Statement for the Record
On Behalf of the Alliance for Integrity in Medicare[1]
Submitted to
U.S. House Ways and Means Health Subcommittee Hearing
"Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program"
July 17, 2018

The Alliance for Integrity in Medicare (AIM) is pleased to submit a Statement for the Record for the House Ways and Means Health Subcommittee Hearing entitled "Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program" held on July 17, 2018. We commend the committee for holding this hearing to examine the urgent need to reform the physician self-referral law. AIM is a broad coalition of medical specialty, laboratory, radiation oncology, and medical imaging groups committed to ending the practice of inappropriate physician self-referral in Medicare. We are pleased to share our recommendations with the committee for vitally needed reforms so that beneficiaries and program integrity may be better protected than under current law.

In-Office Ancillary Services (IOAS) Carve-Outs to Referrals in the Stark Law Must Be Eliminated to Support Transition to Coordinated Care and Alternative Payment Models

Despite all the progress made and still forthcoming in Medicare, fee-for-service (FFS) has not been eliminated from the program. With FFS expected to continue for the foreseeable future, the financial incentive for clinicians to take advantage of the IOAS exception continues to exist. To encourage and ensure the successful transition from volume to value in the Medicare program, AIM strongly supports narrowing the IOAS exception to the Stark Law. The IOAS exception in its current form only bolsters the continuation of questionable utilization patterns of these services in FFS and conflicts with the goals of coordinated care and value-based payment models. Value-based care and alternative payment models (APMs) will not be successful if overutilization continues to be incentivized in the Medicare program.

To further encourage physician participation in APMs, we recommend removing advanced diagnostic imaging, anatomic pathology, physical therapy, and radiation therapy services from the list of designated health services protected under the IOAS exception, for which physicians can self-refer and bill Medicare. By removing the self-referral incentive in FFS, the IOAS exception would continue to apply in truly clinically integrated practices or federally-approved APMs. Removing this barrier would improve quality, reward value, and increase care coordination. The changes we propose to the IOAS would save the Medicare program at least $3.3 billion over ten years, as scored by the Congressional Budget Office.[2]

---

[1] Alliance for Integrity in Medicare, c/o David Cooling, Director, Government Relations, ACLA, 1100 New York Avenue, NW, Suite 725W, Washington, DC, 20005

[2] Congressional Budget Office (2016). *Proposals for Health Care Programs-CBO's Estimate of the President's Fiscal Year 2017 Budget.* Retrieved on 7/12/2018 from: https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/dataandtechnicalinformation/51431-HealthPolicy.pdf

Note that the intent of the IOAS exception was to allow for the provision of certain non-complex services, such as x-rays or simple blood tests, deemed necessary by the clinician to help inform the diagnosis and treatment of a beneficiary during an initial office visit, primarily for beneficiary convenience. But in most instances, advanced diagnostic imaging, anatomic pathology, physical therapy, and radiation therapy services cannot be provided to beneficiaries during an initial or single office visit. Allowing these more complicated services to be protected under the IOAS exception does not facilitate greater patient convenience. Rather, the IOAS exception only bolsters the continuation of questionable utilization patterns of these services under FFS. Narrowing the IOAS exception will realign provider incentives to help ensure appropriate utilization. The ability of all providers to render the highest quality, safest, and most clinically appropriate care to all patients will be maintained, while eliminating the lure of personal financial gain.

Repeated Inquiry into the Stark Law's Effects Consistently Highlights Problematic Referral and Utilization Patterns

The Department of Health & Human Services' (HHS) Office of the Inspector General (OIG), the US Government Accountability Office (GAO), the *New England Journal of Medicine*, and *Health Affairs*, among others, also have called attention to the fact that the IOAS exception has substantially diluted the self-referral law and its policy objectives. Current law allows Medicare providers to avoid the Stark Law's prohibitions by structuring arrangements for advanced diagnostic imaging, anatomic pathology, physical therapy, and radiation therapy services that meet the IOAS exception's technical requirements but otherwise violate the true intent of the exception. Furthermore, it handcuffs physicians who deliver these services to unnecessarily join group practices and lock-in referral patterns that may not be cost-effective for patients.

The deleterious effects of the self-referral law on utilization patterns and health care costs billed to the Medicare program have been known for many years. AIM submits the following examples of the most alarming conclusions illustrating the detrimental effects of patient self-referral laws:

- In an April 2018 article authored by leading urologists about Medicare beneficiaries with prostate cancer diagnoses, researchers found, "Urologists practicing in single-specialty groups with an ownership interest in radiation therapy are more likely to treat men with prostate cancer, including those with a high risk of noncancer mortality."[3]

- In an April 2014 report, the "GAO found that in the year a provider began to self-refer, [physical therapy "PT"] service referrals increased at a higher rate relative to non-self-referring providers of the same specialty. For example, family practice providers that began self-referring in 2009 increased PT referrals 33 percent between 2008 and 2010. In contrast, non-self-referring family practice providers increased their PT service referrals 14 percent during this same period."[4]

---

[3] Urologist Practice Affiliation and Intensity-modulated Radiation Therapy for Prostate Cancer in the Elderly, Hollenbeck, Brent K. et al. European Urology, Volume 73, Issue 4, 491 – 498. Retrieved on 7/12/2018 from: https://www.europeanurology.com/article/S0302-2838(17)30687-5/fulltext

[4] U.S. Government Accountability Office (2014, April). Medicare Physical Therapy: Self-Referring Providers Generally Referred More Beneficiaries by Fewer Services per Beneficiary (Publication No. GAO-14-270). Retrieved on 7/12/2018 from: https://www.gao.gov/assets/670/662860.pdf

- In October 2013, a comprehensive review of Medicare claims for more than 45,000 patients from 2005 through 2010 found that nearly all of the 146 percent increase in intensity-modulated radiation therapy (IMRT) for prostate cancer among urologists with an ownership interest in the treatment was due to self-referral, according to research published in *The New England Journal of Medicine*. This study corroborated the increased IMRT treatment rates among self-referrers reported in the GAO's July 2013 report and concluded that "men treated by self-referring urologists, as compared with men treated by non-self-referring urologists, are much more likely to undergo IMRT."[5]

- In a July 2013 report, the GAO found "[t]he number of Medicare prostate cancer–related IMRT services performed by self-referring groups increased rapidly, while declining for non-self-referring groups from 2006 to 2010. Over this period, the number of prostate cancer–related IMRT services performed by self-referring groups increased from about 80,000 to 366,000. Consistent with that growth, expenditures associated with these services and the number of self-referring groups also increased. The growth in services performed by self-referring groups was due entirely to limited-specialty groups—groups comprised of urologists and a small number of other specialties—rather than multispecialty groups."[6]

- In a June 2013 report, "GAO estimates that in 2010, self-referring providers likely referred over 918,000 more anatomic pathology services than if they had performed biopsy procedures at the same rate as and referred the same number of services per biopsy procedure as non-self-referring providers. These additional referrals for anatomic pathology services cost Medicare about $69 million. To the extent that these additional referrals were unnecessary, avoiding them could result in savings to Medicare and beneficiaries, as they share in the cost of services."[7]

- In its report issued in September 2012, the "GAO estimate[d] that in 2010, providers who self-referred likely made 400,000 more referrals for advanced imaging services than they would have if they were not self-referring. These additional referrals cost Medicare about $109 million. To the extent that these additional referrals were unnecessary, they pose unacceptable risks for beneficiaries, particularly in the case of CT services, which involve the use of ionizing radiation that has been linked to an increased risk of developing cancer."[8]

- A *Health Affairs* study published in 2012 "found that self-referring urologists billed Medicare for 4.3 more specimens per prostate biopsy than the adjusted mean of 6 specimens per biopsy that non-self-referring urologists sent to independent pathology

---

[5] Mitchell JM. Urologists' Use of Intensity-Modulated Radiation Therapy for Prostate Cancer. N Engl J Med 2013; 369:1629-1637. Retrieved on 7/12/2018 from: https://www.nejm.org/doi/full/10.1056/NEJMsa1201141?query=recirc_curatedRelated_article

[6] U.S. Government Accountability Office (2013, July). Medicare: Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny (Publication No. GAO-13-525). Retrieved on 7/12/2018 from: https://www.gao.gov/assets/660/656026.pdf

[7] U.S. Government Accountability Office (2013, June). Medicare: Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer (Publication No. GAO-13-445). Retrieved on 7/12/2018 from: https://www.gao.gov/assets/660/655442.pdf

[8] U.S. Government Accountability Office (2012, September). Medicare: Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions (Publication No. GAO-12-996). Retrieved on 7/12/2018 from: https://www.gao.gov/assets/650/648988.pdf

providers, a difference of almost 72 percent. Additionally, the regression-adjusted cancer detection rate in 2007 was twelve percentage points higher for men treated by urologists who did not self-refer. This suggests that financial incentives prompt self-referring urologists to perform prostate biopsies on men who are unlikely to have prostate cancer. These results support closing the loophole that permits self-referral to 'in-office' pathology laboratories."[9]

Support for Other Executive Agency and Legislative Efforts

AIM appreciates the Administration's efforts to address inappropriate self-referral in the HHS Fiscal Year 2019 Budget by proposing to create an exception to the IOAS for those participating in APMs.[10] We agree that an exception for APMs is appropriate when paired with a restriction on the use of IOAS. Specifically, removing advanced diagnostic imaging, anatomic pathology, physical therapy, and radiation therapy services from the list of designated health services protected under the IOAS exception would encourage FFS providers to join APMs more freely. This reform would allow for providers in truly clinically integrated practices or those who participate in other authorized coordinated care models to continue to operate with the IOAS exception, rather than limit those arrangements to those for services that are costly to Medicare.

AIM has also strongly encouraged Congress to reform the IOAS exception by removing advanced diagnostic imaging, anatomic pathology, physical therapy, and radiation therapy services from the list of permitted designated health services under the exception, while creating a new exception for authorized APMs. We refer the committee to the Promoting Integrity in Medicare Act of 2017 (HR 2066) as model policy that would expedite delivery and payment system reform envisioned by the Medicare Access and CHIP Reauthorization Act (MACRA), while clamping down on abuse. While MACRA and other policy changes will increase the numbers of physicians participating in APMs, many will still participate in a traditional FFS model that incentivizes overutilization of health care services through self-referral. This policy approach would ensure that only physicians participating in approved APMs and other truly integrated medical groups focusing on quality could self-refer under the IOAS exception, thereby rooting out abuse in the traditional FFS system while accelerating participation in APMs.

The Centers for Medicare and Medicaid Services (CMS) has long said that it does not have the statutory authority to address abuse of the IOAS exception. Reforming the IOAS exception through legislation is long overdue, and we urge Congress to act. AIM's recommended changes to the IOAS exception will improve care coordination, prevent unnecessary utilization of resources by providers, protect Medicare patients from unnecessary care, and further the goals of higher quality health care at lower cost, resulting in improved clinical outcomes for beneficiaries. As mentioned previously, the realignment of financial incentives for Medicare providers would save the program at least $3.3 billion over ten years, as scored by the Congressional Budget Office.[11]

---

[9] Mitchell JM. Urologists' self-referral for pathology of biopsy specimens linked to increased use and lower prostate cancer detection. Health Affairs (Millwood) 2012;31:741-749. Retrieved on 7/12/2018 from: https://www.healthaffairs.org/doi/10.1377/hlthaff.2011.1372

[10] Virgil Dickinson, "CMS to form inter-agency group to review Stark law," *Modern Healthcare*, January 17, 2018. Retrieved on 7/12/2018 from: http://www.modernhealthcare.com/article/20180117/NEWS/180119915.

[11] Congressional Budget Office (2016). *Proposals for Health Care Programs-CBO's Estimate of the President's Fiscal Year 2017 Budget.* Retrieved on 7/12/2018 from: https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/dataandtechnicalinformation/51431-HealthPolicy.pdf

In conclusion, AIM strongly encourages the House Ways and Means Committee to modernize the Stark Law by removing anatomic pathology, advanced diagnostic imaging, physical therapy, and radiation therapy from the list of permitted designated health services under the IOAS exception. A value-based Medicare program will not be successful if overutilization continues to be incentivized in FFS. Closing the loophole supports the goals of this committee to transition the Medicare program to pay for value, to improve patient care, and to reduce overutilization. Protecting both Medicare beneficiaries and program integrity from misaligned financial incentives is in the best interests of taxpayers, patients, and the American health care system overall.