



July 31, 2018

The Honorable Lamar Alexander
Chairman
Committee on Health, Education,
Labor, and Pensions
United States Senate
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member
Committee on Health, Education,
Labor, and Pensions
United States Senate
Washington, D.C. 20510

Dear Chairman Alexander and Ranking Member Murray:

The Healthcare Leadership Council (HLC) applauds committee efforts to reduce healthcare costs and improve the value of care for patients.

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.

As the committee explores ways to reduce healthcare spending and increase the quality of care, HLC members encourage the consideration of the following policy areas:

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 inappropriate 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 patients experience 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, but not eliminate, the 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 donations and financial support of electronic health information products that facilitate care coordination, cybersecurity protection, and interoperability goals. HLC unequivocally supports these efforts to align the necessary incentives to move towards a value-based care model and payment system.

Medicaid Best Price

As more healthcare payers and pharmaceutical manufacturers seek to enter into value-based contracts linking drug prices to patient health outcomes, stakeholders need relief from legal and regulatory barriers impeding the movement towards value-based contracts. A significant regulatory hurdle is the Medicaid Best Price rule requiring drug manufacturers to offer the Medicaid program the lowest price negotiated with any other buyer. This requirement can impede the ability of companies to enter into value-based arrangements where manufacturers contract with providers and health plans for prices based on achieving specified clinical outcomes. Under the Medicaid Best Price rule, if a manufacturer sets a substantially discounted price for a drug while waiting for an evaluation of patient outcomes, that artificially lowered price would have to be offered to the Medicaid program. This creates a disincentive for pharmaceutical companies to accept increased risk in value-based contracting and thus, decreases patient access to innovative drug therapies. Value-based care and payment arrangements change the orientation from the current system of a unit price to one where companies will be contracting to deliver an outcome for a population of patients for an agreed upon price and result. It is difficult to reconcile these two approaches in the context of current Medicaid Best Price reporting, which is still oriented toward the unit price approach.

Greater Transparency of Healthcare Price and Quality Information

HLC envisions a future in which public and private sector healthcare organizations securely share information in an efficient, effective manner that utilizes standard formats and is useful to consumers. HLC members have already individually proven that they can harness data to improve care and value in healthcare. Now, we see an opportunity to work collectively toward a future of better healthcare and health by improving the accessibility and quality of health data to accelerate progress in medicines, technologies, and healthcare delivery.

Transparency of healthcare costs must provide accurate information that is of practical use to consumers to allow them to make healthcare decisions that are best for them. It is critically important that consumers be able to understand any information that is made available. Currently, much of the data in the Medicare claims database would not meet this test as it is not representative of the cost a consumer would pay out of pocket.

Any sharing of cost data with consumers should be released alongside accurate information on quality to drive value in healthcare. HLC members are continually innovating to drive higher quality and better value in healthcare. We urge Congress to take a thoughtful and deliberate approach to the release of any cost and quality data to ensure that consumers can make a judgment based on accuracy and value.

Modernizing Substance Abuse Confidentiality Regulations

HLC strongly urges the committee to support the passage of S. 1850, "Protecting Jessica Grubb's Legacy Act," to enable the appropriate exchange of potentially lifesaving information among medical professionals who are treating individuals with substance use disorders, including opioid abuse. To achieve this, 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. Similar legislation passed the U.S. House of Representatives last month with overwhelmingly bipartisan support.

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.

Medical Liability Reform

HLC advocates incentives to encourage continuous quality improvement. With advancements in evidence-based medicine, value-based care delivery, and health information technology, new approaches are needed to modernize our healthcare system. To improve patient safety and quality in the digital age, we need to promote adherence to best practices and evidence-based medicine. To achieve this, HLC supports establishing reasonable incentives and protections for healthcare providers who practice evidence-based medicine and report adverse events while maintaining the ability of patients injured due to negligence to recover damages.

HLC supports the "Saving Lives, Saving Costs Act," sponsored by Representatives Andy Barr (R-KY) and Henry Cuellar (D-TX). This act will incentivize the development and use of quality and safety measures with safe harbors and promote evidence-based medicine through clinical practice guidelines. HLC highly recommends the committee support this legislation to improve patient safety and quality, and ultimately improve health outcomes while lowering costs.

Workforce Care Coordination

HLC believes a stable health system includes having a well-trained workforce to meet the needs of our country's evolving healthcare system, and rapidly aging population. HLC is a strong supporter of increased graduate medical education (GME) funding and increasing the number of residency slots available in primary and specialty care. We also support expanding the use of telemedicine and immigration rules allowing recruitment of healthcare workers crucial to the healthcare industry.

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 (P.L. 115-123), particularly the lifting of 1834(m) restrictions in two-sided risk ACOs. HLC commends Congress for passing this legislation, which expands telehealth and remote patient monitoring services in Medicare. HLC also lauds the introduction of the CONNECT for Health Act (S.1016) and requests the inclusion of provisions granting 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 allowing rural health clinics and federally qualified health centers (FQHCs) to serve as originating and distant sites.

Coverage for Wellness Programs

Chronic disease prevention is an essential component of healthcare. Many chronic diseases are caused by modifiable health risks such as lack of physical activity, poor nutrition, and tobacco use. To avoid these problems, Medicare beneficiaries need comprehensive and evidence-based wellness programs that educate them on how to make healthy choices. Many of these programs have been implemented by employers, and to ensure that Medicare beneficiaries have access to the same opportunities, Congress should pass legislation requiring CMS to cover such programs.

Reducing Unnecessary Regulations

Many current federal rules and regulations are ineffective, costly, and time-consuming. The policy areas that are highlighted in this letter are also delineated in the accompanying HLC "red tape" list that includes a compilation of rules and regulations that our members recommend be altered or eliminated. We are pleased to share this with the committee and look forward to working with you to reduce regulatory burden to improve healthcare quality and efficiency.

Conclusion

HLC and its members stand ready to work on these important issues with you and your colleagues to reduce excess spending and deliver high value care. HLC represents a collaborative group of CEO members from all disciplines of American healthcare, ranging from hospitals to health plans, as well as manufacturers and distributors of healthcare products. These members have a deep knowledge of the systems and structures needed to improve efficiency in the delivery of high-quality care.

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 topics mentioned above.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary R. Grealy". The signature is written in a cursive, flowing style.

Mary R. Grealy
President