorable Greg Walden, Ranking Member
U.S. House of Representatives
Committee on Energy and Commerce

2125 Rayburn House Office Building
Washington, D.C. 20515 Washington, D.C. 20515

The Honorable Lamar Alexander, Chairman
The Honorable Patty Murray, Ranking Member
U.S. Senate Committee on Health, Education, Labor and Pensions
428 Dirksen Senate Office Building
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