

Testimony of Dr. Gary Kirsh
Ways and Means Subcommittee on Health
Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program

July 17, 2018

Good afternoon Chairman Roskam and Ranking Member Levin. Thank you for inviting me to testify on modernizing Stark law to promote the transition from fee-for-service to value-based care in the Medicare program.

I am Dr. Gary Kirsh, a practicing urologist and President of the Urology Group in Cincinnati, an independent, free-standing 35 physician group that provides integrated urologic care to the citizens of our Ohio, Kentucky, and Indiana metropolitan area. I also serve as the immediate past president of the Large Urology Group Practice Association (LUGPA), and the chair of LUGPA's Alternative Payment Model Task Force. LUGPA represents independent, free-standing urology group practices, whose more than 2,100 physicians collectively provide 35 percent of the nation's urology services.

Our commitment to value-based care delivery predates enactment of the Affordable Care Act (ACA) and the Medicare Access and CHIP Reauthorization Act (MACRA). LUGPA groups were early supporters of MACRA and heartily embrace the Congress' vision of value-based care delivery.

Unfortunately, the vision of MACRA and value-based delivery is in jeopardy. According to CMS, currently only 5 percent of U.S. physicians are even participating in an alternative payment model.

More troubling, there are almost no APM's in the pipeline. In the two and a half years that the Physician-Focused Technical Advisory Committee (PTAC) has been operational, only 26 APMs have been submitted for review. Of these 26 submissions, only four have been recommended for implementation and six for limited scale testing. Moreover, not a single PTAC-recommended APM has been enacted by CMS. Last month, PTAC cancelled its meeting for lack of submitted APM proposals.

Existing Stark and associated fraud and abuse laws are one of the principal barriers to the development of APMs and the advancement of value-based care. The Stark law was written nearly 30 years ago in an era of fee-for-service medicine and has not been substantially modified since 1993. Congress recognized long ago that the Stark law was an obstacle to care coordination and value-based delivery when it authorized the Secretary of Health and Human Services to waive the self-referral and anti-kickback prohibitions for Accountable Care

Organizations. Yet independent physician practices were left behind. Congress should level the playing field to provide these same protections for independent physicians to test and participate in APMs.

While Health and Human Services can certainly provide waivers on a case-by-case basis to Stark and other fraud and abuse laws for approved APMs, organizations wishing to engage in APM development find themselves in a proverbial Catch-22: they cannot test an APM in the real world without financial waivers to Stark and anti-kickback laws, yet these waivers cannot be granted unless there is an approved APM. Organizations may spend months, sometimes years of work, resources and substantial investments designing an APM, but it remains a theoretical, mathematical model whose actual impact on patient care and healthcare financing is unknown without testing in the clinical environment.

That is one reason why LUGPA and 24 other diverse physician organizations across different specialties have endorsed The Medicare Care Coordination Improvement Act (H.R. 4206), which provides a means for the OIG to grant waivers to test a proposed APM when it is submitted in writing and approved by the Secretary – importantly, these waivers are not indefinite; they must be recertified on a semi-annual basis until the APM is approved or denied.

Stark law also represents a barrier to the development and adoption of APMs in that it explicitly prohibits remuneration of physicians who receive revenue from designated health services (DHS) based on the “volume or value” of their referrals to these services. While this may be crucial in fee-for-service models, this hampers practices from incentivizing physicians to adhere to treatment pathways and agreed-upon clinical guidelines that improve patient outcomes and promote efficient use of healthcare resources in the context of an APM. Current Stark law prevents practices from utilizing revenue from Designated Health Services (DHS) to financially reward or penalize physicians for adherence or deviation from clinical best practice standards or appropriate increases or decreases in utilization of services.

Although Stark and other fraud and abuse laws for *approved* APMs may be waived by the Office of the Inspector General on a case-by-case basis, these waivers are by their nature narrow and specific. The OIG cannot be expected foresee real-world circumstances that will inevitably emerge when providers implement the treatment pathways under an APM. Evolving standards of care, new procedures and medical innovations, and changed CPT codes may affect both physician behavior and compensation models in unexpected ways. Requiring a new or modified waiver to alter compensation in response to evolutions in care would be cumbersome and could substantively hamper administration of an APM.

Eliminating the “volume or value” from Stark prohibitions for the testing and operation of APMs would result in a clean, targeted modernized version of the Stark and anti-kickback statutes; this is needed for clinicians to be willing to enter into APMs, which by definition limit financial exposure to the Medicare program.

Current law does not reflect the vision of coordinated care shared by both policymakers and the physician community. For example, the Stark law prevents:

- Gainsharing arrangements that would be required for non-employed physicians to create relationships with hospitals that would enable care coordination and distribution of shared savings that result from adoption of value-based care models.
- Orthopedic surgery practices from taking into account the “value” derived through adherence to clinical protocols that shift patients from higher costs and less efficient inpatient rehabilitation facilities into high quality, lower cost models within the medical practice setting.
- Specialty and primary care physicians from jointly sharing savings derived from monitoring and treating patient with chronic conditions through decreased hospitalization and emergency department visits.
- Surgical, radiation and medical oncologists from developing shared savings models based on improved treatment pathways and enhanced care coordination for patients with cancer.

We recognize there is no panacea that would transform health care delivery to a value-based program overnight. We advocate neither absolute repeal nor modification of the Stark law as it relates to Medicare fee-for-service payments. That said, Stark law must be modernized without delay to allow for the creation of innovative delivery systems which increase care coordination across provider groups and serve to improve outcomes and decrease cost. Physicians across various specialties are eager to develop and deliver care under these alternative payment models.

We look forward to working with Congress in a bipartisan way to help deliver these reforms that will improve patient care and provide greater efficiency to the Medicare program. I thank you for your time and attention and will be happy to answer any questions that you may have.