

Jerry Brown  
Governor



# State Of California OFFICE OF HEALTH INFORMATION INTEGRITY (CalOHII)



April 3, 2015

Office of the National Coordinator for Health Information Technology (ONC)  
U.S. Department of Health and Human Services  
200 Independence Avenue S.W.  
Suite 729-D  
Washington, D.C. 20201

Dear Sir or Madam:

The California Health and Human Services Agency Office of Health Information Integrity (CalOHII) is pleased to provide public comments regarding the ONC Nationwide Interoperability Roadmap, Version 1.0.

CalOHII has statutory authority and responsibility to provide leadership, policy formulation, coordination, and direction for Health Insurance Portability and Accountability Act (HIPAA) implementation and ongoing oversight of State Departments throughout the State of California. Comments have been collected regarding this Notice of Proposed Rulemaking from numerous state departments that are covered by HIPAA.

ONC has correctly identified the challenges facing the eventual widespread adoption of the universal interoperable health record as one of an ecosystem. The Roadmap accurately cites the criticality of interoperability standards that were required for other such ecosystems to eventually become effective<sup>1</sup> (e.g. Automated Teller Machine networks). To this end, the Roadmap document establishes four over-arching actions needed for enabling the ONC's vision.

- a. Establish a coordinated governance framework and process for nationwide health information interoperability.
- b. Improve technical standards and implementation guidance for sharing and using a common clinical set.
- c. Advance incentives for sharing health information according to common technical standards, starting with a common clinical data set.

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<sup>1</sup> *Connecting Healthcare for the Nation: A shared Nationwide Interoperability Roadmap*, The Office of the National Coordinator for Health Information Technology, 1 April, 2015.

[www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version1.0.pdf](http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version1.0.pdf), page 11

<sup>2</sup> *Connecting Healthcare for the Nation: A shared Nationwide Interoperability Roadmap*, The Office of the National Coordinator for Health Information Technology, 1 April, 2015,

[www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version1.0.pdf](http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version1.0.pdf), page 12-13

d. Clarify privacy and security requirements that enable interoperability.<sup>2</sup>

In the 2018 to 2020 timeframe, CalOHII supports a nationwide standardized incident management protocol to respond to and recover from impacts to cyber infrastructure. The ONC has articulated, in the 2015-2017 goals and objectives for this category, the work of the National Institute of Standards and Technology (NIST) Critical Infrastructure Cybersecurity Framework<sup>3</sup> and a potential crosswalk with HIPAA.

The ONC has noted, in the 2015-2017 goals and objectives, closer coordination with the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) on issues related to cyber security. Homeland Security Presidential Directives 5 and 8 created a National Response Framework that promulgated a nationwide response and recovery framework for the coordination of activities amongst divergent participants in the private and public sectors. This was accomplished via the use of Emergency Support Functions (ESF) that catalogued response activities and assets (e.g. ESF #2: Telecommunications and Information Technology, ESF #8: Public Health and Medical Services).

ONC articulates, as 2015-2017 goals and objectives, the continued development of encryption standards for data “in transit” and “at rest”. NIST could be a valuable partner in the promulgation of uniform nationwide standards that support the use of encryption technology amongst divergent actors – especially in the area of encryption certificate validation that supports interoperable networking within a nationwide ecosystem.

The issue of “Trusted Identity” is articulated in the document known as “**Personal Identity Verification Interoperability (PIV) for Non-Federal Issuers**”, issued by the Federal Chief Information Officers Council in May 2009<sup>4</sup>. The ONC Roadmap touches on this area within the discussion of the National Strategy for Trusted Identities in Cyberspace (NSTIC)<sup>5</sup>, a program coordinated by NIST. The bio-pharma industry has leveraged the principles of PIV, NSTIC and the “federal bridge certification authority” to create a validation center known as the SAFE Bio-Pharma system to link stand-alone identity management systems of divergent partners. CalOHII would like to point out SAFE Bio-Pharma as an example of a public-private partnership model although CalOHII is not endorsing it .

Finally, because CalOHII’s role involves oversight of HIPAA-covered State departments, we view reducing governance barriers as another important aspect to achieving the ONC’s vision. Such barriers include:

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<sup>3</sup> *Framework for Improving Critical Infrastructure Cybersecurity Version 1.0*, National Institute of Standards and Technology, 12 February, 2014,  
<http://www.nist.gov/cyberframework/upload/cybersecurity-framework-021214-final.pdf>

<sup>4</sup> *Personal Identity Verification Interoperability For Non-Federal Issuers*, Federal CIO Council, May 2009,  
[https://cio.gov/wp-content/uploads/downloads/2012/09/PIV\\_Interoperability\\_Non-Federal\\_Issuers\\_May-2009.pdf](https://cio.gov/wp-content/uploads/downloads/2012/09/PIV_Interoperability_Non-Federal_Issuers_May-2009.pdf)

<sup>5</sup> *Connecting Healthcare for the Nation: A shared Nationwide Interoperability Roadmap*, The Office of the National Coordinator for Health Information Technology. 1 April, 2015,  
[www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version1.0.pdf](http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version1.0.pdf), pg. 60

- Non-uniform interpretation of the HIPAA Privacy and Security Rules, resulting in non-interoperable “islands” of medical information.
- Clarification – and/or amendment when needed – of HIPAA Privacy and Security Rules to enable and support interoperability.
- Building trust frameworks across multiple participants by the alignment and harmonization of data sharing agreements.

CalOHII believes that coordinated governance framework should go hand-in-hand with technology implementation. Although achieving technical interoperability in sharing data sets is vital, larger governance issues must also be a priority to achieve success.

The Roadmap briefly touches on other national initiatives that have been designed and vetted to create the frameworks that ONC is searching for (see *Connecting Healthcare for the Nation: A shared Nationwide Interoperability Roadmap's* discussion of the National Strategy for Trusted Identities in Cyberspace (NSTIC)).

CalOHII supports the development of specific products, with other organizations that share ONC's vision of an interoperable healthcare ecosystem (such as (1) an improved Security Risk Assessment tool to be modified by the Office of Civil Rights, or (2) a HIPAA crosswalk to the Cybersecurity Framework<sup>6</sup>), and encourages ensuring such products smoothly integrate into a holistic governance framework.

Sincerely,



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<sup>6</sup> *Improving Critical Infrastructure Cybersecurity Executive Order 13636 Preliminary Cybersecurity*, U.S. National Institute of Standards and Technology, 12 February, 2014