HEALTHCARE LEADERSHIP COUNCIL

July 13, 2018

The Honorable Alex M. Azar
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 600E
Washington, D.C. 20201

Dear Secretary Azar:

The Healthcare Leadership Council (HLC) appreciates the opportunity to comment on the Administration's recently released Request for Information (RFI) to lower drug prices and reduce out of pocket costs. 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. As a diverse coalition of healthcare stakeholders across the US healthcare system, we believe innovation is crucial to increasing market competition to deliver affordable cutting-edge drug therapies to the public.

HLC believes innovation and competition are conduits for driving and defining value for consumers in healthcare. Innovation is a necessary ingredient to improving healthcare outcomes and lowering costs. Our current healthcare system poses barriers to fostering a collaborative environment for payers, providers, manufacturers, and patients. The most notable barriers, the physician self-referral law ("Stark Law") and the Anti-Kickback Statute (AKS), require modernization as our healthcare system shifts from volume-based care to increasing the value of care. Addressing policies related to Medicaid "best price" as well as fostering more competition in the market are other important factors in lowering prices for consumers. HLC has identified these important policies in need of reform to achieve the sought-after goal of increasing access to affordable drug therapies for all Americans.

Modernizing the Stark Law and Anti-Kickback Statute

We applaud the Administration's "regulatory sprint" to address barriers to integrated, value-based care. Current legal barriers, such as the Federal Anti-Kickback Statute and the Stark Law, initially implemented to discourage inappropriate behavior in a fee-for-service (FFS) payment model, now inhibit the integration of healthcare in a value-based payment system designed to deliver quality of care rather than quantity of care. These new, value-based models align financial interests among stakeholders to incentivize care coordination and improve quality, which may invite scrutiny under the outdated legal framework. A modernized legal

framework must allow appropriate patient-serving care delivery and payment models that encourage broader collaboration among stakeholders to accelerate ongoing improvements in care quality and patient safety while reducing the rate of cost growth.

The Federal Government has issued individual waivers that protect certain arrangements from further scrutiny under the fraud and abuse legal framework, but the waivers are limited and only benefit a small group of stakeholders participating in Medicare initiatives. As such, stakeholders across the entire healthcare system are advocating for changes to the current legal framework to make it more compatible with healthcare delivery system transformation while still retaining appropriate protections against fraud and abuse. 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 a limited number of entities participating in certain programs. Meaningful participation by non-provider entities, such as pharmaceutical and medical device companies, would broaden the scope of innovative clinical services made available to patients. As the healthcare industry continues its shift toward value-based care that necessitates technology and data enablement, we need to include the various entities that must be able to collaborate to drive better value for patients.

As another example, AKS inhibits the ability to improve medication non-adherence, which drives up costs for everyone in the healthcare system. For instance, some pharmaceutical manufacturers have developed online tools to collect prescription claims data from pharmacies to track whether patients are filling prescriptions and calculate whether patients are adhering to prescribed therapies. Longitudinal adherence information is available to physicians using such tools at the point of care for all drugs prescribed to the patient. Manufacturers of these tools would like to make them available to providers at no charge as part of a solution to help achieve improved health outcomes for patients, but in many cases, decide not to, due to concerns that it may be construed as an unlawful inducement to prescribe a manufacturer's drugs, potentially triggering AKS scrutiny. As manufacturers take on more risk in value-based arrangements, these types of "wrap-around" solutions will become important elements in delivering positive clinical outcomes and reducing healthcare costs.

To address these challenges, we urge the Administration to continue to advance the shift to value-based healthcare through:

- Establishment of new Anti-Kickback safe harbors and Stark Law exceptions that provide opportunities for collaborative value-based arrangements between and among all healthcare stakeholders, including providers, payers, and manufacturers; and
- The extension of federal value-based healthcare program waivers to allow for manufacturer participation and risk-sharing in CMMI pilots, APMs, such as the Bundled Payments for Care Improvement-Advanced (BPCI-Advanced) program, and other initiatives.

In both cases, the incorporation of the components of shared financial risk and accountability, such that failure to meet pre-defined and pre-determined clinical and economic outcomes would force parties to incur financial exposure, would serve as a disincentive for overutilization and would protect both patients and federal healthcare dollars.

In addition to this letter, we have included an executive summary and white paper 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 buyer. This requirement can deter companies from entering into value-based contracts, for example, arrangements where manufacturers contract with providers and health plans for prices based on achieving 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.

Lowering CostsThrough Increased Competition

The U.S. healthcare system has seen an increase in the cost of drugs which has adversely affected patients, providers, payers and other healthcare stakeholders. One reason for rapid increases in drug prices is the lack of competition in the prescription drug marketplace. Enhancing competition is a pillar in the Administration's RFI and we support further attention in this area. The Food and Drug Administration's (FDA) regulations have contributed to the backlog of generic drug applications, with more than 4,000 [1] awaiting review. Due to the protracted application approval process, it has taken three to four years for a generic drug to enter the application process to receive FDA approval.[2] FDA regulations and processes have delayed access to treatments and technologies and prevent competition from lowering prices; creating an inefficient and opaque process. This inefficient and ineffective process creates an anticompetitive environment that costs consumers billions in greater drug costs annually. [3] Competition from generic drugs is critical to lowering drug prices. From 2005 to 2015, generic drugs have saved the U.S. healthcare system $1.46 trillion. [4] Restricted access to generic drugs costs the healthcare system $5.4 billion yearly, including $1.8 billion to the federal government.[5]

The Healthcare Leadership Council recommends a continuation of streamlining FDA responsibilities and processes, which would include decreasing the backlog of generic drug

[1] FDA: The Generic Drug Review Dashboard

[2] Premier's Roadmap for a Healthier Drug Market

[3] Ibid

[4] Testimony of Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Before the United States House of Representatives, Committee on Energy and Commerce Subcommittee. HealthQuintilesIMS Institute

[5] Premier's Roadmap for a Healthier Drug Market

approvals at the FDA and broadening FDA authority to accelerate review and approval for new generic drugs.[6] In addition, HLC recommends the FDA review generic drug applications when there is little market competition. By encouraging the entry of new drugs into the market, more competition will catalyze and help to lower drug prices in the generic market.[7]

To that end, we applaud the recent efforts of the FDA to reduce the backlog of approvals for generic drug applications. We encourage the agency to continue a speedy yet thorough approval process that also discloses the types of generics approved (e.g., whether they are complex generics or generics that will introduce competition within classes).

Communication Standards

Lastly, 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. We thank the FDA for its thoughtful approach to this issue.

Conclusion

Health laws and regulations have not kept pace with the evolution of our healthcare delivery and payment system, which demands more coordination between providers, payers and manufacturers. As our healthcare system becomes value-driven, more collaboration among healthcare stakeholders is necessary, as is greater sharing of clinical and economic information to provide higher quality care to improve health outcomes and lower costs. Increased information sharing will help to evaluate drug efficacy and pricing to ensure patients have access to quality, affordable drug therapies in a competitive market. Thank you for the opportunity to comment. 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.

Sincerely,

Mary R. Grealy
President

[6] Ibid
[7] Ibid