

The Honorable Orrin G. Hatch  
Chairman  
Committee on Finance  
U.S. Senate  
219 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Kevin Brady  
Chairman  
Committee on Ways and Means  
U.S. House of Representatives  
1102 Longworth HOB  
Washington, DC 20515

February 5, 2016

Dear Chairmen Hatch and Brady:

On behalf of the undersigned organizations, we would like to thank you for requesting our views on how the Physician Self-Referral law (“Stark Law”) can be modernized to reflect the evolution of health care delivery models.

Enactment of the Medicare Access and CHIP Reauthorization Act (MACRA) fundamentally transformed how health care is delivered and provides important opportunities to move toward value-based payment paradigms rather than the historical fee-for-service model. Coordination of care within and across specialties is essential to improve patient outcomes and constrain overall health care costs. The structure of the Stark law has not been updated statutorily for more than two decades, and is now an anachronistic hindrance to the twenty-first century delivery of health care and a limitation to the full potential envisioned by Congress when it enacted MACRA.

The complexities of the Stark law regulatory infrastructure make it burdensome for clinicians to comply. For example, the “group practice” definition places strict limits on the ways that a physician practice may compensate its owners. In addition, agreements with physician contractors must satisfy seven distinct regulatory conditions, making them prone to technical infractions. Unlike other laws that regulate healthcare, the Stark law does not require demonstration of intentional offers of remuneration to induce referrals or any risk to patient care. Current waivers are skewed toward primary care and financial relationships with hospitals. It is critical to incorporate protections for independent specialty groups. Finally, the Stark law impedes care coordination *outside* of Medicare – a key avenue to qualify for an Alternative Payment Model (APM) in MACRA – due to the Stark Law’s consideration of “other business generated” in its limitations on referrals.

We are gratified that the Finance and Ways & Means Committees have reached out to stakeholders for input in modernizing the Stark law. There are five fundamental updates to the Stark law that will be necessary to align it with MACRA:

- Revise the definition of “group practice” by removing the current “volume” or “value” standard so that physicians who are part of a group practice may be paid on the basis of furnishing care without violating the Stark law. Virtually all the exceptions to the existing Stark law impose restrictions on compensation based on “volume or value” of referrals; however, inclusion of this language in the group practice definition creates enormous confusion and opportunities for technical non-compliance.
- Provide the same protections from the Stark law for physicians operating in an alternative payment model for those provided waivers through Accountable Care Organizations (including the pre-participation period) eligible for the Medicare Shared Savings Program. This recognizes the variety of APMs that utilize various mechanisms and structures for encouraging efficient care.
- Permit physician compensation for providing high-quality and efficient care without violating the Stark Law’s “fair market value” standard even if the compensation is related to the volume or value of the referrals. The statutory definition of “fair market value” created by Congress simply reflects the clear rule that arrangements must reflect arm’s length bargaining. The “volume or value” standard was a regulatory addition created by CMS.
- Define Stark law “technical violations” as compensation arrangements that do not otherwise violate the Anti-Kickback statute.
- Empower the Centers for Medicare and Medicaid Services (CMS) to create new regulatory exceptions to the Stark Law and in the future for purposes of promoting non fee-for-service payment structures. Just as Congress could not in 1993 foresee what exceptions might be necessary in 2016, this Congress cannot foresee how health care may be delivered years hence. It is essential that regulators have flexibility to refine the regulatory landscape as the health system continues to transform and as payment models continue to evolve.

In addition, narrowing or repealing the in-office ancillary services exception would be fundamentally antithetical to modernizing the Stark law and make it even more burdensome and less congruent with integrated health care delivery. That provision has enabled our practices to provide convenient, integrated and less expensive high-quality care. As the House GOP Doctors Caucus pointed out in a letter in June of 2015, studies by Milliman Inc.—commissioned by the American Medical Association and the Digestive Health Physicians Association— showed utilization of ancillary services in physician practices is a small percentage of total spending on ancillary services and is declining or growing more slowly than in hospital settings.<sup>i,iii</sup> Any effort to repeal the in-office ancillary services exception should be rejected. The exception should be preserved to invigorate competition among health care

providers and to ensure that physician practices can offer comprehensive care to keep costs down.

The undersigned organizations have each grappled for years with various aspects of the Stark law and many have additional suggestions. Some of these are more technical in nature and others question the need for parts or all of the Stark law. We jointly believe that addressing the five aforementioned issues would be instrumental in modernizing an antiquated law that does not reflect the policy goals articulated in MACRA. It is time to adopt changes that will allow clinicians to work together to deliver high quality health care to America's patients.

Sincerely,

American Academy of Ophthalmology  
American Society of Nuclear Cardiology  
American College of Gastroenterology  
American College of Cardiology  
Cardiology Advocacy Alliance  
American Association of Neurological Surgeons  
Congress of Neurological Surgeons  
American Society for Dermatologic Surgeons Association  
American College of Rheumatology  
American Academy of Neurology.  
American Association of Clinical Urologists  
American Urological Association  
American Association of Orthopedic Surgeons  
Society for Vascular Surgery  
American Society of Neuroimaging  
American Gastroenterology Association  
LUGPA  
Digestive Health Physicians Association  
Medical Group Management Association  
American Academy of Dermatology Association  
Society for Cardiovascular Angiography and Interventions  
National Association of Spine Specialists

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<sup>i</sup> American Medical Association, Milliman Study, March 2015  
<http://www.ama-assn.org/ama/pub/advocacy/topics/in-office-ancillary-services-exception.page>

<sup>ii</sup> Digestive Health Physicians Association, Milliman Study, February 2015  
<http://cqrcengage.com/dhpa/file/Mqq6fLiKQM1/03-2009-2013 Medicare Utilization Analysis.pdf>