



December 16, 2019

The Honorable Diana DeGette  
US House of Representatives  
2111 Rayburn House Office Building  
Washington, DC 20515

The Honorable Fred Upton  
US House of Representatives  
2183 Rayburn House Office Building  
Washington, DC 20515

Dear Congresswoman DeGette and Congressman Upton:

Thank you for the opportunity to provide input on Cures 2.0.

The American Health Information Management Association (AHIMA) is the national non-profit association of health information management (HIM) professionals. Serving 52 affiliated component state associations including the District of Columbia and Puerto Rico, AHIMA represents over 103,000 health information management professionals with the mission of empowering people to impact health. AHIMA's credentialed and certified HIM members can be found in more than 40 different employer settings in 120 different job functions—consistently ensuring that health information is accurate, timely, and complete.

We applaud your efforts to advance nationwide interoperability and data exchange as part of the 21<sup>st</sup> Century Cures Act and appreciate your continued bipartisan commitment to building upon the success of the Cures Act. We offer the following input for consideration:

### **HIPAA Non-Covered Entities**

With the impending finalization of the Office of the National Coordinator for Health Information Technology (ONC)'s "21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification" rule, AHIMA continues to be concerned that the existing regulatory landscape lacks sufficient privacy and security guardrails to protect health information held by entities not covered by HIPAA.

According to a 2016 report from the ONC, there are many health-related technologies that exist and operate outside of the scope of the Health Insurance Portability and Accountability Act (HIPAA.)<sup>1</sup> While these health-related technologies produce and manage individually identifiable health information, they are not bound by or required to abide by the rules established under HIPAA because they are not considered "covered entities" or "business associates."

As a result, patients and consumers may be unaware that once they authorize a covered entity and/or business associate to share their information with a third-party application (app) and such an entity is not covered by HIPAA, the rights and protections attached to HIPAA, (including limitations on the sale, use, and reuse of protected health information (PHI) by third parties, breach notification, and a patient's

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<sup>1</sup>Examining Oversight of the Privacy & Security of Health Data Collected by Entities Not Regulated by HIPAA, Available at: [https://www.healthit.gov/sites/default/files/non-covered\\_entities\\_report\\_june\\_17\\_2016.pdf](https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf).

right to access their data) no longer apply. Patients may also be largely unaware of how an app and/or app developer intend to use their health information, leaving them at the mercy of an app developer's terms of service and/or privacy policy unless an act on the part of the app developer meets the "unfair or deceptive acts or practices" standard under the Federal Trade Commission (FTC) Act or violates state law. This lack of transparency and oversight is increasingly cause for concern. A recent cross-sectional study of 36 top-ranked apps for depression and smoking cessation revealed that only 16 apps described secondary uses.<sup>2</sup> 81 percent of the 36 apps transmitted data for advertising and marketing purposes to two commercial entities, Google and Facebook, but only 43 percent transmitting data to Google and 50 percent transmitting data to Facebook disclosed this.<sup>3</sup> Failure to provide appropriate, transparent privacy and security practices could invite opportunities for "bad actors" to enter the market and potentially use such sensitive data for nefarious activities.

In our [comments](#) to ONC regarding the proposed information blocking rule, we recommended that ONC develop attestation criteria as part of its certification criterion, allowing app developers to attest "yes or no" to the following: (1) industry recognized guidance such as [Xcertia's™ mHealth App Guidelines](#), (2) transparency statements and best practices including the [Federal Trade Commission's Mobile App Developers: FTC Best Practices](#) and/or the [CARIN Alliance's Code of Conduct](#), and (3) the adoption of either [ONC's Model Privacy Notice](#) or a notice in plain language with substantially the same content as described in ONC's Model Privacy Notice. While voluntary, if an app developer were to attest "yes," a health IT developer could in turn whitelist the app for use.

**Should ONC fail to include attestation criteria in its final rule, we urge that as part of Cures 2.0, Congress instruct ONC to include such criteria as part of its certification criterion.** Such criteria would not interfere with a clinician's use of application programming interface (API) technology and enhance the protection of a patient's health information once it leaves the HIPAA regulatory space. We also believe that such a requirement is consistent with enabling patients' access to their health information "without special effort" as required by the 21<sup>st</sup> Century Cures Act.

### **Patient Identification**

Since 1998, outdated rider language has remained in the Labor, Health and Human Services, and Education and Related Agencies (Labor-HHS) Appropriations bill that prohibits the US Department of Health and Human Services (HHS) from spending any federal dollars to promulgate or adopt a national unique patient identifier (UPI). Due to narrow interpretation of this language, efforts have been stymied at the national level to develop a national strategy to address the challenge of patient identification.

Today, there is no consistent approach to accurately match a patient to their health information, which has led to significant costs to hospitals, health systems, physician practices, long-term, post-acute care (LTPAC) facilities, and other providers. According to a 2016 study of healthcare executives, misidentification costs the average healthcare facility \$17.4 million per year in denied claims and lost revenue.<sup>4</sup> Another study indicates that patient misidentification costs the US healthcare system over \$6

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<sup>2</sup>Huckvale K, Torous J, Larsen ME. Assessment of the Data Sharing and privacy Prices of Smartphone Apps for Depression and Smoking Cessation. *JAMA Netw Open*. 2019; 2(4): e192542.

doi:<https://doi.org/10.1001/jamanetworkopen.2019.2542>

<sup>3</sup>Id.

<sup>4</sup>2016 National Patient Misidentification Report, Available at:

[https://pages.imprivata.com/rs/imprivata/images/Ponemon-Report\\_121416.pdf](https://pages.imprivata.com/rs/imprivata/images/Ponemon-Report_121416.pdf).

billion annually.<sup>5</sup> Lack of a consistent and accurate approach to patient identification has also hindered the advancement of health information exchange across the care continuum. A 2017 study by the American Hospital Association indicates that 45 percent of large hospitals reported that difficulties in accurately identifying patients across health information technology (health IT) systems limits health information exchange.<sup>6</sup>

Failure to accurately identify and match a patient to their health information also raises significant patient safety concerns. Patient identification errors frequently occur during the registration process and can create a cascade of errors for patients including wrong-site surgery, delayed or lost diagnoses, and wrong patient orders. In 2017, one of the nation's leading patient safety organizations, the ECRI Institute, named patient identification as one of its top ten patient safety concerns.<sup>7</sup>

Accurate patient identification is not only essential to coordination of care and a requirement for health system transformation but also a critical, common-sense step Congress could take to help reduce healthcare costs.

As you know, the 21<sup>st</sup> Century Cures Act included a provision for the US Government and Accountability Office (GAO) to study patient matching approaches and related challenges and to identify efforts to improve patient matching. **We ask that Congress build upon this important work and consider legislative solutions to address the challenge of patient identification to ensure that patients are accurately identified and matched to their health information.** Such legislative solutions could include repealing the existing ban on the promulgation or adoption of a UPI and directing the ONC and/or the Centers for Medicare and Medicaid Services (CMS) to lead and contribute to efforts to advance creative, innovative, and effective approaches to addressing patient identification nationwide. These agency efforts could include the creation of a set of voluntary agreed-upon metrics to evaluate algorithm performance across the industry, the creation of a set of metrics developed in part by ONC, CMS, and industry stakeholders to evaluate database duplicate rate, duplicate creation rate, and true match rate, and the adoption of well-tested demographic data standards as part of the US Core Data for Interoperability (USCDI) to enhance patient matching.

### **Coding for Innovative Therapies**

Section 503 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires the Secretary of Health and Human Services to provide for the addition of new diagnosis and procedure codes on April 1 of each year (in addition to October 1). In implementing this criterion, CMS established the following criterion: "if a clear and convincing case is made that the new code is needed to capture new technology, this new code may be implemented on April 1 of the following year." The "clear and convincing" criterion has meant there needs to be public support that the benefit of implementing a new code on April 1 outweighs the challenges, costs, and administrative burdens of making system changes and other changes to implement new codes more than once a year beyond October 1. It is important to note that since implementation of this "clear and convincing" criterion, no codes for new technologies have been implemented on April 1.

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<sup>5</sup>Black Book survey, Available at: <https://blackbookmarketresearch.newswire.com/news/improving-provider-interoperability-congruently-increasing-patient-20426295>.

<sup>6</sup>AHA, *Trendwatch: Sharing Health Information*. Available at: <https://www.aha.org/system/files/2018-03/sharing-health-information.pdf>.

<sup>7</sup>Top 10 Patient Safety Concerns for Healthcare Organizations, Available at: [https://www.ecri.org/EmailResources/PSRQ/Top10/2017\\_PSTop10\\_ExecutiveBrief.pdf](https://www.ecri.org/EmailResources/PSRQ/Top10/2017_PSTop10_ExecutiveBrief.pdf)

AHIMA has long held that if a new service or technology represents a new procedure, a unique ICD-10-PCS code should be created. However, if a new service or technology represents an item, substance, drug, or device, as opposed to a procedure, a new ICD-10-PCS code should not be created. We believe it would be an inappropriate use of ICD-10-PCS to begin incorporating specific items, substances, drugs, or devices into this coding system. If it is necessary to specifically identify specific items, substances, drugs, or devices under the hospital inpatient prospective payment system, we recommend that a separate methodology be used to identify these items, rather than attempting to incorporate them into ICD-10-PCS. For example, in our recent comments to the ICD-10 Coordination and Maintenance (C&M) Committee meeting held in September 2019 regarding ICD-10 code proposals, we reiterated our long-held belief that CMS should consider using a drug terminology such as National Drug Codes (NDC) for new technologies involving drugs, versus creating drug administration codes in ICD-10-PCS. Such an approach would avoid the duplication of existing drug terminologies with another set of drug codes in ICD-10-PCS. Furthermore, reliance on a drug terminology like NDCs could allow the information to be pulled from the electronic health record (EHR) without it being a part of the process of coders assigning ICD-10 CM/PCS codes.

In the past, AHIMA has recommended to CMS that to be fair and consistent to all entities submitting code proposals, the agency should develop criteria for an ICD-10-PCS code to be established for a new service or technology. These criteria should take into consideration the multiple uses of coded data, including the value to researchers, payers, and other users in collecting data on the performance of the procedure. **We welcome the opportunity to share our coding expertise and experience on this critical issue as you seek to further enhance patients' access to innovative therapies.**

We thank you for the opportunity to submit comments on this important legislation and for your continued leadership on these crucial matters. Should you or your staff have any additional questions or comments, please contact Lauren Riplinger, Vice President, Policy and Government Affairs, at [lauren.riplinger@ahima.org](mailto:lauren.riplinger@ahima.org), (202) 839-1218.

Sincerely,



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AHIMA