



American
Clinical Laboratory
Association

August 24, 2018

Ms. Lisa O. Wilson, Senior Technical Advisor
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-1720-NC
P. O. Box 8013
Baltimore, Maryland 21244-8013

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

Dear Ms. Wilson,

The American Clinical Laboratory Association (ACLA) is pleased to submit these comments on the Request for Information Regarding the Physician Self-Referral Law.¹ ACLA is a non-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional specialty, end-stage renal disease, hospital, and nursing home laboratories. The clinical laboratory industry employs nearly 277,000 people directly and generates over 115,000 additional jobs in supplier industries. Clinical laboratories are at the forefront of personalized medicine, driving diagnostic innovation and contributing more than \$100 billion annually to the nation's economy.

As the Centers for Medicare and Medicaid Services (CMS) points out, the Physician Self-Referral Law and its implementing regulations (Stark Law) were intended "to address the concern that health care decision-making can be unduly influenced by a profit motive" and that "overutilization may occur when items and services are ordered that would not have been ordered absent a profit motive."² The Stark Law has been and remains critical for mitigating the effects of financial incentives for inappropriate self-referral and the resulting overutilization of services.

However, as we explain in further detail below, the Stark Law, and procedures related to its interpretation, can and should be improved. ACLA reiterates its long-standing position that these services should be removed from the exception. ACLA supports the establishment of narrowly-tailored exceptions for certain value-based care arrangements if accompanied by appropriate safeguards. We also have suggestions for improving the process by which an entity can request an Advisory Opinion on whether a particular arrangement would comply with the Stark Law.

A. CMS should remove anatomic pathology services from the Stark Law's IOAS exception and take action to prevent further abuse of Stark Law exceptions.

The IOAS exception to the self-referral prohibition allows a physician or group practice to self-refer and bill for anatomic pathology services that are performed in the physician's office or in a space in the same building or a centralized building.³ Most non-pathology practices that self-

¹ 83 Fed. Reg. 29524 (Jun. 25, 2018).

² *Id.* at 29525.

³ 42 C.F.R. § 411.355(b).

refer and bill for anatomic pathology services use the IOAS exception to comply with the Stark Law. As we have discussed with CMS on several occasions throughout the years, an effective way to curtail abusive arrangements involving self-referral of anatomic pathology services would be to exclude these services from the IOAS exception altogether. CMS has the statutory authority to take this action and should do so promptly.

Whether or not pathology services are rightfully considered “ancillary” to the other services furnished by non-pathologists, and therefore, whether they should be eligible for the IOAS exception, is a question that has been raised by various stakeholders in recent years. When a physician performs a biopsy in his or her office, the pathology examination of that biopsy cannot be performed while the patient is present in the office. The pathology examination is too complex and takes too much time for it to be performed while a patient waits for results. Rather, the preparation of a tissue sample by a histotechnologist and its analysis by a pathologist takes place in the days subsequent to an office visit at which a biopsy is taken. Although the physician may bill for the pathology service by taking advantage of the Stark Law’s IOAS exception, the pathology service is not truly “ancillary” to the primary office service and has not in any way had an impact on the physician’s treatment of that patient while he or she is in the physician’s office. In this way, pathology is different from other simple clinical laboratory tests or x-rays that can be done while a patient waits and can be used to guide treatment during an office visit.⁴ Self-referral under this exception may be appropriate for a strep test or CLIA-waived instant urinalysis cups or dipsticks while the patient is in the office, but with anatomic pathology, results almost never are returned to the treating physician while a patient is in the office, and care for patients is in no way improved by including anatomic pathology under the IOAS exception.

The intent of the IOAS exception was to exempt from the application of the self-referral ban “in-office lab tests or X-rays,” reflecting Congress’s “judgment that there often is a clear need for quick turn-around time on crucial tests.”⁵ In implementing the IOAS exception in the “Stark I” regulations, the then-Health Care Financing Administration stated:

In general, the structure of the statutory language suggests that the Congress had two main objectives: *permitting the provision of in-office ancillary services for the convenience of patients during their patient visits* and, in the group practice context, *permitting the provision of in-office ancillary services in a dedicated building used for these services...*⁶

Thus, quick turn-around time and patient convenience were two of the primary reasons for the IOAS exception. However, providing anatomic pathology services under the IOAS exception neither decreases turn-around time nor increases patient convenience, as anatomic pathology

⁴ More recently, other high-complexity laboratory services, such as definitive toxicology testing, also have become services performed under the IOAS exception, but they are well beyond what Congress intended for the law. These types of services cannot be performed while a patient is present in the office, and it typically takes between one and four days to run the tests’ component parts and obtain complete results.

⁵ Rep. Fortney “Pete” Stark, Introduction of the Ethics in Patient Referrals Act of 1989, Congressional Record H241 (Feb. 9, 1989).

⁶ Health Care Financing Administration, “Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships; Final Rule,” 66 Fed. Reg. 856, 888 (Jan. 4, 2001) (emphasis added).

services cannot be performed while the patient waits, and he or she must return to the physician's office for a follow-up visit once a diagnosis is returned. (In fact, the wait time for results often is *increased* under arrangements where the pathologist visits the physician's office only once or twice a week.) The continued inclusion of anatomic pathology services under the IOAS exception exemplifies how implementation of the exception is far from what Congress originally intended. CMS allowed anatomic pathology services to fall under the exception, and the agency now needs to correct the problems caused by the services' inclusion therein.

Anatomic pathology's inclusion in the IOAS exception can result in overutilization and worse outcomes for patients. A seminal study authored by Georgetown University economist Dr. Jean Mitchell, which was published in the journal *Health Affairs* in 2012, showed that urologists who self-referred submitted claims to Medicare for 4.3 more specimens per prostate biopsy than the mean number of six specimens per biopsy sent by urologists to an independent laboratory. These physicians billed the Medicare program for 72 percent more specimens for patients with suspected prostate cancer than those urologists who did not have such arrangements.

The study found that despite the increased testing and billing, the per-patient cancer detection rate for self-referring urologists was actually only 20.9 percent, as opposed to 35.4 percent for non-self-referring physicians—a difference of more than 14 points. The same study suggested that financial incentives encouraged self-referring urologists to order prostate biopsies even on men who were not likely to have prostate cancer in the first place.⁷ In sum, the study found that while the number of prostate biopsies increased in practices availing themselves of the IOAS exception, cancer detection actually worsened. The study supported addressing overutilization and associated increased Medicare costs by removing surgical pathology services, and more generally the category of anatomic pathology services, from the IOAS exception.

In 2013, the Government Accountability Office (GAO) estimated that in 2010 alone, self-referring physicians performed prostate biopsies and referred anatomic pathology services at a far higher rate than they would have if they were not self-referring, and the additional referrals for anatomic pathology services cost the Medicare program approximately \$69 million.⁸ Other studies draw the same conclusion: self-referral often leads to excessive utilization of anatomic pathology services. Certain private payors already have recognized this and have taken steps to curtail self-referral by limiting or eliminating the financial incentive for a physician to self-refer and requiring additional credentialing.

ACLA believes that CMS has the authority to exclude anatomic pathology services from the IOAS exception. Under section 1877(b)(2) of the Social Security Act, a physician may self-refer those designated health services that meet the statutory requirements for who may furnish the services, who may bill for the services, and where the services may be furnished. In the same section, the statute includes an additional condition that applies to the entire IOAS exception, which states: "...the ownership or investment interest in such services meets such other

⁷ Mitchell JM. Urologists' self-referral for pathology of biopsy specimens linked to increased use and lower prostate cancer detection. *Health Aff. (Milwood)* 2012.

⁸ U.S. Government Accountability Office; Medicare: Action Needed to Address Higher Use of Anatomic Pathology Services by Providers who Self-Refer (Pub. No. GAO-13-445) (Jun. 2013).

requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.”⁹

By definition, when a group decides to establish its own in-office pathology laboratory, it is making an investment in the personnel, equipment, space, and related services and supplies necessary to furnish such services; therefore, this language gives CMS the authority to impose additional requirements on that interest, namely mandating that the investment not be used for the provision of anatomic pathology services. We believe that CMS should give close consideration to this solution for eliminating this abuse of the IOAS exception.

B. CMS could create narrowly-tailored exceptions to the Stark Law to accommodate value-based care arrangements, but only where such arrangements eliminate inappropriate financial incentives for self-referral.

ACLA shares the Administration’s goal of transforming the healthcare system into one that pays for value over volume. We would support the establishment of narrowly-tailored exceptions to the Stark Law to accommodate value-based care arrangements and alternative payment models that promote coordinated care, where such arrangements eliminate inappropriate financial incentives for self-referral. For example, a payment model that rewards referrals to a larger integrated entity of which a referring physician is a participant, but that does not have built-in safeguards against over-referral and over-utilization and that is not concerned with quality over quantity, would have little transformative effect at all nor promote the move to value over volume. ACLA urges CMS to use caution when determining whether and how to create additional exceptions to the Stark Law, and to ensure that any new exceptions adequately safeguard the Medicare trust fund.

ACLA further cautions CMS against attempts to address the Stark Law’s perceived obstacles to value-based care arrangements and alternative payment models by revising existing definitions such as “fair market value,” “commercial reasonableness,” and “group practice.” Given the importance of these terms in various provisions of the Stark Law and its implementing regulations, revising them to address one issue such as this could have far-reaching implications beyond the issue that is intended to be addressed, with unintended adverse consequences.

C. CMS can improve the Stark Law Advisory Opinion process.

ACLA recommends changes to the process by which an entity can request an Advisory Opinion about whether a particular arrangement would comply with the Stark Law. In the two decades since the Advisory Opinion process was implemented in regulation, the agency has issued less than one opinion per year. Currently, CMS accepts only those questions involving specific existing or planned arrangements and not those related to interpretation, hypotheticals, or proposed business arrangements.¹⁰ This limits the usefulness of the Advisory Opinion process tremendously.

CMS should establish a system for responding in a timely manner to requests for the agency’s interpretation of the Stark Law that does not require an actual or planned arrangement to

⁹ 42 U.S.C. § 1395nn(b)(2).

¹⁰ 42 C.F.R. § 411.370(b).

be in the works and that does not require a requestor to submit the exhaustive list of documents currently required under 42 C.F.R. § 411.372(b). This would yield useful information for others contemplating arrangements involving referring physicians and provide much-needed guidance on the parameters of the Stark Law. Under the new system, a requestor would be able to obtain the agency's current thinking on how a provision of the Stark Law is to be interpreted by submitting "a complete description of the arrangement ...including: the purpose of the arrangement; the nature of each party's (including each entity's) contribution to the arrangement; the direct or indirect relationships between the parties, with an emphasis on the relationships between physicians involved in the arrangement (or their immediate family members who are involved) and any entities that provide designated health services; the types of services for which a physician wishes to refer, and whether the referrals will involve Medicare or Medicaid patients."¹¹ Given how fact-specific the Stark Law is, the agency generally would need this type of information in order to render a useful interpretation of the law, but it should not be necessary under this type of request for the agency to require the extensive documentation it requires now.

Because of the complexity of the Stark Law and potential major changes to the law to accommodate value-based care models under Medicare, the Advisory Opinion process should be revised so that CMS can provide guidance to stakeholder on current or contemplated arrangements involving physician self-referral and on more general questions of applicability. Additionally, this guidance needs to be provided in a timely manner so that any opinion rendered remains relevant to the requestor.

D. Conclusion

Thank you for your consideration of ACLA's comments and ideas. We look forward to continuing our dialogue with the agency about removing anatomic pathology from the Stark Law's IOAS exception and about ways to reward quality in our healthcare system, rather than quantity.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sharon L. West', followed by a long horizontal line extending to the right.

Sharon L. West
Vice President, Legal & Regulatory Affairs

¹¹ 42 C.F.R. § 411.372(b)(4)(i).