



Center for Digital Health
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By electronic submission

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

Re: UCSF Center for Digital Health Innovation's Comments on ONC's Interim Final Rule Further Delaying Timelines and Compliance, File No. RIN 0955-AA02

Dear National Coordinator Rucker:

The University of California, San Francisco's Center for Digital Health Innovation submits these comments on the interim final rule further extending timelines for compliance with the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule). The University of California, San Francisco (UCSF) is a worldwide leader in health care delivery, discovery, and education. Consistent with this public imperative, UCSF invests heavily in developing a range of health information technology, innovation, and management resources and best practices to give health care providers and patients,¹ researchers and scientists, educators and students, the interoperability and transformative tools to succeed in this rapidly evolving digital health age. We thank you for the opportunity to offer these comments.

The Office of the National Coordinator for Health Information Technology (ONC) invites public comment on its interim final rule, published November 4, 2020,² which further delays the deadlines for EHR developers and health care providers to comply with key requirements on interoperability, information blocking, application programming interfaces (APIs), patient and provider access to structured health data, and app innovation in the ONC Cures Act Final Rule.³ The new rule delays compliance another 5-12 months, depending upon the requirement.⁴

¹ For brevity, these comments refer to "patient" and "care," given that many federal programs and initiatives are rooted in a clinical or medical model. Health and health care, however, embrace more than clinical settings and extend well beyond clinical treatment of episodes of illness and exclusive dependency on medical professionals. Any effort to improve patient and family engagement must include terminology that also resonates with the numerous consumer and community perspectives not adequately reflected by medical model terminology. For example, people with disabilities and others frequently refer to themselves as "consumers" or merely "persons" (rather than patients). Similarly, the health care community uses the terminology "caregivers" and "care plans," while the independent living movement may refer to "peer support" and "integrated person-centered planning."

² Office of the National Coordinator for Health Information Technology, Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes In Response to the COVID-19 Public Health Emergency, 85 Federal Register 70064 (Nov. 4, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24376.pdf>.

³ Office of the National Coordinator for Health Information Technology, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Federal Register 25642, 25670 (May 1, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf>.

⁴ 85 Federal Register at pp. 70066-70067 (Table 1).

The interim final rule delays these requirements to “enable our health care system to focus on addressing the COVID-19 PHE”.⁵ In fact, providers and developers need these advances and requirements *now* to provide health care during the pandemic.⁶ Another five months of information blocking only impedes critical care and health information access during the pandemic. As the Cures Act Final Rule stated, “information blocking is a serious problem” and relief “cannot be further delayed.”⁷ Five more months of barriers to interoperability, impediments to third-party app innovators, and extra effort to access, exchange, and use electronic health information through certified API technology do not help doctors and hospitals provide virtual care across wider settings in this pandemic.⁸ On the contrary, in this pandemic we need these advances more than ever. We acknowledge the significant efforts that the Final Rule entails to improve the nation’s digital health ecosystem for health care. But the benefits far outweigh the burdens. When the interim final rule was first released on October 29, 2020, most if not all of the work to meet the November 2, 2020 deadlines would have been completed. We regret that we have now lost significant momentum at the worst time.

The interim final rule did not identify any new quantifiable costs or benefits due to the rule’s delays. However, the Cures Act Final Rule last May estimated costs and benefits in detail. The net benefit (benefits minus costs, 2016 dollars) is over \$2 billion per year.⁹ Crudely, somewhere between 40-100 percent of that amount is the net economic value—the net economic cost—of the benefits denied patients, providers, etc., by the 5-12 month delays in the interim final rule.

The underlying detail reveals more:

- Benefit of savings to physician time and new efficiencies in care delivery due to new APIs: \$670 million - \$3.4 billion, per year;
- Benefit of interoperability with new APIs on better health care outcomes: \$287 million - \$1.1 billion, per year;
- Benefit of patients’ better access to their health information due to new APIs: \$46 million - \$190 million, per year;
- Benefit of real-world testing for providers: \$99 million - \$493 million, per year;
- Benefit of real-world testing for patients & payers: \$2.6 million - \$26.3 million, per year;
- Benefit of information blocking prohibitions: \$457 million, per year.

⁵ 85 Federal Register at p. 70066; see also pp. 70079-70080.

⁶ [Letter from Aaron Neinstein, Nathaniel Gleason, Mark Savage & Ed Martin, UCSF’s Center for Digital Health Innovation, to Donald Rucker, National Coordinator for Health Information Technology, on United States Core Data for Interoperability version 2](#) (Oct. 22, 2020); [Letter from Aaron Neinstein, Anobel Odisho, Mark Savage & Timothy Judson, UCSF’s Center for Digital Health Innovation, to CMS Administrator Seema Verma on Telehealth and Remote Monitoring Policies in the Proposed CY 2021 Physician Fee Schedule](#) (Oct. 5, 2020); see also Timothy Judson, Anobel Odisho, Aaron Neinstein, Jessica Chao, Aimee Williams, Christopher Miller, Tim Moriarty, Nathaniel Gleason, Gina Intinarelli & Ralph Gonzales, [Rapid design and implementation of an integrated patient self-triage and self-scheduling tool for COVID-19](#), 27 J. Amer. Med. Inform. Ass’n 860 (May 13, 2020).

⁷ 85 Federal Register at p. 25652.

⁸ [Letter from Mark Laret, President & CEO, UCSF Health, to Secretary Alex Azar II, U.S. Department of Health and Human Services](#) (Feb. 18, 2020); [Letter from Michael Blum, Aaron Neinstein, Mark Savage & Ed Martin, UCSF’s Center for Digital Health Innovation, to Donald Rucker, National Coordinator for Health Information Technology](#) (May 24, 2019); Karen DeSalvo & Mark Savage, [The Nationwide Interoperability Roadmap and the ONC’s and CMS’s Proposed New Regulations: Are We Halfway There Yet?](#), Health Affairs (June 25, 2019); see also Mark Savage, Aaron Neinstein & Julia Adler-Milstein, [Measure the Impact of the ONC’s New Interoperability Rules Now](#), Health Affairs (July 7, 2020); Aaron Neinstein, Crishyashi Thao, Mark Savage & Julia Adler-Milstein, [Deploying Patient-Facing Application Programming Interfaces: Thematic Analysis of Health System Experiences](#), 22 Journal of Medical Internet Research e16813 (Apr. 3, 2020); Aaron Neinstein, Mark Savage & Ed Martin, [Electronic Health Record? Comprehensive Health Record? Connected Health Record!](#) (Mar. 13, 2018).

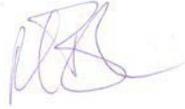
⁹ 85 Federal Register at p. 25938 (Table 30).

In many cases, these benefits reflected reduced avoidable hospitalizations and readmissions, reduced ER visits, reduced adverse drug events, and reduced duplicate testing. There were costs to achieve these benefits, but the *net* benefit, in a pandemic or otherwise, is reduced avoidable hospitalization, reduced ER visits, reduced adverse drug events, and better health outcomes.¹⁰

Conclusion

Thank you for the opportunity to provide these comments on the interim final rule and its impact. UCSF's Center for Digital Health Innovation looks forward to working with the Office of the National Coordinator, providers, vendors, and consumers across the nation to improve interoperability and access, enhance the quality of care, foster trust with patients, bolster meaningful engagement, and improve health outcomes. If you have any thoughts or questions about these comments, please contact Mark Savage at Mark.Savage@ucsf.edu.

Sincerely,



Michael B. Blum, MD
Associate Vice Chancellor, Informatics
Director, Center for Digital Health Innovation



Aaron Neinstein, MD
Director, Clinical Informatics
Center for Digital Health Innovation



Mark Savage, JD
Director, Health Policy
Center for Digital Health Innovation

cc: Steve Posnack, Deputy National Coordinator
Elise Anthony, Executive Director, Office of Policy

¹⁰ 85 Federal Register at pp. 25906-25938.