



March 1, 2019

The Honorable Lamar Alexander
Chairman
U.S. Senate Committee on Health,
Education, Labor and Pensions
Washington, D.C. 20510-7010

Dear Chairman Alexander:

The U.S. healthcare system has seen an increase in the cost of care which has adversely affected patients, providers, payers, and other healthcare stakeholders. The Healthcare Leadership Council (HLC) applauds committee efforts to address America's rising healthcare costs. HLC appreciates the opportunity to offer its response to this important issue.

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.

As the committee explores ways to lower healthcare costs, incentivize care that improves the health and outcomes of patients, and increase the ability for patients to access information about their care, HLC members encourage the consideration of the following policy areas:

Promoting Value-Based Care

Current regulatory barriers, such as the Federal Anti-Kickback Statute and the Physician Self-Referral (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 too 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.

HLC appreciates the administration's work to eliminate obstacles to care coordination and accelerate the transition to a value-based system through its "Regulatory Sprint to Coordinated Care." Specifically, HLC applauds the U.S. Health and Human Services' Office of the Inspector General and the Centers for Medicare and Medicaid Services (CMS) for soliciting input from healthcare industry stakeholders as it evaluates the impact the Anti-Kickback Statute and beneficiary inducements CMP and the Stark Law, respectively.

As more healthcare payers and pharmaceutical manufacturers seek to enter into value-based contracts linking drug prices and medical technologies to patient health outcomes, stakeholders need relief from legal and regulatory barriers impeding the movement towards use of these contracts. A significant regulatory barrier for pharmaceutical manufacturers 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 deter companies from entering into value-based contracts. To utilize value-based contracting, manufacturers must be able to work with providers and health plans to assess the efficacy of a certain drug in a clinical setting and then set prices based on the results. Under current regulations, if a manufacturer sets a substantially discounted price for a drug while waiting for an evaluation of patient outcomes, that artificially lowered price would also 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. Congress should support legislation that excludes drugs purchased through value-based arrangements from Medicaid Best Price and average manufacturer price determinations.

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. 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 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 legislation 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, governance of substance use disorder treatment records needs 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 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. Patient safety is also threatened with the potential for pharmaceutical or treatment contraindications that could occur without access to a full medical record. Without this critical information, providers are prevented from understanding the full extent of their patients' medical needs. To provide access to necessary medical information among healthcare stakeholders, 42 CFR Part 2 should align with HIPAA's treatment, payment and healthcare operations provisions to allow for the responsible exchange of information among providers, payers and patients, to improve the health and outcomes of patients.

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 highly recommends the committee support medical liability reform legislation to improve patient safety and quality, and ultimately improve health outcomes while lowering costs.

Workforce Care Coordination

HLC believes a stable healthcare system includes having a well-trained workforce to meet the needs of our country's changing healthcare landscape 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 improves healthcare quality and lowers costs, while giving more people access to quality healthcare. 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. Additionally, we welcomed the flexible approach that CMS proposed to implement provisions in the Bipartisan Budget Act (BBA) of 2018 to expand telehealth services to Medicare Advantage enrollees. HLC believes Congress and the administration should work to further expand coverage for telehealth services to all Medicare beneficiaries, including those enrolled in fee-for-service Medicare so that all beneficiaries can benefit from increased access, reduced costs, and improved patient health, and outcomes.

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 for the under 65 population, and to ensure that Medicare beneficiaries have access to the same opportunities, Congress should pass legislation requiring CMS to cover such programs.

Optimizing Healthcare for High-Need Patients

Currently, five percent of patients account for 50 percent of healthcare costs in America. They typically experience three or more chronic conditions and a functional limitation in their ability to care for themselves or perform daily routine tasks.¹ There are opportunities to serve these “high-need” patients across the continuum of care with forward-thinking, person-centered legislative and regulatory solutions. The healthcare system works to provide high-quality, efficient care, but there are roadblocks that obstruct the drive to optimal care. HLC has developed a [High Need Patients Playbook](#) to serve as a guide to provide solutions to improve healthcare quality and efficiency while decreasing healthcare cost. Recommendations include regulatory and legislative priorities such as investments in wellness, expanded coverage for proven disease-specific prevention programs, expanded access to telehealth and remote patient monitoring services, community-based care, and ensuring access to high-quality Medicare and Medicaid plans among many others.

Technology

Technology plays an increasingly greater role in delivering care in a more effective and cost-efficient manner. Healthcare technologies have helped to advance interoperability and allow providers to deliver virtual care through telemedicine and remote patient monitoring. Using

¹ Hayes, S.; Salzberg, C.; McCarthy, D.; Radley, D.; Abrams, M.; Shah, T.; and Anderson, G. Issue Brief: “High-Need, High-Cost Patients: Who Are They and How Do They Use Health Care?” The Commonwealth Fund, August 29, 2016.

technology, healthcare stakeholders can coordinate care more efficiently to deliver better health outcomes.

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 better organize care. HLC opposes all forms of information blocking within the exchange of healthcare information and endorses the appropriate flow of information. 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 collaborated with the Bipartisan Policy Center (BPC) to identify ways to further advance the interoperability of systems and electronic information sharing to support better health outcomes and higher-quality, safer, more cost-effective, and patient-centered care for individuals and populations in the United States. HLC and BPC conducted 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. Action to improve interoperability should focus on bringing information to the point of care to support care delivery and meeting the information needs of individuals to support their health and healthcare. We are pleased to share the findings in our [report](#) with the committee and look forward to working with you to advance interoperability, information sharing, and better data access.

Conclusion

HLC and its members stand ready to work on these important issues with you and your colleagues to address America's rising healthcare costs. HLC represents a collaborative group of CEO members from all disciplines of American healthcare. 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 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 fluid and cursive, with a large initial "M" and "G".

Mary R. Grealy
President