Medical Group Management Association®

August 24, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
202 Independence Avenue, S.W., Room 445-G
Washington, D.C. 20201

Re: CMS-1720-NC, Request for Information Regarding the Physician Self-Referral Law

Dear Administrator Verma,

The Medical Group Management Association (MGMA) is pleased to submit the following responses to the Centers for Medicare & Medicaid Services' (CMS') Request for Information (RFI) on how the Physician Self-Referral (Stark) Law might be improved. We commend CMS for recognizing the need to remove unnecessary regulatory barriers to clinical and financial integration and for seeking stakeholder feedback on how this can be done.

MGMA is the premier association for professionals who lead medical practices. Since 1926, through data, people, insights, and advocacy, MGMA empowers medical group practices to innovate and create meaningful change in healthcare. With a membership of more than 40,000 medical practice administrators, executives, and leaders, MGMA represents more than 12,500 organizations of all sizes, types, structures and specialties that deliver almost half of the healthcare in the United States. Our members work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently so physician time and resources can be focused on patient care.

Few, if any, federal regulations affect the structure and operation of physician group practices to the extent of the Stark Law. MGMA has worked with Congress and CMS for almost 30 years in repeated efforts to reduce regulatory burden. Unfortunately, those efforts have been highly frustrating; with each successive CMS rulemaking under the Stark Law, the regulatory scheme has become more complex, to the point where it is now virtually unfathomable to all but the most specialized attorneys and compliance consultants. Many smaller group practices simply cannot afford these resources, and in any group practice, each dollar devoted to them is a dollar diverted away from efforts to promote better patient care.

While MGMA appreciates CMS' efforts to remove unnecessary government obstacles to value-based payment reform, we recognize CMS has not been given the legislative authority to resolve fundamental problems with the Stark Law. Meaningful improvement of this rule requires congressional action, as any progress made to reform regulations implementing the statute will be undercut by the law's strict liability regime and disproportionate penalty provisions.

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As part of our recommendations for improvements to the Stark Law, MGMA encourages CMS to work with Congress to discuss repealing or, at a minimum, significantly revising the compensation portion of the Stark Law. We encourage CMS to pursue legislative relief on this topic in the context of the new value-based care delivery and payment landscape and pledge our support for serious efforts in this direction. Until legislative reform is achieved, there are commonsense regulatory improvements that can be made. Specifically, CMS should develop policy to:

- Protect value-based payment arrangements. MGMA recommends CMS create a single, overarching compensation exception for alternative payment models (APMs) and innovative clinical and financial arrangements. We encourage CMS to work with the Department of Health & Human Services' (HHS') Office of the Inspector General (OIG) to create a companion safe harbor under the Anti-Kickback Statute. We do not recommend changes to the regulations implementing the Stark Law's ownership ban.

- Remove regulatory barriers. To provide effective regulatory relief, CMS must standardize compliance requirements and eliminate the numerous conflicting requirements placed on healthcare providers. Though existing exceptions to the Stark Law's prohibitions are numerous, they contain complex criteria and esoteric terminology that are subject to regulatory interpretation and factual determinations that open the door to inadvertent noncompliance, particularly in the context of innovative arrangements. Any action must be guided by administrative simplification, in line with CMS'—indeed, this Administration's—repeatedly trumpeted focus on burden reduction and regulatory relief.

- Support the group practice model. In addition to changes in Stark Law regulations, it is important that the Administration maintain the flexibility needed to deliver care in the new healthcare system's delivery environment. In particular, preservation of the Stark Law in-office ancillary services exception is crucial to ensuring physicians can continue to provide coordination of care for patients. We seek assurances from CMS that any reform will account for physician group practices of all sizes and specialties and offer protection to all medical groups that participate in or contribute to innovative payment arrangements as a component of a larger entity.

Innovative Payment Arrangements

CMS requests feedback on possible approaches to address the Stark Law's application to financial relationships within an APM or other novel payment arrangement and whether existing exceptions adequately protect payments under those arrangements [questions 1-3].

Current Stark Law exceptions do not adequately protect payments or remuneration under an APM or other innovative model. Outside of models operating under a statutory waiver, group practices face regulatory barriers to achieving the care coordination and clinical alignment required to succeed in a value-based payment system.

Accountable care and innovative payment arrangements can be structured in many ways, including shared savings arrangements between a practice and a health plan that offer physicians a portion of cost savings generated through the efficient delivery of care; gainsharing payments between a hospital and a physician or group that offer incentives for controlling costs; pay-for-performance programs or incentive bonuses that reward physicians for adhering to evidence-based protocols or improving patient outcomes; medical home models that provide routine care management or coordination fees; and bundled payment programs that establish an overall budget for services

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provided to a patient throughout the course of treatment for a given condition.

The passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) created an impetus to increase opportunity to participate in these alternatives to the fee-for-service payment landscape. The movement to a reimbursement system focused on value aligns physician incentives with those of payers and patients, in that a value-based system pays practitioners for delivering cost-effective, quality-driven care, and not simply for delivering more care. This realignment of priorities resolves mismatches in a fee-for-service system, where payers prefer practitioners who deliver care at a lower cost, patients prefer higher quality care, and practitioners are incentivized, from an economic standpoint, to increase the volume of services without necessary regard to quality or patient outcomes. In a value-based system, practitioners are rewarded for reducing costs and enhancing the quality of care.

Outside of Medicare, medical specialty societies, private payers, and other stakeholders are interested in exploring ways to test and develop innovative payment arrangements but are faced with the question of how to structure the business relationships required to operate in a value-based market while still complying with outdated fraud and abuse rules. Given the Stark Law's broad definitions of what constitutes a financial relationship or a prohibited referral, innovative reimbursement programs must be structured to fit within the confines of the existing exceptions framework. Uncertainty about the Stark Law's application and potentially severe penalties for unintentional violations have had a chilling effect on innovation and slowed the progression toward cost-efficient, quality-driven models.

There is a growing consensus supporting the expeditious modernization of existing fraud and abuse rules. Congress has recognized the incongruity between the current framework and the development and implementation of APMs and other value-based payment arrangements and authorized HHS to issue waivers for select programs, such as those created through the Center for Medicare and Medicaid Innovation and for accountable care organizations in the Medicare Shared Savings Program. Waivers are insufficient, however, as they are issued on a case-by-case basis, are limited in duration, and only protect arrangements within specific programs.

Similarly, CMS acknowledges that value-based arrangements, such as a shared savings, gainsharing, or incentive payment programs, implicate fraud and abuse rules such as the Stark Law when the program results in a direct or indirect payment from the entity administering the program to the physician, and that "[u]nless the arrangement satisfies the requirements of an applicable exception, [it] would violate the physician self-referral prohibition" if the physician makes DHS referrals to the entity.[1] Furthermore, CMS observes that "existing exceptions to the physician self-referral prohibition may not be sufficiently flexible to protect payments to physicians" under novel payment arrangements, such as incentive payment, shared savings,[2] and gainsharing programs.[3]

Despite this growing recognition, to date, there are no exceptions or safe harbors to fraud and abuse rules specifically designed for value-based arrangements not covered by a waiver; furthermore, existing exceptions are rigid, narrow, and not drafted with these types of arrangements in mind. Given the lack of an intent requirement, excessively punitive penalties, and the mind-numbing complexity of the Stark Law, the risk of violating the law is prohibitive. The Stark Law is confusing enough on its own, however it has also been a moving target of numerous regulatory revisions. What started as a statute concerned with mitigating the overutilization of select "designated health

[1] 73 Fed. Reg. 38502, 38551 (July 7, 2008).
[2] *Id*.
[3] 73 Fed. Reg 23528, 23694 (April 30, 2008).

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services" and punishing self-dealing physicians that improperly refer patients to entities they own, has transgressed into a disorganized set of regulations filled with complex legalese that thwarts innovation and converts management time into compliance tasks that serve no useful purpose to patient protection or program integrity efforts.

Utility of Existing Exceptions

CMS seeks feedback on the utility of the current exception for risk-sharing arrangements, as well as the special rule protecting certain compensation under a physician incentive plan that is written into the personal services exception [questions 4-5].

While the risk-sharing exception and special rule for physician incentive plans purport to cover arrangements that embrace value-based principles, their narrow application and restrictive terms make them difficult to implement in any practical sense. As noted above, the new world of value-based care requires a much broader and more flexible approach.

The personal services arrangement permits physician incentive plans between a physician and an entity with respect to patients enrolled with the entity, but does not extend to traditional Medicare fee-for-service beneficiaries. We recommend that this exception be amended to remove the restriction that limits application of the incentive plan to beneficiaries in a commercial plan. The revised exception would retain existing safeguards, which would create no additional risk.

The risk-sharing arrangement also restricts its application to patients covered by a commercial plan when the plan imposes financial risk for physicians furnishing services to those commercial patients. We recommend that this exception similarly be expanded to cover traditional Medicare beneficiaries.

Value-based Payment Exception

CMS seeks input on possible approaches to improving its exception policy as it applies to APMs and novel payment arrangements [question 6].

To encourage and facilitate participation in value-based arrangements, the Stark Law must be modernized to allow appropriate flexibility for physician group practices to effectively manage costs and assume accountability for beneficiary care. MGMA submits that the real inquiry should be whether the Stark Law is even necessary in a value-based payment system, but until more comprehensive legislative reform can be achieved, we recommend that CMS develop a single, overarching exception for all accountable, value-based care arrangements that meet certain conditions in order to accommodate the diversity of roles that group practices will play in such arrangements, as well as the diversity and potential complexity of the financial relationships involved.

The new value-based payment exception should protect all financial relationships designed to achieve the goals set forth in MACRA, including promoting accountability for patient outcomes, enhancing quality of care, facilitating care coordination, and promoting efficient use of resources. MGMA encourages an approach that permits maximum flexibility and supports all arrangements that are reasonably related to MACRA's goals, including but not limited to the distribution of incentive payments for better patient outcomes, shared savings based on actual cost reductions, and infrastructure payments or in-kind assistance reasonably related to and used in the start-up or implementation of the arrangement (e.g., electronic health record technology, cybersecurity resources, pre-participation support, and data or clinical analysis tools).

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The exception should protect models both in development and operation and should be sufficiently broad and flexible to protect future arrangements that have not yet been created or contemplated. The exception could allow small, independent practices to work together and collaborate with hospitals and other entities to deliver coordinated care for beneficiaries and commercially-insured patients. As such, the new exception should cover any arrangement between the APM entity, one or more of its participants, downstream care delivery partners, entities, and manufacturers that link outcomes and value to services or products provided. The best way to preserve opportunity for competition in healthcare and choice for patients is to enable physicians to join APMs in ways that enable them to continue practicing independently of a larger hospital system.

To further engage the broader healthcare community, we urge CMS to extend the new value-based payment exception to protect all participants in APMs or novel payment arrangements that meet certain conditions, regardless of whether or not they participate in a Medicare-sponsored project. A common theme MGMA has heard from our own membership is the importance of engaging multiple payers in innovative payment models. A larger patient population in multi-payer models means participants are less vulnerable to the influence of external variables on their patient health outcomes and would be evaluated more accurately on their performance. Aligning monetary incentives across payers would also provide greater financial means for practices to invest in services not reimbursed under fee-for-service contracts to ensure success in the model. With all payers sharing the common goals of decreasing costs and delivering high-value care, there is a clear incentive to work together and partner with providers to achieve these goals. As an example of cooperation among payers, the multi-payer Comprehensive Primary Care Plus model has generated positive feedback.

CMS has the authority to create new exceptions under existing statutory authority, so long as the potentially protected arrangement "does not pose a risk of program or patient abuse."[4] MGMA urges CMS to use this authority expansively, and believes that the strong congressional support for APMs provides context for doing so in a manner that protects against foreseeable, plausible risks as opposed to risks that are largely theoretical. Imposing reasonable safeguards for use of the new exception, coupled with the inherent structure of value-based arrangements, should eliminate the risk of real world abuses. For example, CMS could require basic accountabilities such as:

(1) Standards for documentation on the use of value-based arrangements, which could be made available to HHS upon request;

(2) Use of metrics, such as performance standards used to measure bonuses awarded to practitioners based on quality outcomes or the efficient delivery of care, that are consistent with clinical standards and reasonably fit the purpose of improving patient care;

(3) Development of internal monitoring efforts, such as a compliance program, that guard against unwanted consequences;

(4) Commitment to processes that allow for patient engagement and shared decision-making that take into account each patient's specific needs; and

(5) Reasonable transparency initiatives aimed at promoting more informed patient choice about care delivery within the arrangement.

MGMA urges CMS to create the new exception using clear, easy-to-understand terms and avoid the prohibitively complicated criteria and unnecessary contingencies that plague existing regulatory

[4] 42 USC 1395nn(b)(4).

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exceptions. Establishing narrowly drawn exception policies with proscriptive and overly complex requirements will leave healthcare entities in the same place they are today: cobbling together a patchwork of exceptions not designed to apply to the type of innovative, value-based payment arrangements championed by Congress, the Administration, and the healthcare industry as a whole.

MGMA believes that an exception for incentive payments and coordinated care can, if drafted with sufficient flexibility, assist in removing existing impediments to group practices' ability to incentivize physicians to explore alternatives to fee-for-service until a more comprehensive legislative solution is achieved.

Removing Obstacles for Value-based Care Initiatives

CMS solicits stakeholder feedback on critical definitions contained in Stark Law regulations. MGMA supports efforts to simplify Stark's regulations; however, we are concerned that attempts to improve the compensation provisions will only result in additional layers of complexity.

The vexing construct and ambiguity of critical terminology in the Stark Law allows for uncertainty and introduces risk for anyone subject to its reach, particularly when considering any novel arrangement. Despite countless rulemakings, each of which identified legitimate problems with the regulations and attempted to fix them, the regulatory scheme has grown in complexity to the point where it is well beyond comprehension to the average physician, healthcare administrator, or as one federal appellate judge pointed out, the diligent Stark Law attorney ("In the context of the Stark Law, it is easy to see how even diligent counsel could wind up giving clients incorrect advice. Between the law's being amended to have a broader scope but then narrowed with various exceptions, along with the promulgation and amendment of copious associated rules and regulations, the Stark Law became a classic example of a moving target."[5]).

Group Practice

CMS seeks feedback on the barriers that exist to qualify as a "group practice," and also asks stakeholder groups to identify provisions or definitions for which additional clarification would be useful [questions 13 and 15].

The Stark Law is among the most important federal regulatory schemes affecting medical group practices for several reasons. It defined the characteristics required to be a "group practice" for the first time in Medicare and, in doing so, reached directly into private businesses to define permissible boundaries of practice structure, operation, and physician compensation for care delivery. A group practice, within the meaning of 42 CFR 411.352, requires that: (1) the group must be a single legal entity; (2) it must consist of at least two physician members defined as shareholders, partners, or bona fide employees; (3) each physician must provide substantially the full range of patient care services that the physician routinely furnishes; (4) substantially all (i.e., at least 75% of the total services of the group) of the patient care services of physicians must be furnished through the group; (5) overhead expenses and income must be distributed according to methods determined before receipt of payment; (6) members of the group must conduct no less than 75% of the physician-patient encounters of the group; (7) the group must operate as a unified business; and (8) physician members of the group generally may not directly or indirectly receive compensation based on the volume or value of referrals.

[5] United States ex rel. Drakeford v. Tuomey, 792 F.3d 364, 394 (4th Cir. 2015) (Wynn, J., concurring) (internal citations omitted).

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Medical group practices must satisfy these eight distinct criteria to quality as a bona fide group practice, which is a requirement of several Stark Law exceptions. Failing to meet any one of these criteria due to a technical infraction can potentially implicate any referrals made under the good faith belief that an exception applied. CMS must take efforts to simplify and streamline regulatory standards to remove hyper-technical requirements.

In-office Ancillary Services Exception

For group practices, the in-office ancillary services exception is fundamental. It permits groups to provide comprehensive services to their patients at the point-of-care, to compete with hospitals and other ancillary service providers, and to grow and evolve with changes in technology and therapy, many of which are accompanied by a migration of services from inpatient to ambulatory care settings. Without a workable and stable in-office exception, group practice growth and development would stagnate, and physicians practicing in independent groups would be placed at a serious competitive disadvantage, which conflicts with CMS' own stated goal of increasing patient choice and competition to drive quality, reduce costs, and improve outcomes.

We believe existing regulations, particularly with respect to the location test, are overly prescriptive and largely arbitrary. Under the statute, a group practice's in-office ancillary services must be provided in a building where group physicians provide other services, or in a centralized ancillary facility of the group. This statutory location test seemed reasonable at the time of enactment. However, under the regulations, this "location test" now turns on distinctions like: (1) whether an office is "normally open" at least 35 hours per week; (2) whether a group doctor "regularly practices medicine" at the location at least 30 hours per week; (3) whether the patient receiving the ancillary service "usually receives" care at the location; (4) whether a satellite clinic location is "normally open" at least 8 hours a week and the particular physician ordering the service "regularly practices" there 6 hours a week; and so on. If a group runs afoul of one of these technical (and we would submit, largely arbitrary) distinctions, is the violation technical or serious? Should the government even be attempting to regulate group practice facility configurations at this minute level of detail? We think the location test, as now defined, is an obvious example of intrusive regulatory overreach with little if any demonstrable benefit to patients, practices, or the Medicare program.

Burden of Proof

MGMA strongly opposes the regulatory language at 42 CFR 411.353(c)(2) that places the burden of proof on physicians when CMS denies payment for a claim it alleges was pursuant to a prohibited referral. Placing the burden of proof on physicians is contrary to accepted notions of due process, and there is no reason to believe that Congress intended this result when the Stark Law was originally enacted. Given the complexity of the Medicare system and the amount of resources required to appeal a claim denial, this provision must be removed or revised such that the burden of proof is on the enforcer.

Requirement to Comply with the Anti-Kickback Statute

MGMA strongly believes that it is distinctively unhelpful to link the self-referral exceptions and definitions to compliance with the Anti-Kickback Statute. The self-referral law was intended to be a bright line test, not a facts and circumstances test. The law has become inordinately complicated, and the references to Anti-Kickback compliance create even more uncertainty. This is a classic example of regulators wanting to have their cake and eat it too. The OIG has steadfastly refused to accept Stark Law compliance as an automatic defense under the Anti-Kickback law, even when the

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underlying conduct regulated by both laws is identical.

Virtual Groups

To incentivize broader participation in the Merit-based Incentive Payment System (MIPS), CMS introduced a "virtual group" option for solo practitioners and group practices with 10 or fewer eligible clinicians. The advantage of joining a virtual group, according to the agency, is it allows participants to pool resources and avail themselves to the benefits of group reporting in MIPS, such as collective reporting and scoring. As MGMA has indicated to CMS in the past, we have concerns regarding virtual group policies, and there are a number of hurdles to successful participation in virtual groups that CMS must address, including the potential implications of the Stark Law.

The sharing of resources creates a financial relationship under the Stark Law and therefore can taint any referrals for designated health services among virtual group participants, creating new and very real compliance concerns for any participants. MGMA recommends CMS consider the potential fraud and abuse implications of its virtual group practice policies and consider if, and what, protections are needed such that the agency is not inadvertently creating additional burden on practices that may already have limited resources.

Conclusion

These recommendations could offer a temporary solution to bridge the gap between a healthcare system moving toward value-based payments and a regulatory regime created for an antiquated fee-for-service model. The recent impetus to resolve fundamental aspects of Stark Law regulations, if implemented appropriately, could be a catalyst to increasing opportunities for physician group practices to participate in innovative care delivery and payment reforms and encouraging physician-led, value-based transformation.

Thank you for the opportunity to comment. Should you have any questions, please contact Mollie Gelburd at mgelburd@mgma.org or 202.293.3450.

Sincerely,

/s/

Anders Gilberg

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