



August 3, 2018

The Honorable Mike Kelly
1707 Longworth HOB
Washington, DC 20215

The Honorable Markwayne Mullin
1113 Longworth HOB
Washington, DC 20515

The Honorable Ron Kind
1502 Longworth HOB
Washington, DC 20515

The Honorable Ami Bera, M.D.
1431 Longworth HOB
Washington, DC 20515

Dear Representatives Kelly, Kind, Mullin and Bera:

The Healthcare Leadership Council commends the launch of the Health Care Innovation Caucus, dedicated to pursuing innovation in healthcare to provide higher quality care, lower costs and improve health outcomes.

As a multisector coalition of chief executives across all disciplines within American healthcare, the Healthcare Leadership Council (HLC) recognizes the need to modernize the current policy and legal framework as our healthcare system shifts from volume-based care to increasing the value of care. HLC is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve a high-quality health system that makes affordable 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.

Fraud and Abuse Legal Framework

As the U.S. healthcare system continues to develop innovative quality-driven, value-based delivery and payment models, policy and implementation challenges arise when these models implicate the existing federal fraud and abuse legal framework. In general, this framework is intended to penalize arrangements by and among providers and other industry stakeholders that have the potential to encourage overutilization of healthcare resources or inappropriately influence provider decision-making. Under a fee-for-service payment system, these concerns were more relevant given the financial incentives to provide more services.

The healthcare landscape is shifting, however, to a more value-driven system. To improve quality of care and reduce costs, innovative care delivery and payment models are being designed to encourage greater integration and coordination of care and payment among healthcare stakeholders. In large part, these innovative models eliminate the financial incentive to provide more services and replace it with an incentive to provide more value-driven care across the care continuum. These models, however, may still align financial interests in ways that trigger the current fraud and abuse legal framework. As such, changes to the current framework are necessary 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 and care delivery arrangements that meet certain conditions. 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 and only benefit a small group of stakeholders participating in Medicare initiatives. For example, fraud and abuse waivers for federal value-based healthcare programs, such as Center for Medicare and Medicaid Innovation (CMMI) pilots and Medicare Alternative Payment Models (APMS), protect only certain provider entities participating in certain programs. Meaningful participation by all providers, as well as non-provider entities, such as pharmaceutical and medical device companies, would broaden the scope of innovative clinical services made available to patients. *(For more information on this issue, please see the attached white paper and value-based examples delineating the Stark Law and Anti-Kickback Statute’s relationship to value-based care, recent legislative and regulatory changes, and potential legislative and regulatory options to modernize these laws.)*

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 purchaser. 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.

Communication Standards

HLC applauds the FDA’s recently-released final guidance regarding drug and device manufacturer communications with payors, formulary committees, and similar entities. As providers and payers take on increased risk in a period of accelerated biopharmaceutical innovation, they should have greater access to the pharmacologic and efficacy data developed by manufacturers, while still maintaining protections that prevent premature marketing of a drug prior to FDA approval.

Center for Medicare and Medicaid Innovation (CMMI)

HLC supports the introduction of 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 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 and other health system stakeholders, it is essential that such experimentation comply with the original intent of CMMI, be limited in scope and fully transparent. Also, 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.

Technology

Lastly, technology plays an increasingly greater role in delivering care in a more effective and efficient manner. Healthcare technologies have helped to advance interoperability and allow providers to deliver virtual care through telemedicine and remote patient monitoring. Using 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 match their data 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, 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 are conducting 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. HLC looks forward to disseminating our findings with Congress.

The Healthcare Leadership Council applauds the caucus's mission to explore and pursue policy ideas to incentivize healthcare innovation to lower costs, provide high quality care and improve health outcomes. We look forward to working with the caucus to generate and implement policy solutions to deliver comprehensive patient-centered care.

Please feel free to reach out to Debbie Witchey, Executive Vice President and Chief Operating Officer at HLC at (202) 449-3435 or dwitchey@hlc.org, with any questions or for additional information.

Sincerely,



Mary R. Greal
President

Enclosures:

HLC white paper on Stark and Anti-Kickback

HLC Value-based care examples