

August 1, 2018

Dear Member of Congress:

We applaud recent congressional efforts to advance a value-driven healthcare system. Landmark legislation, such as MACRA and 21st Century Cures, has proven that Congress is committed to promoting better safety and value in healthcare delivery and payment.

With the move toward a healthcare system based on providing better value, it is imperative to recognize the transformational effect of this shift on the existing legal framework governing U.S. healthcare. As patients become more engaged in their healthcare, they expect and deserve high-quality and efficient interactions with the healthcare system. However, healthcare stakeholders have been deterred from implementing value-based payment approaches that would support delivering more efficient, coordinated care, at least in part due to an outdated legal framework. To enable better-coordinated patient care, as envisioned by members of Congress, the legal framework must promote and facilitate appropriate patient-serving care delivery and payment models involving broader collaboration among stakeholders. Both of these changes can help to accelerate ongoing improvements in care quality and patient safety while reducing the rate of cost growth.

As the U.S. healthcare system adopts value-based models of care and payment, policy and implementation challenges arise when these models implicate the federal fraud and abuse legal framework, specifically the Federal Anti-Kickback Statute and regulatory safe harbors, the Physician Self-Referral (Stark) Law and regulatory exceptions, and the Civil Monetary Penalties (CMP) Law. In general, this framework was built on a fee-for-service environment and is intended to address arrangements by and among providers and other industry stakeholders that have the potential to encourage overutilization of healthcare resources and/or inappropriately influence provider decision-making. To improve quality of care and reduce cost growth, new care delivery and payment models are designed to encourage greater integration, coordination of care, and reimbursement for healthcare services and products that is linked to outcomes. In large part, these new models eliminate the financial incentive to provide more services and replace it with an incentive to provide more value-driven care across the healthcare continuum.

However, these new value-based care and payment models designed to encourage improved patient care may still align financial interests in ways that implicate the existing fraud and abuse legal framework. For example, compensating physicians with savings generated from care plan coordination among clinical and non-clinical partners as well as new contracting approaches that allocate risk based on outcomes may trigger scrutiny. While “safe harbors” to the Anti-Kickback Statute and “exceptions” to the Stark Law exist to protect certain financial arrangements in healthcare, these protections are narrow in scope. As such, improvements to the current framework are needed to make it more compatible with healthcare delivery and payment system transformation while still retaining appropriate protections against fraud and abuse. Improving these statutes

and regulations in a thoughtful way will help to improve patient outcomes through the delivery of more cost-efficient, higher quality care. We urge Congress to change and modernize these laws to enable healthcare stakeholders to effectively engage in value-based arrangements, to improve the quality and efficiency of care for patients and their families, and to allow for more comprehensive and efficient solutions.

Patients deserve a future in which providers are able to better collaborate and coordinate healthcare delivery and one in which payers can utilize payment models that reward improved health outcomes. There is wide support among healthcare consumers, providers, manufacturers, and payers for modifying and improving the current fraud and abuse framework to make it more compatible with value-based healthcare while retaining important protections against fraud and abuse.

The undersigned organizations stand ready to work with Congress on modifications to the existing legal framework to better enable patient-centered, value-based care and payment models. These organizations have a deep knowledge of the systems and structures needed to improve efficiency in the delivery of high-quality care. We urge Congress to act on this effort.

Sincerely,

Academy of Managed Care Pharmacy  
Advanced Medical Technology Association (AdvaMed)  
American Alliance of Orthopaedic Executives  
American Association of Neurological Surgeons  
American Association of Orthopaedic Surgeons  
American College of Radiology  
America's Physician Groups  
California Life Sciences Association  
Congress of Neurological Surgeons  
Federation of American Hospitals  
Health Care Transformation Task Force  
Health Management Academy  
Healthcare Leadership Council  
Medical Alley Association  
Medical Group Management Association  
Pharmaceutical Research and Manufacturers of America  
Third Way