

December 16, 2019

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

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

Dear Congresswoman DeGette and Congressman Upton:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to respond to your request for feedback on areas of focus for “Cures 2.0” legislation.

The AHA commends your work on the 21st Century Cures Act, which became law in December 2016. This legislation included many important changes to health information technology (IT) policy, such as taking steps to advance interoperability, adding new certification and transparency requirements for developers of health IT, and taking steps to improve patient access to health records. As you develop Cures 2.0 legislation, we encourage you to, in parallel, continue to conduct thorough oversight of the ongoing implementation of the 21st Century Act.

DIGITAL HEALTH

The AHA appreciates the prioritization of digital health as a mechanism to increase access to quality care. As stated in your document, modernizing health care will require updating coverage and reimbursement for the technologies that support this transformation. We encourage you to address current statutory barriers to using digital technologies in health care delivery, such as telehealth, while also recognizing those reforms must account for the increasingly rapid pace of innovation in the digital health space.

Telehealth expands access to services that may not otherwise be sustained locally. Medicare should cover telehealth delivery for all services that are safe to provide, eliminate geographic and setting requirements, and expand the types of technology that may be used. Payers also should provide payment parity with services delivered in-



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person. Moreover, Congress should pass legislation to facilitate virtual care across state lines and to allow eligible hospitals to pilot and test telehealth services for Medicare patients.

Congress also should address the disparity between the actual cost of providing care at the site where the patient is located (originating site) and the originating site fee. Even in cases where originating sites are eligible to bill Medicare for a telehealth facility fee, rates are marginal compared to the overall costs. Congress needs to ensure adequate reimbursement in the Medicare program for hospitals serving as originating sites.

The AHA [supports](#) passage of the bipartisan, bicameral CONNECT for Health Act of 2019. This includes the expansion of telehealth for mental health services and emergency medical care, along with the ability to waive restrictions on the use of telehealth during national and public health emergencies. This legislation also would appropriately expand the ability of rural health clinics and federally qualified health centers to provide telehealth services.

In addition, access to high quality broadband is a critical enabler for connected health tools. However, according to the Federal Communications Commission (FCC), 34 million Americans still lack access to adequate broadband. The AHA has long-supported full funding of the FCC Rural Healthcare Program as a mechanism for meeting the broadband connectivity needs of rural areas. While we applaud recent efforts by the [FCC](#) and the United States Department of Agriculture ([USDA](#)) to provide more funding opportunities to support telehealth in rural and underserved areas, we urge Congress to appropriate significant federal dollars to ensure every hospital in every community has the broadband infrastructure needed to leverage 21st century technologies in patient care.

OVERSIGHT OF HEALTH IT PROVISIONS IN THE 21ST CENTURY CURES ACT

The AHA broadly supports removing barriers to interoperability that inhibit information sharing. Specifically, we appreciate that Congress prioritized “information blocking” in the 21st Century Cures Act as these practices can prevent providers from having access to critical information needed to support patient care. We further appreciate Congress’ focus on enabling greater patient access to their health information, a goal our members strongly support and have taken key steps to advance over the past several years, including through significant investments in secure patient portals and applications that comply with the privacy requirements under HIPAA.

While we appreciate Congress’ intent, we have significant concerns with the Office of the National Coordinator (ONC) for Health Information Technology’s proposed rule to implement the “information blocking” provisions. The rule contains a number of concerning policies related to definitions, deadlines and documentation requirements that we believe could place significant burden on hospitals and health systems and

have the potential to adversely impact patients. Specific areas of concern addressed in our [comment letter](#) to ONC include:

- The lack of patient privacy protections to account for non-HIPAA covered applications and tools that may misuse or exploit individuals' health information for commercial gain.
- An overly broad definition of electronic health information (EHI), to potentially include price information, that goes well beyond what Congress intended.
- Complex and poorly defined information blocking exceptions that would create significant documentation burden and potentially be in conflict with HIPAA and other laws.
- Unrealistic timelines for enforcement that would leave organizations with no time to ensure they are in compliance.

The AHA urges strong congressional oversight of the ONC's approach to regulating "information blocking" to ensure it does not result in harm to patients and undue burden on providers.

CODING, COVERAGE AND PAYMENT TO SUPPORT ACCESS TO INNOVATIVE THERAPIES

Coverage and Payment. Personalized medicine holds promise to improve well-being and save lives. Gene therapies, such as Chimeric Antigen Receptor T-Cell (CAR T) therapy, have already begun to demonstrate the potential of these technologies to treat certain cancers. However, without appropriate reimbursement in place, the extraordinarily high cost of these therapies – in some recent cases, nearly \$400,000 per case not including patient care – calls their continued access into question. Current payment rates in the Medicare inpatient prospective payment system greatly under-reimburse for these expensive therapies – even when accounting for the available outlier payments for costly cases and add-on payments for new technologies. In addition, as CAR T products and other gene therapies become more widespread, such cases would likely take up a substantial portion of outlier funds, making it more difficult for other high-cost cases to receive these reserved payments. Thus, the AHA remains concerned about beneficiary access to CAR T and similar forthcoming technologies given their costliness. It is clear that the current system does not ensure appropriate rate-setting or payment for CAR T, forcing hospitals and health systems to take on unsustainable losses in order to provide these individualized treatments.

Unless an appropriate payment approach for these costly personalized medicines is created, beneficiary access to these life-saving technologies may be in jeopardy. The need to do this is accelerating given that both new and existing therapies are expected to be approved for additional indications in the coming years. According to the IQVIA

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2019 Global Oncology Report, 24 CAR T therapies are in late-stage development.¹ It is critical that a precedent is set that ensures beneficiary access to care. We look forward to working with the Centers for Medicare & Medicaid Services and other stakeholders to develop a long-term solution.

Coding. To recognize newer technologies in an expedited manner, code creation should be within the rules and existing structure of the HIPAA code sets. There should be a balance between the need for expedited implementation of unique codes to recognize the rapid development of new products and technologies without sacrificing the careful deliberative process to review the merits of code proposals and allow for public comments of both the codes and the potential coverage and payment impacts. The code development process should be broad-based and take into consideration the needs of all users. The process should be predictable and take into account the capabilities of the users to adapt to coding changes when they occur. Proposed code changes should be well publicized and allow for public comments along with a transparent, predictable process for Medicare to evaluate the medical efficacy of the new technology associated with the codes, as well as how payment for that technology is to be reimbursed.

We look forward to working with you as you craft legislation in this area and appreciate your consideration of these issues.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

¹ IQVIA Institute for Human Data Science (May 2019). Global Oncology Trends 2019.
<https://www.iqvia.com/institute/reports/global-oncology-trends-2019>.