

June 21, 2023

By electronic submission

Mr. John Ohanian
Chief Data Officer, California Health and Human Services Agency
Director, Center for Data Insights and Innovation
1215 O Street, 11th Floor MS-08,
Sacramento, California 95814

re: Privacy Standards and Security Safeguards Policy & Procedure, ver. 1.1 (revised June 2, 2023)

Dear Mr. Ohanian:

Thank you very much for the request and opportunity to provide public comment and expertise regarding the draft Privacy Standards and Security Safeguards Policy & Procedure, version 1.1 (“Draft Privacy and Security P&P”), which the Center for Data Insights and Innovation circulated for comment on June 13, 2023. I write to reiterate my prior public comments and strong concern that, under certain provisions of this Draft Privacy and Security P&P, Participants could use conflicting provisions in their Business Associate Agreements (BAA) to trump the requirements of the Data Sharing Agreement and Policies & Procedures. I suggest amendments below.

The Draft Privacy and Security P&P provides in Section III:

- b. Participants who are Covered Entities or Business Associates under the HIPAA Regulations
 - i. If the Participant is a Covered Entity or a covered component of a Hybrid Entity, the Participant shall comply with the HIPAA Regulations as applicable and all other Applicable Law.
 - ii. If the Participant is a Business Associate, the Participant ***shall comply with the provisions of its Business Associate Agreements*** (or for governmental entities relying upon 45 C.F.R. section 164.504(e)(3)(i)(A), its Memoranda of Understanding) and all other Applicable Law. [Emphasis added.]

As I noted during the last joint meeting on June 5, 2023, this is a very real concern, because I know that there are BAAs out there where covered entities prohibit business associates from providing individuals with access to their health information. This conflicts with the Data Sharing Agreement (DSA) and Individual Access Services P&P. The issue reaches throughout the DSA and P&Ps because the DSA understandably defines “Agreement” as an integrated agreement of the DSA and all

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P&Ps, and the DSA requires compliance with all P&Ps, including the Privacy and Security P&P and its explicit requirement to comply with any conflicting provisions of a BAA.

The best solution is not just to delete or change this language of the Draft Privacy and Security P&P, but also to amend the DSA and include a broad provision that Participants shall not include terms in BAAs that conflict with the DSA and P&Ps as amended, and that any such term is void and unenforceable; that Participants shall notify all business associates that any provision in existing BAAs that violates the DSA and P&Ps, as amended, is void and will not be enforced; and that Participants shall then amend the BAAs to remove or void any and all such inconsistent provisions when the BAAs are next modified. This borrows from what ONC did in the Cures Act final regulations in 45 C.F.R. § 170.403(b):

(2) Contracts and agreements. (i) A health IT developer must not establish, renew, or enforce any contract or agreement that contravenes paragraph (a) of this section.

(ii) If a health IT developer has a contract or agreement in existence as of November 2, 2020, that contravenes paragraph (a) of this section, then the developer must amend the contract or agreement to remove or void the contractual provision that contravenes paragraph (a) of this section whenever the contract is next modified for other reasons or renewed.¹

Thank you again for the opportunity to share these thoughts and expertise. If you have any questions, or if I can provide any further help, please contact me at MarkSavage.eHealth@pacbell.net.

Very truly yours,



Mark Savage
Managing Director,
Digital Health Strategy & Policy

cc: DeeAnne McCallin
Courtney Hansen
Johan Frohlich

¹ 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, 25738-25739, 25947 (May 1, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf>.