



COLLEGE of AMERICAN PATHOLOGISTS

August 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-NC
P.O. Box 8013
Baltimore, MD 21244–8013

Submitted electronically to: <http://www.regulations.gov>

Re: Medicare Program; Request for Information Regarding the Physician Self-Referral Law

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to provide feedback on the request for information (RFI) regarding the physician self-referral law (CMS-1720-NC). As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. With extensive experience as a quality standards-setting organization, the CAP believes reform to the physician self-referral law should be approached cautiously, and any efforts should include action to close the in-office ancillary services (IOAS) exception for anatomic pathology (AP) services.

The CAP welcomes the opportunity to comment on the efforts to advance care coordination and development of alternative payment models (APMs), and we applaud efforts by the Centers for Medicare & Medicaid Services (CMS) to address unnecessary regulatory burdens in health care. To aid in this effort, we have previously suggested a number of areas for regulatory relief action, including reforming the local coverage determination (LCD) process and the misvalued code initiative. However, regulatory relief changes to the physician self-referral law (or "Stark law") pose a unique challenge. As the agency notes in this RFI, "when physicians have a financial incentive to refer patients for health care services, this incentive may affect utilization, patient choice, and competition." Therefore, we urge CMS to ensure any change to the Stark law does not further incentivize providers to over-utilize services in self-referring arrangements; or create new opportunities for abusive self-referral arrangements to develop in new payment models. While we agree with the agency that it is important to assess regulatory obstacles to coordinated care, we urge the CMS to move cautiously and consider our concerns to address overutilization of services in the Medicare program and avoid unintended consequences on physician self-referrals in the future. **In particular, the CAP strongly encourages action that closes the IOAS exception for AP services as part of any reform to the Stark law.**

The CAP looks forward to continued engagement with CMS on this issue, but we recognize that in some instances, action from Congress may be necessary. To that point, we have submitted a letter for the record to the House Ways and Means Subcommittee on Health as they engage in parallel efforts to address issues related to the physician self-referral law. The CAP has also provided comments to the Senate Finance Committee and the full House Ways and Means Committee in 2016 related to the Stark law.



Alternative Payment Models and the Physician Self-Referral Law

Within this RFI, the CMS requests information on alternative payment models or other novel financial arrangements, and any comments on possible approaches to address the application of the physician self-referral law to these arrangements. The CAP has been actively engaged in efforts to assess opportunities for pathologists in care coordination initiatives, including the development of alternative payment models under the Medicare Access and CHIP Reauthorization Act (MACRA) and engagement with the Physician-Focused Payment Model Technical Advisory Committee (PTAC). As diagnosticians, pathologists apply their expertise to the diagnosis and management of a wide variety of medical conditions, and thus are integral in any care coordination efforts. In fact, by virtue of their capabilities and roles, many pathologists already coordinate care and undertake efforts targeted at increasing integration to improve patient care and the patient care experience overall.

However, for MACRA's APM pathway to truly be successful, more options are needed that would provide a meaningful opportunity for pathologists' participation. Of the Advanced APMs currently available under the Quality Payment Program, pathologists are only able to participate in at most three models, and only to a very limited extent. Additionally, the fact that CMS has yet to take up any of the models recommended by PTAC demonstrates the complexity in creating appropriate physician-developed APMs as envisioned under MACRA. Having physician input and buy-in is critical to effective delivery system reform. More innovative health care payment and delivery models must be developed in an open and transparent fashion with the input of those specialties impacted by the models.

While concerns about the availability and success of APMs are most appropriately addressed by increasing specialty provider participation through added flexibility, physician input in model development, and meaningful collaboration with PTAC, we agree with CMS that some aspects of the Stark law other than IOAS may pose "a potential barrier to coordinated care," and an additional exception for APMs could be appropriate when paired with a removal of certain IOAS exceptions in fee-for-service (FFS) Medicare. Narrowing the exceptions to the Stark law in FFS Medicare would not only address improper utilization and improve patient care, but could encourage FFS providers to transition into APMs. Still, it is critical that as CMS continues to contemplate barriers to value-based care transformation, any technical changes or reforms to the current Stark law restrictions or exceptions do not have unintended consequences on physician self-referrals that may lead to increased improper utilization, other disruptive behavior, and unnecessary costs to the Medicare program. The CAP shares CMS' objective of protecting the integrity of the Medicare program. Increased improper utilization detracts from that goal and from the goal of value-based, coordinated care.

Concerns Regarding Existing Exceptions to the Physician Self-Referral Law

The CAP is concerned with the problem of overutilization of AP services by some self-referring arrangements that we believe will continue to proliferate under MACRA. Specifically, we are concerned with the IOAS exception to the Stark law that incentivizes physicians to self-refer AP services. The intent of the IOAS exception was to allow for the provision of certain non-complex ancillary services, such as simple blood tests, that are deemed necessary by the clinician to help inform the diagnosis and treatment of a beneficiary during an initial office visit. However, AP services are specialized physician services in which pathologists prepare and analyze biopsied tissues to diagnose the absence or presence of disease. These highly technical AP services typically require at least 24 hours to be completed. As such, AP services differ greatly from routine clinical laboratory tests that reasonably can be performed while the patient is in the office, providing results rapidly at



the point of care. Any patient convenience argument in favor of an IOAS exception for AP services is nullified because the patient is no longer physically in the office when the specimen is interpreted.

Over the past several years, there has been an increase of arrangements under which specialty physician groups have utilized the IOAS exception to profit from self-referred AP services performed on their own patients. There is sufficient evidence to demonstrate that the IOAS exception increases utilization rates and costs to the Medicare program to the detriment of patient care. In 2013, the Government Accounting Office (GAO) released a report titled “Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer.” The report clearly showed the impact the IOAS exception was having on the increased utilization of AP services and rising costs to the Medicare program. In 2010, GAO determined that self-referring providers made an estimated 918,000 more referrals for AP services than if they were not self-referring at an added cost of \$69 million to Medicare. (GAO-13-445).

The GAO also found that physician referral patterns for AP services increased dramatically when they switched from a non-referring to a self-referring arrangement. The GAO found that providers who did not self-refer in 2007, but had begun to self-refer by 2010, increased the number of AP referrals by as much as 58 percent. GAO concluded that “financial incentives for self-referring providers were likely a major factor driving the increase in referrals.” (GAO-13-445). These additional referrals by self-referring physicians for AP services put patients at risk. According to the GAO, “this increase raises concerns, in part because biopsy procedures, although generally safe, can result in serious complications for Medicare beneficiaries.” In addition, the GAO did not capture downstream costs if a patient receives a complication from an unnecessary service who will need continued treatment in the Medicare program.

The GAO report is among a plethora of studies demonstrating the impact the IOAS exception is having on increased utilization of AP and other services. We believe this trend will continue unless the IOAS exception loophole is closed for AP and other services, and we ask CMS to take any steps possible to assist in this effort. In addition to stopping the trend of increasing overutilization, closing the IOAS exception would save the Medicare program billions of dollars. The Office of Management and Budget and the Congressional Budget Office respectively estimated savings from the closure of the IOAS exception for these services at approximately \$6 billion and \$3.5 billion in savings over 10 years.

Recent Studies

As we have expressed with our coalition partners, the harmful effects of the Stark law’s IOAS exception on utilization patterns and health care costs have long been known. *The New England Journal of Medicine, Health Affairs*, as well as the Department of Health & Human Services’ Office of the Inspector General, have all called attention to the fact that the IOAS exception has substantially diluted the Stark law and its policy objectives. As we have also shared in comments with our coalition partners, below are a number of studies that further illustrate this point:

- In an April 2018 article 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.”¹

¹ 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 from: [https://www.europeanurology.com/article/S0302-2838\(17\)30687-5/fulltext](https://www.europeanurology.com/article/S0302-2838(17)30687-5/fulltext)



- 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.”²
- 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.”³
- A July 2013 GAO report 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.”⁴
- As referenced above, 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.”⁵
- 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.”⁶

² 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 from: <https://www.gao.gov/assets/670/662860.pdf>

³ Mitchell JM. Urologists’ Use of Intensity-Modulated Radiation Therapy for Prostate Cancer. *N Engl J Med* 2013; 369:1629-1637. Retrieved from: https://www.nejm.org/doi/full/10.1056/NEJMsa1201141?query=recirc_curatedRelated_article

⁴ 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 from: <https://www.gao.gov/assets/660/656026.pdf>

⁵ 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 from: <https://www.gao.gov/assets/660/655442.pdf>

⁶ 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 from:



- 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.”⁷

Summary

The CAP appreciates the opportunity to provide feedback on this RFI to address issues related to the physician self-referral law. We urge CMS to proceed cautiously to ensure any reforms to the Stark law do not further develop or create abusive self-referring arrangements that over-utilize services. Unfortunately, loopholes in the Stark law under the IOAS exception already exist and have created an unintended financial incentive for self-referral arrangements to increase utilization of AP services that increase the costs to the Medicare program and potential harm to its beneficiaries. These arrangements offer no benefit to patient care. In fact, many of these arrangements, given the increase in utilization, create a potential harm to beneficiaries. **Therefore, the CAP strongly encourages action that closes the IOAS exception for AP services as part of any reform to the Stark law.**

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The College of American Pathologists appreciates your consideration of these comments. Please direct questions on these comments to: Elizabeth Fassbender (202) 354-7125 / efassbe@cap.org.

<https://www.gao.gov/assets/650/648988.pdf>

⁷ 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 from: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2011.1372>