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Submitted Electronically to [cures2@mail.house.gov](mailto:cures2@mail.house.gov)

The Honorable Diana DeGette  
U.S. House of Representatives  
2111 Rayburn House Office Building  
Washington, DC 20515

The Honorable Fred Upton  
U.S. House of Representatives  
2183 Rayburn House Office Building  
Washington, DC 20515

Dear Representatives DeGette and Upton:

The Federation of American Hospitals (FAH) writes to express our appreciation for your efforts that led to the enactment of the *21<sup>st</sup> Century Cures Act* in 2016 and to commend you for initiating the “Cures 2.0” process.

The FAH is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching full-service community hospitals in urban and rural parts of America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. We share your commitment to a modernized health care delivery system that unleashes the promise of digital technologies and data to empower patients, their families, and health care providers to improve their health and health care. As such, the FAH offers the below comments and recommendations regarding oversight of continuing implementation of the *21<sup>st</sup> Century Cures Act*, as well as future opportunities.

### **Congressional Oversight of *21<sup>st</sup> Century Cures Act* Implementation**

The FAH encourages continued Congressional oversight of the Administration’s implementation of the *21<sup>st</sup> Century Cures Act*. The proposed rule released earlier this year by the Office of the National Coordinator for Health Information Technology (ONC) advances many of the Congressional priorities contained in the *21<sup>st</sup> Century Cures Act*, such as the use of application programming interfaces (APIs), more robust electronic health record (EHR) certification requirements, and policies addressing EHR vendor business practices. The FAH appreciates these policies and looks forward to their continued implementation.

The FAH is concerned, however, that the Administration’s implementation of another Congressional priority – curtailing information blocking – will not be effective or implementable due to vague, overly broad proposed definitions and exceptions as well as a lack of clarity regarding the interaction of the information blocking proposals with HIPAA and state privacy and security laws. The FAH urges Congress to ensure that these provisions are implemented in such a way that they are both understandable and achievable.

More detail regarding the FAH’s concerns and recommendations can be found in the FAH comment letter in response to the ONC Proposed Rule.<sup>1</sup>

## **Interoperability Considerations for Cures 2.0**

### *Implementation ROI*

As you develop interoperability and health IT policies for potential inclusion in a Cures 2.0 package, the FAH urges you to first evaluate the impact and implementation burden of current policies (i.e., “implementation ROI”) and then use those findings to guide future efforts. For example, the implementation of the meaningful use program was difficult for all stakeholders. While it did increase the number of health care providers using EHRs, that progress came at a significant cost – in both time and money – to the government and to health care providers. We encourage you to evaluate the “implementation ROI” of the *21<sup>st</sup> Century Cures Act* and the *HITECH Act* in determining what policies to pursue in Cures 2.0.

### *Beyond EHRs*

To date, much of the interoperability focus in Congress and the Administration has been on the exchange and use of information between health information networks (HINs) and between EHRs. While EHR-to-EHR and HIN-to-HIN exchange is an important piece of the interoperability puzzle, it is not sufficient to achieve comprehensive interoperability, which involves health IT beyond EHRs and HINs. As such, the FAH urges Congress to consider policies that would advance information exchange throughout the health care system, including during an episode of care to care transitions to an applications-based marketplace and to ensure those policies align with private-sector led efforts that are already underway to advance other components of the interoperability puzzle, such as plug-and-play interoperability among devices and systems.<sup>2</sup>

### *Patient Identity and Record Matching*

Stakeholders across the health care continuum have identified the lack of patient identity and record matching as a critical hinderance to achieving robust, accurate, and safe data sharing and utilization. The FAH supports efforts to remove the appropriations rider impacting the

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<sup>1</sup> FAH comment letter Re: 21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule (June 3, 2019), available at: [https://www.fah.org/fah-ee2-uploads/website/documents/060319\\_ONC\\_Proposed\\_Rule\\_-\\_FAH\\_LETTER\\_-\\_FINAL.pdf](https://www.fah.org/fah-ee2-uploads/website/documents/060319_ONC_Proposed_Rule_-_FAH_LETTER_-_FINAL.pdf).

<sup>2</sup> Center for Medical Interoperability, *Fact Sheet*, available at: <http://medicalinteroperability.org/wp-content/uploads/2017/01/CMI-Overview-Jan2017.pdf>.

Administration's ability to develop or adopt a unique patient identifier (UPI) and urges you to consider this important issue in any Cures 2.0 package.

## **Advancing the Use of Digital Health Technologies**

### *Telehealth*

Telehealth is pivotal to bringing personalized care to rural America, and the FAH agrees with your assessment that coverage and reimbursement are essential factors in realizing the potential of these important digital technologies. New technological advancements can increase timely access to patient-centered care, enhance patient choice and, through early intervention, can help prevent long-term, costly health events for many Americans who call rural America home.

As the utilization of telehealth continues to grow, the FAH believes that such modalities should be reimbursed by Medicare, Medicaid, private insurance, and other payers at the same level as when those services are delivered in person.

As policymakers consider opportunities to improve the delivery of services via telehealth, the FAH recommends the following principles to guide future legislative and regulatory activity:

- Reimburse medical and behavioral health services that can be appropriately delivered via telehealth technology at the same level as when those services are delivered in person
- Support efforts for providers to participate in multi-state telemedicine programs
- Continually update originating site restrictions as new technologies develop with the goal of eliminating originating site restrictions in order to make telehealth services available to patients where most convenient for them
- Ensure access to telehealth services for all patients, whether in rural, suburban, or urban areas by removing geographic restrictions
- Ensure the reimbursement does not discriminate based on the technology and encourage the use of real-time secure bi-directional audio and video, home health monitoring technologies, store-and-forward technologies, and other synchronous, asynchronous, and remote monitoring technologies
- Encourage states to broadly adopt telehealth services in state Medicaid programs through Federal oversight of the Medicaid program
- Ensure that health care providers and practitioners engaged in the delivery of services via telehealth continually strengthen safeguards that ensure the privacy and security of patient data.

### *Broadband Internet*

Using telehealth in rural areas expands access to and improves the quality of health care millions of Americans receive. However, there is often a lack of infrastructure in place to achieve the expansion of telehealth – namely, a lack of broadband internet. While broadband is used in everything from agriculture to education, expanding rural America's access to reliable internet service is pivotal to increasing access to quality health care for rural communities.

While not under the Committee’s jurisdiction, the Federal Communications Commission’s (FCC) Connected Care Pilot Program, designed to support the delivery of telehealth services to low-income Americans, is an example where the definition of a provider – as determined by the Rural Health Care Program (RHCP) - would make investor-owned hospitals ineligible for participation in the Connected Care Pilot Program. This lack of parity unjustly penalizes patients living in rural communities across the United States that are served by an investor-owned hospital.

### **Harnessing the Power of Data**

In an increasingly connected and data-rich world, the key to improving health care delivery and health more broadly lies in harnessing, analyzing, and utilizing this data in ways that advance these goals while ensuring patient safety, as well as the privacy and security of such data.

#### *FDA Draft Guidance re: Clinical Decision Support (CDS) Software*

As you will recall, Section 3060(a) of the *21<sup>st</sup> Century Cures Act* amended the Federal Food, Drug, and Cosmetic Act (FDCA) to exclude certain CDS software functions from the statutory definition of a medical device. This provision is meant to prevent the over-regulation of certain rapidly-evolving technologies with the potential to transform the way we use information to facilitate and improve patient care, provided those technologies satisfy four criteria enumerated in the statute.

The FDA issued revised Draft Guidance on September 27, 2019, and the FAH has multiple concerns with the FDA’s proposed interpretation of the criteria in the statute. First and foremost, the Draft Guidance purports to substantively interpret and expand upon the statutory criteria set forth in the *21<sup>st</sup> Century Cures Act* in opposition to both the plain language of that Act and the procedural requirements under the *Administrative Procedures Act*. The FAH believes that, if implemented in its current form, the Draft Guidance will likely stifle critical innovation, and ultimately cause patient harm by impeding the development of CDS algorithms.

The FAH will be submitting comments to the FDA regarding the Draft Guidance in the coming days and will provide your staff with a copy for review.

#### *Data Privacy and Security*

The FAH has long supported patients’ rights to access their health care information under HIPAA and believes the HIPAA Privacy and Security Rules provide important protections for patients and their providers regarding the exchange of protected health information (PHI). The FAH agrees that it is an individual’s prerogative to specify where and to whom to send their information. The FAH does not agree, however, that individuals understand how the information they are sharing will be used and monetized.

As ONC and the Centers for Medicare & Medicaid Services (CMS) implement provisions of the *21<sup>st</sup> Century Cures Act* and generally work to advance interoperability and patient access to data,

the FAH remains concerned by the lack of data privacy and security protections, particularly with regard to non-HIPAA-covered third-party applications.

As you know, most third-party applications are not governed by the HIPAA security and privacy requirements. Unfortunately, most patients and their families do not know that such applications fall outside of HIPAA protections. The FAH believes that ONC, CMS, the Office for Civil Rights (OCR), and the Federal Trade Commission (FTC) should undertake a joint campaign to educate patients about the differences between HIPAA and non-HIPAA-covered entities and how those differences may affect the ways in which their data is used, stored, and shared with others.

In addition to patient education, the FAH believes there is a need for an industry-supported vetting / certification process for non-HIPAA covered third-party applications and other products to ensure they are: a) meeting all relevant security standards; b) using data appropriately and in line with consumer expectations – and informing consumers of those data uses; and c) clinically sound (for those applications that offer medical advice). The vetting process results should be made public in the form of an application “safe list.”

More detail regarding the vetting process can be found in the FAH comment letter in response to the recent ONC Proposed Rule.<sup>3</sup>

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The FAH looks forward to working with you and your staff throughout the Cures 2.0 process. If you have any questions regarding our comments, please do not hesitate to contact me or Erin Richardson on my staff at (202) 624-1500.

Sincerely,



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<sup>3</sup> See FAH comment letter re: ONC Proposed Rule.