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March 16<sup>th</sup>, 2020

RE: Draft 2020-2025 Federal Health IT Strategic Plan<sup>1</sup>

Dear Sir or Madam:

In regard to your RFC for the aforementioned Draft Plan please consider the following comments.

- 1) At p 10, as it pertains to patient centered care: HIPAA requirements for access are too restrictive, see 45 C.F.R. § 164.524 (b)(1), to allow seamless interchange of protected health information. For example, in order to exchange information between two covered entities 45 C.F.R. § 164.524 (b)(1) may require *written* access request of the sending entity. In an analogous fashion I exchange money between two banking entities without written consent to the sending bank. A similar system must be available for true interoperability of protected health information. A reasonable remedy would be to modify C.F.R. Title 45, Part 164, Subpart E, so as to facilitate this use case. You could cite the 21<sup>st</sup> Century CURES Act in this regard, as these HIPAA privacy regulations in-and-of-themselves cause information blocking, to which this Act specifically rules against. I would recommend that one of your strategic goals is to form a task force that will review the current HIPAA legislation and recommend to Congress those areas of change where facilitation of interoperability can benefit without compromising patient information.<sup>2</sup>
- 2) At p 11 – as it pertains to interoperability: Many vendors claim interoperability of records now exist<sup>3</sup>, but this is not the case – images cannot be exchanged, and in most cases reports of imaging, pathology, laboratory studies, office notes, surgical procedures and so on, cannot be exchanged<sup>4</sup>. True interoperability and exchange would substantially reduce the cost of medical care by reducing unnecessary duplicate testing spawned either by lack of access to reports, or more importantly, an inability to personally review the images associated with the report.<sup>5</sup> Adopting a central repository

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<sup>1</sup> [https://www.healthit.gov/sites/default/files/page/2020-01/2020-2025FederalHealthIT%20StrategicPlan\\_0.pdf](https://www.healthit.gov/sites/default/files/page/2020-01/2020-2025FederalHealthIT%20StrategicPlan_0.pdf)

<sup>2</sup> PL 114-255, December 13, 2016, 130 Stat 1033 §3002(a)

<sup>3</sup> <https://www.cnbc.com/2020/01/22/epic-ceo-sends-letter-urging-hospitals-to-oppose-hhs-data-sharing-rule.html>

<sup>4</sup> In addition to being unable to exchange images and imaging reports, basic medical records exchange is unusable. Medical records are currently exchanged and imported as "large blobs". Other than prescriptions, patient history and conditions, past surgeries, immunizations, allergies, and test results are not distributed in a readable manner to the appropriate location in the new EMR. This is no more interoperable than a paper scan.

<sup>5</sup> Most physicians would want to personally look at image sets rather than use a report of that image to treat or diagnose. Consider a CT scan of a lung showing a mass, and the patient seeks care at another institution for surgery. The surgeon will not use the report of the CT scan to localize surgery, they will use CT – and if no CT is available for review, they will repeat the examination at an unnecessary expense to the payer and unnecessary radiation burden to the patient.

link (hub-and-spoke) of all images (as is done Canada, Austria, and others) should be a central core part of your strategy<sup>6</sup>.

- 3) At p 13, Goal 1a: (see ¶ 1 supra), to meet this goal changes in HIPAA privacy regulations are required. Also be aware that over ¼ of the United States population does not have a smartphone thus limiting access to their records and to the value of this goal<sup>7</sup>. One could argue that those without a smartphone represent patients who have the highest need for effective interoperability (elderly, socioeconomic disadvantaged). Your strategy should deemphasize individual access to records for these reasons and instead should emphasize facilitating access of protected health information between covered entities and providers (see ¶1 and 2 supra) who provide care to these individuals.
- 4) At p14, Goal 1c: a major failure of all current EHR implementations is the lack of bidirectional ambulatory order entry. As a result, untenable patient safety issues exist for ordering longitudinal studies (especially imaging studies) in the ambulatory environment.<sup>8</sup> While EHR implementation of pharmacy ordering in an ambulatory environment works through a central hub-spoke system (Surescripts) no such system exists for computerized order entry. I would recommend that the goals in 1c be revised to include a hub-spoke model for bidirectional order entry (perhaps in partnership with CMS and third party payers). I would further recommend that regulations be established to require the prompt adaptation of IHE scheduled workflows for all United States actors (ordering and performing) as a template for this process. This should be one of your core goals with immediate priority.
- 5) At p15, Goal 2a: This priority, while important, should be deemphasized save the 7<sup>th</sup> bullet, "Promote interoperability..." until as which time EHR systems act to improve patient safety and reduce staff and provider burdens.
- 6) At p 16, Goal 2c: The document should more clearly identify the actual means that ONC proposes to reduce regulatory burdens given that these burdens are outside of their jurisdiction and reside with CMS and HHS.
- 7) At pp17-18, Goal 3: this is important work but should be deemphasized until EHR systems can meet patient safety goals (see ¶4) and reduce provider and staff burdens for documentation.

Respectfully submitted.



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<sup>6</sup> <https://link.springer.com/article/10.1007/s10278-019-00294-0>

<sup>7</sup> <https://www.statista.com/statistics/201183/forecast-of-smartphone-penetration-in-the-us/>.

<sup>8</sup> See *AMRHEIN v. ECLINICAL WORKS, LLC*, D Mass 3/26/2019, wherein Plaintiffs brought action against Defendant, *inter alia*, "... the ECW software either dropped the order or failed to populate the appropriate screens through which orders are communicated and tracked", and as a result Amerhein died with failure to diagnose as a result.