December 16, 2019

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

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

Dear Congresswoman DeGette and Congressman Upton:

The Healthcare Leadership Council (HLC) applauds your leadership in consideration of "Cures 2.0" to modernize coverage and access to life-saving cures. We are grateful for your thoughtful bipartisan approach and appreciate the opportunity to comment.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

Digital Health

HLC has been a strong supporter of using new and innovative digital health technologies in the prevention and treatment of disease and to connect providers with patients across various locations to coordinate care. HLC members have seen firsthand the value of digital health services, such as those furnished through telehealth and remote patient monitoring, which make the delivery of healthcare more efficient and effective. Increased access to telehealth can make it easier for providers to treat patients, improve continuity of care, address workforce shortages, and lower healthcare costs.

Although there has been tremendous advancement in telehealth services and technologies since payment for telehealth services was first added to the Social Security Act in 2000, outdated regulatory barriers make it challenging to fully deploy these innovative services and technologies. Collectively, these restrictions are often referred to as "1834(m) restrictions" – and they include: limitations on the type of services provided, geographic location, the type of clinical site the patient is located in, type of institution delivering the services, and type of health provider. Additionally, under Section 1834(m), store-and-forward technology is not

reimbursable except in Alaska and Hawaii, where it is permitted as part of a federal demonstration program.

A 2018 CMS report to Congress cited restrictions under Section 1834(m), such as originating site and geographic restrictions, as some of the greatest barriers to telehealth expansion in Medicare reported by stakeholders.[1] For these reasons, we support the "Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act" (H.R. 4932/ S. 2741). This legislation represents a significant step forward toward enabling patients and providers to utilize the promise of telehealth and remote patient monitoring to improve healthcare quality, value, and patient care.

We are particularly supportive of Section 3 of the "CONNECT for Health Act," which gives the Department of Health and Human Services Secretary direct authority to lift existing 1834(m) restrictions when certain quality and cost-effectiveness criteria are met. HLC believes Congress should work to further expand coverage for telehealth services and that payment for telehealth services always connect to the type of service being provided, not the method by which it is provided, so that providers are able to choose the means that are most effective for each patient.

Real-World Evidence

Real-World Evidence (RWE) is playing an increasing role in healthcare and regulatory decision making. The application of RWE has the potential to supplement the insights obtained through traditionally designed clinical trials and observational studies.[2] Nontraditional sources of patient health data captured through the ever expanding array of health-applications, wearable devices, and internet-based forums can ultimately lead to inferences about the effectiveness of medical treatments and products.[2] Often nontraditional sources of health data are collected and held by entities that are not Health Insurance Portability and Accountability Act (HIPAA) Covered Entities or Business Associates. Individuals may not fully appreciate that health information collected outside of a HIPAA Covered Entity or Business Associate Agreement is not afforded HIPAA privacy and security protections. As health data flows in and out of non-HIPAA covered entities, we believe these entities have a responsibility to take necessary steps to maintain the trust of individuals. However, new regulations are needed to ensure privacy and security of health information collected and held by entities that fall outside of HIPAA. Enclosed you will find the HLC-led Confidentiality Coalition's "Beyond HIPAA" Privacy Principles which convey our views on the protection of health information that is not subject to HIPAA.

Coverage Reform

As a diverse coalition of healthcare stakeholders across the U.S. healthcare system, we believe innovation is essential to deliver pioneering drug and device therapies to the public. Innovations in the treatment of disease have led to transformative, lifesaving therapeutic options for patients

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[1] *Information on Medicare Telehealth*. (2018, November 15). Retrieved https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Information-on-Medicare-Telehealth-Report.pdf

[2] Sherman, R., Anderson, S., Dal Pan, G., Gray, G., Gross, T., Hunter, N., LaVange, L., Marinac-Dabic, D., Marks, P., Robb, M., Shuren, J., Temple, R., Woodcock, J., Yue, L. and Califf, R. (2016). Real-World Evidence — What Is It and What Can It Tell Us?. *New England Journal of Medicine*, 375(23), pp.2293-2297.

whose care needs were previously unmet by contemporary treatments. We believe a high priority should be to avoid impeding access to new medical innovations, but current reimbursement models for some of the most innovative treatments are unsustainable, jeopardizing providers' ability to provide access to such treatments.

For example, Chimeric Antigen Receptor (CAR) T-cell therapies represent a marked advancement in the field of cancer care and have proven to be lifesaving in the treatment of patients with certain types of refractory or relapsed cancers. However, the Centers for Medicare and Medicaid Services' payment polices for CAR-T leaves providers absorbing significant losses when administering CAR T-cell therapies to Medicare patients. If medical centers continue to absorb substantial financial losses on a per-patient basis to treat Medicare beneficiaries with CAR T-cell therapies, the ability to provide access to this lifesaving treatment is at risk.

It is critical that appropriate value-based payment reimbursement models are developed and encouraged to ensure that Medicare beneficiaries have access to life-saving treatments. To that end, HLC is encouraged by the shift to a value-based healthcare system that pays based on value versus volume and believes it is an important step toward addressing access and reimbursement challenges. In a value-based system, payment is tied to patient outcomes and achieving clinical targets. However, the adoption of value-based systems, including for new innovative therapies, has been stifled by laws designed to discourage inappropriate behavior in a fee-for-service payment model. The most notable barriers in our current healthcare system, the physician self-referral law ("Stark Law") and the Anti-Kickback Statute, require modernization as our healthcare system shifts from volume-based care to increasing the value of care. Modernization of federal fraud and abuse laws will enable pro-patient, value-focused collaboration among payers, providers, and manufacturers.

Thank you for the opportunity to comment as you consider Cures 2.0. HLC looks forward to continuing to collaborate with you on ways to modernize access and coverage for life-saving cures. If you have any questions, please contact Tina Grande at (202) 449-3433 or tgrande@hlc.org.

Sincerely,

Mary R. Grealy
President

Enclosure: "Beyond HIPAA" Privacy Principles

Beyond HIPAA Privacy Principles

1. For the last 20 years, the HIPAA Privacy and Security Rules have engendered public trust that individually identifiable health information collected by providers and insurers (HIPAA covered entities) would be disclosed only for health functions like treatment, payment processing, and safety, and not used or disclosed for other purposes without an individual's authorization. Any future legislation or rulemaking that addresses individually identifiable health information should not conflict with HIPAA's Privacy and Security Rules.

    a. HIPAA's required "Notice of Privacy Practices" provides an overview of individuals' rights as well as permitted and required uses and disclosures of identifiable health information.

    b. HIPAA's approach requires use of risk-based administrative, technical, and physical safeguards allowing organizations the flexibility to implement policies and controls commensurate with the level of risks they have identified.

2. Congress should establish a single national privacy and security standard for *all* health information *not* subject to HIPAA. This single standard:

    a. Should not conflict with HIPAA,
    b. Should not disrupt day to day practices for HIPAA Covered Entities and Business Associates,
    c. Should align with HIPAA's definitions of health information, and
    d. Should adopt a risk-based approach like HIPAA.

3. Individuals may not fully appreciate that individually identifiable health information collected outside of a HIPAA Covered Entity or Business Associate Agreement are not afforded HIPAA privacy and security protections. Individuals should be given clear, succinct notice concerning collection, use, disclosure, and protection of individually identifiable health information that is not subject to HIPAA.

4. Individual authorization processes (including revocation of authorization) for use and disclosure of identifiable health information not covered by HIPAA should be written in a meaningful and understandable manner and should be easily accessible to individuals prior to and after information is used or shared.

5. Entities that hold or collect identifiable health information have a responsibility to take necessary steps to maintain the trust of individuals. Entities that are not HIPAA Covered Entities or Business Associates that hold identifiable health information should clearly stipulate the purposes for which they collect, use, and disclose identifiable health information.

6. Individuals must provide authorization for entities outside of HIPAA to collect individually identifiable health information. Such information collected, used or disclosed by entities outside of HIPAA should be limited to only that information needed to accomplish the purposes for data collection. This practice provides privacy protection while allowing for continued innovation.

7. Individuals should be informed of their right to seek redress – from the entity and from regulators – in the case of unauthorized access, misuse, or harm attributable to how their identifiable health information was collected, used or disclosed.

8. Penalties and enforcement must be meaningful in order to discourage misuse and unpermitted collection, use or disclosure of identifiable health information.