



July 17, 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) commends the Subcommittee for holding its hearing, “Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program.” HLC applauds the committee for highlighting the need to modernize the Stark Law as our healthcare system shifts from volume-based care to increasing the value of care. As a multisector coalition of chief executives across all disciplines within American healthcare, HLC strongly supports modernization of the Stark Law and recommends congressional efforts to modernize the Anti-Kickback Statute with equal consideration. As the U.S. healthcare system requires greater coordination across the continuum of care, the current fraud and abuse legal framework governing providers, plans, payers, and manufacturers, needs to be modernized to foster the delivery of comprehensive patient centered healthcare.

HLC 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 efficient, coordinated care.

Current regulatory barriers, such as the Stark Law and the Federal Anti-Kickback Statute, initially implemented to discourage inappropriate behavior under a fee-for-service payment model, now inhibit the integration of healthcare in value-based payment models 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 existing, outdated legal framework. We need a modernized legal framework that allows appropriate patient 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.

While “exceptions” to the Stark Law and “safe harbors” under the Anti-Kickback Statute protect certain financial arrangements in healthcare, these protections are narrow in scope. 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 Stark Law and Anti-Kickback Statute to allow waivers for stakeholders engaged in alternative payment arrangements that meet certain conditions. Even though the federal government has issued waivers that protect certain arrangements from scrutiny under the fraud and abuse legal framework, these waivers are limited to demonstration projects 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 the Center for Medicare and Medication Innovation (CMMI) pilots and Medicare Alternative Payment Models (APMs), protect only certain provider entities participating in certain programs, also allowing 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 account for the various entities that must be able to collaborate to drive better value for patients. 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.

Congress should also extend existing Stark Law exceptions and Anti-Kickback Statute safe harbors for donation 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.

To ensure our healthcare system successfully coordinates across the continuum of care on behalf of patients, the legal framework pertaining to both the Stark Law and Anti-Kickback Statute must be modernized to reflect the move towards a value-based care delivery and payment model. In addition to this letter, we have included real world examples of the difficulties our members encounter when providing value-based care as well as 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. We have also included examples of how anti-fraud laws will still be in place to protect beneficiaries.

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](mailto:tgrande@hlc.org) with any questions or for additional details on any of the positions mentioned above.

Sincerely,



Mary R. Grealy  
President

Enclosure(s)