



**American Society for
Gastrointestinal Endoscopy**

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The Honorable Seema Verma
Administrator
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Washington, DC 20201

Re: CMS-1720-P — Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations

Dear Administrator Verma:

The American Society for Gastrointestinal Endoscopy (ASGE) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule "Modernizing and Clarifying the Physician Self-Referral Regulations" (CMS-1720-P), published in the *Federal Register* on October 17, 2019.

The ASGE was founded in 1941 and since that time has been dedicated to advancing patient care and digestive health by promoting excellence in gastrointestinal endoscopy. ASGE, with more than 14,000 members worldwide, promotes the highest standards for endoscopic training and practice, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education.

In comments to the Agency in August 2018, ASGE wrote that the most straightforward approach to reduce confusion and anxiety associated with compliance of the physician-self referral law, and thereby encourage better care coordination, is the creation of a single, comprehensive waiver for participants in alternative payment models (APMs) that can reasonably be expected to meet the "triple aim" of improved individual beneficiary quality of care; improved quality of care for patient populations; and lower growth of health care expenditures.

As Medicare and other payers gradually shift from a largely volume-based payment to value-based payment, it is important that payment and regulatory policies reflect this shift. The ASGE commends the Agency for proposals in this rule aimed at removing barriers — real or perceived — to care coordination and value-based care by creating three new exceptions to the physician self-referral law. Notably, ASGE strongly supports that the proposed exceptions would apply regardless of whether a value-based arrangement relates to care furnished to Medicare beneficiaries, non-Medicare patients, or a combination of both.

It is important that new exceptions do not add complexity and burden, but, at the same time, ensure Medicare program integrity and protect Medicare beneficiaries. ASGE appreciates that CMS has attempted to achieve that balance with the proposed new exceptions and offers the following comments which center on ensuring that the proposed exceptions: are attainable; do not contribute to further market consolidation; will ease administrative burden and risk of violating the physician self-referral law; and will facilitate care coordination and participation in value-based activities that benefit patients and the health care system overall.

FACILITATING THE TRANSITION TO VALUE-BASED CARE AND FOSTERING CARE COORDINATION

Proposed Definitions

In the proposed rule, CMS emphasizes that the proposed exceptions to the physician self-referral law apply only to compensation arrangements that qualify as value-based arrangements. Because these definitions, and their inter-connectivity, are essential to the application of the exceptions, it is therefore important that they capture the range of value-based arrangements.

a. Value-based activity

CMS proposes to define a value-based activity as one that includes any of the following activities so long as the activity is “reasonably designed” to achieve at least one value-based purpose of a value-based enterprise (VBE): 1) The provision of an item or service; 2) the taking of an action; and 3) the refraining from taking an action.

We caution CMS from potentially further interpreting how an activity is “reasonably designed” to achieve a value-based purpose. ASGE recommends that the determination of “reasonably designed” be based on all relevant facts and circumstances and that a value-based activity will satisfy this standard if it has a reasonable chance of achieving a value-based purpose, for which CMS is proposing to define as: 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 the quality of care for a target patient population; or 4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

ASGE joins the American Medical Association (AMA) in supporting the exclusion from the definition of “value-based activity” any activity that results in information blocking, thereby preventing data exchange.

b. Value-based arrangement

CMS proposes a value-based arrangement would mean an arrangement for the provision of at least one value-based activity for a target population between or among: 1) the value-based enterprise and one or more of its participants; and 2) VBE participants in the same value-based enterprise.

ASGE agrees with CMS’ assessment that most arrangements, but, importantly, not all arrangements, would involve the coordination and management of care of a target patient population.

c. Value-based enterprise

CMS is proposing to define a VBE as two or more VBE participants: 1) collaborating to achieve at least one value-based purpose; 2) each of which is party to a value-based arrangement with the other or at least

one other VBE participant in the value-based enterprise; 3) that have an accountable body or person responsible for financial and operational oversight of the VBE; and 4) have a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purpose(s).

We appreciate that CMS is not intending to dictate or limit the appropriate legal structures for qualifying as a VBE, rather an enterprise could be a distinct legal entity, such as an accountable care organization, or two parties in a value-based arrangement under a written agreement of how the parties will achieve their value-based purpose. ASGE asks that CMS expressly allow individual physicians and other clinicians to be added to a value-based arrangement on an ongoing basis. In fact, most Medicare APM entities allow clinicians and TINs to join an APM entity throughout the calendar year on a rolling basis.

d. Value-based purpose

CMS proposes that at least one value-based purpose must anchor every compensation arrangement that qualifies as a value-based arrangement. Those proposed value-based purposes include: 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 the quality of care for a target patient population; or 4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

In response to CMS' request for comment on whether to require that the value-based purpose of appropriately reducing the costs to, or the growth in expenditures of, to payers without reducing the quality of care for the target patient population should be revised to require that quality be improved or that already-improved quality of care be maintained, ASGE suggests that the value-based purpose be finalized as proposed. Requiring that costs or growth in expenditures be appropriately reduced without reducing the quality of care allows for continuous quality improvement.

With regard to the value-based purpose of "improving the quality of care for a target patient population," we suggest modifying it to "improving the quality of care *or maintaining the already-improved quality of care for the target population*." This modification ensures the VBE can continue to qualify for an exception under this purpose after there has been an improvement in quality of care. A VBE and its participants should not lose its exception if quality metrics demonstrate topped out quality performance. To determine whether quality of care has been improved (or if improved care is maintained) or if costs have been reduced, CMS could use existing metrics, such as those collected through the Merit-based Incentive Payment System (MIPS), as well as data registries.

ASGE believes CMS has appropriately not included reduction in costs alone as a value-based purpose, but instead couples reduction in or control of costs alongside maintaining or improving or quality of care.

With respect to defining "coordinating and managing care," in its corresponding anti-kickback safe harbors proposed rule (84 FR 55694), the Office of Inspector General (OIG) has proposed to define "coordinating and managing care" as "the deliberate organization of patient care activities and sharing of information between two or more VBE participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population."

ASGE agrees with the AMA that while the goal of coordinating care should be to be achieve more effective care, requiring constant achievement is not practical in the practice of medicine. Therefore, "coordination and management of care" should be defined to mean "the deliberate organization of patient

care activities and sharing of information between two or more VBE participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population, *in an attempt* to achieve safer and more effective care for the target patient population.”

e. VBE participant

CMS is proposing to define a VBE participant as an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.

f. Target patient population

CMS is proposing that for the purposes of an exception, a target patient population would be an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the VBE’s value-based purpose.

The ASGE agrees with the AMA that a physician’s or a VBE’s entire patient population could be considered a target patient population as long as such determination is based off legitimate and verifiable criteria. This consideration would decrease the significant administrative burden by not requiring a physician to first determine whether one patient is the subject of value-based activities while another patient is not. Including the VBE’s entire patient population would also minimize the potential for a VBE or its participants, particularly participants in multi-specialty group practices, to run afoul of rules relating to compensation arrangements that take into consideration the volume or value of referrals. Moreover, allowing the entire patient population to be included also further promotes population health management and all-payer models operating outside of the Centers for Medicare and Medicaid Innovation. Furthermore, limiting the definition of target patient population to patients with identifiable medical or health characteristics may inadvertently exclude preventive care, including services like screening colonoscopy. We believe that how CMS defines the target patient population will represent a strong determinant of whether physicians can effectively use the new proposed exceptions to further value-based arrangements without added complexity and concern of violating the physician self-referral laws.

Proposed Exceptions

Under the proposed value-based exceptions, CMS is not proposing to require that remuneration is consistent with fair market value and not determined in any manner that takes into account the volume or value of a physician’s referrals or the other business generated by the physician for the entity. Instead, CMS is proposing safeguards against abuse, including requirements incorporated through the applicable value-based definitions.

ASGE strongly supports that the proposed exceptions not take into account volume or value or require that the fair market value standard be met and instead rely on value-based definitions. However, these exceptions will only be easier to navigate than the current Stark limitations if CMS does not narrowly apply an exception to the services and items provided to a narrowly defined target population. Rather, there should be protection for downstream arrangements that will result in the vast majority of individuals and entities wishing to engage in value-based arrangements, otherwise they will likely find these proposed exceptions to be of limited utility. Narrow exceptions perpetuate current rules — which require the creation of multiple pools of physician for compensation allocation purposes — that are confusing, complex and contradictory to the proposed value-based purposes and goal of reduced administrative burden.

CMS is also proposing to not limit the value-based exceptions to CMS-sponsored models or to establish separate exceptions with different criteria for arrangements that exist outside of CMS-sponsored models. ASGE strongly supports the decision to establish a single suite of value-based exceptions that apply to care furnished to Medicare beneficiaries, non-Medicare patients, or a combination of both.

a. Full financial risk

Under this proposed value-based arrangement exception, the VBE must, during the entire term of the arrangement, assume full financial risk — Parts A and B items and services at a minimum — for a payor for patient care services for a target patient population.

ASGE agrees with the AMA that not many value-based arrangements take on total financial risk. And, in fact, the full financial risk safe harbor will lead to further consolidation of the health care industry because hospitals must be included in the VBE to account for all items and services covered by Medicare Parts A and B for a target patient population. Nonetheless, the VBE should be considered at full financial risk if it is responsible for the cost of *only* a defined set of patient care services for a target patient population.

CMS is also proposing to protect value-based arrangements entered into in preparation for implementation of the VBE's full financial risk payor contract. ASGE supports this protection and believes a one-year period of protection would be a sufficient timeframe.

b. Meaningful downside financial risk

Under this proposed value-based arrangement exception, the physician must be at meaningful downside financial risk for failure to achieve the value-based purposes of the VBE during the entire term of the arrangement. CMS proposes to define meaningful downside risk as the physician being at risk for no less than 25 percent of the *value of the remuneration* the physician receives under the value-based arrangement. We request clarification in the final rule whether the value of remuneration means all the compensation that a physician receives under the value-based arrangement for services and any additional incentives or if it relates only to the incentive payment. If the former, 25 percent is extraordinarily high and inconsistent with financial risk for existing CMS programs (e.g., 8 percent for Advanced APMs; 5 percent for medical homes; and 9 percent under MIPS). We assume CMS means the latter based on the request for comment of whether 25 percent “of only a nominal amount of remuneration would be sufficient to curb the influence of traditional FFS, volume-based payment.” In this regard, we suggest that whether the amount is “nominal” depends on the value-based arrangement and the size of the target population. Therefore, ASGE would oppose an amount higher than 25 percent.

The exception does not seem to apply where the physician's risk involves receiving less than full payment as opposed to making repayments. Many current value-based arrangements withhold payment from physicians for not potentially meeting a benchmark and have the clinically integrated network or group practice assume the risk on behalf of the individual physicians. The proposed exception reads such that a physician must pay out of pocket for potentially missing a benchmark, and the network or group practice cannot assume risk on behalf of individual physicians. Accordingly, we ask CMS to provide clarification that the exception allow for physician withholdings and for allowing the network or group to assume the risk to meet the requirements of substantial downside risk.

Also with regard to this exception, ASGE:

- Supports inclusion of a protection, of at least a one-year period, for preparation for the implementation of a meaningful downside/substantial downside risk exception/safe harbor.

- Seeks clarification as to whether a physician could join the value-based arrangement while the arrangement is already ongoing, assume financial risk for the duration of their participation, and still receive protection. The alternative would require that prior to the start of the value-based arrangement, all VBE participants must be locked into participating and no additional participants could be added during the existences of the VBE. We believe this to be an untenable scenario.
- Recommends that the “set-in-advance” requirements be softened to permit substitution of metrics and other adjustments as long as the substitute metrics are consistent with the value-based purposes.
- Requests protections that allow a VBE participant to exit a VBE for cause without having ongoing financial liability. Examples could include loss of a key responsible individual (death, disability), collapse of administrative infrastructure, etc.

c. Value-based arrangement

ASGE is pleased that CMS is proposing that a value-based arrangement, provided that the arrangement satisfies specified requirements, could qualify for the exception even if the VBE and its participants do not assume financial risk. And, while CMS feels compelled to propose that a value-based arrangement in which the VBE does not assume financial risk should meet more requirements than a VBE that has taken on full or partial risk, it is important that these requirements do not impede the intent of these exceptions, and that geared toward improved care coordination and management.

In contrast to the full- and partial risk exceptions, CMS is proposing that under this exception, remuneration could not be conditioned on the volume or value of referrals of any patients to the entity or the volume or value of any other business generated by the physician for the entity. This requirement, or imposing a fair market value requirement, will seriously constrain care coordination efforts. Instead, ASGE recommends the requirement be modified such that remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

As proposed, this exception permits monetary and non-monetary remuneration and exception is allowed regardless of the level of risk. CMS is considering whether it should limit this exception to non-monetary remuneration. ASGE supports, as proposed, that the exception would permit both monetary and non-monetary remuneration and that excluding monetary remuneration would unnecessarily limit the advancement of and participation in value-based activities. For example a VBE working to reduce hospital admissions for patients with inflammatory bowel disease or cirrhosis through better control of their disease should be rewarded monetarily for improved quality of care and savings to the health care system overall.

CMS states in the rule that it is considering whether to require the recipient of any non-monetary remuneration under a value-based arrangement to contribute at least 15 percent of the donor’s cost of the non-monetary remuneration. While the 15 percent is predicated on the electronic health record (EHR) safe harbor, it is regarded as a significant impediment to the adoption of EHR by small physician practices and physicians providing care in underserved areas. In addition to a contribution requirement being potentially cost prohibitive, a contribution requirement adds unnecessary burden and complexity (particularly in cases where the non-monetary contribution is shared among VBE participants), requiring setting the contribution amount in writing and ongoing monitoring and tracking of contribution amounts to ensure compliance.

Also, with regard to this exception, ASGE:

- Supports that the “set-in-advance” requirements allow, while the value-based arrangement is active, adjustments to or substitutions of quality metrics against the recipient of which the remuneration will be measured, so long as metrics remain consistent with the value-based purposes.
- Recommend that quality standards be meaningful and achievable and designed to improve quality, patient outcomes and improve more cost-effective care, and oppose performance of quality standards that “drive meaningful improvements in physician performance.” This requirement could be interpreted as requiring constant achievement which is not practical. Reaching a high-level of performance should not diminish the importance of a quality measure, its continued use, or the value-based activity. Furthermore, VBEs and their participants, particularly as it relates to non-Medicare arrangements, should have control over the quality measures to which performance of the value-based activity is tied and should not be limited to only those quality measures accepted for use in the MIPS.
- In response to CMS’ request for comment on a specified timeline for determine whether the value-based purpose was achieved, ASGE believes that three years is an insufficient period of time for ascertaining success. With lags in performance data (two years for Medicare data), there must be at least sufficient time for VBEs and VBE participants to examine performance and cost data and take corrective actions if the goals of the value-based purpose are not being met. Therefore, we recommend five years, at a minimum, will be necessary to adequately assess whether a VBE is meeting its value-based purpose.

INDIRECT COMPENSATION ARRANGEMENTS TO WHICH THE EXCEPTIONS AT PROPOSED §411.357(AA) ARE APPLICABLE (PROPOSED §411.354(C)(4))

CMS is proposing to identify circumstances under which the proposed new exceptions would apply to an indirect compensation arrangement that includes a value-based arrangement in the unbroken chain of financial relationships. ASGE supports CMS’ proposal that when the value-based arrangement is the link in the chain closest to the physician (the physician is a direct party to the value-based arrangement) the indirect compensation arrangement would qualify as a value-based arrangement. ASGE concurs with the AMA that CMS’ alternative to define “indirect value-based arrangement” and specify in regulation that the exceptions proposed at § 411.357(aa) would be available to protect the arrangement. Either proposal is necessary to protect an unbroken chain of financial relationships that includes a value-based arrangement because an indirect compensation arrangement that includes a value-based arrangement may not satisfy the requirements of the indirect compensation exception because the compensation paid to a physician may take into account the volume or value of referrals or other business generated by the physician or the compensation may not meet fair market value standards.

PRICE TRANSPARENCY

In this proposed rule, CMS suggests that the point of referral presents “an ideal opportunity” to have cost-of-care discussions. And, while the point of referral *may* present an opportunity to have cost-of-care discussions, such as patient cost differences based on site of service (e.g., an ambulatory surgery center vs. a hospital outpatient department), *requiring* a physician to provide notice or have policy regarding the provision of a public notice that alerts patients that their out-of-pocket costs for items and services for which they are referred by the physician may vary based on the site where the services are furnished and based on the type of insurance they have should not be a requirement of the proposed value-based arrangements. More directly, the physician-self referral exceptions are an inappropriate mechanism to promote price transparency because the desired pricing information is generally held and controlled by health plans.

Instead the appropriate mechanism for discussion about price transparency is the proposed rules [CMS-9915-P] for requiring group health plans and health insurance issuers in the individual and group markets to disclose cost-sharing information upon request, to a participant, beneficiary, or enrollee (or his or her authorized representative), including an estimate of such individual's cost-sharing liability for covered items or services furnished by a particular provider. ASGE intends to comment on this proposal by the January 29, 2020 deadline.

FUNDAMENTAL TERMINOLOGY AND REQUIREMENTS

Key terms and their definitions have been the subject of ongoing discussion and commentary, including “commercially reasonable” and “fair market value,” and creating a “bright-line” test for determining when compensation is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. ASGE appreciates that CMS has reviewed the statute and its regulations in a fresh light and has endeavored in this rule to provide clarity on fundamental terminology and requirements.

a. Commercially reasonable

Of the two definitions proposed, the AGSE concurs with the AMA that the preferable definition of “commercially reasonable” is to mean that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and condition as like arrangements. This definition offers more certainty and more continuity to current interpretation of the term because the “legitimate business purpose” language is used in current Stark exceptions including the personal services arrangements and fair market value compensation exceptions. That said, any additional guidance from CMS as to interpreting “legitimate business purpose” would be beneficial beyond non-criminal activity.

ASGE also supports regulatory language that clarifies that an arrangement may be commercially reasonable even if it does not result in profit for one or more parties and it not one on valuation. This clarification will reduce administrative burden and legal costs for physicians.

b. Volume or value standard and the other business generated standard

In response to requests that CMS has received for clarifying when compensation will be considered to take into account the volume or value of referrals, ASGE appreciates that in this rule CMS is proposing objective tests for determining whether compensation takes into account the volume or value of referrals or the volume or value of other business generated by the physician.

We support the proposed simple mathematic formula that clarifies that compensation from an entity furnishing designated health services to a physician is allowed to take into account the volume or value of referrals in certain circumstances where, for example, the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that correlates with the number or value of the physician's referrals to the entity.

To take into account fixed-rate compensation arrangements, we also support that compensation from an entity furnishing designated health services to a physician may take into account the volume or value of referrals when there is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

We believe these bright-line tests will improve physician confidence that they are operating within the parameters of the physician self-referral law and corresponding regulations.

c. Fair market value

ASGE supports that CMS is attempting in this proposed rule to bring clarity to the term “fair market value” as it pertains to the physician self-referral law, by eliminating the connection between “fair market value” and the volume or value standard. We note that CMS is proposing to modify the definition of “fair market value” by creating three clear definitional distinctions for general application of “fair market value,” as well as for rental of equipment and rental of office space, bringing the definitions back to statutory intent.

Because some flexibility is needed within these revised definitions, we are pleased that CMS has proposed changes to the definition of “general market value” within the definition of “fair market value” to mean the price that assets or services would bring as the result of *bona fide* bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement; or, in the case of the rental of equipment or office space, the price that rental property would bring as the result of bona fide bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement. We believe these revisions will better allow for geographic variances, as well as the training and expertise of physicians when considering compensation arrangements.

GROUP PRACTICES

Special Rules for Profit Shares and Productivity Bonuses

a. Distribution of revenue related to participation in a value-based enterprise

Consistent with ASGE’s above comments regarding the proposed value-based activity exceptions, we strongly support CMS’ proposed deeming provision that would allow a group practice to distribute directly to a physician in the group the profits from designated health services furnished by the group that are derived from the physician’s participation in a VBE, including profits from designated health services referred by the physician, and such remuneration would be deemed not to directly take into account the volume or value of the physician’s referrals.

b. Clarifying revisions

Overall profits

In an attempt to introduce clarity related to profit shares and productivity bonuses, CMS is proposing a revision that defines “overall profits” as “profits derived from *all* the designated health services of the group” must be aggregated and distributed in a manner that does not take into account the volume or value of a physician’s referrals. Under this proposal, a physician practice that wishes to qualify as a group practice could not distribute profits from designated health services on a service-by-service basis. ASGE opposes this modification. Group practices should be able to distribute profit shares of only some types of designated health services provided by a group practice without distributing the profits from the other types of designated health services provided by the group practice. Moreover, group practices should also be able to share the profits from each of the types of designated health services independently, making it permissible to share profits from one type of designated health service with a subset of physicians in a

group practice and the profits from another type of designated health service with a different subset of physicians in the group practice. This would allow physicians to receive profit shares or productivity bonuses more closely related to the services performed or their specialty.

ASGE supports removing the reference to Medicaid from the definition of overall profits because the definition of designated health services includes only those services payable in whole or in part by Medicare. And, as CMS highlights, including Medicaid unnecessarily complicates the regulation.

Lastly, CMS is seeking comment whether it should limit the methodology for determining a physician's productivity bonus. While we agree the bonus must be calculated in a reasonable and verifiable manner, the methodology should not be listed to physician work relative value units. Rather, there are other methodologies that do not take into account the volume or value of referrals that should be permissible.

CONCLUSION

On behalf of the ASGE, we thank you for your consideration of our comments. Requests for additional information should be directed to Lakitia Mayo, ASGE's Senior Director, Membership and Health Policy at lmayo@asge.org or (630) 570-5641.

Sincerely, Sincerely,

A handwritten signature in black ink, appearing to read 'J. Vargo, II', with a stylized flourish at the end.

John. J. Vargo, II, MD, MPH, FASGE
President
American Society for Gastrointestinal Endoscopy