PREMIER TRANSFORMING HEALTHCARE TOGETHER®

February 2, 2024

Honorable Christi A. Grimm
HHS Inspector General
Cohen Building
330 Independence Avenue SW
Washington, DC 20201
Attention: Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts (OIG–1123–N)

Submitted electronically to: http://www.regulations.gov

RE: Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts (OIG–1123–N)

Dear Honorable Grimm:

Premier Inc. appreciates the opportunity to submit comments in response to the HHS Office of Inspector General's (OIG's) solicitation for new and modified safe harbors. Since the enactment of the Anti-Kickback Statute in 1972, there have been significant changes to how healthcare is delivered and paid for by both federal health programs and private payers. Today, more and more payers and healthcare providers are focused on moving toward a value-based system that pays based on outcomes.

In 2020, the HHS OIG, in coordination with the Centers for Medicare & Medicaid Services (CMS), finalized several significant policies to modernize the Anti-Kickback Statute and rules around beneficiary inducement to better align with the movement to value-based care. Specifically, the OIG established and modified several safe harbors for compensation arrangements that meet certain value-based criteria. These policies, along with changes to the regulations governing the Physician Self-Referral Law ("Stark Law"), were intended to reduce significant regulatory barriers that have impeded providers as they look to provide high-value care to their patients.

While these policies made significant strides to modernize the requirements to align with the needs of a changing healthcare ecosystem, several key opportunities exist to further strengthen and improve the Anti-Kickback Statute regulations to help reduce unnecessary regulatory barriers while still ensuring appropriate safeguards are in place. In addition, modernization of the Anti-Kickback Statute is essential to meeting the Administration's goal of moving all Medicare beneficiaries to a value-based care model by 2030. This includes:

- Providing greater alignment between Anti-Kickback Statute safe harbors and Stark Law exceptions for value-based care arrangements.
- Clarifying Anti-Kickback Statute safe harbors for value-based care arrangements.
- Removing exclusions on certain participants for value-based arrangements and patient engagement safe harbors.
- Modifying the care coordination arrangement, value-based arrangements with full financial risk, and personal services and management contracts and outcomes-based payment arrangements safe harbors.
- Providing guidance on the interaction between new artificial intelligence (AI) policies and Anti-Kickback Statute.

Premier provides additional details on each of these recommendations below.

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I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,350 U.S. hospitals and approximately 300,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,400 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products. In addition, Premier operates the nation's largest population health collaborative, having worked with more than 200 accountable care organizations (ACOs).

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

II. ALIGN ANTI-KICKBACK STATUTE SAFE HARBORS AND STARK LAW EXCEPTIONS FOR VALUE-BASED CARE ARRANGEMENTS

As noted above, the OIG and CMS worked closely to develop their corresponding safe harbors and exceptions for value-based care arrangements. However, in several places the OIG finalized further refinements that went beyond CMS policy, such as additional requirements that value-based entities (VBE) must meet or additional definitions that narrow the scope of value-based arrangements.

For example, both OIG and CMS established protections for certain arrangements regardless of the level of financial risk. Under the OIG safe harbor, at least one of the value-based activities must be connected to care coordination and management. This differs from the corresponding CMS exception, which requires participants to include an activity that meets one of four core goals, of which only one is related to care coordination and management.

Lack of alignment creates additional administrative burden for providers as they manage compliance against two different metrics. Additionally, in the face of uncertainty of whether an arrangement will be covered, providers are likely to abide by the most stringent requirements, especially given the penalties associated with lack of compliance. As a result, lack of alignment reduces the likelihood that providers will maximize the full flexibilities or benefits created under these new exceptions and safe harbors. ***Premier urges the OIG to revisit the additional requirements that it adopted for the value-based arrangement safe harbors and align its policies more closely with CMS' Stark Law exceptions.*** At a minimum, the OIG should evaluate what additional benefits are gained by these prescriptive requirements and if they outweigh the associated burden.

III. GREATER CLARITY NEEDED AROUND THE ANTI-KICKBACK STATUTE SAFE HARBORS FOR VALUE-BASED CARE ARRANGEMENTS

In several places the OIG finalized broad definitions and requirements that cover a range of innovative value-based arrangements. While Premier appreciates that the OIG established broad and comprehensive definitions, we are concerned that a lack of clarity around these definitions have left many providers uncertain about whether arrangements are protected and therefore less likely to utilize the flexibilities given

the risk of non-compliance with the Anti-Kickback Statute, which can result in civil monetary penalties, criminal charges and exclusion from federal health programs.

For example, both the OIG and CMS define value-based purpose as meeting one of four core goals: (1) coordinating and managing the care of the target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to, or growth in expenditures of payors without reducing the quality of care for a target patient population; or (4) transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

While Premier appreciates how broadly the OIG and CMS defined value-based purpose for both the safe harbors and Stark Law exceptions, we are concerned that additional guidance is necessary. For example, the OIG and CMS do not define what would be considered a payment mechanism as providers transition to new healthcare delivery systems. Additionally, the OIG and CMS provide little guidance on how VBEs should assess whether a value-based arrangement meets one of the four goals or how the OIG or CMS would ultimately determine if the VBE has complied and met the standards of the definition.

Additional guidance should focus on criteria that entities would be able to reasonably assess at the start of an arrangement. For example, the OIG should clarify what would be considered an appropriate reduction in cost or what is considered a payment mechanism based on quality of care. Additional guidance should be provided on how entities would need to document that the arrangement meets one of these four goals.

In addition to clarifying the definition of value-based purpose, ***Premier recommends that the OIG work with the stakeholder community to identify areas for additional guidance, such as through listening sessions or requests for information***.

IV. REMOVE EXCLUSION ON PARTICIPANTS FOR VALUE-BASED ARRANGEMENT AND PATIENT ENGAGEMENT SAFE HARBORS

The OIG opted to exclude the following entities from utilizing the value-based care and patient engagement safe harbors citing past oversight experiences with these entities: pharmaceutical manufacturers, durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS) suppliers and manufacturers and laboratories. Specifically, the OIG, among other concerns, stated that manufacturers are not as directly engaged in care coordination activities as providers and clinician and therefore questioned whether expanding opportunities to manufacturers was necessary.

***Premier continues to have significant concern about the OIG's decision to exclude these entities from the value-based arrangement and patient engagement safe harbors*.** Value-based contracts through these types of entities, even if not clinicians themselves, are critical to the movement towards value and can be useful in addressing rising healthcare costs. While Premier has been successful in implementing several value-based contracts for drugs and devices, concerns with violating Anti-Kickback Statute and Stark Law have inhibited our members' ability to pursue value-based contracts as a robust strategy for lowering healthcare costs.

Value-based contracts are typically structured in one of four ways:

1. Evidence-based care discount – Manufacturer discount aligned with provider's execution or standardization of an evidence-based care practice.
2. Product or service guarantee – If the manufacturer's product or service fails to deliver a defined outcome, the manufacturer will provide a rebate tied to the aggregate cost of the product to the system.

3. Risk share by product – If the manufacturer's product or service fails to deliver a defined outcome, the manufacturer will provide a rebate tied to a cost that the system incurred as a result of the failure.
4. Risk share by alternative payment model – Shared upside/downside risk between a healthcare system and manufacturer.

Under the current legal infrastructure and constraints within both Anti-Kickback Statute and Stark Law, most value-based contracts are structured as evidence-based care discounts. Reduction and/or elimination of these barriers is necessary to permit value-based contracts for drugs and devices to be implemented that are structured as product/service guarantees or risk sharing arrangements. For example, the following are types of value-based arrangements that are currently *not* permissible under the existing legal infrastructure:

Scenario 1 - A medical device manufacturer and payer enter into a value-based contract. The manufacturer will reimburse all costs associated with re-hospitalization if the device fails.

- This arrangement would not be permissible as the warranty safe harbor under Anti-Kickback Statute only covers the cost of replacing the device. The payment of costs associated with re-hospitalization would be considered remuneration.

Scenario 2 - A manufacturer and payer enter into a value-based contract. The manufacturer will discount the cost of therapy by 40 percent if a patient relapses within a five-year time frame.

- This arrangement would not be permissible as the discount safe harbor requires that the payer claim the benefit within a two-year time frame. It is also unclear if the discount safe harbor can be extended to payers as a "buyer" of the product or service.

Scenario 3 - A medical device manufacturer and provider enter into a value-based contract. The manufacturer will reimburse the cost of the device if the device fails.

- This arrangement would not be permissible as while the warranty safe harbor permits the manufacturer to reimburse the value of the device if it fails, the OIG may see this as an inducement for the provider to use a certain device over others. This is an example where a value-based contract would be permissible for a manufacturer-payer relationship, but not for a manufacturer-provider relationship.

To truly move the needle and expand the utilization of value-based contracts, it is critical that the OIG remove the exclusion on certain entities from participating in value-based arrangement and patient engagement safe harbors**.** At a minimum, Premier urges the OIG to consider the following two options that can serve as guardrails to strike an appropriate balance between advancing innovation in value-based contracting to address the rising cost of healthcare while still providing the OIG oversight to protect from unintended consequences. Furthermore, these options provide an opportunity for the OIG to understand if its previously stated concerns around the motives of manufacturers or the indirect proximity of manufacturers to these issues are factual or not.

***First*, *Premier recommends that the OIG work with CMS to study, over the course of at least five years, the implementation of value-based contracts through a model that waives the restriction for manufacturers to partake in the value-based arrangement and patient engagement safe harbors* .** This will provide an opportunity for entities to enter into value-based contracts and truly test the ability of these arrangements to lower healthcare costs while still providing the OIG oversight to determine if these arrangements are being utilized inappropriately and take appropriate action if necessary. A runway of at least five years is recommended to provide an opportunity for entities to enter into these agreements, have a sufficient sample size for the study and also review the outcomes of these arrangements.

Second, if the OIG is not willing to remove the exclusion on these entities either in whole or via a test model, Premier recommends that the OIG explore opportunities to expand the applicability of the OIG advisory opinions either through rulemaking or potential

Congressional action. Currently, entities wishing to enter into a value-based contract that may evoke Anti-Kickback Statute must seek an advisory opinion from the OIG. Seeking an advisory opinion is a cumbersome process and is only applicable to the parties named in the opinion. Therefore, entities who wish to enter into a similar agreement in the future must seek their own advisory opinion from the OIG. As an interim compromise, the OIG could expand the applicability of the OIG advisory opinions beyond the named parties. This would allow additional entities who wish to enter into a value-based contract that is structured similarly to an arrangement already reviewed and approved by the OIG to do so without seeking an additional opinion. This model would still provide the OIG with the oversight to review and approve value-based contracts but would also expand the feasibility of others to enter into similar agreements.

V. MODIFY THE CARE COORDINATION ARRANGEMENT SAFE HARBOR

The care coordination arrangement safe harbor includes several conditions and restrictions that go beyond the complementary CMS value-based arrangement exception. As noted above, lack of alignment creates operational challenges and may result in entities not utilizing either the safe harbor or CMS exception to its fullest potential.

For example, OIG limits the safe harbor to in-kind remuneration, noting its long-held view that monetary remuneration poses a heighted risk of fraud and abuse. However, this belief is based on a volume-based payment system. While CMS' value-based arrangement exception is not tied to financial risk, there are several other conditions and criteria that help mitigate the potential for increased risk, such as definitions of a value-based purpose and the documentation and monitoring requirements. Limiting the exception to only in-kind remuneration will hamper efforts to improve care coordination and develop innovative value-based arrangements. Additionally, it is inconsistent with CMS' value-based arrangement exception, which would allow protection of both monetary and in-kind remuneration.

The OIG also requires that the arrangements be commercially reasonable, which is inconsistent with CMS' exception. The movement to value-based care helps eliminate many of the program integrity concerns that both CMS and the OIG have sought to address by requiring compensation arrangements to meet certain conditions, such as commercial reasonableness. These requirements could also hinder innovation in care and create unnecessary burden for providers, who have historically found it challenging to assess aspects of value-based arrangements against these standards.

Premier encourages the OIG to work with CMS to develop consistent parameters across their respective safe harbor and exception and consider refinements to the care coordination safe harbor to ensure it does not hinder healthcare innovation, as discussed below.

Additionally, under this safe harbor, VBE participants must establish one or more specific evidence-based valid outcome measures against which the VBE participants would be measured. The measure must be closely related to the value-based activity and grounded in legitimate verifiable data. While ideally participants would be able to measure the outcomes of the value-based arrangements, in practice VBEs may struggle to identify appropriate outcome measures related to the value-based activities they are undertaking. Additionally, outcome measurement can be a resource-intensive process and the results may not be known for some time, possibly for several years. Recognizing these challenges, ***the OIG should consider allowing flexibilities around measurement, such as allowing participants to change measures retrospectively if data is unavailable to another legitimate outcome or process measure for which data is available***.

Finally, under the safe harbor, recipients must pay at least 15 percent of the offerors' cost of the in-kind contribution. In establishing this policy, the OIG noted that the contribution would ensure the remuneration would actually be used for care coordination and management. This requirement is overly prescriptive. There is no evidence that a contribution will add any additional protections and increase the likelihood of

recipients utilizing the remuneration. In fact, the contribution requirement may hinder care coordination efforts for entities that are unable to afford the contribution and could divert resources from activities beneficial to patients. This issue is particularly pertinent in light of efforts to address inequities in health care and improve access to care for underserved populations. Finally, assessing the value of a contribution (especially for in-kind donations) could be challenging and may further limit entities abilities to utilize this safe harbor. ***Premier recommends that the OIG reevaluate the requirement that recipients contribute at least 15 percent and remove the requirement if it determines no additional protection is provided.***

VI. MODIFY THE VALUE-BASED ARRANGEMENTS WITH FULL FINANCIAL RISK SAFE HARBOR

The full financial risk safe harbor is available for entities that are financially responsible for the cost of all patient care items and services for a target patient population. As Premier has noted previously, few entities will be positioned to utilize this exception as very few arrangements are at true full financial risk. Oftentimes there are carveouts for certain high-cost services or populations (e.g., patients with End-Stage Renal Disease). ***Premier recommends that the OIG modify the Full Financial Risk safe harbor to allow for protections when entities assume full financial risk for a subset of services or items.*** Given the exception would only cover remuneration related to the items and services under the arrangement, or the subset for which the provider would be at full financial risk for, providers would face the same incentives to maximize quality and efficiency of care.

Additionally, most arrangements include risk mitigation frameworks that would limit the amount that entities must repay above certain thresholds (e.g., stop-loss thresholds). The OIG notes that participants would still be allowed to utilize risk mitigation frameworks, such as global risk adjustments, risk coordinators, or stop loss agreements to protect against catastrophic losses. However, additional clarification is needed around which risk mitigation frameworks would be allowed under this safe harbor. ***Premier recommends that the OIG provide greater clarity on the interaction of risk mitigation frameworks and full financial risk and if limitations would apply***, especially around the definition of catastrophic losses.

VII. MODIFY THE PERSONAL SERVICES AND MANAGEMENT CONTRACTS AND OUTCOMES-BASED PAYMENT ARRANGEMENTS SAFE HARBOR

In addition to establishing new safe harbors around value-based care, the OIG also modified the existing personal services and management contracts safe harbor to protect outcomes-based payments arrangements outside the context of VBEs, including gainsharing, shared savings payments, episodic payments and pay-for-performance. Under the safe harbor, the OIG defines an outcomes-based payment as a payment from a principal to an agent to reward achievement of outcome measures to either (i) improve patient or population health; or (ii) reduce payor costs while maintaining or improving quality. The arrangement must also satisfy evidence-based, valid outcome measures to receive payment; must be related to improving or maintaining the improved, quality of patient care or appropriately reducing costs while improving or maintain quality of care; and must be selected based on clinical evidence or credible medical support.

While we support the intent of this policy, ***Premier continues to be concerned that the outcomes-based payments protection is inconsistent with existing requirements for these types of payments under other programs***, such as CMS-sponsored models, including the Medicare Shared Savings Programs and other Innovation Center payment models. Additionally, some of the conditions under the safe harbor are onerous and may be difficult to achieve. For example, parties to an outcomes-based arrangement would have to establish evidence-based valid outcome measures for individual participants under the arrangement. Existing models tie payments of savings to an entity, such as an accountable care organization (ACO), to quality metrics by the ACO as a whole. That entity then distributes savings to

participants pursuant to a pre-established methodology. It is not always the case that these metrics are applied to gainsharing payments to all the individual participants in the ACO.

Measuring outcomes can be a challenging and resource-intensive process that takes time to evaluate, especially on the individual participant level in a large entity with significant numbers of participants and multiple specialty areas. Participant outcomes measurement can take up to two years after an arrangement. The added complexity of the requirements under the safe harbor will likely further delay distribution of shared savings and will create an overly burdensome process for healthcare providers and practitioners seeking to improve care quality and efficiency as well as patient outcomes.

As a result, ***Premier recommends that OIG modify the safe harbor to instead align requirements for outcomes-based payment arrangements with those imposed under CMS alternative payment models*** to reduce complexity, avoid confusion from different requirements under different programs and reduce burden on providers that participate in multiple alternative payment arrangements.

Finally, as noted above, Premier strongly opposes the exclusion of manufacturers of drugs, medical devices and supplies under the value-based safe harbors and encourages the OIG to modify these policies to include these entities.

VIII. CLARIFY HOW ANTI-KICKBACK STATUTE APPLIES TO ARTIFICIAL INTELLIGENCE

HHS and the healthcare industry as a whole continue to evaluate how to implement, incorporate and regulate the role of artificial intelligence (AI) in healthcare. As part of this effort, ***Premier encourages the OIG to work with its HHS counterparts and stakeholders to evaluate and issue clarifications on how the Anti-Kickback Statute would be applied to the use and funding of AI technology.*** For example, in the context of clinical trials and drug development, the provision of AI or digital health technologies to individual providers by manufacturers, even if intended to help identify clinical trial treatment options for their patients, could be construed as a kickback or a violation of the False Claims Act. Previous OIG compliance guidance has specified that recruitment bonuses should only be provided to researchers (not physicians identifying subjects) and should be linked to additional effort expended to identify and recruit participants. The use of AI technology to enhance clinical trial diversity, reduce prohibitive costs and accelerate the development of crucial new drugs and devices do not explicitly conflict with Anti-Kickback Statute or previous compliance guidance. However, explicit clarifying guidance that acknowledges potential innovations in trial design and execution, such as equipping physicians with AI technology to identify potential trial participants, is needed. As a result, ***Premier urges the OIG to work with stakeholders to clarify the applicability of relevant statutes and, where necessary, include explicit safe harbor exceptions for these other instances of financing models for AI technology.***

IX. CONCLUSION

In closing, Premier appreciates the opportunity to submit comments in response to the OIG's solicitation for new or modified safe harbors. If you have any questions regarding our comments, please contact Melissa Medeiros, Senior Director of Policy, at melissa_medeiros@premierinc.com.

Sincerely,

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Senior Vice President of Government Affairs
Premier Inc.