

August 23, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
Attention: CMS-1720-NC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

DELIVERED ELECTRONICALLY

RE: Medicare Program; Request for Information Regarding the Physician Self-Referral Law (CMS-1720-NC)

Dear Administrator Verma:

The Alliance for Integrity in Medicare (“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. Our coalition is encouraged by the Centers for Medicare & Medicaid Services (“CMS”) June 24, 2018 publication of the *Request for Information Regarding the Physician Self-Referral Law* (CMS-1720-NC) seeking information regarding ways to eliminate barriers posed by the physician self-referral law (the “Stark Law”) to coordinated care and value-based care models and is pleased to submit these comments in response.

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

AIM applauds CMS’s promotion of coordinated care and alternative payment models (“APMs”), among other coordinated care and value-based care models, to assist in improving patient care. To encourage greater participation among providers in APMs, we strongly support strengthening the in-office ancillary services (“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 Fee-for-Service (“FFS”) Medicare and conflicts with the goals of coordinated care and value-based payment models. Organizations and other 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 designed health services protected under the IOAS exception. Narrowing the IOAS exception will realign provider incentives to help ensure appropriate utilization. The changes we propose to the IOAS alone would save the Medicare program at least \$3.3 billion over ten years,

as scored by the Congressional Budget Office.¹

The IOAS exception's intent is 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 quality, safe, and 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 significantly 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 that 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. In response to the Stark RFI, AIM submits the following examples of the most alarming conclusions illustrating the detrimental effects of patient self-referral laws:

- In an April 2018 *European Urology* article authored by leading urologists about Medicare beneficiaries with prostate cancer diagnoses, researchers found, “[u]rologists 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... than those affiliated with a multispecialty practice or a group without an ownership stake.”² They may even potentially overtreat, patients with IMRT.
- In a April 2014 report, the “GAO found that in the year a provider began to self-refer,

¹ 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>

² *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.europanurology.com/article/S0302-2838\(17\)30687-5/fulltext](https://www.europanurology.com/article/S0302-2838(17)30687-5/fulltext)

[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.”³

- 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 June 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.”⁴
- 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. At the same time, use of brachytherapy among self-referring groups declined by 50 percent. 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.”⁵
- 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.”⁶
- 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

³ 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>

⁴ 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

⁵ 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>

⁶ 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>

the use of ionizing radiation that has been linked to an increased risk of developing cancer.”⁷

- 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 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.”⁸

We are also providing copies of these studies in their entirety for your convenience.

Support for Other Executive Agency and Legislative Efforts

AIM appreciates HHS 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.⁹ 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 under 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 to for authorized APMs. We refer CMS 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 may still participate in a traditional fee-for-service 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.

Accountable Care Organizations and other APMs will not be successful if overutilization

⁷ 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>

⁸ 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>

⁹ 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>.

continues to be incentivized in the Medicare program. The Administration must consider whether certain providers will want to take on financial risk under an APM when the IOAS exception to the self-referral law continues to make traditional Medicare FFS so financially attractive. Closing the loophole supports the original intent of the Stark Law to improve patient care and 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.

As Congress and the Administration continue to examine additional changes to the Stark Law, including the amendment of the IOAS exception, we would welcome support of those efforts to facilitate better and more cost-effective care. While the Stark law needs reform to accommodate and support the drive to value-based care, it is important not to throw the “baby out with the bathwater.” The underlying protections against abuse that form the foundation of the Stark law must be preserved and strengthened or patients will continue to suffer and wasted spending will continue to mount.

Thank you for the opportunity to submit these comments concerning the RFI. AIM looks forward to working with you on supporting care coordination and strengthening Medicare program integrity to protect beneficiaries and improve patient care. If you have any questions, please do not hesitate to contact David Cooling, Director of Government Relations, American Clinical Laboratory Association at 202-637-9466.

Sincerely,

The Alliance for Integrity in Medicare

American Brachytherapy Society
American Clinical Laboratory Association
American Physical Therapy Association
Association for Quality Imaging
American Society for Radiation Oncology
American Society for Clinical Pathology
College of American Pathologists

ENCLOSURES