December 30, 2019

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

Re: OIG-0936-AA10-P Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

Dear Acting Inspector General Chiedi,

The Medical Group Management Association (MGMA) is pleased to submit the following comments to the Office of Inspector General's (OIG) proposed rule modernizing the Anti-kickback Statute (AKS). We commend OIG for recognizing the need to modernize existing laws to reflect a more coordinated approach to care delivery and appreciate the opportunity to comment on OIG's proposed 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.

We are supportive overall of efforts to remove regulatory barriers to clinical and financial integration efforts aimed to achieve care coordination or other value-based initiatives. We appreciate that OIG is working with the Centers for Medicare & Medicaid Services (CMS) to coordinate proposals modernizing fraud and abuse rules. However, MGMA is concerned about the degree of administrative burden that would be required to meet certain proposed safe harbors.

When considering modifications to or creation of new safe harbor 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. **MGMA is concerned that the regulatory burden associated with complying with overly complex safe harbors may prevent all but the most sophisticated health systems and entities from utilizing proposed safe harbors.** We encourage an approach that avoids prohibitively complicated criteria and unnecessary contingencies. In addition, we appreciate the opportunity to comment on the specific proposals at hand. We urge OIG to:

1717 Pennsylvania Ave NW, #600 . Washington, D.C. 20006 . T 202.293.3450 . F 202.293.2787 . mgma.com

- **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.
- **More closely align proposed safe harbors with exceptions to the Physician Self-referral ("Stark") Law proposed by CMS.** MGMA believes incongruity between these rules will lead to confusion and uncertainty for physician group practices and healthcare entities, which we presume is not OIG's intended consequence.
- **Revise the care coordination arrangement safe harbor at proposed 42 CFR 1001.952(ee).** Specifically, we strongly urge OIG to protect monetary remuneration, eliminate the 15% contribution requirement, and remove complex requirements such as having an outcome measure.
- **Create a safe harbor protecting the waiver of beneficiary cost-sharing obligations.** OIG should allow group practices to waive certain cost-sharing requirements for care management services and services with only a nominal copayment.
- **Extend the availability of the EHR safe harbor and add a cybersecurity safe harbor.** We urge OIG to remove the requirement for the recipient to contribute a minimum of 15% to the cost. We also recommend permitting data backup hardware to be included in the list of permitted cybersecurity donations.
- **Finalize the proposal to eliminate the aggregate compensation test from the personal services safe harbor at 42 CFR 1001.952(d)(1).** MGMA supports this proposal as this change would more closely align the safe harbor with the Stark Law exception.
- **Simplify the safe harbor for outcomes-based payments at 42 CFR 952(d)(2).** While we support the creation of this safe harbor, we believe the proposed detailed requirements introduce too much vagueness and uncertainty.

Proposed Value-based Terminology

Value-based arrangement: This definition as proposed, coupled with additional safeguards incorporated in other definitions and within each safe harbor, is sufficient to protect against program or patient abuse. MGMA does not believe that any additional requirements are necessary.

Value-based enterprise (VBE): MGMA supports OIG's proposed definition and appreciates that OIG has chosen to define VBE in terms of the function of an enterprise, rather than the legal structure.

Value-based purpose: MGMA supports the four proposed purposes but opposes imposing a requirement under each of the proposed safe harbors at 1001.952(ee), (ff), and (gg) that the protected arrangement include activities that directly further the first of the four purposes (coordination and management of care for the target patient population). Instead, OIG should only require that value-based activities be directly connected to, or be reasonably designed to achieve, *any one* of the value-based purposes. Value-based arrangements can cover activities beyond care coordination. Importantly, by not requiring coordination and management of care, these safe harbors would be more closely aligned with the Stark Law exceptions. Lastly, as we suggested in response to CMS' proposed definition of value-based purpose, we recommend that the third purpose (appropriately reducing costs) be expanded to cover provider and supplier costs, not

1717 Pennsylvania Ave NW, #600 . Washington, D.C. 20006 . T 202.293.3450 . F 202.293.2787 . mgma.com

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 OIG that a qualifying target population could include all patients covered by a certain payer, such as Medicare.

Care Coordination Arrangements Safe Harbor (Proposed 1001.952(ee))

MGMA is supportive of efforts to protect value-based arrangements through the issuance of a safe harbor that protects arrangements that do not entail downside risk yet are aimed at achieving value-based purposes. **However, we do not support the care coordination safe harbor as proposed because it contains overly complex and burdensome criteria.**

There is limited overlap between the requirements of the proposed AKS safe harbor and the Stark Law exception for value-based arrangements, requiring any group practice hoping to utilize these companion protections to ensure that an arrangement meets a long list of largely separate and distinct requirements. **OIG should more closely align its approach to protecting care coordination arrangements with CMS' value-arrangements exception at proposed 411.357(aa)(3).**

The care coordination safe harbor alone entails compliance with 11 conditions, which disadvantages group practices that do not have the resources or capability to engage expensive counsel and compliance consultants to assist with meeting these requirements.

OIG's approach to implementing any AKS protections should allow all group practices, regardless of size or access to resources, to utilize safe harbors. 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 having access to the infrastructure and resources necessary to participate in innovative arrangements. This approach would be in-line with the Department of Health and Human Services' (HHS) own goal of increasing patient choice and competition to drive quality, reduce costs, and improve outcomes.

Outcome Measures

We oppose requiring entities to a value-based arrangement to establish one or more specific evidence-based outcome measures against which recipients of remuneration will be measured, and which the parties reasonably anticipate will advance the coordination and management of care of the target patient population. This requirement is administratively burdensome, prone to ambiguity, and potentially conflicting with other CMS quality initiatives that define and utilize outcome measures, a term of art not defined in OIG's proposal.

We oppose the proposed requirement that an arrangement be monitored, assessed, and reported to the VBE's accountable body, including an annual review addressing the achievement of care coordination and management, any deficiencies in achieving quality of care under the arrangement, and progress toward achieving the evidence-based, valid outcome measures. Imposing this condition would create a moving target that hinges on subjective standards. Measuring success on metrics related to outcomes 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 Medicare Shared

1717 Pennsylvania Ave NW, #600 . Washington, D.C. 20006 . T 202.293.3450 . F 202.293.2787 . mgma.com

Savings Program (MSSP) ACOs and other Centers for Medicare and Medicaid Innovation Center (CMMI) initiatives.[1]

We also oppose the requirement that parties must terminate an arrangement within 60 days if the VBE's accountable body determines the arrangement is unlikely to achieve performance goals or has resulted in material deficiencies in care. MGMA is concerned that implementing any explicit monitoring and "cut off" provision to this safe harbor 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. A 60-day time period is unrealistic and would not allow for meaningful evaluation of the progress of any care coordination or value-based arrangement.

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?

Commercially Reasonable

MGMA opposes the requirement that a value-based arrangement be commercially reasonable as this would add unnecessary complexity and uncertainty. We are concerned that small, rural, and underserved practices will have difficulty demonstrating this requirement without the assistance of legal counsel or compliance experts.

Should OIG move forward with this this requirement, we ask that OIG harmonize the definition of commercially reasonable with CMS' proposed definition. Specifically, we ask that OIG clarify that an entity may enter into a commercially reasonable arrangement even when the arrangement results in a financial loss.

Limits on Remuneration

OIG should expand protection under this safe harbor to include monetary remuneration. Limiting this safe harbor to only in-kind remuneration would significantly restrict the ability of group practices to implement economic incentives to drive changes in physician behavior. It would create incongruity between the AKS safe harbor and proposed Stark Law exception for value-based arrangements, thereby limiting the utility of the Stark exception and increasing regulatory complexity.

Further, this would restrict a group practice from receiving funds to secure their own clinical services or tools that may be necessary to further the value-based purposes of the VBE. Particularly in the context of professional services, it is important to allow group practices sufficient flexibility to secure professionals that integrate effectively into their care team.

MGMA members have identified the sharing of staff, such as a care coordinator, nurse manager, behavioral health clinician, or other professional, as a critical benefit of the proposed AKS safe harbors. Hiring additional staff can constitute a significant expense for some group practices yet could help improve the

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

1717 Pennsylvania Ave NW, #600 . Washington, D.C. 20006 . T 202.293.3450 . F 202.293.2787 . mgma.com

patient experience and lead to better outcomes. For example, a primary care practice reported wanting to engage a psychologist or behavioral health professional to assist with patients presenting with depressive symptoms or needing additional assistance managing mental health conditions. The practice currently does not have the working capital to front the costs to hire such a professional even on a part time basis, and under current law, would be restricted from accepting assistance provided by another healthcare entity. Expanding this safe harbor to protect monetary remuneration could allow such a practice to select a behavioral health professional who best meets the needs of the practice's patient population and whose clinical care paradigm is in-line with the practice's own mission.

Contribution Requirement

MGMA strongly urges OIG against requiring that a recipient of remuneration contribute at least 15% of the donor's costs. 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 the Administration is attempting to reduce burden.

OIG considers whether to permit varying contribution amounts depending on the entity (i.e., those with financial constraints, small or rural providers) or remuneration type. While we oppose any contribution requirement, if OIG finalizes such a component in the care coordination safe harbor, it must create an exemption for certain entities, such as small or rural group practices, or those furnishing care to underserved patient populations.

Value-based Arrangements with Substantial Downside Financial Risk (Proposed 1001.952(ff))

MGMA strongly encourages OIG to align this safe harbor with CMS' proposed exception for arrangements that entail meaningful financial risk at proposed 411.357(aa)(2)). OIG's proposed safe harbor includes detailed definitions for what would constitute "substantial downside financial risk" and "meaningfully sharing," requiring group practices and healthcare entities seeking to protect arrangements under this safe harbor to ensure proper financial risk assumptions separate and apart from the other conditions outlined in the safe harbor.

OIG's definition of financial risk is too narrow, and MGMA recommends that OIG to clarify in the final rule that "risk" within the meaning of the continuum of AKS safe harbors can include other types of risk such as upside, clinical, operational, contractual, or investment.

For example, OIG 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 group bears financial risk in that failing to achieve the value-based purpose will result in a downward adjustment to its compensation. Performance-based risk is used throughout HHS-sponsored initiatives, such as the Merit-based Incentive Payment System (MIPS) and

1717 Pennsylvania Ave NW, #600 . Washington, D.C. 20006 . T 202.293.3450 . F 202.293.2787 . mgma.com

several models spearheaded by CMMI (i.e., Primary Care First, Kidney Care First).

We support including protection for preparing to implement a meaningful downside/substantial downside risk arrangement. Similar to the MSSP pre-participation waiver, OIG should implement a one-year start-up protection period.

Arrangements for Patient Engagement (Proposed 1001.952(hh))

Overall, MGMA supports the proposal to establish a safe harbor to protect arrangements for patient engagement tools and supports to improve quality, health outcomes, and efficiency for specified patients.

We encourage OIG to expand this proposed safe harbor to apply to *any* arrangement involving patient engagement tools or supports, rather than limit its applicability to VBEs. Patients should be involved in their healthcare, regardless of whether their physicians are participating in a value-based arrangement or enterprise. Patient engagement support can be valuable in almost any arrangement, so long as protections against abuse are included.

We support taking a flexible approach to defining engagement tools. We support the three categories of tools and supports that OIG proposes to protect and believe OIG strikes an appropriate balance between offering sufficient flexibility while protecting against risks of fraud and abuse. We encourage OIG to provide examples of permissible engagement tools and supports based on comments received on this proposal.

MGMA supports OIG's proposal to defer to physicians in determining what constitutes preventive services for the purpose of this safe harbor, as physicians are in the best position to assess the value of a particular service aimed at prevention. MGMA also supports covering additional items that are relevant to social determinants of health. We agree with OIG that transportation to medical appointments and education to address clinical conditions are activities that are relevant to this safe harbor and should be covered.

The $500 limit is likely too low for patients who are chronically ill or have serious conditions and we urge OIG to consider increasing this annual limit. Furthermore, the safe harbor should not be limited to in-kind remuneration as certain patients may benefit from the receipt of gift cards or even cash payments if provided within reasonable limits.

Waiver or Reduction of Cost-Sharing Obligations

OIG is considering for the final rule whether to offer safe harbor protections for cost-sharing waivers.

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 valuable services. Services such as CCM are a step in the right direction for enhancing Medicare beneficiary care management and preventing adverse events, such as unnecessary hospital readmissions. However, medical group practices have been limited in their ability to implement this important service due to administrative billing requirements. MGMA members cite the requirement to collect beneficiary co-insurance as the most significant barrier to adopting CCM services; for example, one primary care practice in Alabama reported: "When we try to gain consent from the patient, they decline the service based on copay. We had a big push to increase CCM – it was unsuccessful for this reason. Any code changes to CCM will only work if we can eliminate the amount the patient is responsible for."

1717 Pennsylvania Ave NW, #600 . Washington, D.C. 20006 . T 202.293.3450 . F 202.293.2787 . mgma.com

A Nov. 2018 report commissioned by CMMI indicated that utilizing CCM services reduced costs by $74 per beneficiary per month relative to a comparison group over the 18-month period studied. The report found "clear support that CCM is having a positive effect on lowering the growth in Medicare expenditures on those that received CCM services" and that beneficiaries in the CCM program had lower hospital, emergency department, and nursing home costs. [2] This data tends to show that CCM services have the potential to decrease costs for both the program and beneficiaries, while improving quality of care.

To avoid restricting application of any waiver to only existing care management codes, MGMA encourages OIG to take a flexible approach that allows group practices to waive cost-sharing requirements for services that may not be covered by Medicare yet. For example, in the 2020 PFS, CMS finalized coverage for a Principal Care Management code (HCPCS code G2064) to address a gap in coding and payment policy for care management services for patients with a single high risk or complex condition.[3] To avoid incongruity or confusion across waiver policies for CCM-*related* services, OIG should finalize a waiver that protects high-value services without enumerating an exhaustive list of codes. OIG should instead provide examples of services that would qualify.

In addition to protecting the waiver of copayments for high-value services like CCM, **MGMA also urges OIG to create a safe harbor waiving cost-sharing amounts when the cost-sharing amount is nominal.** In the 2019 Physician Fee Schedule, CMS finalized new covered codes describing virtual care, remote monitoring, and consultation services.[4] MGMA is very appreciative of CMS' policies expanding access to digital medicine services, however we have learned through conversations with MGMA members that physician group practices are deterred from incorporating these services into their practices due to administrative hurdles, such as billing beneficiaries for nominal copayment amounts.

In addition to patients declining these important services due to their cost-sharing obligation, the amount to bill a patient will often exceed the amount collected. For example, the virtual visit code (HCPCS G2012) pays a national average of $14.78 in 2019; a 20% patient copayment amount for this service would be less than $3. Based on a poll of MGMA members, the average cost to prepare and transmit a patient bill is $7.62, over half of the amount the practice is reimbursed for a service such as G2012 and more than double the beneficiary copayment amount.[5]

CMS-sponsored Model Arrangements (Proposed 1001.952(ii))

MGMA is generally supportive of the CMS-sponsored model safe harbor. As part of their Participation Agreements with CMS, healthcare entities participating in CMS-sponsored models agree to reporting, compliance, transparency, and accountability requirements that exceed the requirements placed on nonparticipants. CMS also has greater oversight over participants in Medicare models, including the authority to take administrative action to address any harms associated with undesirable activities. Taken together, these factors should ameliorate any concerns over patient or program abuse.

---

[2] Evaluation of the Diffusion and Impact of the Chronic Care Management (CCM) Services: Final Report (Nov. 2017).
[3] 84 Fed. Reg. 62568, 62692 (Nov. 15, 2019).
[4] 83 Fed. Reg. 59452, 59483 (Nov. 23, 2018)
[5] 2019 MGMA survey on billing procedures. This data is based on 238 responses to a poll that asked about the average costs to produce and send a patient bill, factoring in, *inter alia*, postage, paper, staff time, cost of third-party billing companies, and internal accounting procedures.

1717 Pennsylvania Ave NW, #600 . Washington, D.C. 20006 . T 202.293.3450 . F 202.293.2787 . mgma.com

While we are generally supportive of this proposed safe harbor, we encourage OIG to continue implementation of waivers for existing and future CMS-sponsored arrangements. The reason we suggest concurrent implementation of both a waiver and a safe harbor is that there are benefits to waivers that may not be realized in a safe harbor. Therefore, we encourage OIG to monitor implementation of the safe harbor to determine whether it offers sufficient and reciprocal protection to a waiver.

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. OIG should also urge CMS to provide a similar Stark exception for CMMI models.

Cybersecurity (Proposed 1001.952 (jj))

We are strongly supportive of the proposal to establish a cybersecurity safe harbor. When seeking to address the growing threat presented by cyberattacks, 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.

While cybersecurity items and services could be donated along with health information technology, we assert that the two need not be required to be donated in tandem to meet the definition of coordination and management of care. Coordination and management of care are critical components of the care delivery process as physician practices move into value-based care arrangements. However, cyberattacks can significantly impede the ability of practices to coordinate and manage patient care. For example, a successful ransomware attack could temporarily or permanently disable the practice's EHR and prevent clinicians from accessing patient data.

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 and thus reducing the ability of the practice 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 assert that omitting a contribution requirement for the cybersecurity donation to be permitted will allow practices with limited resources to receive cybersecurity assistance while allowing them to invest in other technology necessary to improve cyber hygiene not protected by the safe harbor or not offered by the donor.

We support the inclusion of a broad array of cybersecurity services as part of the safe harbor. 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, 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

1717 Pennsylvania Ave NW, #600 . Washington, D.C. 20006 . T 202.293.3450 . F 202.293.2787 . mgma.com

the types of services that are necessary and used predominantly for effective cybersecurity.

We would recommend adding additional services to this list, including consulting services deployed not just to conduct a risk assessment or analysis, but to work with the practice to develop and implement specific cybersecurity policies and procedures. As well, the safe harbor should cover any subscription fees to vendor security products that assist practices 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 safe harbor.

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

The rule 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 safe harbor could be broadened is data backup and data 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 would urge OIG 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.

Electronic Health Records (1001.952(y))

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 OIG that

1717 Pennsylvania Ave NW, #600 . Washington, D.C. 20006 . T 202.293.3450 . F 202.293.2787 . mgma.com

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.

OIG 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.**

Changes to the Personal Services Safe Harbor (42 CFR 1001.952(d))

We support OIG's proposal to eliminate the aggregate compensation test from the personal services safe harbor at 1001.952(d)(1) as this change would more closely align with the Stark Law exception.

New Provision for Outcomes-based Payments

OIG also proposes to add a new paragraph to the existing personal services safe harbor at 1001.952(d)(2) to protect certain outcomes-based payments. **While MGMA supports the intent behind creating such protection, we do not support the prohibitive restrictions outlined in the proposal.** In particular, MGMA opposes requiring satisfaction of an outcome measure in order to receive an outcomes-based payment.

We do not support linking protection for outcomes-based payments to *achieving* an outcome measure. We agree with the laudable goal of using outcome measures to achieve higher quality care, however requiring

1717 Pennsylvania Ave NW, #600 . Washington, D.C. 20006 . T 202.293.3450 . F 202.293.2787 . mgma.com

achievement is impractical in clinical settings and does not take into consideration a multitude of factors that may impede achieving desired outcomes. Measuring success on metrics related to outcomes is an inexact science, and metrics may be met during some performance periods but not others. OIG should allow for outcome-based payments when a physician endeavors to achieve an outcome measure.

The goals of outcomes-based payments outlined by OIG introduce uncertainty and therefore MGMA cautions against including certain terminology in the final rule. Terms like "measurably," "appropriately," and "materially" are too vague and difficult to apply in practical, clinical scenarios.

We are concerned with OIG's proposal to require parties to rebase outcome measures when feasible given there are a number of factors that go into rebasing. Should OIG include this requirement in the final rule, MGMA recommends a timeframe of five-to-ten years.

As an alternative to the outcomes-based measure requirement, MGMA recommends this criteria be expanded to included process measures. Process measures, such as providing or not providing a specific treatment, can improve patient outcomes or safety, and therefore should be included.

The compensation methodology requirements including "fair market value" and "volume or value of referrals" will severely limit this safe harbor's usefulness in any incentive-based outcomes payment arrangement. There are limited data or agreed upon appraisal methods available to assist in determining the fair market value of quality-related payments.

Conclusion

MGMA appreciates the opportunity to provide recommendations to the OIG on ways to improve the AKS 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 M. Gilberg
Senior Vice President, Government Affairs

1717 Pennsylvania Ave NW, #600 . Washington, D.C. 20006 . T 202.293.3450 . F 202.293.2787 . mgma.com