233 N. Michigan Ave.,21st Fl. Chicago, IL 60601-5800

phone » (312) 233-1100 fax » (312) 233-1090 web » www.ahima.org



July 15, 2021

Representative Diana DeGette US House of Representatives 2111 Rayburn House Office Building Washington, DC 20515 Representative Fred Upton US House of Representatives 2183 Rayburn House Office Building Washington, DC 20515

RE: 21st Century Cures 2.0

Submitted via email to Cures2@mail.house.gov

Dear Representatives DeGette and Upton:

Thank you for the opportunity to provide feedback on the 21st Century Cures 2.0 draft legislation. The past year the coronavirus pandemic has shown the increasing need for investing in our health system, and we applaud your continued leadership in this area.

AHIMA is a global nonprofit association of health information (HI) professionals. AHIMA represents professionals who work with health data for more than one billion patient visits each year. AHIMA's mission of empowering people to impact health drives our members and credentialed HI professionals to ensure that health information is accurate, complete, and available to patients and clinicians. Our leaders work at the intersection of healthcare, technology, and business, and are found in data integrity and information privacy job functions worldwide. AHIMA members also bring the expertise and knowledge around health information and data that is necessary to inform investments in our healthcare system, including data modernization, patient identification and access, public health, social determinants of health (SDOH), and privacy.

We appreciate the commitment to addressing challenges within the healthcare system. To ensure a robust bill that meets the needs of patients, providers, public health, and research, AHIMA suggests some critical areas of focus below that we feel would strengthen this already forward-looking piece of legislation.

Section 102 – National Strategy to Prevent and Respond to Pandemics

We are pleased to see the prioritization of developing a national strategy to prevent and respond to pandemics and other health emergencies. As a strong proponent of increased interoperability and improved data quality during this pandemic, AHIMA believes that attention must be given to the harmonization of data across local, state, federal, tribal, and territorial levels, as well as the need for improved methods of data collection. Without the best quality data possible, our responses to public health emergencies will always be less than ideal. Even once we have that data, if we are unable to share it in an effective and timely manner across all levels of public health surveillance, we will be unable to fully address public health needs. Pandemics do not stop at jurisdictional lines, nor should our data flow.

Therefore, AHIMA recommends the following addition to Section 102(b)(2) on p. 5, lines 4-6:

- Add the words "collection and" before "sharing."
- Add the words "across federal, state, local, tribal, and territorial systems" after the word "sharing."

The final Section 102(b)(2) would read: "Methods of data collection and sharing across federal, state, local, tribal, and territorial systems to use testing to inform surveillance and other pandemic monitoring and response efforts."

Section 202 – Increasing Health Literacy to Promote Better Outcomes for Patients

AHIMA applauds the inclusion of Section 202, focusing on health literacy. As we increasingly have more interoperable information technology systems and patients have better access to their electronic health information, we must make sure that patients are not only able to understand their own health but be empowered to make decisions about their health and healthcare, including understanding their health plan coverage and payment.

We are pleased to see the emphasis on identifying culturally competent and evidence-based interventions. We would recommend two additions to the language in this section.

In Section 202(2)(B), on p. 50, lines 10-13, we recommend inserting the words "and/or outcomes," so that the language reads "have been proven to increase patient satisfaction, or improve the quality of care and/or outcomes for at risk populations, including holistic and non-medication-based forms of care." Working toward improved outcomes should be a key component of increased health literacy, and including this language strengthens that goal.

The second recommendation falls in In Section 202(4), on p. 50, lines 20-24. While ensuring patients understand the differences between various payors, it is also important that patients understand the differences in plans offered by the same payor. A single payor may have multiple plan options available, such as Health Maintenance Organization (HMO) plans and Preferred Provider Organization (PPO) plans. Our recommendation is to insert the words "plans within the same payor, and between different" on lines 23-24, so that it reads: "(4) improving patient health literacy with respect to health insurance, including an understanding of in-network providers, deductibles, co-insurance, co-payments, and differences between plans within the same payors, and between different payors."

Accurate Identification of Patients

AHIMA echoes the recommendation of the Patient ID Now coalition and requests the following language be inserted into the bill:

AMENDING THE SOCIAL SECURITY ACT TO REQUIRE THE DEVELOPMENT OF A STRATEGY FOR UNIQUE IDENTIFICATION OF PATIENTS

(a) It is the intention of the Congress to amend the Social Security Act in order to give the Secretary authority to adopt a national strategy for accurate patient identification and matching that may consist of one or multiple solutions, including but not limited to patient-empowered solutions, unique identifiers, demographic data standards, referential matching standards, or other solutions.

- (b) Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is therefore amended by striking the word "individual" in Section 1173(b)(1) and inserting the following:
 - "(b): UNIQUE HEALTH IDENTIFIERS

(2) IN GENERAL—The Secretary shall adopt a national strategy providing for the accurate unique identification of each individual for use in the healthcare system.

(3) In carrying out the preceding item, the Secretary shall take into account the goal of improving accurate identification and match rates, standardization, patient privacy and security, interoperability, data quality, patient access, and any other area the Secretary deems necessary.

(4) USE OF PATIENT IDENTIFICATION STRATEGY—The strategy or standards adopted under paragraph (2) for unique identification of individuals shall specify that the purpose for which the patient identification strategy may be used are limited to healthcare-related purposes."

The 21st Century Cures 2.0 Act aims to modernize several parts of our current healthcare system, including our public health systems, and the Centers for Medicare and Medicaid Services (CMS). Yet as the US healthcare information systems becomes increasingly interoperable, including between payers, plans, providers, and public health surveillance systems, patient misidentification is a consistent barrier to realizing the promise of interoperability. Now is the time to ensure that patient records are complete and accurate to facilitate increased patient safety, patient privacy, and public health efficacy.

Section 402-403 – Telehealth Provisions

AHIMA is pleased to see the focus on expanding access to and support for telehealth in this legislation. In Section 402, the focus on providing technical assistance and best practices within the Medicaid and Children's Health Insurance Program (CHIP), and the requirement for the provision of a study on the impact of telehealth will bolster the healthcare system's use of evidence-based practices in providing care.

With respect to providing technical assistance and best practices, AHIMA recommends the inclusion and prioritization of privacy and parity of care and services. We request the inclusion of these items in Section 402(a)(1) so that it reads: "(1) existing strategies States can use to integrate telehealth and other virtual health care services into value-based healthcare models, including strategies on protecting patient privacy, patient access, and ensuring parity of care between in-person and virtual care and services."

In Section 403, AHIMA is also supportive of the elimination of originating site restrictions, the expansion of providers that can provide telehealth services, and the expansion of types of services that can be reimbursed under Medicare. We appreciate the attention to these issues and applaud the inclusion of these provisions.

Section 404 – Coverage and Payment for Breakthrough Devices Under the Medicare Program

AHIMA appreciates the attention to coding in this legislation, especially on the issue of breakthrough devices. However, we have identified some areas of concern relating to the assignment of codes to these devices.

On p. 87, lines 9-16, the language states "Prompt Assignment – Not later than three months after the date of approval or clearance of a breakthrough device by the Food and Drug Administration, the Secretary shall assign a unique temporary or permanent code or codes for purposes of coverage and payment for such breakthrough devices under the applicable payment systems."

Related, on p. 88, lines 12 - 15, the language states "Transparency – The process for the assignment of a code or codes under this subsection shall provide for public notice and a meaningful opportunity for public comment from affected parties."

AHIMA is concerned about the proposed timeline for the development of temporary or permanent codes. Three months is not long enough to obtain public comments, evaluate those comments, finalize a code or codes, and provide adequate time for providers and vendors to incorporate the new code(s) into their systems. Currently, the ICD-10 Coordination and Maintenance Committee which is responsible for updating the ICD-10-PCS code set meets twice per year, with a public comment period following each meeting. Assigning a temporary or permanent code for breakthrough devices outside of the existing code set process is problematic because it hinders the ability to provide a meaningful opportunity for all affected stakeholders to comment and it would be administratively burdensome for the healthcare industry to implement new codes on an inconsistent, fluctuating, and unpredictable schedule. Rather, we believe new ICD-10-PCS code sfor procedures involving breakthrough devices should be created through this existing ICD-10-PCS code update process.

Section 409 – Biometrics

In Section 409, as biometrics is one component that could affect a strategy around the issue of patient identification, AHIMA is concerned with the potential that this may limit hospitals' ability to identify patients using biometrics, a potential piece of a broader patient identification strategy. AHIMA requests clarifying language that this section would not prohibit a hospital or provider from using biometrics to identify patients for purposes of treatment, payment or healthcare operations as defined by the Health Insurance Portability and Accountability Act (HIPAA).

AHIMA thanks Representative DeGette and Representative Upton for their leadership in strengthening our health system and for the opportunity to provide feedback. We look forward to working with you to ensure a healthcare system that fulfills the needs of patients and provides health systems the support they need to do so. Should you or your staff have any additional questions or comments, please contact Kate McFadyen, Director, Government Affairs, at <u>kate.mcfadyen@ahima.org</u> or (202) 480-6058.

Sincerely,

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Wylecia Wiggs Harris, PhD, CAE Chief Executive Officer