



December 19, 2019

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

Dear Administrator Verma,

The Medical Group Management Association (MGMA) is pleased to submit the following comments to the Centers for Medicare & Medicaid Services (“CMS” or “the Agency”) on its proposed rule modernizing and clarifying the Physician Self-referral (“Stark”) Law. We appreciate the Agency’s recognition that the Stark Law must be revised to remove barriers to value-based payment reform and its acknowledgment that the physician community needs greater clarity and certainty regarding several exceptions and definitions in the current regulations.

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 55,000 medical practice administrators, executives, and leaders, MGMA represents more than 15,500 organizations of all sizes, types, structures, and specialties that deliver almost half of the healthcare in the United States.

MGMA recognizes that CMS has a difficult task in implementing the Stark Law, which was enacted in a fee-for-service environment to protect against possible overutilization in a system that rewarded volume. As reimbursement approaches continue to evolve and move away from a volume-based payment system and toward an approach that ties payments to value-based metrics, fraud and abuse laws and their implementing regulations have struggled to keep pace. Unfortunately, piecemeal modifications have resulted in an exceedingly complex fraud and abuse framework that introduces uncertainty into any novel payment arrangement not explicitly protected by a waiver or other exception authority. We appreciate efforts by the Agency through this proposed rule to act within its statutory authority to assist the physician community with added flexibility for group practices and other healthcare entities participating in value-based arrangements.

From the beginning, the Stark Law has had two very distinct prongs. The first prong, and the original impetus for the law, prohibits physician referral to joint venture entities outside the referring physician’s medical practice if the physician has an ownership or investment interest in the entity. The second prong prohibits, or heavily regulates, the other compensation relationships referring

physicians have with entities to which they refer. MGMA did not initially oppose either prong of the law, choosing to work with Congress towards a workable statutory scheme. We still believe that the investment interest prong of the law is workable, and equally important, understandable, although we question whether it is now needed to the extent it may have been thirty years ago. On the other hand, the compensation relationship prong of the law quickly proved itself less workable and not understandable.

We are convinced that CMS does not have adequate authority to significantly simplify or “fix” the Stark Law’s compensation provisions. Genuine solutions **require congressional action, as piecemeal efforts to reform regulations implementing the current statute will be undercut by the law’s strict liability regime, disproportionate penalty provisions, and vexing construct.** For this reason, we strongly urge the Agency to work with Congress on developing workable legislative solutions in order to achieve real regulatory relief. MGMA offers our assistance to CMS on possible legislative solutions.

In addition, we appreciate the opportunity to comment on the specific proposals at hand. We urge CMS to:

- **Strive for greater simplicity and true regulatory relief while accommodating value-based payments.** The regulatory regime has grown in both breadth and complexity to the point where the average medical group administrator or physician cannot begin to understand it. Time and money are spent on elusive compliance requirements, which would be better spent on patient care.
- **Finalize the exception establishing regulatory protections for value-based arrangements (proposed 42 CFR 411.357(aa)(3)).** We appreciate the Agency’s recognition that not all group practices are prepared to assume financial risk yet may still be interested in developing innovative, integrated arrangements. With certain modifications, this proposed exception could assist group practices and their practicing physicians to begin pursuing value-based arrangements on a smaller scale before entering into a more comprehensive arrangement that entails significant downside financial risk.
- **Modify the meaningful financial risk exception (proposed 42 CFR 411.357(aa)(2)) to increase its utility and align it with arrangements that exist in real world settings.** MGMA recommends CMS take a flexible approach to defining meaningful financial risk to permit performance-based and upside risk and to modify the risk threshold to 9%.
- **Retract the Agency’s confusing preamble discussion concerning permissible compensation methodologies for group practice physicians.** It is not clear what perceived problem the Agency is attempting to fix. In MGMA’s opinion, this is one aspect of existing regulations where the Agency would be well served to leave well enough alone.
- **Finalize the proposal to decouple Stark Law exceptions from the Anti-kickback Statute (AKS).** MGMA appreciates CMS’ recognition that it is unhelpful to link Stark Law exceptions and definitions to compliance with the AKS. Instead, CMS and the OIG should move further towards policy alignment so that compliance with Stark Law exceptions do not leave physicians in regulatory limbo under differing safe harbor standards. This is critically important in accommodating value-based payment reforms.

- **Finalize the limited remuneration exception ((proposed 42 CFR 411.357(z)).** This exception could help ameliorate concerns around innocuous technical non-compliance. The Agency should consider increasing the \$3,500 threshold. When a group practice, rather than an individual physician, contracts with an entity, CMS should apply this threshold to each physician individually.
- **Extend the availability of the EHR exception and add a cybersecurity exception.** We urge CMS to remove the requirement for the recipient to contribute a minimum of 15% to the cost of both exceptions. We also recommend permitting data backup hardware to be included in the list of permitted cybersecurity donations.

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

CMS proposes three new exceptions at 42 CFR 411.357(aa) to compensation relationships for arrangements that involve either: (1) full financial risk, (2) meaningful financial risk, or (3) remuneration paid under a value-based arrangement. While each proposed exception includes its own technical requirements, a predicate for protection under any new exception is to satisfy key terminology outlined in newly proposed value-based definitions.

MGMA strongly supports removing the fair market value and “volume or value” standards from exceptions that protect value-based arrangements. The volume or value standard significantly restricts the ability to offer economic rewards to physicians that perform activities aimed to increase value or reduce volume, thereby restricting the very incentives that could drive the value-based movement. Further, we believe it is appropriate to remove the fair market value requirement as there are limited data or agreed upon appraisal methods available to assist in determining the fair market value of quality-related payments.

We offer more detailed recommendations on how to improve all three of the proposed value-based exceptions below.

Definitions (42 CFR 411.351)

Value-based arrangement: This definition as proposed, coupled with additional safeguards incorporated in other definitions and within each exception, is sufficient to protect against program or patient abuse. MGMA does not believe that any additional requirements, e.g. that an arrangement include care coordination and management, are necessary. MGMA recommends, however, that CMS make clear that a medical group can be the value-based enterprise (VBE) participant in an arrangement as opposed to looking only to the physicians in the group as individual participants.

VBE: MGMA supports CMS’ proposed definition and appreciates that the Agency has chosen to define VBE in terms of the function of an enterprise, rather than the legal structure. Defining a VBE in terms of legal structure risks creating layers of complexity, such as those that currently exist within the definition of a bona fide group practice. Again, MGMA urges CMS to explicitly recognize a medical group as eligible to be a direct party to the value-based arrangement as an alternative to individual physician participants.

Value-based purpose: We agree with the four purposes outlined in the proposal and are encouraged by CMS’ use of sufficiently broad descriptions. We recommend that the third purpose (appropriately reducing costs) be expanded to cover provider and supplier costs, not just payer costs, so as to

eliminate any uncertainty with respect to the eligibility for protection of gainsharing arrangements.

Target patient population: Based on the examples outlined in the preamble of a qualifying target patient population, MGMA generally supports this definition. We seek assurances from CMS that a qualifying target population could include all patients covered by a certain payer, such as Medicare, as indicated in the preamble text.

Full Financial Risk Exception (Proposed 411.357(aa)(1))

MGMA is not optimistic that this exception could be widely utilized as proposed, as we are not aware of many existing arrangements that would meet the stringent definition of “full financial risk.” We agree with the Agency that the existing fraud and abuse framework has chilled innovation, and therefore it is possible that there are not many arrangements that meet the criteria for “full financial risk” because they are prohibited under existing rules. Notwithstanding this possibility, we believe that the definition of “full financial risk” must be modified such that is workable in the types of global budget, population health, or capitated arrangements that are being pursued or actively considered.

The restrictive approach to defining “full financial risk” appears to disallow a payer from making any type of infrastructural, operational, or administrative investments in a VBE. During an arrangement, a payer may evaluate a participating entity’s performance on certain metrics and determine that a participant provider is struggling in certain areas and could be aided by the provision of certain resources to facilitate improvement. Under CMS’ current description, it is unclear whether an in-kind or monetary investment to facilitate performance improvement would be at odds with the definition of “full risk.”

Further, we suggest that CMS modify this definition to limit VBE responsibility to the cost of only a defined set of patient care services for the target patient population to allow for additional flexibility in instances that may require some fee-for-service payments be made.

MGMA supports including a protection for a pre-participation period. Similar to the Medicare Shared Savings Program (MSSP) pre-participation waiver, CMS should implement a one-year protection period.

Data from the Health Care Payment Learning & Action Network (LAN) APM methodology reports demonstrate how few of these arrangements exist today. Specifically, LAN’s 2019 APM Methodology Report indicates that only 5.1% of healthcare payments were made to providers participating in models that included no fee-for-service payments.¹ LAN data is illustrative of the type of arrangements being pursued by other payers and may assist CMS in structuring this exception around payment arrangements contemplated by the payer and provider community.

To improve the utility of the full financial risk exception, we encourage CMS to leverage the resources available to it, such as the LAN, PTAC, the Centers for Medicare and Medicaid Innovation

¹ LAN 2019 APM Methodology [Report](#), page 15. The LAN evaluated payments made by payers to providers in 2018 by examining data that represented 77% of the national payer market. The LAN divides payments into one of four categories: Category 1 payments are fee-for-service payments with no link to quality and value; Category 2 payments are fee-for-service payments linked to quality and value; Category 3 are APMs built on a fee-for-service architecture; and Category 4 are population-based payments. Based on these descriptions, it appears that only Category 4 payments would be eligible to qualify as prospectively paid full risk arrangements.

(CMMI), and stakeholders engaged in APM development, to determine an appropriate definition for full financial risk, such that it is reflective of the type of arrangements being pursued in the real world.

Meaningful Downside Financial Risk Exception (Proposed 411.357(aa)(2))

Arrangements wherein a *physician* repays payments to a DHS entity, such as an accountable care organization (ACO) or clinically integrated network, are not common and therefore, as written, this exception may have limited use. MGMA recommends the following changes to improve this exception.

CMS should clarify in the final rule that financial risk includes both: (1) risk that entails forfeiting potential payments (e.g., upside risk) and (2) performance-based risk.

CMS should permit risk where a physician or group forfeits a potential payment under a value-based arrangement if s/he/it does not satisfy certain metrics under the arrangement. Gainsharing arrangements, for example, focus on reducing costs by improving efficiency without reducing quality of care. A hospital or health system may share a portion of any cost savings generated with physicians successfully participating in a gainsharing program through a direct payment. In many cases, the risk under a gainsharing arrangement is that a physician or group will spend time and effort but will not achieve the desired cost savings and therefore will not receive any payment for the extra effort. The meaningful risk exception would not clearly protect these types of arrangements unless the definition of financial risk is modified to include forfeiture of potential payments.

Under performance-based risk, the physician bears financial risk in that failing to achieve the value-based purpose will result in a downward adjustment to their compensation. Performance-based risk is used throughout CMS-sponsored initiatives, such as the Merit-based Incentive Payment System (MIPS) and several models spearheaded by CMMI (i.e., Primary Care First, Kidney Care First).

In addition to taking a more flexible approach to defining financial risk, MGMA recommends that CMS decrease the threshold required for “meaningful” assumption of downside risk from 25% to 9%. A 9% threshold would align with the MIPS program, which entails a performance-based payment adjustment of +/- 9% starting in performance year 2019 (2021 payment year).

Creating an exception to the Stark Law that aligns with MIPS could further the Agency’s own goal of encouraging participation in the program, which is intended as an on-ramp to APM participation. Furthermore, this could help facilitate participation in “virtual groups” by offering protection to separate group practices that collaborate for purposes of MIPS reporting. Virtual groups, by definition, are not group practices under the Stark Law given they will not constitute a single legal entity, but rather are multiple small group practices independent of one another that pool resources together. This type of sharing of resources invokes the Stark Law, which may be a contributing factor in the slow growth of virtual group adoption. As CMS develops the newly finalized MIPS Value Pathways concept, it may be necessary to create flexibilities under the existing fraud and abuse framework to allow participants to work together as necessary in controlling costs under any population-based measures or other metrics that entail collaboration from multiple distinct legal entities.

If the risk level was lowered to 9%, MGMA believes that MIPS participation could meet the remaining proposed requirements of the meaningful risk exception. The four value-based purposes

outlined in the Stark Law proposed rule (including explicit recognition of provider cost savings as recommended above) align, and in fact mirror, the goals of MACRA and the MIPS program to increase quality, reduce costs, facilitate care coordination, and transition healthcare practitioners into a system that pays for value over volume. These goals are evidenced in each of the MIPS categories, which each fulfill at least one of the value-based purposes outlined in the proposed Stark rule. Specifically:

- The promoting interoperability category was developed from the foundational objectives of the HITECH Act's meaningful use program, which was designed to improve care coordination.² As implemented in MIPS, the promoting interoperability category's objectives entail reporting on efforts to share data with other clinicians, engaging patients through providing specific education materials or access to patient portals, and facilitating the exchange of health information.
- The quality component of MIPS requires reporting on measures designed around patient experience, outcomes, and safety; community and population health; and improving quality of care.³
- The cost performance category evaluates clinicians on episode-based measures as well as total per capita costs and Medicare spending per beneficiary and encourages efficient use of resources by tying cost measure scores to performance in these measures based on administrative claims data.⁴
- The improvement activities category focuses on use of patient-centric approaches and driving movement toward delivery system reform and participation in APMs.⁵

A 9% risk threshold is more realistic, as physicians may be unwilling to tie 25% of their compensation to quality or cost measures, particularly if they have limited experience in these types of contracts.

Lastly, MGMA encourages CMS to include a protection for a pre-participation period, as it has proposed in the full financial risk exception.

Value-based Arrangement Exception (Proposed 411.357(aa)(3))

MGMA strongly supports this exception as we believe this will have the greatest utility for group practices and their physicians. It provides a clearer pathway toward entering into value-based payment arrangements where there is no viable pathway under current regulations. We appreciate the Agency's recognition that not all group practices are prepared to accept downside financial risk, yet still desire to participate in value-based efforts.

Allowing longstanding types of compensation relationships, such as physician employment agreements, to include value-based components without fear of violating the volume or value and fair market value standards could help drive value-based payment reform. It could permit hospitals and independent physicians or their group practices to pursue financial and clinical integration while

² 81 Fed. Reg. 77008, 77200 (Nov. 4, 2016).

³ *Id.* at 77097.

⁴ *Id.* at 77162.

⁵ *Id.* at 77177.

allowing the physician to maintain independence. Moreover, hospitals that seek to engage independent physicians are limited in their ability to offer even non-monetary remuneration. Physician practices may not be equipped to invest in the infrastructure, employee training, and/or ancillary support services necessary to make patient-centric reforms. Current exceptions are not sufficient to cover these arrangements, preventing entities from subsidizing resources that could be very valuable to independent physician group practices. Even when an existing exception may potentially apply to a desired arrangement, a physician group practice may forgo support due to compliance concerns. To ameliorate continued compliance concerns should this exception be finalized, MGMA encourages CMS to work with OIG to align the proposed AKS safe harbors with Stark Law exceptions.

CMS proposes to require that the value-based arrangement be set forth in writing and include a description of the performance or quality standards against which the recipient of remuneration will be measured, if any.

In the preamble, CMS elaborates that, if applicable, performance or quality standards must be objective and measurable and set forth prospectively in writing. The criteria cannot simply reflect “status quo.” We respect CMS’ intent to create additional safeguards for this exception as it does not entail downside financial risk, however it is entirely unclear what CMS would consider “objective and measurable” and not reflective of “status quo,” which creates a mire of subjectivity, and therefore uncertainty.

MGMA is also concerned that this requirement could restrict entities from making adjustments to standards during the course of an arrangement to more closely align them with quality, patient safety, or efficiency goals based on evidence-based observations. Practices should be permitted to revise or substitute metrics, or make other necessary adjustments, when those substitutes or amendments are supported by reasonable rationale, such as clinical guidelines or objective observations on performance, and remain consistent with the arrangement’s value-based purpose.

For example, a practice may outline a standard for avoiding overuse of bone scans for staging low risk prostate cancer patients that enumerates alternative interventions such as external beam radiotherapy and cryotherapy. During the course of the arrangement, clinical guidelines change and no longer recommend cryotherapy as a routine primary therapy.⁶ A urology practice may need to adjust clinical protocol to remove cryotherapy as an intervention, in turn necessitating changes to performance metrics that align with new clinical guidelines. If this condition is finalized for the value-based arrangement exception, CMS should allow practices appropriate flexibility to substitute metrics during an existing value-based arrangement without violating the “set in advance” requirement. Within CMS’ own suite of value-based models, such as ACOs or MIPS, quality metrics change and are adjusted over time, evidencing the need for modifications.

As an alternative, CMS should consider whether the “performance or quality standards” requirement is even necessary given that all value-based exceptions would require that value-based activities under an arrangement be made to achieve a value-based purpose. CMS’ own example describing an arrangement for dual modality screenings at 84 Fed. Reg. 55784 outlines an

⁶ See, e.g., Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients Quality Measure (NQF#0389/Quality #102) (revised under the 2020 Physician Fee Schedule final rule).

arrangement wherein value-based activities (adhering to revised care protocol by ordering dual-modality screenings rather than single screenings) are undertaken to achieve a value-based purpose (improve the quality of care for patients in the hospital's service area by detecting more cancer and avoiding overtreatment). Taken together, this would appear to meet the definition of objective and measurable criteria, against which participants in the arrangement are measured. MGMA believes that creating superfluous criteria under this exception could potentially result in unnecessary confusion around overlapping, but inexact, requirements that accomplish the same intent. As we have seen in other areas where there are overlapping requirements within Stark regulations (i.e., the importation of the volume or value standard into the definition of fair market value), this is perplexing and unnecessary. **Our preferred approach is to remove this element to mitigate potential ambiguity.**

Lastly, we recommend CMS change the name of this exception as "value-based arrangement" is also a definitional term.

Alternative Proposals

CMS states in the preamble text that, implicit to value-based arrangements is an obligation to monitor the arrangement for progress toward the value-based purpose of the VBE. The Agency is also considering whether to explicitly require monitoring as a condition of the value-based arrangement exception and whether to require monitoring at specific intervals. **MGMA opposes including an explicit monitoring requirement as this would create a moving target that hinges on subjective standards.** Measuring success on metrics related to performance and quality standards is an inexact science. Further, metrics may be met during some performance periods but not others. It takes time to achieve success in value-based arrangements, as evidenced by the performance results of MSSP ACOs and other CMMI initiatives.⁷ Historic performance results demonstrate that innovative arrangements take time to generate positive results, particularly when the goal is related to achieving cost savings, and that experience influences success. For this reason, MGMA is concerned that implementing any explicit monitoring and "cut off" provision could chill innovation. Moreover, requiring physicians and VBEs to stop value-based initiatives under such a tight turn around has the potential to be disruptive to clinical workflows and patient care.

Yet another problem with monitoring is that at least some of the obligation, if not all, would presumably fall on payers. Providers would then be at risk of losing protection under this exception because of insufficient diligence on someone else's part. In fact, how would VBE participants even know at any given point in time exactly what the payer's monitoring program was or whether the payer was living up to that program?

CMS does not propose, but seeks comment on, whether to require the recipient of remuneration to contribute at least 15% of the donor's cost. MGMA opposes this concept and strongly cautions against requiring such a contribution. Most importantly, such a requirement would disadvantage the entities that would benefit the most from the donation of resources. Further, implementing this requirement adds complexity to value-based protections at a time when CMS is attempting to reduce burden.

⁷ *Medicare ACO Results for 2018: More Downside Risk Adoption, More Savings, and All ACO Types Now Averaging Savings*, Health Affairs (Oct. 25, 2019) (discussing "that the proportion of ACOs achieving shared savings and receiving a bonus increases the longer an ACO has been in MSSP.").

Lastly, we urge CMS to finalize its proposal to cover both monetary and in-kind compensation under this exception. Limiting this exception to only in-kind compensation would significantly restrict the ability to implement economic incentives to drive changes in physician behavior. It would preclude distribution of shared savings, gainsharing, or bundled payments not protected under other value-based exceptions. CMS should instead redouble its efforts to bring the OIG's approach to value-based arrangements more closely in line with what CMS has proposed in 411.357(aa)(3).

Waivers

CMS seeks comment on whether the three proposed exceptions could offer sufficient protections to APMs currently covered by a waiver.

As currently written, the three proposed value-based exceptions are not sufficiently flexible, broad, or tailored to Medicare models or CMMI demonstration projects to offer a viable alternative to the existing regulatory waiver process.

The benefit of a waiver, such as the one applicable to the MSSP, is that it is self-executing, broadly applicable, protects both pre-participation and participation, allows for use of beneficiary incentive programs, and protects the distribution of shared savings payments. **Therefore, we strongly encourage CMS to continue implementation of waivers for existing and future CMMI demonstrations and the MSSP.**

At the same time, MGMA recognizes the need to create a more permanent solution to the regulatory waiver scheme. CMS should finalize the three value-based exceptions, while keeping the waiver process in place, and let several years of experience under both options inform a later discussion on the necessity of waivers.

Indirect Compensation Arrangements (§411.354(c)(4))

As MGMA has previously suggested, the final rules should clarify that physicians are eligible for the new value-based exceptions if the medical group of which they are a part is a participant in the value-based arrangement. Clarity on this point would make reliance on the arcane provisions of the indirect compensation definition and exception less important. That said, MGMA also supports, as a “belt and suspenders” approach, finalization of the “special rule” proposed in 411.354(c)(4)(ii).

In MGMA's opinion, few things illustrate the need for comprehensive legislative reform better than the regulatory “work arounds” dealing with indirect compensation. With fewer than 15% of America's practicing physicians in solo practice, the vast majority of physician compensation relationships with payers, networks, hospitals, and other providers run through a medical practice whether physician-owned, hospital-based, or otherwise. Yet the statute as enacted still deals with individual physician relationships, necessitating first a definition of indirect compensation relationships, then an accompanying exception for a subset of the same, then a limitation on eligibility for protection under exceptions designed for direct compensation, then the mandatory “stand in the shoes” policy, then the permissive “stand in the shoes” policy, and now the special rule for indirect compensation resulting from a physician's participation in a value-based arrangement. MGMA questions why any stakeholder would wish to continue a regulatory scheme this convoluted in order to make it possible for medical group members to do exactly what the government wants them to do—namely move towards value-based care and payment?

PROPOSED AMENDMENTS TO FUNDAMENTAL TERMINOLOGY AND STARK LAW REQUIREMENTS

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 beyond comprehension to the average physician or healthcare administrator. MGMA appreciates efforts through this proposed rule to clarify singular terms, such as the three cornerstones of Stark Law exceptions, however we continue to believe that this law cannot be meaningfully improved through regulatory revisions only.

The framework of the Stark Law includes codified regulatory text, rulemaking through preamble language, “special rules,” and deeming provisions; together, these elements make up a general prohibition coupled with dozens of exceptions. At times, key definitions may (or may not) mean different things depending on the context. Some examples of Stark’s perplexing terminology and concepts include:

- Within the meaning of the in-office ancillary services exception, a permissible referral is from a physician “in the practice,” which is not the same as being a “member” of a practice.
- Indirect compensation relationships can form the basis of both a prohibition and an exception, both called the same thing. The definitions of the prohibition and the exception are similar, but not identical.
- The “volume or value” language appears 48 times in Stark Law regulations codified in 42 CFR 411, but with different modifiers, e.g., “takes into account,” “based on,” “varies with,” and “related to,” making it unclear whether these phrasings were used intentionally to convey different rules,⁸ or were merely drafting inconsistencies.

We provide these examples to show that each individual term or standard within the Stark Law does not exist in a vacuum but rather works in concert with the entire regime. Until the foundation of the law is fixed, layering bandages on the building blocks will do little to fix structural deficiencies.

Furthermore, the problems do not stop at ambiguous or confusing terms. The law is also incredibly broad and far reaching. For example:

- A financial relationship can be triggered by the provision of in-kind remuneration, such as a hospital providing a physician parking or a group practice sending a physician in a separate and distinct group practice a gift as a courtesy. Once a “relationship” exists, regardless of whether that relationship is abusive, any referrals for DHS between these entities must be covered by an exception to avoid liability.

Lastly, the complexity and breadth of the law is undercut by the lack of intent requirement and severe penalty provisions. We raise these issues such that CMS can consider how burden reduction may not be possible by simply clarifying certain terminology. Thus, while generally supporting the clarification offered through modifications to the fundamental terminology and modest flexibilities in new exceptions and special rules, we do not believe that this will meaningfully reduce regulatory burden for the majority of group practices.

⁸See, e.g., U.S. ex rel. J. William Bookwalter, III, M.D. et al. v. UPMC et al, No. 18-1693 (3rd Cir., Sept. 17, 2019) (concluding that “takes into account” involves a causal relationship while “varies with” means correlation).

Commercial Reasonableness

MGMA supports the regulatory text providing that a lack of profitability does not automatically indicate lack of commercial reasonableness. This could help provide clarification for group practices and healthcare entities that employ or engage physicians at a loss when considering only professional fees, but who serve an appropriate business or mission purpose. At the same time, a rule that says an unprofitable arrangement “may” still be commercially reasonableness is hardly a bright-line test.

Volume or Value

MGMA supports CMS’ proposed approach to create an objective test for determining when compensation is determined to take into account the volume or value of referrals or other business generated between parties. This distinction likely creates as close to a bright line rule as is possible under the statute and may reduce confusion surrounding the meaning of this term, in turn mitigating burdens associated with meeting this standard.

The Agency discusses the inclusion of the volume or value standard or other business generated standard as they apply to the definition of “remuneration” under the statute, exceptions, and indirect compensation relationships, however CMS does not mention the inclusion of this standard in the definition of group practice (84 Fed. Reg. 55792). Qualifying as a bona fide group practice within the meaning of the Stark Law is not an exception itself, but rather a *sin qua non* for meeting many exceptions. **MGMA requests that CMS be explicit in the final rule that this interpretation applies for purposes of 411.352(g) and (i) in the definition of group practice.**

Fair Market Value

MGMA agrees with CMS’ statement that the fair market value requirement should be separate and distinct from the volume and value of referrals and other business generated standards. The inclusion of this language in the fair market value definition is superfluous and has led entities and even courts to conflate these distinct rules.

We do not agree with CMS’ preamble discussion of extenuating circumstances that could require a downward deviation from salary surveys. In the example given, a small hospital should be permitted to rely on salary surveys and good faith bargaining when compensating a physician. This example ignores the physician’s value as well as the hospital’s need for the physician. That CMS even considered being this granular in its preamble discussion illustrates, we fear, that even though the new formulation of fair market value may be preferable to the old, it certainly remains elusive.

Group Practices (42 CFR 411.352)

CMS acknowledges in the preamble that current regulations reference differing terms when describing the volume or value standard (e.g., “takes into account,” “based on,” and “related to”). The Agency clarifies in the preamble that despite differing language, these terms all refer to the same volume or value standard in the context of exceptions and indirect compensation relationships. However, because the terms in the regulatory definition of “group practice” at 411.352(g) and 411.352(i) mirror the statutory language, the Agency does not propose any changes to the regulatory text to align it with other references to the volume or value standard.

MGMA seeks assurances from CMS that proposed changes to the volume or value standard under 411.354(d)(5) and (6) would apply to the group practice compensation test.

Distribution of Revenue [sic] Related to Participation in a Value-based Enterprise

CMS' proposal to deem as acceptable any distribution of profits from DHS that are directly attributable to a physician's participation in a VBE could offer group practices much-needed flexibility and clarity by allowing them to reward physicians for results achieved through participation in a VBE. MGMA supports this proposal but encourages the Agency to revise the regulatory text to protect revenues. Revenues, rather than profits, will be easier to calculate for group practices, and will allow for greater flexibility in the distribution of value-based funds.

Special Rule for Profit Shares (411.352(i))

In response to inquiries from the physician community regarding permissible distributions of profit shares, CMS attempts to "provide a clear expression of [] policy" regarding the distribution of "overall profits" from DHS (84 Fed. Reg. 55801). Specifically, CMS states that "a physician practice that wishes to qualify as a group practice could not distribute profits from DHS on a service-by-service basis." MGMA strongly opposes further attempts to micromanage the organization, governance, and operation of group practices and opposes any change, including the revised interpretation of overall profit shares, that exacerbates this interference. **If CMS did not intend to create additional regulatory burden for group practices, we strongly urge the Agency to withdraw this statement in the final rule and reinstate longstanding existing rules around profit sharing.**

The effect of any interpretive change to the overall profit distribution policy may further restrict permissible methodologies for distributing DHS profits among group practice physicians, and at a minimum, serves to confuse an element of existing regulations that in MGMA's view is not prone to abuse. If finalized, this policy will require all group practices using profit sharing as a mechanism for distributing DHS profits to consult with their attorneys to ensure their compensation systems are compliant under CMS' revised interpretation.

One frequently asked question within the MGMA membership is how to distribute ancillary revenue in a compliant manner. These are not individuals seeking to circumvent the law, improperly attribute revenue to physicians, or promote overutilization, but rather professionals at a loss for how to interpret a complex set of rules that have become a constantly moving target.

We are concerned that the change in interpretation could negatively impact group practices, particularly those that cannot afford to allocate resources away from patient care and toward expensive attorneys and consultants.

The Agency states its intent in "clarifying" this policy is to align regulations with the statute (section 1877(h)(4)(B)). However, the statute is not proscriptive with respect to what methodologies are permissible for distributing overall profits (or bonuses) to physicians; the statute simply states the share or bonus may not be "determined in any manner which is **directly** related to the volume or value of referrals by such physician" (emphasis added). Moreover, the underlying intent of the statute is to prevent physicians from getting direct credit for their referrals.

To reiterate, the statute makes clear what it intends to regulate: self-referrals.⁹ CMS recognized early

⁹ 135 Cong. Rec. H240-01 (Feb. 9, 1989) ("The Ethics in Patient Referrals Act is intended to deal with a diverse wave of commercial activity that has the principal purpose of attempting to 'lock-in' a referral base for a particular

on in the Phase I preamble that the Stark Law is not meant to micromanage physician compensation structures:

“As a starting point, we do not believe that the Congress intended [the Stark Law] to regulate physician compensation practices, except as necessary to minimize financial incentives to DHS to entities with which the physicians have financial relationships.”¹⁰

And yet, the Stark Law has the most significant impact on physician compensation of any authority to date.

If the Agency is truly promoting value-based care, we strongly urge it to maintain flexibility for group practice physicians. We recommend CMS pull back on the clarification around profit shares articulated in the proposed rule. Instead, **CMS should maintain the existing profit-sharing standards, withdraw its clarifications articulated in the preamble through a clear statement in the final rule, and underscore that the critical question in profit share distribution is whether there is a direct correlation with referrals.**

Special Rule for Productivity Bonuses (411.352(i))

Many group practices utilize productivity bonuses that involve RVU-based calculations. Tinkering with the requirements of this exception potentially requires physician group practices using productivity bonuses to revisit how their bonuses are calculated and will require some to restructure their compensation distribution methodologies. The productivity bonus deeming provision works as currently structured and revising it will only create additional regulatory burden.

RECALIBRATING THE SCOPE AND APPLICATION OF THE REGULATIONS

AKS

We strongly support decoupling Stark Law exceptions from AKS and billing and claims requirements. The reference to AKS compliance is inconsistent with the Stark Law’s original intent to create bright line rules and has been a source of uncertainty and compliance risk since it was first included.

Special Rules on Compensation Arrangements (411.354(e))

MGMA supports CMS’ clarification that the “set in advance” requirement does not require parties to set out compensation in writing in advance of providing services and that 42 CFR 411.354(d)(1) *deems* compensation to have met the “set in advance” component of the corresponding exception, rather than requiring it.

Electronic Health Records Items and Services (411.357(w))

MGMA supports CMS’ proposal clarifying that, on the date the software is provided, it “is” certified and the proposal to delete the regulatory reference to “editions” of certification criteria to align with proposed changes to the certification program.

provider by creating an entangling web of financial relationships that bind referring physicians to the provider,” Rep. Pete Stark introducing H.R. 939).

¹⁰ 66 Fed. Reg. 856, 875 (Jan. 4, 2001).

ONC's certified EHR technology (CEHRT) standards are voluntary for software vendors. To date, there have been three editions of the certification (2011, 2014, and 2015). While MGMA agrees with CMS that software should facilitate interoperability, the current ONC proposed rule includes a significant number of certification enhancements and there is the expectation that ONC will develop new CEHRT nomenclature (i.e., the "2021" edition).

It is important to note that the requirement for clinicians to use CEHRT is directly related to their participation in the Quality Payment Program (QPP). For those clinicians who are not required to participate in the QPP, we recommend that, for a period of no less than five years, the donated EHR software only be required to be certified at the 2015 edition level.

We support the proposal to eliminate the sunset provision. We believe that despite the high level of physician practice EHR adoption there will be a need for this type of software donation going forward as new practices look to acquire the technology and practices needing to upgrade their current technology could potentially be recipients of these donations. We support elimination of the sunset provision, rather than an extension.

MGMA agrees that donors should not engage in any action that constitutes information blocking according to the 21st Century Cures Act. ONC, however, has issued a proposed rule that includes a wide array of exceptions to the information blocking prohibition. We support aligning the definition of interoperability with the statutory definition, but caution referencing proposed regulatory sections given the unknown outcome of proposed policies.

Additional Proposals and Considerations

CMS has set out two proposals, each of which serve to improve the current donation process that requires recipients to contribute a minimum of 15% of the total donation. The current 15% requirement can serve as a significant barrier to the initial donation of health information technology and any subsequent and necessary technology upgrades. Moreover, any new certification enhancements ONC is considering will likely require more complex and costly functionalities for vendors, which may further limit the number of software vendors making this upgrade, thereby limiting the number of products available to users and potentially driving up costs for purchasers. This could exacerbate a group practice's ability to meet the 15% contribution requirement. With the establishment of the EHR exception and the proposed cybersecurity technology exception, the intent of the government is clearly to ensure that these critical technologies are implemented by physician practices that have limited financial resources. **With that in mind, we urge that the 15% contribution requirement be eliminated for all physicians.**

PROVIDING FLEXIBILITY FOR NON-ABUSIVE BUSINESS PRACTICES

Limited Remuneration to a Physician (Proposed 411.357(z))

MGMA agrees with the Agency that this exception could protect non-abusive practices and ameliorate concerns over technical non-compliance. We emphasize again that the original purpose of the Stark Law was to limit overutilization and protect patients; many technical violations do not involve concerns of overutilization, conflicts of interest, or instances of patient harm, but rather innocuous oversights or misunderstandings of this complex law. As acknowledged in the *Tuomey* concurrence, "[i]n the context of the Stark Law, it is easy to see how even diligent counsel could

wind up giving clients incorrect advice.”¹¹ A strict liability statute riddled with ambiguities misunderstood by even lawyers creates a nearly untenable situation for all parties involved, but imposing “ruinous” penalties for inadvertent, minor infractions is particularly troubling.

This exception could be used to cover arrangements wherein a DHS entity contracts with a physician to perform necessary and meaningful services but does not have the opportunity to reduce the agreement to writing prior to commencement of the relationship. This could also protect situations where an entity offers in-kind remuneration to a physician or group and inadvertently triggers the Stark Law. For example, a hospital may provide a group’s physicians with temporary parking or pay for meals throughout the year as a matter of convenience or courtesy. The reality is, the Stark Law could result in liability for conduct considered routine and courteous between colleagues in all other professional settings (i.e., a hospital sending flowers to a physician to express condolences or congratulations, inviting a physician colleague to a holiday party held at a referral source, a health system sending a gift basket to a group practice; while all of these “relationships” may be protected under an existing exception, there is no single exception that would apply to all examples).

We encourage CMS to increase the value of this exception to afford adequate flexibilities for physician compensation arrangements. We support applying this threshold at the individual physician level when a group practice enters into an arrangement with a DHS entity.

Cybersecurity Technology and Related Services (Proposed 411.357(bb) Exceptions

MGMA strongly supports of the proposal to establish a cybersecurity exception. When seeking to address the growing threat presented by cyber-attacks, physician practices, especially smaller ones, typically face the dual challenges of a lack of expertise in the area of cybersecurity and a lack of financial resources. Financial constraints can impede an organization’s ability to identify, purchase, implement, and maintain the policies and procedures required to adequately protect patient records. An entire healthcare system can benefit when cybersecurity resources are distributed to each of its participants.

Interoperable electronic systems permit patient data to flow between clinical sites either directly or via a health information exchange entity. Cyberattacks, or even the threat of cyberattacks, can lead to disruption in that flow of data, thus impeding the ability of healthcare entities to coordinate or manage care. Practice cyber hygiene is particularly vulnerable when connecting with outside entities, and this is precisely where cybersecurity technology and services would be the most helpful.

We oppose any recipient contribution requirement for cybersecurity donations. Recipients of cybersecurity assistance should be permitted to allocate their limited resources toward investments in other technologies not protected by the exception or not offered by the donor.

We support the inclusion of a broad array of cybersecurity services as part of the exception. These would include services associated with developing, installing, and updating cybersecurity software; training services; cybersecurity services for business continuity and data recovery services to ensure the recipient’s operations can continue during and after a cyberattack; “cybersecurity as a service” models that rely on a third-party service provider to manage, monitor, or operate cybersecurity of a recipient; services associated with performing a cybersecurity risk assessment or analysis,

¹¹ United States ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015) (Wynn, J., concurring).

vulnerability analysis, or penetration test; and any services associated with sharing information about known cyber threats, and assisting recipients responding to threats or attacks on their systems. We concur that these types of services are indicative of the types of services that are necessary and used predominantly for effective cybersecurity.

MGMA recommends expanding this list to include consulting services deployed not only to conduct a risk assessment or analysis, but to work with the practice to develop and implement specific cybersecurity policies and procedures. The exception should also cover any subscription fees required by vendor security products that assist practices to develop policies and procedures in support of a risk assessment. Finally, off-site, cloud-based data backup services and data recovery services should also be covered under the exception.

We appreciate CMS' consideration of broadening the scope of protected donations to include certain cybersecurity-related hardware. We strongly support this approach as we believe it best meets the overall intent of the cybersecurity exception. Practices, especially smaller organizations, typically lack the technical expertise to accurately determine their cybersecurity risks and vulnerabilities. While the exception covers a donated risk assessment, this assessment is only the first step in developing specific protocols and processes to protect against a cyberattack or situation that could endanger patient data. The risk assessment can identify a specific vulnerability, but the practice must then take action to address that vulnerability, whether that be development and implementation of a policy or deployment of hardware technology.

The preamble states that the key differentiator between hardware that would be permitted and that which would be excluded relates to its ability to be "multifunctional." Most hardware specific to the issue of cybersecurity would have as its sole purpose maintaining the security of patient data. Thus, the list of associated hardware should include patient and staff identification systems such as Kiosks, identification badges, identification key fobs or other devices used to accurately identify individuals, and card and device readers. Further, intrusion detection hardware should also be included in the definition of permissible donations. This technology assists the practice by monitoring network traffic and issuing a warning should there be any type of unauthorized access being attempted. This is a critical facet of cybersecurity technology and can prevent a cyberattack from being successful and impacting patient care.

Another example of where the exception could be broadened is to data backup and recovery systems. A typical security risk assessment includes an examination of the practice's contingency planning and disaster recovery options. For practices hit by a cyberattack, protecting their patients' electronic data and having in place protocols that allow the practice to continue treating patients is paramount. Practices must maintain current, flexible, secure, and speedy solutions to keep their patient data accessible and fully usable. Employing data backup, a well-executed data recovery solution, and a thorough contingency plan in the event of a cyberattack or natural disaster can mean the difference between a major event leading to an interruption of patient care and continuing operations with a minimum of disruption.

Finally, we urge CMS to consider including donations of cybersecurity measures outside of technology and services, such as installation or improvement of physical safeguards such as upgraded wiring, security systems, fire retardant or warning technology, or high security doors. These and other physical safeguards are integral to the protection of patient data.

FUTURE CONSIDERATIONS FOR GROUP PRACTICES

Through the Stark Law Request for Information published on June 25, 2018, CMS sought comments on what barriers exist to qualifying as a group practice under Stark regulations. CMS acknowledges in this proposed rule stakeholder comments identifying areas where policy simplification could enhance certainty of compliance with how to meet the eight regulatory tests required to qualify as a bona fide group practice, but declines to address many of these concerns. Instead, CMS limits proposals to the main purposes of the proposed rule, i.e., the three cornerstones of existing exceptions and the transition from volume-based to value-based payments.

MGMA submits that CMS cannot meaningfully address the transition from a volume-based to value-based system or Stark Law clarification without significantly simplifying the regulatory definition of a bona fide group practice. **We encourage the Agency to find ways to simplify the group practice regulation and reduce regulatory burden through future rulemaking. In concert with this effort, CMS should work with Congress on legislative solutions given certain requirements are codified in statute.**

Qualifying as a bona fide group practice within the meaning of 42 CFR 411.352 is not an exception itself, but rather a condition for meeting many exceptions, including the in-office ancillary services (IOAS) exception. The IOAS exception allows physicians to effectively provide patient services at the point of care. The ability to offer ancillary services within a medical group practice allows physicians to have swift access to necessary testing such as imaging or laboratory work that is critical to the treatment of certain patients. Simply put, it permits groups to coordinate care for their patients—one of the very goals of this proposal.

For example, an MGMA member from a nephrology practice explained how physicians incorporate testing results generated from their in-office laboratory into same-day patient appointments. The patient arrives early to the appointment to have blood drawn, the in-office laboratory processes results, transmits them to the physician, and the physician incorporates these results into the patient's subsequent appointment. Having an in-office laboratory integrated into the clinical workflow is vital to the practice's care of patients with kidney disease and the monitoring of comorbidities such as anemia. Moreover, having on-site testing assists with continuity of care, is convenient for patients, and facilitates the physician-patient relationship. In another example, a radiation oncology practice described how precise, quality imaging is necessary to target radiation doses to the exact location of a tumor. Imaging undertaken at outside facilities may lack the precision necessary to target such cancer, highlighting the need to conduct CT, MRI, or PET scans in a radiation oncology setting by professionals trained in radiation treatment planning.

From a strictly economic perspective, the IOAS exception allows ancillary services to be performed in non-hospital settings where the quality of care is the same, but costs are lower. Group practices have historically maintained a range of diagnostic and therapeutic services provided through their practice. We are aware of no valid policy reason to give hospitals or free-standing diagnostic and therapy companies monopoly rights with respect to the provision of ancillary services. **While we recognize that CMS is not proposing any changes to the IOAS exception, we wish to highlight its value because we are concerned that imposing any additional burdens on meeting this exception could jeopardize its utility, in turn potentially disrupting patient care and threatening the viability of group practices. Furthermore, we encourage the Agency to look for**

opportunities in the near future to enhance the group practice model by reducing regulatory burden where the statute allows.

Conclusion

MGMA appreciates the opportunity to provide recommendations to the CMS on proposals aimed at improving the Stark Law to better align it with value-based care efforts. MGMA is committed to engaging with CMS going forward to identify and inform focused and efficient program integrity efforts. We offer our assistance to efforts to modernize and reform fraud and abuse laws. Should you have any questions, please contact Mollie Gelburd at mgelburd@mgma.org or 202.293.3450.

Sincerely,

/s/

Anders M. Gilberg
Senior Vice President, Government Affairs