Policy Action Items for "Crossing the Health IT Chasm"

Immediate actions can be taken by policymakers and stakeholders to cross our current health IT chasm. As outlined in the recently published "Crossing the Health IT Chasm," policymakers should focus on liberating data for patients, improving interoperability for clinicians, and enhancing the capacity for research and innovation to impact patient care. Below are specific policies to consider:

Improve patients' access and use of their data

Immediately

HHS should clarify the HIPAA "right to access"[1] includes a right to all data maintained by a covered entity's designated record set;[2] or, to a digital copy of their legal medical record through guidance by the Office of Civil Rights.

Immediately

ONC should develop certification requirements alongside provider attestation that patient data is transmittable in a manner that preserves computability. One potential approach is to amend certification, which prohibits the use of the "unstructured document," template as part of the CCDA, and require vendors to develop an import/export functionality for all data maintained electronically, making computable records access easier for patients and less burdensome for providers.[3]

Near-term

Efforts to allow research participants to have access to their data and their results, as articulated by the Precision Medicine Initiative – renamed to the All of Us Research program – must continue to develop.[4] This effort can and should be used as a testbed for new technologies and new policies. For example, patient identification and matching will be a required to ensure that patient data contributed to the program belongs to the right patient and it will be required to return research results to those that want results.

On the Horizon

Increasingly patients are using mobile apps, wearables and social media communities to monitor and manage their health. Non-covered entities or NCEs are poised to handle more patient data, and there are very few controls or norms around how mHealth solutions handle patient data, or what protections such solutions should provide. Congress would be smart to skate to where the puck is heading by investigating this issue as outlined in a recent ONC report[5] in the near-future.

Improve interoperability and clinical utility of patient data

Immediately

Encourage continued adoption of 2015 Edition Certified Health IT so that standards-based APIs, published in the public domain, become a standard feature and can continue to be deployed by providers.[6] Additionally, efforts by ONC to support standards development and harmonization through its Tech Lab[7] must continue.

Near-term

Encourage partnerships among specialty societies, informatics experts, standards developers and health IT developers to develop more robust APIs, and leverage the National Library of Medicine to house and manage such works for others to use.[8]

Immediately

Aggressively pursue alternative payment models through Medicare and Medicaid that have demonstrated benefits to cost and quality outcomes.[9]

Near-term

Invest Agency for Healthcare Research & Quality (AHRQ) funds to conduct research on clinical documentation and pilot alternatives to evaluation and management (E&M) coding through the CMS Innovation Center (CMMI) as outlined in Section 941 of the Medicare Modernization Act of 2003.

Enhance the capacity for research and innovation to impact patient care

Immediately

Make effective Common Rule revisions as finalized in the January 19, 2017 issue of the Federal Register.[10] There are numerous provisions of that final rule that will facilitate secondary research with EHRs and other health IT.[11,12,13]

Immediately

Develop the trusted exchange framework and common agreement outlined in the 21st Century Cures Act,[14] and include extensions of that framework to include provisions for research.

Near-term

Establish a public-private partnership to develop an application and mHealth vetting process that ensures a minimum level of privacy, security, safety and effectiveness. Such an effort could be sustained by making participation in such evaluations a "clinical practice improvement activity" under CMS's Quality Payment Program.[15]

1. 45 CFR §164.524(c)(2)(ii)
2. 45 CFR § 164.501
3. 45 CFR § 170.205
4. https://www.nih.gov/research-training/allofus-research-program
5. https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf
6. 45 CFR 170.315(g)(8)
7. https://www.healthit.gov/techlab/
8. https://www.nlm.nih.gov/
9. https://qpp.cms.gov/
10. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 12 (January 19, 2017)
11. §___.116(d) discussion beginning 82 Fed. Reg. 12, page 7216
12. §___.104(d)(4) discussion beginning 82 Fed. Reg. 12, page 7191
13. §___.109(f) discussion beginning 82 Fed. Reg. 12, page 7205
14. PL114-255 Sec. 4003(b)(9)(E)
15. https://qpp.cms.gov/measures/ia

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