Federation of American Hospitals®

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President & CEO

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Chairman Fred Upton
House Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

Ranking Member Frank Pallone
House Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Upton and Ranking Member Pallone:

The Federation of American Hospitals and the more than 1000 hospitals we represent appreciates the opportunity to comment on the May 13th draft of the *21st Century Cures Act*. The FAH applauds the work of the Committee in its efforts to develop legislation to accelerate the development of medical innovation that could provide cures for millions of Americans. Further, we appreciate the thoughtful process the Committee undertook to develop these policies including engaging with stakeholders and consumers over the last year.

Below are our comments on key sections of interest to America's hospitals. The FAH and our caregivers see promise in many of the proposals contained in the draft legislation. It is our hope these comments provide critical direction to the Committee as the legislation proceeds.

However, the FAH has significant concerns and would strongly object to any cuts to hospitals payments to pay for any component of this legislation. Since 2010, more than $140 billion in cumulative cuts have been imposed on hospitals. These continued cuts jeopardize the ability of hospitals to deliver the care seniors expect and deserve, and the health care security all Americans count on hospitals to provide. The cuts hospitals must already absorb contributes to record-low Medicare hospital margins, projected by MedPAC to reach negative nine percent this year. While we welcome legislation to speed access to critical cures, further cuts to Medicare hospital payments would be counterproductive by threatening access to care.

Detailed Comments on Key Sections

Section 1124 – Accessing, Sharing, and Using Health Data for Research Purposes

Section 1124 would amend the following sections of the HITECH Act:

Sec. 13442

Section 13442 appears intended to ensure that covered entities are permitted to make certain disclosures of protected health information ("PHI") for research purposes. The FAH supports this end goal, and believes that it is important to empower covered entities and business associates to be able to use existing data sources to achieve quality assurance and improvement goals, and to engage in data-driven research. This can aid in controlling health care costs and developing and instituting quality of care improvements.

Sec. 13443

The FAH generally supports Section 13443(a) to allow the sale of PHI for research purposes. This provision would encourage more research, which in turn contributes to improved quality of care and controlling health care costs.

The FAH, however, has concerns about the breadth of the language in Section 13443(b). This provision appears to allow covered entities to broadly share PHI, as part of research activities, including comparative research activities, related to the quality, safety, or effectiveness of a product or activity regulated by the Food and Drug Administration ("FDA"). This section appears to connect FDA jurisdiction to quality improvement and comparative effectiveness research, which raises some confusion about the intent of the provision because these functions do not currently rest under the FDA's jurisdiction. Therefore, we are unclear regarding the end goal of Section 13443(b), and urge the Committee to consider whether this provision could be drafted in a manner that is more transparent, as well as more narrow and targeted in its approach.

Sec. 13444

The FAH generally supports Section 13444. It would update the existing HIPAA "preparatory to research" pathway rules, which require that the reviewed PHI may not be removed from the covered entity that maintains the PHI. This "on premise" rule is outdated, and Section 13444 appears intended to reflect the current digital health environment, in which covered entities often have cloud-based and business associate-based storage and data access modalities. The FAH is concerned, however, that the language in Section 13444 is somewhat vague, and therefore we urge the Committee to consider revising the language to ensure that this provision allows researchers to remotely access PHI that exists in cloud storage and other similar remote storage areas. The FAH participates as a member of the Confidentiality Coalition, and we support the specific recommendations that the Coalition has offered to the Committee concerning this provision.

Sec. 13445

The FAH supports Section 13445. This provision allows a one-time authorization, under certain circumstances, for the use and disclosure of PHI for future research purposes. This appears to

codify current practice, and is important for reducing administration burden and promoting health care research activities.

Section 2061 – Broader Application of Bayesian Statistic And Adaptive Trial Designs

This section of the proposed legislation calls for modernizing trial design and evidence development through the application of innovative statistical models and more adaptive trial designs. The FAH supports the direction and intent of the draft language that permits the use of these innovative models so that the most appropriate statistical method could be used depending on the research and what the data indicates. In particular, our members believe that allowing broader application of alternative statistical models will assist in analyzing the increasing number clinical trials and the resultant increase in targeted therapies. In our view, the legislative language protects patients while more quickly moving promising research through the approval process.

Section 2121 – Approval Of Certain Drugs For Use In A Limited Population Of Patients

The FAH commends the Committee's work on developing creative and streamlined processes for new antimicrobial pharmaceutical products. The development of new antimicrobial products will assist in treating patients with rare or intractable diseases. We encourage the Committee to ensure any new regulatory drug development/approval framework includes an emphasis on patient safety and adequate patient testing prior to final approval.

Section 3001 – Ensuring Interoperability

The FAH has been, and continues to be, a strong supporter of the HITECH law. Our member hospitals recognize that interoperable Certified EHR Technology ("CEHRT") can be a conduit for having the right information in the right place at the right time, resulting in better care for patients. CEHRT also can facilitate greater access to critical information for non-clinicians, empowering patients (and their caregivers) to assume a more active role in their health care to achieve patient centered care.

However, we have encountered various problems on the road to establishing interoperability, and have not yet achieved "macro" interoperability – the movement of patient information outside the walls of a facility. Macro-interoperability is happening in pockets of the country, but certainly not on the scale Congress envisioned when it passed the HITECH.

Steps can be taken to promote greater macro-interoperability, especially those business practices that run contrary to the spirit of HITECH. For example, vendors should be held accountable for delivering a quality product, on time, and at a reasonable cost. The vendor community must bring HIT products to market that have the capability to allow data needed for care to seamlessly follow the patient across care settings. We remain concerned that vendor incentives are not aligned with provider requirements. This lack of alignment has resulted in vendor business practices that actively stifle interoperability, including closed networks and assessment of fees per transactions and for interfaces. Increasing the rigor of the certification program would be one potential avenue to drive greater vendor accountability.

Further, the Office of the National Coordinator for Health Information Technology ("ONC") should facilitate and invest resources in field testing with vendors and providers. The "lab testing" approach currently used in the EHR certification program does not account for the conditions in a real-world clinical environment. Developing standards, such as HL-7 FHIR, hold promise, but should not be mandated until they have been fully field tested.

Another area of focus is the high level of variability that currently exists in health IT functionality and implementation, which significantly inhibits advancing interoperability. This comes in many forms, such as lack of a standard patient ID algorithm, inconsistent implementation of electronic clinical quality measures, conflicting state privacy and security requirements, and variable standards implementation. The federal government has a critical role to play in promoting and driving standardization in some of these areas.

We commend the Committee for including in its latest draft of the *21st Century Cures Act* a new section addressing interoperability (Section 3001), including provisions that address some of the principles discussed above. Given the breadth and scope of the specific language included in Section 3001, we look forward to analyzing this section further and working with the Committee to develop appropriate incentives on a timely basis that effectively advance the health care community on the road to interoperability.

Section 3021 – Telehealth Services Under the Medicare Program

This section would require the CMS and Medpac to undertake analyses to be submitted one year after enactment that would advise the Congress on paths to proceed on telehealth. The FAH appreciates the efforts of the Committee to advance the use of telehealth. Telehealth services clearly improve access to health care, increase health care quality, and advance health care efficiency.

Expanding the scope of telehealth services with respect to covered services, eligible providers, and geographic reach will allow patients, particularly patients in underserved areas, to access care more quickly. It will enable health care providers to more quickly assess their patients' medical conditions and in particular, further improve health care delivery for chronic illnesses. Expanding telehealth services also can improve efficiency by reducing emergency room visits, hospital readmissions, and deterring unnecessary and expensive "in-person" patient visits.

It is our hope that any new policy in this area would eliminate restrictions such as originating site and geographic location restrictions, presume that all Medicare-covered telehealth services are 100 percent reimbursable, and provide coverage for "store and forward" and remote patient monitoring technologies. In addition, any new policy should apply to both Medicare and Medicaid to maximize the impact of a telehealth provision and create consistency on this issue across public payers.

Section 3081 - Improvements in the Medicare Local Coverage Determination Process

This section would improve transparency of local Medicare Administrative Contractors' ("MAC") local coverage determinations by requiring public website posting of standard information related to those coverage determinations. The FAH supports this provision, particularly with regard to the requirement for public posting of MAC responses to comments submitted on proposed local coverage determinations. We question whether a 180-day delayed effective date is necessary with regard to this process, and suggest considering modifying the effective date to the date of enactment.

Section 3121 - Medicare Site of Service Price Transparency

This section would require HHS to publish the cost to both the federal government and to patients of an appropriate number of Medicare-covered items and services furnished in hospital outpatient departments ("HOPDs") and ambulatory surgical centers ("ASCs"). The FAH has long supported transparency initiatives, provided they result in information that is meaningful and actionable for consumers. While the goals of this section are laudable, the FAH is concerned that it could result in information being provided to Medicare beneficiaries that is at least confusing and potentially misleading.

First, the bill should clarify what is meant by "cost." The FAH believes that cost should mean the payment that the Medicare program will make to the provider and the cost sharing its beneficiaries will be responsible for related to the services. Cost should not mean charges, which often do not reflect the actual payment amount.

By fostering transparency of cost information from both HOPDs and ASCs, we presume part of the bill's objective is to create comparable information for Medicare beneficiaries. However, given the way that the different payment systems for HOPDs and ASCs package services and bundle payments, a true "apples-to-apples" comparison can be challenging, even for keen observers of the systems. We believe this provision should go further to require HHS to ensure that Medicare beneficiaries receive this cost information in a form where the prices for the different sites of service are presented in an accurate and most easily comparable way to limit confusion and potential misleading information. For this cost information to be most meaningful and actionable for beneficiaries, the comparability of the mix of service should be as close and accurate as possible.

Again, we thank you for this open and transparent process which allows the hospital community weigh in on these critical issues. Please do not hesitate to contact me should you have any questions.

Sincerely,

