



COLLEGE of AMERICAN PATHOLOGISTS

November 21, 2016

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

The Honorable Ron Wyden Ranking
Member
Committee on Finance
U.S. Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Kevin Brady Chairman
Committee on Ways and Means
U.S. House of Representatives
1102 Longworth House Office Building
Washington, D.C. 20515

The Honorable Sander Levin Ranking
Member
Committee on Ways and Means
U.S. House of Representatives
1106 Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Hatch, Ranking Member Wyden, Chairman Brady, and Ranking Member Levin:

The College of American Pathologists (CAP) wants to take this opportunity to comment on physician self-referral arrangements as the Senate Finance Committee, and the House Ways Means Committee explore ways to make the Stark law more applicable to The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). We respectfully request the Committees move cautiously to ensure that any change or reform 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 that over-utilize services as provider's transition into new payment models. We also urge the committee to close the In-office ancillary services (IOASE) exception loopholes for anatomic pathology (AP) services as part of any Stark law reform package to deal with the ongoing problem of overutilization of these services in the Medicare program now and in the future.

The CAP represents 18,000 pathologists who practice clinical and/or anatomic pathology in community hospitals, independent laboratories, academic medical centers and federal and state health facilities. With extensive experience as a quality standards-setting organization, the CAP accredits more than 7,000 laboratories and enrolls as many as 23,000 laboratories in its Proficiency Testing (PT) programs.

MACRA impact on self-referral

The CAP appreciates the effort of the Finance and Ways and Means Committees in passing the MACRA law that replaced the sustainable growth rate formula and created new incentives in the Medicare program. As implementation of MACRA begins, some stakeholders have expressed concern that aspects of the current Stark statute inhibit their ability to incentivize performance and collaboration in accountable care organizations (ACOs) or other alternative payment models (APM) due to the risk of violating the Stark law. As you know, the Stark law generally prohibits physicians from referring Medicare services to themselves or an entity in which they have a financial interest. The intent of the Stark law was to ensure clinicians were not incentivized to refer medical services based on financial gain instead of clinical decisions. While the CAP supports efforts to move providers into coordinated care models, we also want to ensure that 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 utilization of anatomic pathology (AP) services and unnecessary costs to the Medicare program.

We recommend the Committee to consider the report from the Secretary of Health and Human Services on fraud and abuse related to APMs required under MACRA when seeking legislative reforms to the Stark law. Specifically, it requires the Secretary, in consultation with the Inspector General, to release a report within two years of the law to examine the applicability of the Federal fraud laws to services furnished under an APM. In addition, the report will identify aspects of APMs that are vulnerable to fraudulent activity and the implication of CMS waivers granted for APMs under the Medicare Shared Savings Program. The passage of MACRA encourages incentivizing the value of care rather than the volume of services and the movement to APMs. Therefore, we recommend Congress to consider the forthcoming report when examining potential changes to the Stark law to prevent potential abuse to services within the new payment models under MACRA.

IOASE loophole to the Stark law

The CAP is also concerned with the problem of overutilization of AP services by some self-referring arrangements under the current law 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, 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 often 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. The patient convenience for AP service is nullified since the patient is not physically in the office when the specimen is examined.

Over the past several years, there has been an increase of arrangements under which specialty physician groups have utilized the IOASE to profit from self-referred AP services performed on their own patients. There is sufficient evidence to demonstrate that the IOASE increases utilization rates and costs to the Medicare program to the detriment of patient care. In 2013, 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 IOASE 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 – known as switchers - 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%. 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 IOASE is having on increased utilization of AP and other services. We believe this trend will continue under MACRA unless Congress acts to close the IOASE loophole for AP services. In addition, closing the IOASE would save the Medicare program billions of dollars. The Office of Management and Budget and the Congressional Budget Office estimated in 2016 that closure of the IOAS exception for these services would generate approximately \$6 billion to \$3.5 billion in savings over 10 years, respectively.

Conclusion

The CAP appreciates the opportunity to submit comments to the Senate Finance Committee and House Ways and Means Committee as you explore potential changes to the Stark law and providers’ transition into new payment models under MACRA. We urge the Committees to oppose any technical or broad-based reforms to the Stark law if there is a potential to further develop or create abusive self-referring arrangements that over utilize services. Unfortunately, loopholes in the Stark law under the IOASE already exist and have created a financial incentive for self-referral arrangements to increase utilization of AP services that increase the costs to the Medicare program. 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 both committees to take legislative action that closes the IOASE as part of any legislative reform to the Stark law.