May 10, 2018

The Honorable Peter Roskam
Chairman
Subcommittee on Health
Committee on Ways and Means
U.S House of Representatives
Washington, D.C. 20515

The Honorable Sander Levin
Ranking Member
Subcommittee on Health
Committee on Ways and Means
U.S House of Representatives
Washington, D.C. 20515

Dear Chairman Roskam and Ranking Member Levin:

The Healthcare Leadership Council (HLC) appreciates the opportunity to comment on committee efforts to incentivize healthcare innovation to improve the delivery of care. 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 health 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, pharmacies, post-acute care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach. Through this diversity, we develop a nuanced perspective on the impact of any legislation or regulation affecting the delivery and quality of healthcare. We believe value-based transformation will lead to both improvements in quality and safety, and the delivery of high quality coordinated care.

The healthcare industry is constantly changing as technology evolves to help deliver care in a more effective and efficient manner. Healthcare technologies have helped to advance interoperability and increase data access between and among healthcare stakeholders and allow providers to deliver virtual care through telemedicine and remote patient monitoring. Through the use of technology, healthcare stakeholders, can coordinate care more nimbly to deliver better health outcomes. To better coordinate and deliver patient care, the current legal framework must be modernized as our system shifts toward a quality-driven, value-based care.

The Healthcare Leadership Council supports healthcare innovation through the use of the Center for Medicare and Medicaid Innovation (CMMI) demonstration projects, the removal of regulatory barriers to value-based care, such as the Stark Law and Federal Anti-Kickback Statute, the advancement of nationwide interoperability and the use of telemedicine.

CMMI Demonstration Projects

HLC looks forward to seeing new value-based care models proposed by CMMI. As our healthcare system evolves toward value-based care, it is essential to test new ideas that have the potential to make healthcare more quality-driven, cost-efficient, and patient-focused. Fortunately, CMMI provides such a robust research and development platform to experiment and evaluate new payment and delivery approaches and determine what works and why. Because of the potential impact, however, on patients, healthcare providers, and other health system stakeholders, it is essential that such experimentation comply with the original intent of CMMI and be limited in scope and fully transparent. Concerns over both the scale and scope of some of CMMI's recent demonstrations and its claim of authority to expand demonstrations nationwide and, in effect, enact permanent policy changes should be addressed. Congress should have the ability to intervene in these matters, but its ability to do so is hampered by Congressional Budget Office scoring rules that assume theoretical savings from CMMI initiatives. Clearly establishing CMMI's role to verify "proof of concept" and Congress's role to act on that proof would help build the trust and confidence needed to ensure CMMI's success.

Modernizing the Stark Law and Anti-Kickback Statute

Current regulatory barriers, such as the Federal Anti-Kickback Statute and the Stark Law, initially implemented to discourage unethical behavior in a fee-for-service payment model, now inhibit the integration of healthcare in a value-based payment model designed to deliver quality of care rather than quantity of care. While "exceptions" to the Stark Law and "safe harbors" under the Anti-Kickback Statute exist to protect certain financial arrangements in healthcare, these protections are narrow in scope. Modernizing these laws will help to reduce burden and deliver more cost-efficient and higher quality care. Modernization of the current legal framework is needed to make it more compatible with healthcare delivery system transformation while retaining appropriate protections against fraud and abuse. Congress should amend Anti-Kickback Statute and Stark Law to allow waivers for stakeholders engaged in alternative payment arrangements that meet certain conditions. Congress should also extend existing Anti-Kickback Statute and Stark Law exceptions for donation and financial support of electronic health information products that facilitate care coordination, cybersecurity protection, and compliance with Advancing Care Information performance category goals. HLC unequivocally supports these efforts to align the necessary incentives to move towards a value-based care model and payment system.

Interoperability

HLC is a strong advocate of improving the exchange of electronic health information across healthcare stakeholders to deliver efficient care. For a health information system to seamlessly transfer patient healthcare information, irrespective of location to coordinate care, our healthcare system must be interoperable. An interoperable healthcare system also needs to correctly identify patients to match their data to organize care. HLC opposes all forms of information blocking within the exchange of healthcare information and endorses the flow of information across all entities. The digitization of our healthcare system presents an opportunity to advance interoperability to deliver high quality healthcare and produce better health outcomes. Considering this, HLC, in collaboration with the Bipartisan Policy Center (BPC) is developing a common framework to measure private sector progress on nationwide

interoperability. To develop this framework, HLC and BPC will conduct interviews and discussion roundtables with key interoperability experts and stakeholders, including HLC and BPC members, to identify challenges, private sector actions and public policies intended to expedite interoperability, information sharing and data access. As part of the project, a "call to action" from HLC and BPC member CEOs endorsing public and private sector actions recommended to promote interoperability will be issued. HLC looks forward to disseminating our findings to Congress to recommend how to best advance interoperability to improve health outcomes.

Information Sharing

To enable the appropriate exchange of necessary information among medical professionals who are treating individuals with substance use disorders, including opioid abuse, substance use disorder treatment records need to align with the Health Insurance Portability and Accountability Act (HIPAA). Current federal regulations governing the confidentiality of drug and alcohol treatment and prevention records (42.C.F.R. Part 2 (Part 2)) preclude the Centers for Medicare and Medicaid Services (CMS) from disclosing certain medical information to healthcare providers for care coordination, including those engaged in accountable care organizations and bundled payment organizations. These regulations currently require complex and multiple patient consents for the use and disclosure of patients' substance use records that go beyond the sufficiently strong patient confidentiality protections that are required by HIPAA.

Electronic health records and value-based payment models such as Accountable Care Organizations (ACOs), Health Information Exchanges (HIEs), Medicaid Health Homes, and related Medicare and Medicaid integrated care programs were designed to create a more holistic, patient-centered approach to healthcare where providers work together to coordinate across their traditional silos and in some cases are held jointly accountable for the quality, outcomes, and cost of that care. Critical to making these new models work for patients is having access to the individuals' health records, including those related to substance use disorders. CMS provides participating providers of Medicare ACO and bundled payment organizations with monthly Medicare Parts A, B and D claims under data use agreements that include criminal penalties for misuse. Yet, due to the outdated 42 CFR Part 2 regulation, CMS is forced to remove *all* claims where substance use disorder is a primary or secondary diagnosis. Patient safety is also threatened with the potential pharmaceutical contraindications that could occur without access to the full medical record. Without this critical information, providers are prevented from understanding the full extent of their patients' medical needs. To increase data flow and access to necessary medical information among healthcare stakeholders, 42 CFR Part 2 should align with HIPAA's treatment, payment and healthcare operations to allow the exchange of information among providers, payers and patients, to deliver whole person care.

Telehealth

HLC is a strong supporter of using telehealth and remote patient monitoring to connect with patients across various locations to coordinate care. Telehealth can increase access to care, improve the quality of care and decrease the costs of care. HLC has been a staunch supporter of telehealth provisions in the CHRONIC Care Act, particularly the lifting of 1834(m) restrictions in two-sided risk ACOs. HLC commends Congress for passing this legislation to expand telehealth and remote patient monitoring services in Medicare, including the addition of home

dialysis sites as originating sites for home dialysis patients and lifting of evaluation restrictions for telestroke. HLC also lauds the introduction of the CONNECT for Health Act, and requests the inclusion of provisions to grant the Secretary of Health and Human Services (HHS) waiver authority to lift existing restrictions when certain quality and cost-effective criteria are met, and to lift restrictions for certain mental health services. Lastly, HLC supports the provision to allow rural health clinics and federally qualified health centers (FQHCs) to serve as originating and distant sites. Both pieces of legislation will help to increase access to virtual care for various patient populations in need.

Our increasingly interconnected healthcare system requires innovative delivery and payment models to deliver high quality coordinated care. To ensure our healthcare system maintains the incentive to innovate on behalf of patients, our legal framework must be modernized to reflect the move towards a value-based care delivery and payment model. It is imperative that our legislative and regulatory framework provide the legal flexibility needed to accommodate changes in healthcare technologies to better arrange patient care. A flexible framework is needed to increase information sharing, access to data, and enhance the exchange of healthcare information across all stakeholders to meet the demands of a 21st century healthcare system.

These issues are important, with far-reaching implications for healthcare in America. Please feel free to reach out to Tina Grande, Senior Vice President for Policy at the Healthcare Leadership Council at (202) 449-3433 or tgrande@hlc.org with any questions or for additional details on any of the positions mentioned above.

Sincerely,

Mary R. Grealy
President
Healthcare Leadership Council