

December 20, 2019

Seema Verma, MPH  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

Re: File code CMS-1720-P

Dear Ms. Verma:

The Medicare Payment Advisory Commission welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services proposed rule entitled “Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations,” *Federal Register*, vol. 84, no. 201, p. 55766 (October 17, 2019). We appreciate your staff’s efforts to evaluate and potentially modify the self-referral rules to better support Medicare’s movement to value-based payment models, particularly given the many competing demands on the agency’s resources.

Although there are many important issues addressed in the notice of proposed rule-making (NPRM), we focus our comments on the following four aspects of the proposed rule:

- the proposed exceptions for certain value-based compensation arrangements between physicians and others,
- the proposed “volume or value standard,”
- the proposed exclusion of certain providers and suppliers from value-based enterprise participation, and
- the regulatory impact analysis.

## Background

The Commission has long supported regulatory relief for entities that are at two-sided risk for all Part A and Part B Medicare spending for a defined population of beneficiaries and accountable for quality and clinical outcomes. We have communicated this position in numerous reports to the Congress and comment letters to the Secretary and the Administrator of CMS.<sup>1</sup> This principle is

---

<sup>1</sup> Medicare Payment Advisory Commission. 2018. Comment letter to CMS on Medicare Shared Savings Program: Accountable Care Organizations—Pathways to Success proposed rule. October 15. Medicare Payment Advisory

rooted in the notion that only models with strong incentives for improving quality and controlling Medicare spending will overcome the incentives in Medicare fee-for-service (FFS) to increase the volume of services provided. Encouraging participation in models that are not at two-sided risk will be unlikely to change incentives sufficiently to move the program toward rewarding value instead of volume. Thus, we maintain that the measure of success is not how many entities participate in “value-based” models, but rather if the models that they participate in do, in fact, control Medicare spending and improve or maintain quality. To make that judgment, CMS needs to be able to evaluate the models and their success or lack thereof.

The physician self-referral law (also known as the Stark law) is intended to limit the incentive to increase the volume of Medicare services by prohibiting financial relationships between physicians and providers of designated health services, unless those relationships fit within an exception. The Stark law provides an absolutely necessary safeguard for the Medicare program and its beneficiaries. Revisions to the law and its regulations must be approached carefully and with due regard for the law’s importance and the possibility of unintended consequences for increased and unnecessary utilization of Medicare-covered services. A large body of research suggests that financial incentives influence some physicians’ behavior. For example, compared with non-self-referring physicians, self-referring physicians were 53 percent more likely to refer their prostate cancer patients for a particular type of treatment—intensity modulated radiation therapy (IMRT)—instead of other treatments when they had a financial interest in an IMRT machine.<sup>2</sup> In addition, physicians who began self-referring for MRI and CT scans increased their MRI and CT referrals by about 67 percent, on average, over a two-year period, compared with a small decline for non-self-referring physicians.<sup>3</sup>

In the proposed rule, CMS proposes new exceptions to the Stark law for value-based compensation arrangements. CMS defines the following key terms that are critical to understanding the proposed exceptions:

- *Value-based activity* includes any of the following activities: (1) provision of an item or service; (2) the taking of an action; or (3) refraining from taking an action, as long as the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise.
- *Value-based enterprise* (VBE) means two or more VBE participants (1) collaborating to achieve at least one value-based purpose; (2) each of which is a party to a value-based arrangement with the other (or at least one other participant in the VBE); (3) that have an accountable body or person responsible for financial and operational oversight of the VBE;

---

Commission. 2015. Comment letter to CMS on Medicare Shared Savings Program: Accountable Care Organizations proposed rule. February 2. Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare and the healthcare delivery system*. Washington, DC: MedPAC.

<sup>2</sup> Government Accountability Office. 2013. *Medicare: Higher use of costly prostate cancer treatment by providers who self-refer warrants scrutiny*. GAO-13-525. Washington, DC: GAO.

<sup>3</sup> Government Accountability Office. 2012. *Medicare: Higher use of advanced imaging services by providers who self-refer costing Medicare millions*. GAO-12-966. Washington, DC: GAO.

(4) that have a governing document that describes the VBE and how the participants intend to achieve its value-based purpose.

- *Value-based arrangement* is an arrangement for the provision of at least one value-based activity for a target population between or among (1) the VBE and one or more of its VBE participants or (2) VBE participants in the same VBE.
- *Value-based purpose* means any of the following: (1) coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to (or growth in expenditures of) payors without reducing quality of care for a target patient population; (4) transitioning from health care delivery and payment mechanisms based on the volume of items and services to mechanisms based on the quality of care and control of costs for a target population.

Concurrent with CMS's proposal to create new exceptions to the Stark law under Title XVIII of the Social Security Act, the Office of Inspector General (OIG) has proposed new safe harbors to the anti-kickback statute (AKS) for a similar set of value-based arrangements under Title XI of the Act. We commend the OIG for recognizing and addressing key risks the proposed new safe harbors might pose for the Medicare program and its beneficiaries. Although we do not separately comment on the OIG's proposals under Title XI, we anticipate that the OIG may be interested in our comments in this letter related to concerns about issues common to both sets of proposals. We also reference the OIG's proposals where pertinent to our discussion of CMS's proposed exceptions to the Stark law.

### **Proposed exceptions for certain value-based compensation arrangements between physicians and others**

CMS proposes three new exceptions to the physician self-referral law:

#### (1) Full financial risk

CMS proposes an exception to the physician self-referral law that would apply to value-based arrangements between VBE participants in a VBE that has assumed "full financial risk" for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. In other words, the VBE would be financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for a target patient population. For Medicare beneficiaries, CMS proposes this requirement to mean that the VBE, at a minimum, is responsible for all items and services covered under Parts A and B.

#### (2) Meaningful downside financial risk to physicians

CMS proposes an exception that would protect remuneration paid under a value-based arrangement where the physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the VBE.

(3) Value-based arrangements

CMS proposes an exception for compensation arrangements that qualify as value-based arrangements, regardless of the level of risk undertaken by the VBE or any of its VBE participants.

*Comment*

Full financial risk

The “full financial risk” exception would apply to VBEs that have arrangements with Medicare and non-Medicare payors.<sup>4</sup> However, CMS already has the authority to waive the Stark law for Medicare accountable care organizations (ACOs) in the Medicare Shared Savings Program (MSSP) and for Medicare models developed by the Center for Medicare & Medicaid Innovation (CMMI). It is unclear whether the proposed full risk exception differs substantively from CMS’s current authority to waive the Stark law for certain models. It is also unclear whether CMS has the authority to develop Medicare FFS arrangements outside of MSSP and CMMI models to which the proposed full risk exception would apply. To the extent that CMS plans to apply the “full financial risk” exception outside of the MSSP and CMMI models, we have the following four concerns.

First, our principle for providing regulatory relief requires the entity to be at two-sided risk and to be accountable for quality outcomes. Thus, the VBE should be at true financial risk in order to qualify for the full financial risk exception. However, CMS states that a payor could make payments to a VBE to offset losses incurred by the enterprise above those prospectively agreed to by the parties (84 FR 55780). This essentially allows payors to create risk corridors for VBEs. While the Commission does not object to the creation of risk corridors, CMS does not provide any details regarding the minimum amount of risk that VBEs would need to assume to qualify for the exception. For example, if the payor is able to offset 100 percent of the VBE’s losses, the VBE would, in reality, bear no risk. We suggest that CMS set a limit on the share of the VBE’s losses that a payor could offset. CMS has taken this approach in defining significant risk for advanced alternative payment models.

Second, the VBE is not required to be accountable for quality outcomes. Although the definition of a “value-based purpose” references the “quality of care,” “quality” is not defined and could include quality measured solely by process measures instead of by outcomes. In contrast, the OIG’s proposed rule for new safe harbors to the AKS for similar value-based exceptions states that “coordination and management of care,” which is required for each of its safe harbors parallel to the three exceptions we are discussing, must be tailored to “improving the health outcomes” of the target population (84 FR 55707). We suggest CMS use similar specificity if it proceeds with this exception.

---

<sup>4</sup> The impact of this exception on non-Medicare patients and payors is beyond the scope of this letter, which focuses on the implications for Medicare and its beneficiaries.

Third, CMS can learn from payment models which incentive arrangements work and which do not. Without that knowledge, it will be difficult to advance the movement toward true value-based care. CMS currently has the authority to pursue value-based payment models through the MSSP and CMMI. Under those models, it can set per beneficiary spending benchmarks, risk-adjust payments, and monitor for changes in quality. CMS already has the authority to waive the Stark law and the AKS for these models and to require these models to provide data to CMS that enable it to evaluate the success or failure of the models. This framework allows CMS to test new payment models and determine which ones are best able to reduce spending while maintaining or improving quality. It would not seem desirable to develop new models outside this framework, even if CMS determines it has the authority to do so. When CMS establishes models with full risk arrangements within the current framework of MSSP and CMMI, the agency is able to evaluate the success or failure of these arrangements.<sup>5</sup>

Fourth, the proposed rule does not discuss the extent to which the value-based arrangements should be transparent to CMS and others, including beneficiaries, oversight agencies, and researchers. The Commission believes that there should be transparency regarding who participates in full risk arrangements and other value-based arrangements that are exempted from the Stark law. This principle applies whether or not the arrangement involves Medicare beneficiaries because financial relationships involving non-Medicare beneficiaries could affect the way in which clinicians treat Medicare beneficiaries. Transparency could discourage arrangements that result in higher spending or worse outcomes. Requiring transparency is also consistent with the OIG's proposal to require disclosure of the VBE, VBE participants, and value-based arrangements as a requirement to qualify for a new safe harbor to the AKS (84 FR 55713). CMS should adopt similar requirements under the proposed revisions to the physician self-referral regulations.

#### Meaningful downside financial risk

The Commission does not support the proposed exception for value-based arrangements with meaningful downside financial risk to the physician. The proposed exception refers only to the arrangement between a physician and the VBE and not the arrangement between the VBE and a payor. Fundamentally, in the Commission's view, a VBE should have a risk arrangement with a payor before any exception can be contemplated, and this proposal does not require such an arrangement. If the VBE does not share risk with a payor, the VBE could have an incentive to increase volume and spending. This principle is recognized in the OIG's proposal to create an AKS safe harbor for value-based arrangements with substantial downside financial risk. In its proposal, the OIG notes that a VBE would assume downside risk from a payor, and the VBE could then share savings or losses with VBE participants (84 FR 55716).

Accordingly, we believe that this exception poses a risk of higher spending for the Medicare program and lower quality for beneficiaries. For example, it could lead a physician who is receiving payments from a hospital for a value-based activity to refer more patients to the hospital

---

<sup>5</sup>Alternatively, if CMS establishes full risk arrangements outside of the MSSP and CMMI-approved models, providers would have a diminished incentive to enroll in MSSP and CMMI models because they could receive at least part of the benefit of enrolling in such models (a waiver of the Stark law) without having to be evaluated by CMS.

for more services, some of which may be unnecessary. The Medicare program would have to pay for any overall increase in volume. Because there is not necessarily a VBE at risk for total Medicare payments for a population, there is no constraint on total spending.

Moreover, the proposed definition of “meaningful downside financial risk” does not, in fact, represent meaningful risk. For example, under the proposed exception, a physician may only be at “risk” for 25 percent of the “extra” compensation he or she receives from the VBE for performing a specified value-based activity. For example, if a physician’s patients had total Medicare spending of \$1,000,000 and the physician was paid \$10,000 by a VBE for performing a specific value-based activity, the physician would only be at risk for 25 percent of the \$10,000 (i.e., \$2,500)—even if the physician failed to meet the goal for the value-based activity. The physician would still receive \$7,500 from the VBE as well as whatever Medicare paid for the physician’s services. The physician would not be at risk for a percentage of total spending or even a percentage of his or her revenue from Medicare. We do not believe this constitutes meaningful downside risk.

#### Value-based arrangements

The Commission does not support the proposed “value-based arrangements” exception because providers would face no downside financial risk, and the safeguards CMS proposes are likely insufficient to guard against program abuse or risks to patients. Putting providers at financial risk is a key safeguard because otherwise the remuneration that physicians receive from entities, such as hospitals or imaging centers, could induce referrals for unnecessary services. Unnecessary services drive up Medicare spending and expose beneficiaries to additional costs and potential harms from inappropriate procedures. In lieu of physicians facing downside risk, CMS proposes alternative safeguards, such as having the value-based arrangement set forth in writing and signed by the parties. However, we believe these safeguards are insufficient and do not provide the same level of protection to patients and the Medicare program as requiring that providers accept two-sided risk on a fully transparent and verifiable basis.

We are also concerned that providers could use value-based arrangements to steer patients to providers for reasons other than improving the quality of care. While referring patients to certain providers could legitimately be part of a value-based arrangement, it could also result in lower quality care and higher expenditures if motivated by financial considerations. This risk is heightened if providers do not face downside risk. The fact that steering could be used in both appropriate and inappropriate ways again underscores the need for all three types of value-based arrangements that are exempted from the Stark law to be transparent to CMS, beneficiaries, and others.

Our concerns are consistent with those expressed by the OIG in its proposal to develop a safe harbor to the AKS for care coordination arrangements. The OIG states that the agency is “concerned that the offer or provision of remuneration under value-based arrangements could present opportunities for the type of fraud and abuse traditionally seen in the FFS system, particularly where the parties offering or receiving the remuneration have not assumed downside financial risk...” (84 FR 55708). Therefore, the OIG proposes a substantial number of safeguards, such as limiting remuneration to only in-kind compensation and requiring the recipient of that compensation to pay at least 15 percent of its cost (e.g., if a hospital pays for a care coordinator in

a skilled nursing facility, the nursing facility would be required to pay at least 15 percent of the cost of the coordinator). While the Commission does not support CMS's proposed exception for value-based arrangements, if the agency decides to move forward with this exception, we believe that it should adopt a more robust set of safeguards, akin to those proposed by the OIG for the safe harbor.

### **Proposed "volume or value standard"**

Many current exceptions to the Stark law require that compensation paid under an arrangement is not determined in a manner that takes into account the volume or value of referrals by the physician. In this proposed rule, CMS states that industry stakeholders have expressed concern that CMS has not defined an objective standard for when compensation does, in fact, vary based on the volume or value of referrals. In response, CMS proposes that compensation will be considered to take into account the volume or value of referrals only when (1) the mathematical formula used to calculate that compensation includes referrals as a variable and (2) the amount of the compensation correlates with the volume or value of the physician's referrals.

#### *Comment*

The Commission does not support this proposal because the proposed standard is too narrow to protect the Medicare program from abuse. For example, payments from hospitals to physicians could increase based on the expectation of future referrals without a mathematical formula explicitly delineating it—that would be acceptable under the proposed standard. Because the volume or value standard underlies many current Stark exceptions, establishing such a narrow definition could undermine CMS's ability to enforce the law. However, CMS should use the advisory opinion process to provide clearer guidance to providers about whether compensation agreements take into account the volume or value of referrals.

### **Proposed exclusion of certain providers and suppliers from VBE participation**

Out of concern for potential abuses, CMS proposes excluding the following providers and suppliers from the definition of "VBE participant:" pharmaceutical manufacturers; manufacturers and distributors of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); pharmacy benefit managers (PBMs); wholesalers; and distributors.

#### *Comment*

The Commission supports removing these providers and suppliers from the definition of VBE participants. In its June 2018 report to the Congress, the Commission detailed certain abuses associated with physician-owned distributors (PODs) and raised concerns about relationships involving DMEPOS suppliers and other actors that resulted in widespread beneficiary harassment and substantial increases in Medicare spending for off-the-shelf orthotics.<sup>6</sup> This provision will

---

<sup>6</sup> PODs are entities that derive revenue from selling, or arranging for the sale of, devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients. Medicare Payment Advisory

maintain the status quo in relation to these providers; however, continued vigilance will be required.

### **Regulatory impact analysis**

Although CMS states that the proposed rule is “economically significant” and has been designated a “major rule,” it does not present estimates of any increases in utilization or spending resulting from the new exceptions to the Stark law (84 FR 55836). CMS states that the proposed changes, if finalized, will reduce provider burden and will be a deregulatory action.

#### *Comment*

CMS should present its best, detailed estimates of changes in Medicare program spending that it expects to result from the proposed new exceptions and other regulatory changes. It should also explain whether any estimated increases in Medicare spending are more or less than the expected benefits. The costs of increased volume could easily outweigh any benefit. Successful value-based programs often produce limited savings (e.g., 1 or 2 percent of total spending), and many value-based programs produce no savings or even increase spending.<sup>7</sup> CMS seeks “comment on the economic impact of this proposed rule, including any potential increase or decrease in utilization, any potential effects due to behavioral changes, or any other potential cost savings or expenses to the government as a result of this rule” (84 FR 55837). We agree that such estimates are important, but CMS is better placed to make those estimates than others and should do so because they are crucial to determining whether the proposed changes would pose an unacceptable risk to the program and its beneficiaries.

### **Summary**

The Commission supports the movement toward value-based models for Medicare. We also support regulatory relief for models that place providers at two-sided risk and hold them accountable for quality outcomes. However, the Stark law and the AKS contain important protections for the Medicare program and its beneficiaries from unnecessary and wasteful utilization of Medicare-covered services. Any changes to the regulations implementing the Stark law must be undertaken carefully and with acknowledgement of any reduction in the protections for the program and its beneficiaries. At the very least, CMS should estimate the effects of these proposed changes on the use of Medicare services, Medicare spending, and Medicare beneficiaries. Such estimates would help the Commission and others make a more informed judgment about these proposed changes.

---

Commission. 2018. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

<sup>7</sup> Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.



Seema Verma  
Administrator  
Page 9

MedPAC appreciates the opportunity to comment on this proposed rule. The Commission also values the ongoing cooperation and collaboration between CMS and MedPAC staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact James E. Mathews, MedPAC's Executive Director at (202) 220-3700.

Sincerely,

A handwritten signature in cursive script that reads "Francis J. Crosson M.D.".

Francis J. Crosson, M.D.  
Chairman