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May 12, 2015

The Honorable Fred Upton
Chairman
U.S. House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Re: 21st Century Cures Discussion Draft

Dear Chairman Upton:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) is pleased to offer comments on your 21st Century Cures Discussion Draft released April 30. The discussion draft outlines a series of proposals to accelerate and improve the discovery, development and delivery of new cures and treatments to patients.

We applaud the committee for engaging in extensive conversations with patients, providers, researchers, consumers and other stakeholders to identify better ways to accelerate the discovery of new cures and improve health care innovation. While the AHA supports the intent of the draft bill, we are concerned that many of the policies would require new – and potentially extensive – funding. We urge the committee to specifically identify and delineate financing for the proposals, including whether “new” money would be used or whether the proposals would be “budget neutral.” **The AHA strongly objects to any reductions to hospital payments to pay for any of the provisions in the discussion draft.**

The AHA supports that the bill would eliminate current barriers to information sharing needed in more clinically integrated settings, such as accountable care organizations. We also appreciate the committee’s attempt to relax the Health Insurance Portability and Accountability Act (HIPAA) medical privacy regulations to allow greater access to hospital and health care provider data for purposes of research, but are concerned that the discussion draft is too broad in its use and disclosure of personal health information. We urge the committee to ensure an appropriate level of protection for the security, integrity and accessibility of these data. Hospitals take seriously the trust patients place in them to maintain confidentiality.



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We also are concerned that the discussion draft would require the publication of Medicare pricing information for services furnished in hospital outpatient departments and ambulatory surgery centers. While we support the intent of this provision, it could provide a limited and misleading picture of the total price of a given item or service.

Importantly, the discussion draft contains placeholder language for proposals related to interoperability and telemedicine. The AHA supports sharing health information across patient care settings and views this information exchange as vital to care improvement. On April 16, the Medicare Access and CHIP Reauthorization Act of 2015 was adopted, establishing a number of new interoperability requirements for health care providers. Additional requirements imposed on providers are not necessary, and could result in limiting provider flexibility and innovation. If the committee chooses to legislate further in this area, we urge it to focus on developing policies that ensure vendors are accountable for designing and supporting interoperable products.

Similarly, telemedicine allows health care providers to connect with patients and consulting practitioners across geographic areas. Given advancements in this technology and the changing health care landscape, we urge the committee to modernize Medicare coverage and payment for telemedicine to eliminate “originating site” requirements as well as expand the types of covered services, including “store-and-forward” technologies and remote patient monitoring.

Our detailed comments on the discussion draft are attached. We look forward to continuing to work with the committee as it further refines and updates the discussion draft. If you have any questions, please contact Ashley Thompson, vice president and deputy director of policy, at (202) 626-2688 or athompson@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President

American Hospital Association (AHA) Detailed Comments

TITLE I: DISCOVERY

Title I of the discussion draft addresses funding for the National Institutes of Health (NIH) and includes provisions to strengthen the agency's mission, improve accountability, streamline processes and remove barriers in support of expanded research. The draft also includes provisions to foster collaboration and sharing of data within the nation's health care system.

The AHA commends the committee's efforts to strengthen the nation's basic research enterprise and believes this will enhance the development of innovative and promising scientific research to improve human health. Academic medical centers and teaching hospitals provide an environment in which such research can flourish.

Provisions of special interest or concern for hospitals and health care systems are discussed below.

Accessing, Sharing and Using Health Data for Research Purposes (Sec. 1124). The draft language would permit wide-ranging access to protected health information (PHI) held by hospitals and other Health Insurance Portability and Accountability Act (HIPAA)-covered entities under the guise of research. Specifically, it would require the Secretary of Health and Human Services (HHS) to revise the HIPAA regulations to define use and disclosure of PHI for research as a HIPAA-permissible use/disclosure for health care operations. Such broader access to PHI also would extend to research activities related to the quality, safety or effectiveness of a Food and Drug Administration (FDA)-regulated product or activity, including comparative research. The proposal would require a revision of the regulations to make disclosure of PHI for such purposes a permissible use and disclosure for public health purposes. The revision would eliminate the existing restriction that the disclosure be to only "a person subject to the jurisdiction of the FDA" for the explicit purposes of adverse event reporting; tracking of FDA regulated products; recalls, repairs or replacement; and post-marketing surveillance.

In addition, the bill would require a revision of the current regulation to permit remote access to PHI by researchers engaging in activities "preparatory to research." Additionally, it would ensure that the current limitation in the HIPAA privacy rule, which is that no PHI be removed from the covered entity by the researcher, does not foreclose accessing data remotely when the researcher maintains "appropriate security and privacy safeguards" and does not "copy or otherwise retain" the data. The bill would incentivize covered entities to open up access for researchers to the patient information they hold in trust by authorizing the commercial sale of data (currently, a covered entity can charge only a reasonable fee to cover the actual costs for preparation and transmission of the data to a researcher, if consistent with HIPAA restrictions on the use and disclosure of patient information the researcher is even permitted to have access to patient-specific data).

The AHA appreciates that the bill would eliminate the barriers the current HIPAA privacy rule poses for robust information sharing for clinical care improvement in an environment where accountable care organizations (ACOs) and other multi-stakeholder entities

permeate the landscape in support of value-based purchasing. Under the current rule, the use and/or disclosure of PHI for another hospital's or health care provider's health care operations is permissible only when both the disclosing and receiving entities have – or have had – a relationship with the particular patients whose information is shared, and only for activities that expressly qualify as quality assessment and improvement. These could include outcomes or the evaluation of provider qualifications, competence or performance. The challenge that such a strict regulatory prohibition poses in the integrated care setting is that, frequently, patients do not have a relationship with all of the providers among whom information should be coordinated. Where a direct patient relationship does not exist for all providers that are part of the clinically integrated setting, the current rule requires providers to follow an administratively cumbersome process to permit information sharing. Without greater regulatory flexibility for the use and disclosure of PHI that would support clinical integration, HIPAA stands as a barrier to the clinically integrated care settings, the foundation for achieving the goals of health care reform. Moreover, achieving the meaningful quality and efficiency improvements that a clinically integrated setting promises requires that all participating providers be able to share and conduct population-based data analyses.

The AHA supports the elimination of the current rule's requirements that would prevent or inhibit undertaking robust population-based analyses in a clinically integrated setting that are essential to improving the quality of care, creating better patient outcomes, and making health care delivery less expensive, more efficient and easier to navigate for patients and providers alike. We believe that the HIPAA medical privacy regulation should permit PHI to be used by and disclosed to all participating providers in an integrated care setting without requiring that individual patients have a direct relationship with all of the organizations and providers that technically "use" and have access to data that meets the rule's definition of PHI. An appropriate level of protection for the security, integrity and accessibility of the patient information exchanged across the participating providers in the clinically integrated setting would continue to be ensured by the standards and obligations imposed by the HIPAA security rule. If it is determined that there is a need in limited special circumstances to ensure greater confidentiality and privacy protection for an individual patient's information, the PHI used and disclosed in an integrated care setting could be stripped of all direct individual patient identifiers.

While the bill restricts research disclosures to other covered entities and certain business associates of covered entities, we are concerned that it facilitates and encourages overly broad access to patient-specific data for undefined research purposes at the expense of undermining the trusted relationship between patients and their providers. We also are concerned that the requirement for researchers to maintain security and privacy safeguards in order to remotely access the PHI of a covered entity is unspecified and undefined in the bill. The bill's endorsement of researchers' access to PHI remotely comes at the expense of unnecessarily increasing cybersecurity vulnerabilities and risks for the information systems of covered entities and significantly raising liability exposure for covered entities.

TITLE II: DEVELOPMENT

Title II of the discussion draft includes a broad range of proposals to expedite and improve the Food and Drug Administration's (FDA) review and approval of new drugs, biologics and medical devices. These include drugs and devices for unmet needs and rare diseases, breakthrough technologies, products that benefit limited populations and new antimicrobial and antifungal drugs.

The AHA supports the committee's intent to foster the development of new treatments and cures and to incorporate patients' perspectives into the development process. While faster access to a wider range of drugs treatments and medical device technologies is expected to benefit our patients, we urge the committee to proceed with caution to ensure that expedited FDA review and approval does not compromise drug and device safety and effectiveness, thus putting patients at risk. Further, while we support many of the proposals in Title II, it is unclear how they will be paid for. Clearly, additional resources and funding for FDA will be necessary in order to support the agency's ability to carry out the many new responsibilities and prepare the numerous guidance documents mandated in the discussion draft. The AHA would object strongly to any reduction in hospital payments being used as a way to pay for these provisions in this legislation.

An additional concern is the rising cost of prescription drugs. In 2013, the U.S. health care system spent more than \$80 billion on specialty drugs, which cost on average 37 times as much as traditional drugs. Specialty drugs currently represent only 1 percent of all U.S. prescriptions but make up more than 31 percent of drug spending, and are expected to increase to 44 percent of overall drug spending by 2017. Annual price increases are equally, if not more, troubling given the tendency for manufacturers to raise prices of specialty drugs far in excess of inflation. At a time when hospitals and other health care providers and payers are trying to hold the line on health care costs, these pricing trends are unsustainable, especially given that federal programs, including Medicare and Medicaid, will ultimately bear the brunt of skyrocketing drug prices.

This trend needs to be considered by Congress and health policymakers, and potential solutions must be considered, as the current environment is not containing drug pricing, while drug costs continue to take greater percentages of scarce Medicare and Medicaid program resources.

Provisions of special interest or concern for hospitals and health care systems are discussed below.

Additional Payment for New Antimicrobial Drugs under Medicare (Sec. 2123). This section would provide for an additional payment under Medicare Part A with respect to patient discharges involving new antimicrobial drugs. The additional payment would be based on average sales price and would apply to certain new antimicrobial drugs to treat infections that are associated with high morbidity/mortality and for which there is an unmet medical need. As drafted, it is not clear whether this provision would be implemented in a budget-neutral manner – that is, whether the additional funding would require reduction of inpatient prospective payment system (PPS) payments to maintain budget neutrality. **While the AHA supports efforts to encourage the development and responsible use of new antimicrobial drugs, we encourage the committee to state explicitly in the discussion draft that “new” additional money**

outside the current DRG system will be used to provide this additional payment. The AHA strongly objects to any reductions in hospital payments to pay for this provision.

Sensible Oversight for Technology Which Advances Regulatory Efficiency (Subtitle M, Sections 2221 to 2223). This subtitle addresses FDA regulation of health information technology (IT) products. Specifically, Section 2221 creates a definition for the new category of health software that Sec. 2223 then excludes from the definition of a medical device, thereby removing it from FDA oversight. Under Sec. 2221, health software would include software that meets a six-part definition that includes administrative or financial information support software or software that facilitates the movement, aggregation or storage of clinical information. Existing medical device software would not be considered health software.

While the AHA appreciates the need for a nimble approach to regulating technology, we are concerned that the draft language derived from the Sensible Oversight for Technology Which Advances Regulatory Efficiency (SOFTWARE) Act would limit the scope of FDA too extensively to ensure patient safety. We believe a risk-based analysis that considers clinician reliance on the accuracy of data is more appropriate for determining the need for FDA review rather than a categorization of data by their source or one intended use of the data. In addition, such a narrow approach to safety oversight of products could leave hospitals with liability for safety issues resulting from technology problems.

In Section 2222, the draft legislation exempts health software from FDA regulation with one exception. In the one exception, health software could be regulated by FDA if it is intended to analyze information to provide patient-specific recommended options for the prevention, diagnosis, treatment, mitigation or cure of a disease or condition. Sec. 2222 also establishes six criteria that the Secretary shall consider when determining if health software poses a significant risk to patient safety and, therefore, should not be eligible for an exemption from regulation. Specifically, the Secretary would consider the following: (1) the likelihood and severity of patient harm if the product were to function improperly; (2) the clinical significance of the information or recommendations supplied by the product; (3) the extent to which the product is intended to replace the clinical judgment of a medical professional; (4) whether a review of the means by which the product performed with respect to a particular disease or condition could be reasonably performed by a medical professional; (5) whether there is a means to independently evaluate and verify the accuracy of the product's analysis; and (6) the intended use of the product, intended user and user environment. **The AHA is concerned that, as drafted, analysis of any one of these criteria could be considered sufficient to exempt a product from regulation. Rather than taking an approach that relies on categorical definitions of software functionality, we believe a risk-based analysis that considers clinician reliance on the accuracy of data is more appropriate for determining the scope of FDA regulation of software.**

TITLE III: DELIVERY

Title III of the discussion draft offers proposals to improve the delivery of treatments and cures to patients. The draft includes placeholder language for two key policies of significant interest to

hospitals and health systems – interoperability and telemedicine. Our comments on other proposals are discussed below.

Interoperability (Sec. 3001). America’s hospitals strongly support the creation of an efficient and effective infrastructure for health information exchange that supports the delivery of high-quality, patient-centered care across health care settings. AHA members are actively engaged in building their information infrastructures and view information exchange as vital to care improvement, as well as to successful implementation of new models of care. As the primary purchasers of electronic health records (EHRs), we have a vested interest in purchasing systems that support our growing information-sharing needs. Yet, hospitals and health systems report that the EHRs purchased during the past five years do not easily share information. Furthermore, the cost and complexity of the many interfaces needed to connect systems today are not sustainable. Similarly, the new transaction fees being imposed for information exchange also present an unsustainable model for widespread sharing of health information.

Hospitals and health systems face an increasing confluence of pressures to share information to support care, but need the technical capabilities and infrastructure to do so. The Medicare and Medicaid EHR Incentive Programs already include regulatory requirements to share information. In addition, hospitals must share information across the continuum of care in support of reducing readmissions and adopting new models of care. Increasingly, consumers expect that their information will follow them as they move through the health system, including settings as diverse as individual provider offices, general and specialty hospitals, skilled nursing facilities and other post-acute care providers, and behavioral health providers, among others. Individuals and their family members or other caregivers also are coming to expect electronic access to such information. Furthermore, new payment models, such as ACOs, bundling initiatives and capitation arrangements, require a better understanding of where patients are receiving care, and what care is being provided.

In that context, we note that the interoperability language included in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), establishes a new requirement for health care providers to make an affirmative attestation to the government that they have not taken steps to limit the interoperability of their EHRs as part of the requirements to meet meaningful use and avoid payment penalties through the Medicare EHR Incentive Program. This provision is effective April 16, 2016. **The combination of existing pressures on providers to share information, as well as the new measures in the MACRA, already make clear the need for providers to share information. Additional levers imposed on providers are not necessary and could have unintended consequences by limiting provider flexibility and innovation.**

The MACRA also declares interoperability of EHRs a national objective, establishes an expectation that the country will achieve widespread interoperability by Dec. 31, 2018, and directs the Secretary to establish interoperability metrics, in consultation with stakeholders, no later than July 1, 2016. If interoperability is not achieved in a timely manner, the Secretary must submit a report to Congress by Dec. 31, 2019, on remaining barriers and recommendations for achieving interoperability. Recommended actions may include increased penalties under the Medicare EHR Incentive Program and decertification of EHRs. The AHA is committed to

working with the Secretary on implementation of these provisions, as well as on improvement of the data and technical standards that are the underpinning of interoperability.

As the committee considers whether it needs to develop additional language on interoperability, we recommend a focus on policies that hold vendors accountable for the design and marketing of interoperable products. At a minimum, the Office of the National Coordinator for Health Information Technology (ONC) must fix the certification program for EHRs so that vendor products go through rigorous testing in a way that reflects real-world conditions. ONC also should provide more oversight of vendors, including developing transparency metrics on vendor performance parallel to the many quality reporting programs HHS has implemented for providers, such as *Hospital Compare*. The MACRA directs ONC to conduct a study of the feasibility of establishing a website or other mechanism to assist providers in comparing and selecting certified EHRs. We believe, however, that much greater transparency of vendor activities is needed and ONC should act quickly to provide it.

Beyond certification, federal support of widely available conformance testing would improve the ability of vendors and providers to create solutions that work particularly with the involvement of the National Institute of Standards and Technology (NIST). It is only by thorough and widely available testing that true interoperability can be ascertained. In the EHR space, testing should include both the EHR itself, as well as interfaces to ancillary systems (such as laboratory information systems) that connect to EHRs. Test beds should be widely available to developers and end-users of EHRs on an ongoing basis to support development, certification and assessment of implementations. Testing requirements should be developed in consultation with providers – the end-users of the products tested. We recommend including the NIST in any plans to develop test beds. NIST has significant expertise in helping craft industry consensus on standards and developing methods to test standards conformance.

Finally, the issue of how to match patients with their medical records remains unresolved despite the continued push for interoperability on a national scale. The need to resolve this problem is urgent, and **the AHA recommends the creation of a nationally unique identifier system to connect records so that hospitals and physicians have the best information available when providing care for each patient.** Such a system would facilitate efforts to increase the safety and quality of care given to patients and reduce unnecessary spending by hospitals and other providers to use less-effective and duplicative approaches to identify patients and match records.

Telemedicine (Sec. 3021). We encourage the committee to offer a comprehensive telemedicine proposal. Telemedicine (also known as telehealth) increasingly is vital to our health care delivery system, enabling health care providers to connect with patients and consulting practitioners across vast distances. Hospitals are embracing the use of telehealth technologies because they offer benefits such as virtual consultations with distant specialists, the ability to perform high-tech monitoring without requiring patients to leave their homes, and less expensive and more convenient care options for patients. According to AHA survey data, in 2013, 52 percent of hospitals used telehealth and another 10 percent were beginning the process of implementing telehealth services.

Telehealth offers great promise for health care patients and providers, yet significant barriers to expansion remain, limiting health care access for many patients. Coverage and payment for telehealth services remains a major obstacle for providers seeking to improve patient care through telehealth technologies. Medicare, in particular, lags far behind other payers due to its restrictive statutes and regulations. Though the Medicare telehealth benefit was originally created to increase access to care in rural areas, telehealth technologies increasingly are useful regardless of geographic location – for example, to fill gaps in subspecialist care. Further, telehealth can allow a patient to connect with a primary care physician or health system on a more flexible basis and often without an in-person visit.

Given the growing body of evidence that telehealth increases quality, improves patient satisfaction and reduces cost, we urge the committee to adopt a global approach to expanding Medicare coverage of telehealth. In order to modernize Medicare coverage and payment for telehealth, any legislative proposal should:

- **Eliminate geographic location and practice setting “originating site” requirements.** By statute, Medicare covers telehealth only for beneficiaries receiving services at an originating site listed in law, such as a hospital, skilled nursing facility or physician office. In addition, the originating site must be located in a rural area. As our nation’s telecommunications systems continue to improve, it is becoming increasingly possible to provide care safely to patients in other settings, including, potentially, the office, school or home. Further, while Medicare beneficiaries in rural areas may not have easy access to primary care or specialist services, patients in urban areas also face challenges due to physician shortages.
- **Expand the basis of covered services.** Today, the Centers for Medicare & Medicaid Services (CMS) approves new telehealth services on a case-by-case basis, with the result that Medicare pays for only 75 services when they are delivered via telehealth. This process should be simplified, such as by a presumption that Medicare-covered services also are covered when delivered via telehealth, unless CMS determines on a case-by-case basis that such coverage is inappropriate.
- **Include services provided via store-and-forward technologies and remote patient monitoring as covered services.** Store-and-forward technologies provide access to patient data after they have been collected, and are particularly beneficial to patients requiring specialty care when providers are not otherwise available locally. Remote patient monitoring involves collection of a patient’s personal health and medical data via electronic communication technologies. Once collected, the data is transmitted to a health care provider at a different location. This allows the provider to continue tracking the patient’s data once the patient has been released to his/her home or another care facility.

We encourage you to review two recent AHA reports that highlight hospitals’ use of telehealth technologies to improve access to care, as well as barriers to implementation of telehealth – [“The Promise of Telehealth For Hospitals, Health Systems and Their Communities”](#) and [“Realizing the Promise of Telehealth: Understanding the Legal and Regulatory Challenges.”](#) We look

forward to providing more detailed comments upon review of specific proposal(s) released by the committee in the future.

Exempting from Manufacturer Transparency Reporting Certain Transfers Used for Educational Purposes (Sec. 3041). The Physician Payment Sunshine Act, or “Sunshine Act,” requires manufacturers of covered drugs, devices, biologicals and medical supplies to disclose certain payments or other transfers of value to physicians and teaching hospitals. The Sunshine Act includes an explicit exception in the reporting requirements for payments to physicians for continuing medical education (CME) when certain safeguards are in place to prevent a direct financial relationship between the physician and the manufacturer or pharmaceutical company. The discussion draft would add an exception for specific educational materials, such as peer-reviewed journals, journal reprints, journal supplements and medical textbooks. The draft also would create an exception for indirect payments or transfers of value to physicians that serve the sole purpose of providing the physician with medical education, or for speaking at or preparing educational materials for educational events for other physicians that do not promote a specific product. **The AHA supports these exclusions, which are important to ensure that physicians continue to have access to resources and materials that will contribute to their ongoing medical training.**

Medicare Site-of-Service Price Transparency (Sec. 3131). This section would require the HHS to publish, via a searchable website, the price to both the federal government and to beneficiaries of certain items and services furnished in hospital outpatient departments (HOPDs) and ambulatory surgery centers (ASCs) under the Medicare program.

While the AHA is supportive of the intent of this provision, we are concerned that it could provide a limited and misleading picture of the total price of a given item or service. Specifically, under the HOPD and ASC payment systems, Medicare packages the price of many ancillary items and services into the price it pays for a primary service. However, in certain circumstances, Medicare packages different items and services into the primary service under the HOPD vs. ASC payment system. For example, the HOPD payment system pays for certain services using an all-inclusive “comprehensive” rate. However, the ASC payment system pays for these same services on a much more fragmented basis. If HHS were to publish their prices, they would look much higher in the HOPD, but only because they include many more items and services, all of which are paid separately in the ambulatory payment classifications (APC) payment system. The comparison would be inaccurate and misleading.

In addition, Medicare pays separately for physician services. The price of physician services can be substantial, but would not be reflected in the price of the primary service listed on the required website. Thus, users of this site would be armed with price information that is not fully reflective of the actual cost of a service because it would not include the price of physician services.

Establishing Prescription Drug Plan (PDP) Safety Program to Prevent Fraud and Abuse in Medicare Prescription Drug Plans (Sec. 3151). Title III, Subtitle H seeks to reduce fraudulent acquisition of controlled substances. It would require organizations administering PDPs to identify individuals who have obtained coverage for a drug that is frequently abused. The PDPs would need to create a safe pharmacy network to share information on individuals that have been

so identified. The controlled substances in question have known medical uses, and also carry some risk for abuse or potential dependency (Drug Enforcement Administration Schedule II to V drugs, such as codeine, cocaine, hydrocodone, ketamine, chlorhexadol, barbitol and diazepam). When frequent users are identified by the PDP, the PDP must let the individuals know they have been identified as frequent users and limit their access to these drugs. The PDP would have to provide a mechanism for appeal of this identification.

Because America's hospitals care for patients who have suffered painful injuries, are undergoing painful treatments, or who are battling chronic and life-limiting diseases, they deeply understand the need to carefully balance supplying sufficient medications to ease patient's pain and suffering with the risk of a patient becoming addicted or dependent on a drug. Many factors influence the choice of medication, the dosage, and the frequency of administration of medication, and it will be challenging for PDPs to take all of that into account to identify which patients should be included on a frequent users list. Further, if each PDP crafts its own rules to determine which patients belong on such a list, it would create conflicting and confusing protocols that would be difficult for providers and patients.

The AHA urges the committee to consider tasking HHS to work with clinical experts and the PDPs to craft a single protocol for identifying patients whose medication use warrants limitation in such a program. Additionally, we recommend the committee incorporate language that allows HHS to take into account the life expectancy of the patient, the patient's living situation, the length of time the patient has been taking a particular medication and other clinically relevant factors.