October 26, 2018

Susan Edwards
Office of Inspector General,
Department of Health and Human Services
330 Independence Avenue, S.W., Room 5513
Washington, D.C. 20201

Re: OIG-0803-N, Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducement Civil Monetary Penalty

Dear Ms. Edwards,

The Medical Group Management Association (MGMA) is pleased to submit the following responses to the Office of Inspector General's (OIG) Request for Information (RFI) on ways to address regulatory provisions under the Anti-Kickback Statute (AKS) and beneficiary inducement provision of the Civil Monetary Penalty (CMP) law that act as barriers to value-based care initiatives. We commend OIG for recognizing the need to modernize existing laws to reflect a more coordinated approach to care delivery 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.

MGMA recognizes that the OIG has the difficult task of implementing laws like the AKS and CMP that were drafted in a fee-for-service environment to protect against overutilization in a system based on volume. As reimbursement approaches continue to change over time and move toward alternative payment models (APMs) that pay for value, fraud and abuse laws and their implementing regulations have attempted to keep pace through modifications. Unfortunately, piecemeal modifications have resulted in an exceedingly complex fraud and abuse framework that introduces uncertainty and risk into any novel payment arrangement not explicitly protected by a waiver or other exception authority.

The AKS criminalizes the knowing and willful offer, payment, solicitation, or receipt of remuneration to induce (or reward) the referral of federal healthcare program business.[1] For purposes of the AKS, "remuneration" is defined broadly to include anything of value, whether in cash or in-kind. The beneficiary inducements provision of the CMP prohibits offering remuneration to any Medicare or Medicaid beneficiary that a person knows or should know is likely to influence the beneficiary to seek reimbursable care from a particular provider.[2] "Remuneration" under the CMP includes "transfers of items or services

[1] Section 1128B of the Social Security Act classifies violations as a felony punishable by a fine and/or imprisonment. An AKS violation can also result in imported penalties under the CMP, False Claims Act, and exclusion from participation in federal healthcare programs.
[2] Section 1128A of the Social Security Act provides for administrative sanctions including program exclusion and other penalties.

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for free or for other than fair market value" but does not include "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs."

There are exceptions to each law, as well as voluntary safe harbors to the AKS, that protect certain arrangements. An arrangement permitted under the AKS, whether under a statutory exception or regulatory safe harbor, is also excepted from the beneficiary inducements CMP.[3] However, CMP exceptions do not provide reciprocal protection under the AKS, meaning an arrangement may be permissible under a CMP exception yet still run afoul of the AKS.[4] MGMA believes this incongruity leads to confusion and uncertainty for physician group practices and healthcare entities, which we presume is not OIG's intended consequence. Therefore, to align exceptions policies under these two laws, we recommend that OIG create safe harbors to the AKS as outlined below, since such safe harbors would also be construed to protect arrangements that could otherwise be prohibited under the beneficiary inducements CMP by virtue of the statutory construct.

While it is possible to interpret fraud and abuse laws like the AKS as being so restrictive that they prohibit many positive, innovative arrangements that our healthcare system encourages, MGMA believes it is also possible for OIG to recognize, as it has already through Advisory Opinions and other policy guidance, that certain behaviors and changes in healthcare delivery are well-intended to improve care, reduce costs, and increase patient satisfaction. As the OIG considers how to best proceed, MGMA encourages an approach that permits maximum flexibility and facilitates the types of innovation that Congress, the Administration, and the broader healthcare community are seeking to promote.

When considering modifications to or creation of new exceptions policies, OIG must ensure that any change is entity-agnostic and does not further promote or drive consolidation within the healthcare system. This means that a solo practitioner with limited resources should have the same capability to implement a new exception or safe harbor as a large, sophisticated hospital system with access to high-priced resources like attorneys and compliance consultants.

Promoting Care Coordination and Value-based Care

OIG requests feedback on potential arrangements that promote value-based care or care coordination principles but may implicate the AKS or CMP beneficiary inducement provision. OIG also seeks input on possible approaches to improving its safe harbor and exceptions policies as they apply to such arrangements.

While well-intended, the AKS and CMP are broadly construed such that they effectively prohibit or introduce uncertainties regarding clinical and financial integration arrangements that have the potential to improve care for patients. For example, tying compensation to patient outcomes and efficient care delivery; equipping physicians with tools to improve care; and investing in tools to clinically and financially integrate all further the goals of value-based payment reform, but also may violate existing fraud and abuse laws.

There are exceptions and safe harbors that protect certain arrangements from scrutiny, however existing policies do not offer sufficient protection for novel payment or care delivery arrangements. Uncertainty about the application of fraud and abuse rules, and potential for severe penalties for any violation, have had a chilling effect on innovation and slowed the progression toward cost-efficient, quality-driven models.

To more effectively promote a shift toward value-based care delivery, **MGMA urges OIG to create a broad, flexible safe harbor for value-based arrangements using clear, easy-to-understand terms**. We

[3] Section 1128A(i)(6)(B) of the Social Security Act; 81 Fed. Reg. 88368, 88369 (Dec. 7, 2016).
[4] 81 Fed. Reg. 88368, 88399 (Dec. 7, 2016).

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encourage an approach that avoids prohibitively complicated criteria and unnecessary contingencies. MGMA believes that a single exception—if broad enough—could provide sufficient protection for all types of novel, value-based financial arrangements.

The safe harbor should be broadly structured such that it protects any arrangement designed to achieve or reasonably related to one or more goals set forth in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), including promoting accountability for patient outcomes, enhancing quality of care, facilitating care coordination, and promoting efficient use of resources. It should protect participants of delivery and payment arrangements both in development and operation and should be sufficiently flexible to protect future arrangements that have not yet been created or contemplated. As discussed below, MGMA made a similar recommendation to the Centers for Medicare & Medicaid Services (CMS) in regards to a new exception to the Physician Self-Referral (Stark) Law, and we encourage OIG to work with CMS to create consistent value-based exceptions policies for both the AKS and the Stark Law.

Any new safe AKS harbor must allow independent practices of all sizes to work together and collaborate with hospitals and other entities to deliver coordinated care for patients. As such, the safe harbor should provide adequate protection for the entire care delivery continuum, including 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 value-based initiatives in ways that enable them to maintain independence while at the same time having access to the infrastructure and resources necessary to participate in APMs. This approach would meet the Department of Health and Human Services' (HHS) own stated goal of increasing patient choice and competition to drive quality, reduce costs, and improve outcomes.

Imposing reasonable safeguards for use of the new safe harbor, coupled with the inherent structure of value-based arrangements, would eliminate the risk of real world abuses. For example, use of the safe harbors could require basic accountabilities such as:

- Requiring that the arrangement have a declared objective and credible narrative explanation of how the arrangement will serve one or more of the pillars of MACRA;
- Standards for documenting the use of the safe harbor, which could be made available to HHS upon request; and
- Reasonable transparency initiatives to promote more informed patient choice about care delivery within the arrangement.

Participation in APMs and value-based arrangements requires at least partial financial and clinical integration, and integration inevitably influences referrals within a network. The very purpose of care coordination, organizing and sharing patient care responsibilities among providers, places these efforts in the zone of scrutiny under the AKS, which is why protection for these laudable aims is so critical. More options and increased flexibility is needed to help realize the full potential of innovative models.

Beneficiary Engagement

OIG solicits input on the types of beneficiary incentives that the community wishes to provide and how such incentives would contribute to the goals of payment reform. OIG is interested in hearing about potential risks, benefits, and safeguards that could be adopted.

Arrangements whereby a physician group practice furnishes an item or service to a patient as an in-kind engagement incentive can violate the AKS or beneficiary inducements CMP, even when provision of the item or service is intended only to achieve improved patient outcomes. For example, beneficiary

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inducement prohibitions could apply to:

- Financial assistance programs that offer car seats to low-income mothers once discharged from the hospital;
- Healthcare coaches that remotely monitor high-risk patients to encourage intervention before a hospital admission;
- Bereavement or education programs offered by an oncology clinic to the families of terminal patients not eligible for hospice care;
- Digital tools offered to diabetic patients to track and transmit physiological data to a provider; and
- Motivational incentives for substance abuse patients to adhere to a treatment regimen.

In many instances, the "inducement" offered by a physician or provider can result in benefits to the patient, the program, or both. MGMA supports providing patients with incentives that are linked to health and wellness or have a reasonable connection to medical care. **We recommend that OIG create a patient assistance safe harbor to the AKS that protects efforts to promote access to care or is based on financial need.** The safe harbor should protect in-kind incentives to seek care, support for accessing care, assistance to enhance compliance with a treatment plan, and incentives to improve patient engagement or involvement in their care.

MGMA recognizes that beneficiary incentive programs can either improve or undermine care delivery, but with proper safeguards, these initiatives can have a positive effect that results in a more patient-centric care delivery model that is both safe and cost-effective. Certain restrictions or patient protections could be implemented to allow physician group practices to use proper beneficiary incentives while preventing those incentives that negatively impact professional independence. Potential safeguards could include:

- Limitation to only in-kind incentives;
- Incentives must bear a reasonable connection to the beneficiary's health and wellbeing; and
- Prohibition of advertisements about the incentive.

Cost-sharing Obligations

OIG requests input on how relieving or removing beneficiary cost-sharing obligations might improve care delivery. The agency also requests information on any corresponding financial impact on providers, risks to beneficiaries, and potential safe harbor protections to mitigate such risks.

MGMA recommends that OIG create a safe harbor for group practices to waive cost-sharing amounts for beneficiaries that receive chronic care management (CCM) and other high-value services.

Regular appointments with and monitoring efforts by clinicians can help ensure chronic conditions are kept from unduly progressing and prevent new conditions or exacerbations of existing conditions. However, MGMA has heard from our members that when it comes to CCM services for instance, patients are discouraged from taking advantage of this high-value service due to the copay. Because routinely waiving patient co-payments can potentially implicate both the CMP beneficiary inducement provisions and the AKS, physician practices wishing to deliver and be reimbursed for these services are in a catch-22. **Therefore, MGMA urges OIG to issue a safe harbor to protect the waiver of copayments for high-value services.** This protection should be available whether or not the copay waiver is needs-based.

Removing this unnecessary impediment to patient and clinician interaction is a small step that could yield

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impressive results. Regular appointments allow providers to more closely monitor patients and spot complications before they worsen, preventing more expensive downstream costs. Moreover, establishing a more regular, wellness-based relationship between a clinician and patient encourages the patient to contact the provider first before resorting to more drastic, expensive options such as calling an ambulance.

In addition to protecting the waiver of copayments for high-value services like CCM, **MGMA also requests that OIG issue policy clarification allowing for the waiver of cost-sharing amounts when the cost-sharing amount is nominal.** In the 2019 proposed Physician Fee Schedule, CMS proposed to cover certain virtual care or remote monitoring services.[5] MGMA is very appreciative of CMS' proposed policies expanding access to digital medicine services, however we are concerned that physician group practices will be deterred from incorporating these services into their practices due to administrative hurdles, such as billing beneficiaries for nominal copayment amounts. For example, CMS proposes to pay approximately $15 for a virtual check-in service.[6] With a 20 percent cost-sharing amount, a beneficiary would pay approximately $3. Billing this copayment can create confusion for beneficiaries not accustomed to paying for services without a face-to-face component. In addition, the administrative costs of monthly collections may deter some practices from billing this service altogether.

Clarification of Existing Access to Care Exception

Through 2016 rulemaking, OIG implemented an exception to the beneficiary inducement CMP for assistance that "promotes access to care."[7] The 2016 rule declined to extend the new exception to the AKS and adopted a narrow interpretation of the types of activities that qualify for the promoting access to care CMP exception. While MGMA strongly supports exceptions to permit programs that increase beneficiary engagement and access to care in manners that are safe and transparent, we are concerned about incongruity between the CMP and AKS, such that conduct may be excepted under the CMP yet potentially be a violation of the AKS. This exacerbates confusion surrounding the application of fraud and abuse rules, which are already unnecessarily complex and riddled with legalese, and contributes to uncertainty for physician practices wishing to engage with their patients.

MGMA requests that OIG issue a safe harbor under the AKS that aligns with the requirements for satisfying the "promoting access to care" exception from the definition of remuneration under the CMP. We seek assurances from OIG, through the issuance of policy guidance or other statements, that the agency will use its enforcement discretion to not pursue potential AKS matters where the items or services at issue meet the "promoting access to care" CMP exception.

Cybersecurity-related Items or Services

OIG requests input on how existing fraud and abuse laws inhibit collaborative industry cybersecurity efforts, including the donation or subsidization of cybersecurity tools among providers that share information.

Physician practices, especially smaller organizations and those located in rural areas, simply are not equipped to ward off sophisticated cyberattacks and typically do not have sufficient internal technical expertise or the budget necessary to effectively meet new and evolving cybersecurity challenges. Exceedingly sophisticated cyberattacks, coupled with the rapid growth of digital medicine and connected devices, underscore the critical importance of improving cybersecurity efforts. Unfortunately, the AKS prevents the sharing of cybersecurity tools and resources, thereby hindering collaborative industry

[5] 83 Fed. Reg. 35704, 35723 (July 27, 2018).
[6] 83 Fed. Reg. 35704, 35786 (July 27, 2018).
[7] 81 Fed. Reg. 88368, 88390 (Dec. 7, 2016).

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cybersecurity efforts.

Like the OIG, MGMA believes that cybersecurity is a national priority. **MGMA believes that OIG should use its own policy lever by issuing a safe harbor to promote cybersecurity throughout the healthcare system and allow for the sharing or donating of cybersecurity software, hardware, training, and services.** The safe harbor should be easy to understand and enforce such that donors and recipients of resources can readily distinguish between permissible activities and those that violate federal fraud and abuse rules. OIG could use the current EHR safe harbor as a template for a new cybersecurity safe harbor, however we strongly encourage OIG to make the cybersecurity and EHR safe harbor both permanent.

MGMA supports a broad scope of protected donors, recipients, and resources. Non-monetary remuneration should be included in permissible items protected by the exception. This should also include upgrades to equipment and software to enhance functionality; licensure and right to use permissions; security education and support; hardware network appliances; and shared management resources.

Intersection of the Stark Law and AKS

OIG seeks feedback on circumstances in which exceptions to the Stark Law and safe harbors to the AKS should align for purposes of the goals addressed in the RFI.

MGMA appreciates OIG's acknowledgment concerning the potential for disconnect between Stark Law exceptions and AKS safe harbors, as we have long advocated for consistency across both rules. In response to CMS' RFI on ways to modernize the Stark Law, MGMA urged the agency to create a broad exception for value-based and care coordination arrangements and to work with the OIG to create a companion safe harbor for the AKS. We similarly request that OIG consider Stark Law implications when developing exception and safe harbor policy pursuant to this RFI and to work with CMS to create companion AKS safe harbors and Stark Law exceptions to avoid further promulgation of inconsistent rules.

Conclusion

MGMA appreciates the opportunity to provide recommendations to the OIG on ways to improve the AKS and beneficiary inducement CMP to better align with value-based care efforts. MGMA is committed to engaging with the OIG 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 Gilberg, MGM
Senior Vice President, Government Affairs
Medical Group Management Association