PREMIER TRANSFORMING HEALTHCARE TOGETHER

October 26, 2018

Daniel R. Levinson
Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG–0803-N
Submitted electronically to: http://www.regulations.gov

Re: Title: Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP

Dear Inspector Levinson:

On behalf of the Premier healthcare alliance serving approximately 4,000 leading hospitals and health systems, hundreds of thousands of clinicians and 165,000 other provider organizations, we appreciate the opportunity to provide input on the Request for Information (RFI) on the Anti-Kickback Statute (AKS) and the Beneficiary Inducement CMP. Premier healthcare alliance, a 2006 Malcolm Baldrige National Quality Award recipient, maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Premier runs the largest population health collaboratives in the country, the Population Health Management Collaborative which has worked with well over 200 ACOs and is currently comprised of more than 70 ACOs. In addition, Premier is a Facilitator Convener under the Bundled Payment for Care Improvement (BPCI) initiative and runs an extensive Bundled Payment Collaborative with 120 participating organizations across the Medicare bundled payment programs. Our comments primarily reflect the concerns of our hospitals and health systems, their employed physicians and independent physicians aligned with them.

We commend the Office of the Inspector General (OIG) for reviewing existing safe harbors and considering new safe harbors to the anti-kickback statute as well as exceptions to the beneficiary inducements civil monetary penalty (CMP) definition of "remuneration" to foster arrangements that promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse. The anti-kickback statute and the beneficiary inducements CMP pose needless barriers to innovative arrangements among healthcare providers and suppliers and undue burden on the healthcare industry generally as it strives to improve the quality and value of healthcare delivery for patients, especially through care coordination.

The federal AKS and Physician Self-Referral Law were enacted to address issues for a different healthcare delivery system where providers of services and other stakeholders could encourage overutilization of services. However, new models of healthcare delivery encourage value and emphasize care coordination and integration to increase both the quality and efficiency in the delivery of services to patients. Providers of services, suppliers, and related stakeholders are concerned about inadvertent or potential violations of the AKS and the beneficiary inducement CMP because of the substantial breadth of the AKS statute and the definition of remuneration for purposes of the beneficiary inducement CMP. Existing safe harbors are not designed to accommodate innovative arrangements used in new models of care delivery and those that do apply do not address specific issues raised under these arrangements or do not afford adequate protection from liability.

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These laws and implementing regulations and guidance pose barriers which hamper innovative arrangements because providers and suppliers are unwilling to take the risk of incurring legal liability in designing flexible payment arrangements for innovative coordinated care delivery. As a result, innovation suffers because providers (i.e. hospitals, physicians, physician practices, non-physician practitioners) and suppliers are unwilling to make significant investments in care coordination and care delivery redesign required for new these relationships among the parties. The current safe harbors and guidance under the fraud and abuse laws are not sufficiently flexible to promote change in the healthcare delivery system on a larger scale.

PROMOTING CARE COORDINATION and VALUE-BASED CARE

Potential Arrangements that May Implicate the AKS or Beneficiary Inducement CMP

The Anti-Kickback Statute imposes barriers for hospitals that seek to incentivize physicians to improve patient outcomes. Hospitals are wary of entering into arrangements to reward physicians not employed by those hospitals to improve care delivery practices, such as reducing hospital-acquired infections or hospital readmissions, because of potential AKS liability. Specifically, where an arrangement rewards a physician based on patient outcomes, that "reward" could be considered something of "value" which might constitute an improper inducement of referrals between the hospital and physicians in violation of the AKS. For example, if a physician who is not employed by a hospital establishes a plan of care for a hospital patient that involves coordinating items, services and practitioners which results in improved outcomes for the patient, the hospital may face legal liability under the AKS if it compensates the physician. This would constitute something of "value" under the AKS which could be construed as an improper inducement of referrals by the hospital and physician. Additionally, that compensation could also potentially violate the Stark Law prohibition against compensation based on volume or value of services rendered. Accordingly, hospitals may not be inclined to reward or incentivize non-employed physicians for their efforts to improve care coordination for hospital patients. Similarly, physicians may be less willing to commit to the extra time and effort required for these patients in light of their own potential liability under the AKS which may include fines, jail terms, and exclusion from participation in the federal healthcare programs.

The AKS also complicates the establishment and operation of accountable care organizations (ACOs). ACOs have been granted waivers of the AKS for some of the requisite arrangements among hospitals, physicians, and other providers and organizations. However, if an ACO seeks to expand the patients for which it assumes responsibility to patients who are not eligible for Medicare, the AKS may be implicated. Because any savings realized by the ACO for the expanded patient population and distributed among ACO participants are considered something of "value," and the waiver is limited to Medicare patients, the ACO could run afoul of the AKS. In the absence of a safe harbor or other guidance from the OIG that would permit these arrangements for non-Medicare patients and associated distributions of savings, hospitals, physicians and physician groups, and other practitioners are unwilling to risk potential legal liability under the AKS as well as under the Stark Law.

The AKS prohibits physicians and other providers and suppliers from furnishing anything of "value" to anyone if it might induce the purchase or order of any Medicare covered services. The prohibition extends to patient benefits provided by healthcare providers such as scales, blood pressure cuffs, and vouchers for certain transportation for non-established patients which are often provided to encourage a patient to follow post-discharge treatment plans. There is no AKS safe harbor or exception that protects these types of patient benefits.

The AKS constrains the establishment of arrangements among providers, manufacturers of drugs or devices, and payors under which pricing for drugs or devices is based on patient outcomes or under which manufacturers offer certain warranties based on clinical outcomes (as opposed to defective product warranties). These types of value-based contracting arrangements are not clearly protected under current AKS safe harbors for discounts or warranties in part because of the breadth of the AKS statute and the shift from volume-based to value-based, patient-centered care models which occasion the establishment of new arrangements among providers, payors and manufacturers of drugs and devices. For example, arrangements between payors and manufacturers of prescription drugs to base payment for medications with high upfront costs on the clinical experience of the patient after using the medication are beneficial for new treatments and other new therapies which may provide dramatic health improvements. Payment levels may be tied to both short-term and long-term efficacy of the medication, including reductions in emergency room visits or inpatient hospitalizations. Under these arrangements, manufacturers could pay for a part of the cost of the data collection necessary to provide the proof required under the contract. However, the negotiated discounts could be construed as an inducement to use the medication which may give rise to AKS liability. Also, payment by the manufacturer for the collection of data necessary under the arrangement could also be seen as an unlawful inducement to use the manufacturer's drug which may also trigger scrutiny under the AKS.

The AKS inhibits also inhibits value-based contracting arrangements between manufacturers and providers of services, including ACOs, constraining innovative contracting arrangements that would provide value to patients and ensure accountability of care. Subject to appropriate safeguards against waste, fraud and abuse, Premier believes providers of services should be able to enter into risk-based contracts with manufacturers of drugs or devices under a variety of models, including the following:

- Evidence-based care discounts where a manufacturer will provide discounts to the provider based on the provider's adherence to a particular evidence-based practice guideline;
- Outcome-based guarantees where a manufacturer will provide rebates to the provider where the item or service does not meet a defined outcome; the amount of the rebate would be tied to the aggregate cost of the item or service to the episode of care involved, such as readmissions costs (including penalties) or costs of items and services that are not reimbursed, such as diagnostic tests; and
- Alternative payment model (APM) risk-sharing where manufacturers and providers of services and suppliers, such as ACOs, share savings and losses based on clinical outcomes and other metrics.

Premier welcomes the opportunity to discuss with the OIG specific use cases for the models described above.

Additional or Modified AKS Safe Harbors or Exceptions to the Definition of "Remuneration" under the Beneficiary Inducements CMP to Protect Arrangements; Key Provisions to Be Included

The OIG should issue safe harbors under the AKS to provide to all organizations implementing APMs the kind of protections that apply to the Medicare ACOs under the AKS waivers approved for Medicare Shared Savings Program (MSSP). These safe harbors should apply to APMs, including ACOs, without regard to payer (i.e. exceptions should apply to payers other than Medicare) or levels of risk in the model. The safe harbors would apply to ACOs that meet certain conditions to protect against fraud and abuse. Additionally, current waivers protecting distributions and uses of shared savings of MSSP ACOs should also apply shared savings or internal cost savings distributed to or used by the APM entities in comparable commercial or state models.

The OIG should issue "pre-participation: safe harbors for APMs to protect APM-related start up arrangements.

The OIG should create a safe harbor for clinical integration arrangements among hospitals, physicians, and other providers under APMs as these arrangements are critical to care coordination and value-based care delivery. The safe harbor should protect clinical integration arrangements that:

- Promote shared accountability for the quality, cost and overall care for patients;
- Manage and coordinate patient care according to evidence-based practices; or
- Encourage investment in care delivery infrastructure and redesigned care processes to improve quality and efficiency in care delivery.

Additionally, the safe harbor should protect remuneration, including any program start-up or support contribution, in cash or in-kind. The safe harbor should include safeguards, appropriate documentation of the arrangements among the parties involved, and appropriate performance monitoring. Performance monitoring should protect against reductions or limitations in medically necessary patient care services and be objective, verifiable and supported by credible medical evidence. Any payments under a clinical integration arrangement should account for care quality, efficiency and patient outcomes, and should be auditable through the arrangement's documentation.

While value-based contracts have historically been seen as arrangements between manufacturers and payers, Premier believes there is significant opportunity for agreements between manufacturers and providers moving forward. Therefore, any safe harbors that are amended or created to accommodate the move towards value and value-based contracts should account for arrangements between manufacturers and providers as well. The OIG should either modify existing safe harbors, for example the discount safe harbor and the warranty safe harbor, or provide for a new safe harbor that protects arrangements among parties under which manufacturers of drugs or devices offer outcome-based pricing or outcome-based warranties to providers of services and suppliers, including ACOs, as well as to payors. For the existing safe harbors, the OIG should clarify that the discount safe harbor applies in the context of these value-based contracting arrangements notwithstanding the fact that payment is made under a different methodology than is otherwise provided for under a bundled payment model. The OIG should update the warranty safe harbor to expand protection from the AKS beyond payment for a defective product to permit outcomes-based warranties from manufacturers (such as rebates or the provision of additional services where the promised outcome is not achieved). Additionally, the OIG should clarify that protection under the warranty safe harbor extends to value-based contract arrangements where manufacturers provide items or services that exceed the cost of the drug or device involved in the episode of care. Any modifications to existing safe harbors or the establishment of a new safe harbor should include requirements for appropriate transparency and accountability among the parties to protect against waste, fraud and abuse.

Definitions

The OIG's guidance on fair market value should be revised to accommodate if not encourage APMs and other new models that incentivize performance and promote accountability for the care furnished to beneficiaries. The AKS does not define fair market value though it is a component of some safe harbors, such as those for personal services agreements, management agreements, and leases for space and equipment. The agency's presumption is that payment that is greater or less than fair market value is a payment for referrals, which if paid with the intent to induce referrals violates the AKS. The OIG should provide greater flexibility for hospitals, physicians, physician practices, and other providers to collaborate to improve the delivery of patient care, including better patient outcomes and greater efficiency. Accordingly, the OIG should provide additional guidance to stakeholders with respect to how

fair market value should be established and documented, and the types of data that may be used to document fair market value under different arrangements

The fair market value standard should be revised. To determine fair market value, the OIG should examine whether the value is established in an arms-length transaction consistent with general market value. The definition of general market value under guidance should be the price of an asset or compensation for a service that would result from bona fide bargaining between well-informed parties to the agreement.

Use of Guidance in Lieu of Regulations for Clarification

The OIG should issue a clarification of its guidance that supersedes or restructures the one purpose test to establish liability under the AKS to accommodate alternative payment arrangements and redesign in care delivery. Under the "One Purpose Test," a party may violate the AKS if just one purpose of a payment or other transfer of value to a potential referral source is to induce or reward referrals even when that purpose is not the primary purpose of the remuneration. Instead of the one purpose test, the OIG should assess the overall impact of an arrangement. Under this balancing test approach, the OIG would assess the arrangement's overall impact on quality of care and to weigh any benefits against the potential risk of fraud and abuse to determine whether the transaction is permissible, without regard to one purpose of the arrangement is potentially problematic. Additionally, the OIG should demonstrate that the arrangement (or transfer of value thereunder) either increased the cost of services or did actual harm to a patient. This clarification could permit arrangements where healthcare providers and manufacturers of medical devices or pharmaceuticals provide items or services of value to patients to assist with prescription medication adherence, perioperative regimen adherence, or access to healthcare services.

The volume or value standard not apply in the context of APMs where payment for physicians' services is based on the healthcare services personally performed by those physicians under terms that include accountability for the care of the patient. The volume or value standard applied by the OIG to certain arrangements constrains hospitals and other providers of services from establishing programs with physicians to improve quality and efficiency of patient care, especially in the case of programs that include quality bonus or shared savings arrangements or provide infrastructure or other assistance at no charge. Ideally, if a physician who receives remuneration under an APM personally furnishes physicians' services, the volume/value or other business generated element of the exception should not be implicated; this should be the case even if those physicians' services incidentally increase or decrease the delivery of designated health services by an entity. The OIG should also clarify for purposes of the AKS generally that a referral only has AKS implications when the referral results in an additional or increased payment from the government to the provider of services.

BENEFICIARY ENGAGEMENT

Beneficiary Incentives

As noted above, the AKS prohibits physicians, physician practices, and other providers and suppliers from furnishing anything of "value" to anyone if it might induce the purchase or order of any Medicare covered services. The prohibition extends to patient benefits provided by healthcare providers such as scales or blood pressure cuffs because these are items of more than nominal value as well as vouchers for certain forms of patient transportation, or transportation greater than 25 miles, which are often provided to encourage a patient to follow post-discharge treatment plans.

Beyond the limitations that apply to providing patients items or services of more than nominal value, the law also places barriers on efforts of manufacturers to assist hospitals, physician practices, and health systems in treating or managing patients' diseases. For example, blood pressure monitoring devices may transmit readings at regular intervals to a patient's physician which the physician uses to implement a treatment plan that manages patient activities connected with blood pressure fluctuations. A manufacturer of such a device may also offer to provide health and nutrition support services at a conditional discounted rate for patients of physicians who are part of a health system to assist those patients in implementing their care plans and achieve set outcome thresholds; the discounted rate would apply if patients do not achieve the outcome threshold. The discount may be an improper inducement for referrals between the manufacturer and the health system because the discounted rate for the health and nutrition support services would be considered something of value under the AKS. This would be the case even if the health system paid full cost for those support services where the patients met the outcome threshold. Concerned by potential legal liability, the manufacturer may not offer this type of discounting arrangement, and the health system would be unlikely to pay for support services even though they may contribute to improved patient outcomes.

Cost-Sharing Obligations

While the OIG has made refinements to the conditions under which assistance with beneficiary cost-sharing is permissible under the fraud and abuse laws, the requirements to qualify for protection from AKS liability place barriers on healthcare providers and health systems if they seek to assist greater numbers of patients in the context of redesigned care delivery models which emphasize care coordination, improved quality and patient outcomes, and greater efficiency.

OTHER RELATED TOPICS

Current Fraud and Abuse Waivers

Current safe harbors do not provide adequate protection for clinical integration arrangements among hospitals, physicians, physician practices, health systems, and other healthcare providers and suppliers. **The OIG should issue a new safe harbor protecting clinical integration arrangements as noted above.**

Alternatively, it should extend existing waivers of the AKS and the Stark Law applicable under certain Medicare programs (such as ACOs, bundled payment initiatives, and other Medicare APMs) to activities or initiatives that involve the integration of care and meet established value-based healthcare criteria that are designed to improve patient outcomes and reduce the overall cost of providing care. This protection should be made available to providers who are engaging in population health programs that may not be a Medicare APM; for example, contributing to a VBP model or participating in private-sector APMs. Similarly, the OIG should consider how waivers could apply when the provider wants to expand activities to patients who may not align with a Medicare APM; for example, implanting processes across the entire practice rather than just the APM-aligned subset.

Cybersecurity-Related Items and Services

The OIG's electronic health record (HER) safe harbor extended exceptions for the donation of interoperable EHR software or information technology and training services. Under the 2013 final rule, the EHR exception at 42 CFR 1001.952(y) was modified to extend the sunset date from December 31, 2013

to December 31, 2021, and to make other clarifications and modifications. The rationale for the agency's extension was to facilitate widespread adoption of interoperable EHRs.

This exception is an essential component to the successful coordination of care among hospitals, physicians and physician practices, ACOs, other organizations, and other providers and suppliers to improve the quality and value of healthcare delivery for patients through improved processes and care coordination. The ability of the various participants to transmit EHRs electronically greatly improves efficiency and quality of care as patients transition across care settings. This exception should be a permanent safe harbor in part because of additional requirements for interoperability as well as assisting a number of provider types (such as nursing homes) that were not included in the Medicare and Medicaid EHR Incentive Program.

The current exception is also too narrow. **The agency should expand the scope of the exception to include more types of health information technology (IT); this must include health IT that relates to cyber-security protection.** Cyber-security programs that protect patient records in EHR systems are expensive and difficult to manage. As a result, some providers may not have implemented adequate security systems which makes both those providers and the providers with whom they exchange information vulnerable to security breaches. The OIG should also consider including subscription fees for cyber-security protection related to the use and exchange of health information as part of the exception.

Additionally, technology related to information sharing such as application program interfaces, health information exchange networks, care coordination services, care management tools, population health management and quality management tools, and patient engagement and communication tools should be included in the exception.

The requirement that the donated technology may not replace a similar technology should also be eliminated. Technology advances rapidly, and a system adopted and implemented 10 years ago may have difficulty functioning with newer technologies. Older technologies are also more likely to be vulnerable to security breaches. This requirement effectively sunsets the applicability of the safe harbor since the number of providers that have not acquired and implemented EHR technology grows smaller over time.

INTERSECTION OF PHYSICIAN SELF-REFERRAL LAW AND ANTI-KICKBACK STATUTE

Both the AKS and the Stark Law address "remuneration" related to improper referrals. The AKS is a criminal law that applies broadly and prohibits knowing and willful payment of remuneration to induce or reward patient referrals or the generation of business involving any item or service payable by federal healthcare programs. The Physician Self-Referral Law is a civil, strict liability statute prohibiting physicians from referring patients for designated health services payable by Medicare or Medicaid to entities with which the physician or an immediate family member has a financial relationship.

Penalties for violating the AKS, the Stark Law, or both are substantial, and the risk of incurring those penalties dissuades providers and suppliers of healthcare items and services from making the significant investment of time and resources to redesign care delivery to move to a value-based system and care coordination. Thus, health systems, providers and suppliers must invest significant resources not only in care redesign efforts but also in legal counsel to prepare for compliance with these federal laws as well as others, such as the False Claims Act. As a result, many providers and suppliers may determine the investment is too great or the risk too large to move to or participate in value-based payment models.

As a first step, CMS should eliminate the requirement under Stark Law regulations that a financial arrangement exception may not violate AKS. The requirement is unnecessary, and it places additional burdens on DHS entities with no additional protection to the Medicare program. It slows the development of comprehensive, coordinated care models because entities must meet higher burdens of proof for payment.

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on the RFI on the Anti-Kickback Statute and the Beneficiary Inducement CMP. If you have any questions regarding our comments or need more information, please contact Aisha Pittman, senior director, payment and quality policy, at aisha_pittman@premierinc.com or 202.879.8013.

Sincerely,

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