COLLEGE of AMERICAN PATHOLOGISTS

December 19, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-P
P.O. Box 8013
Baltimore, MD 21244–1850

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

Re: Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to provide comments on the agency's proposed rule regarding the physician self-referral law (CMS-1720-P). 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 that reform to the physician self-referral law should be approached cautiously and only with appropriate guardrails to address improper utilization and protect patient care. Further, as we have expressed before[1], **any efforts to reform the Stark law must include action to close the in-office ancillary services (IOAS) exception for anatomic pathology (AP) services**.

In this proposed rule, the Centers for Medicare & Medicaid Services (CMS) seeks to modernize the physician self-referral law (or "Stark law") in light of "changes in the delivery of health care services and the payment for such services." Additionally, this proposed rule seeks to provide clarity and remove regulatory barriers that impede care coordination. The CAP supports efforts to improve care coordination and advance value-based care, as well as the CMS's efforts to address unnecessary regulatory burdens in health care. However, the CAP continues to have serious concerns about further incentivizing providers to over-utilize services or creating new opportunities for abusive self-referral arrangements. Appropriately, the agency notes that "we continue to operate substantially in a volume-based payment system" and changes to the Stark law must be approached with caution. The CAP agrees, and in addition to the aforementioned concern, provides comment on three main issue areas: (1) the value-based arrangement exceptions and laboratory exclusion; (2) remuneration exception and clarification; and (3) the Electronic Health Records (EHR) and cybersecurity exceptions.

We understand that the IOAS exception was outside the scope of the agency's earlier request for information and is not addressed in this proposed rule. However, the CAP strongly believes that the agency must not finalize rules related to the Stark law without considering the entire structure of the statute – including the IOAS exception – together with the pressures that result from the push towards value and the issues impeding access to quality care. Changing health care delivery and payment dynamics do not

[1] https://documents.cap.org/documents/CAP-2018-stark-RFI-comments.pdf

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automatically remove perverse incentives and may actually cause certain abusive billing practices and unfair contractual arrangements to be more prevalent. Further, protection of and access to quality care, especially for rural areas, necessitates addressing the full range of inappropriate self-referral practices while promoting value-based care.

An exclusion of AP services from the IOAS exception is the most effective means of preventing program abuses and protecting quality care for patients. Even as the CMS has taken steps to close ambiguities to deter pod labs and other abusive referral practices, physician groups are creating new arrangements to take advantage of the IOAS exception and profit from pathology services. Our members report specialty groups building large "physician office" AP laboratories serving broad geographic areas using contracted or part-time pathologists in a central location who are reimbursed at a fraction of the billed professional amount. These super group referral arrangements for high volumes of highly selected biopsy types constitute classic “cherry-picking” arrangements that effectively devalue the benefit, and destabilize the availability, of local hospital pathologists for clinician relationships that support the care of patients with complex diseases like cancer. Physicians groups continue to create new arrangements structured around any technical requirements to retain the ability to profit from highly selected pathology services. Closing the IOAS exception for AP services would go a long way towards eliminating the incentives to engage in this kind of behavior and ensuring clinical decisions are determined solely on the basis of quality, saving billions of dollars for the Medicare program.[2]

(1) Value-Based Arrangement Exceptions and Laboratory Exclusion

The CAP supports the voluntary development of innovative health care payment and delivery models and has been actively engaged in efforts to assess opportunities for pathologists in care coordination initiatives. 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. For example, pathologists are uniquely able to assist clinicians in meeting their objectives through application of evidence-based approaches to eliminate waste and inefficiencies in laboratory medicine. Given the appropriate resources and role, pathologists can share clinical and financial data as well as vital education “about the efficacy of new tests and appropriate utilization.”[3]

[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 from: https://www.europeanurology.com/article/S0302-2838(17)30687-5/fulltext; 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; 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; 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; 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; 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: https://www.gao.gov/assets/650/648988.pdf; 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

[3] http://info.cap.org/health-care-executives/downloads/executive-dialogue-role-in-value-based-care.pdf

Yet, despite the CMS's assertion that "a value-based health care delivery and payment system itself provides safeguards against harms such as overutilization, care stinting, patient steering, and negative impacts on the medical marketplace," the total absence of perverse incentives in a value-based system has not been shown. The CMS itself notes that value-based payment models pose risks of their own, including cherry-picking (selecting a target patient population consisting of only lucrative or adherent patients), lemon-dropping (avoiding costly or noncompliant patients), and manipulation or falsification of data used to verify outcomes. In particular, the CMS notes concern about compensation arrangements between physicians and laboratories that may be intended to improperly influence or capture referrals without contributing to the better coordination of care for patients. As we have stated in earlier comments, it is critical that the CMS avoid making changes to the Stark law that could have unintended consequences on physician self-referrals, leading to increased improper utilization, disruptive and/or abusive behavior/practices, and unnecessary costs to the Medicare program.

Therefore, the CAP supports the CMS's decision to exclude laboratories from the proposed value-based arrangement exceptions, and believes this is best accomplished through including such a requirement in the individual exceptions at §411.357(aa) if finalized. Finalization of the three value-based arrangement exceptions contributes to the CMS's goal of improving care coordination and increasing adoption of value-based models in the health care industry, while the exclusion of laboratories from the exceptions at §411.357(aa) helps protect against abusive arrangements and provides for future flexibility (e.g. exceptions can be created/altered for laboratories if appropriate without having to adjust the definition of VBE participant).

The CMS can provide further safeguards in its definition of "target patient population." Currently, the CMS is proposing to define the target patient population for which VBE participants undertake value-based activities to mean the identified patient population selected by a value-based enterprise or its VBE participants using legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s). In particular, the CAP appreciates the CMS's acknowledgement that cherry-picking and lemon-dropping (as explained above) would not be permissible under most circumstances, as the CMS would not consider the selection criteria to be legitimate. The CAP also supports setting out the criteria in writing in advance of the commencement of the value-based arrangement.

(2) Remuneration Exception and Clarification

In addition to changes that address value-based arrangements, the CMS in this proposed rule reexamines current regulations with an eye towards balancing "genuine program integrity concerns against the considerable burden of the physician self-referral law's billing and claims submission prohibitions."

Limited Remuneration Exception

First, the CMS proposes an exception for limited remuneration from an entity to a physician for items or services actually provided by the physician where the remuneration does not exceed an aggregate of $3,500 per calendar year. While the CMS notes that the low annual limit of the proposed exception together with other safeguards leave this exception with little risk of program or patient abuse, the CAP believes that in an attempt to accommodate non-abusive compensation arrangements

and offer more flexibility, the agency may be providing room for questionable business arrangements that are susceptible to abuse. Thus, while we have concerns that the proposed limit may be too high, the CAP urges the CMS to maintain the annual aggregate limit of $3,500 and to provide additional safeguards, including as CMS suggests, limiting the applicability of the exception to services that are personally performed by the physician and items provided by the physician. We also recognize the CMS's considerations related to the anti-kickback statute but would urge CMS to include a requirement that the arrangement must not violate the anti-kickback statute or other Federal or State law or regulation governing billing or claims submission.

Ensuring there are adequate safeguards around this exception makes especially good sense when considered together with the CMS's recent updates to the Stark law advisory opinion process. Having a clearer, "more robust advisory process" with fewer limitations and restrictions will help ensure an accessible process that produces meaningful opinions on the applicability of Stark law restrictions. Every attempt should be made to comply with the Stark law, including utilizing the updated advisory opinion process, before resorting to a catch-all exception such as the one proposed.

Remuneration Definition Changes

The CMS also proposes to clarify terminology related to remuneration. The CAP appreciates the CMS's attention to this area but is concerned with the potential for these changes to vitiate the restrictions around what is and is not considered remuneration, increasing the risk of missing items that should otherwise be considered compensation, thereby increasing the risk of overutilization.

As it stands today, the definition of "remuneration" does not include the "furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are used solely for one or more" of the permitted purposes (i.e. collecting specimens, storing specimens, ordering tests). The CMS proposes to clarify this definition by removing the parenthetical regarding surgical items, devices, or supplies. According to the CMS, Congress intended this remuneration carve-out to cover "single-use items, devices, or supplies of low value that are primarily provided by laboratories to ensure proper collection of specimens," and a surgical item may fall within that carve out. The CAP understands that this change may provide some flexibility while maintaining the more relevant "used solely" requirement, but we urge the CMS to ensure items not considered remuneration continue to be truly single-use items, devices, or supplies with "little, if any, independent economic value to the physicians who receive them."[4] For example, while the CMS has previously stated that "biopsy needles and like devices, such as snares and reusable aspiration and injection needles, are categorically excluded from the items, devices, and supplies covered by section 1877(h)(1)(C)(ii) of the Act,"[5] our members have expressed concern about any flexibility to provide bone marrow kits for free or below fair market value, as these kits have significant value. As the CMS knows, with that value comes an increased risk that the provision of the kits constitutes compensation from laboratories for the physician's referrals. We would urge CMS to take additional steps to prevent these kinds of actions.

Similarly, we have concerns with the CMS proposal to clarify "used solely" by adding that it is "in fact used solely" (so as not to eliminate items that theoretically could serve other

[4] https://www.govinfo.gov/content/pkg/FR-2001-01-04/pdf/01-4.pdf
[5] https://www.govinfo.gov/content/pkg/FR-2001-01-04/pdf/01-4.pdf

purposes). While we agree with CMS in concept that clarifying this requirement is helpful, we are worried about the administration and real-world enforcement of this change. Any "slippery slope" changes that could erode important restrictions around remuneration is problematic, despite the CMS's guidance on steps a party can take to ensure the furnished items, supplies, or devices are used appropriately. As the agency has argued, we believe that when used for other purposes, used repeatedly or potentially used repeatedly, or having a primary function of some other purpose besides one of the six purposes listed in the statute, "the provision of such items for free or below fair market value poses a risk that the items may constitute compensation from the laboratories for the physician's referrals and increase the risk of overutilization."[6] We urge the CMS to ensure remuneration restrictions continue to prevent this behavior.

(3) The EHR and Cybersecurity Exceptions

In this proposed rule, the CMS offers changes to the EHR exception intended to update the provision and ensure consistency across statutes. According to the CMS, these modifications are "modest" and include removing the sunset date, clarifying that certain cybersecurity technology is included as part of an EHR arrangement, updating provisions regarding interoperability and data lock-in, modifying the 15 percent physician contribution requirement, and permitting certain donations of replacement technology. Importantly, the EHR exception would continue to be available to physicians and entities other than laboratories.

As you may know, the CAP has objected to the inclusion of pathology practices and laboratories that provide anatomic and clinical pathology services as protected donors since the EHR exception to the Stark law was first promulgated. These objections arise from abusive practices and improper inducements reported by our members, including arrangements as a condition of doing business. While we recognize that there have been "significant updates" since the 2013 EHR final rule to address issues such as interoperability and lock-in/information blocking, we appreciate the CMS decision to continue excluding laboratories from the EHR exception. The risks identified by our members and this agency have not dissipated despite continued adoption of EHR technology. We note that if it were not for the continued exclusion of laboratories from this exception, we would have serious concern about the CMS's proposals to remove the sunset provision and the 15 percent recipient cost-sharing requirement. We do, however, note that the changes around replacement technology are generally positive.

However, the CAP believes these same concerns apply to the newly proposed cybersecurity exception and we suggest that laboratories be similarly excluded from this exception if finalized. Alternatively, the CMS could choose to not finalize this additional exception as the clarification/expansion of the EHR exception to include cybersecurity is adequate to address the agency's concerns.

The CAP understands the benefits that strong cybersecurity technology and services can provide in protection of health information and addressing "the growing threat of cyberattacks." However, as we argued in 2013 regarding the EHR exception, the inclusion of pathology practices and laboratories as potential donors would negatively affect access to health care services, quality, competition, cost to the federal health care programs, and utilization. While CMS believes that cybersecurity donations do not present the same type of risks as EHR donations, there remains the risk to condition the

[6] https://www.govinfo.gov/content/pkg/FR-2001-01-04/pdf/01-4.pdf

donation on doing business or otherwise engage in abusive or unfair practices. The agency's proposal to preclude the potential donation recipient, their practice, or any affiliated individual or entity, from demanding (explicitly or implicitly) a cybersecurity donation as a condition of doing or continuing to do business with the donor, may not be enough. The best way to protect against this behavior is to mirror the EHR exception and exclude laboratories, or to simply not finalize this exception.

Summary

The CAP appreciates the opportunity to provide comments on this proposed rule to address issues related to the physician self-referral law. While we agree that it is appropriate to evaluate ways to advance value-based care and remove regulatory burdens, the CAP strongly urges closure of the IOAS exception for AP services as part of any reform to the Stark law. Further, we support the CMS's decision to exclude laboratories from the proposed value-based arrangement exceptions by including such a requirement in the individual exceptions at §411.357(aa) if finalized. The CAP also acknowledges the CMS's attention to terminology related to remuneration but expresses concern with the potential for these changes to erode remuneration restrictions and increase the risk of missing items that should otherwise be considered compensation. Finally, we support the continued exclusion of laboratories from the EHR exception and urge the CMS to take similar action in the new cybersecurity exception if finalized.

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The College of American Pathologists appreciates your consideration of these comments. Please direct questions to Elizabeth Fassbender, JD, Assistant Director, Economic and Regulatory Affairs, at (202) 354-7125 / efassbe@cap.org.

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