PREMIER TRANSFORMING HEALTHCARE TOGETHER®

December 20, 2019

Ms. Joanne Chiedi
Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: RIN 0936-AA10
Submitted electronically to: http://www.regulations.gov

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:

On behalf of the Premier healthcare alliance serving more than 4,000 leading hospitals and health systems, hundreds of thousands of clinicians, and more than 175,000 other providers and organizations, we appreciate the opportunity to submit comments on the Department of Health and Human Services' Office of the Inspector General (OIG) Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements proposed rule. Premier, 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 more than 200 ACOs and is currently comprised of more than 70 ACOs. Additionally, Premier maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Our comments primarily reflect the concerns of our hospitals and health systems, their employed physicians and independent physicians aligned with them.

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. However, regulatory frameworks have not kept pace with changes in payment and care practices. As a result, these regulations, such as Anti-Kickback Statute and civil monetary penalty (CMP) rules around beneficiary inducements, have created significant barriers to the development of innovative value-based arrangements.

Premier commends the OIG for taking steps to modernize the Anti-Kickback Statute and rules around beneficiary inducement to better align with the movement to value-based care. The proposed regulation will reduce significant regulatory barriers that have impeded providers as they look to provide high-value care to their patients. The existing regulatory framework often forces providers to inappropriately differentiate the care they provide based on whether patients are privately insured or receive care through federal health programs. The proposed regulation, in conjunction with the policies proposed by the Centers for Medicare and Medicaid Services (CMS), will provide much needed protections that will allow providers to furnish the best care for their patients and drive toward better health outcomes.

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While the proposed regulation makes 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 proposed policies to help reduce unnecessary regulatory barriers while still ensuring appropriate safeguards are in place.

The movement to value-based care has inherent safeguards that help address many of the concerns related to fraud and abuse that exist in a predominantly fee-for-service system. When providers are paid based on outcomes and quality of care – and no longer paid based on volume – providers are incentivized to provide the most effective and efficient care that leads to the best patient outcomes. As a result, the same concerns regarding overutilization or inappropriate patient care are mitigated as providers are no longer incentivized to induce referrals. While some risks do remain, particularly around care stinting, value-based arrangements are often designed with important safeguards in place, such as monitoring for quality of care and ensuring patient choice. Additionally, other safeguards exist outside of the Anti-Kickback Statute to help ensure incentives are aligned for proper care.

We applaud the OIG and CMS for making strides to reform Anti-Kickback Statute and the Physician Self-Referral Law (Stark Law) to better support our changing healthcare system. However, the rules are still constrained within the confines of a statutory framework that was designed to address vulnerabilities in a fee-for-service system. To fully address these barriers to value-based care, legislative reform is needed.

VALUE-BASED FRAMEWORK

The OIG proposes three new safe harbors for compensation arrangements that meet the certain value-based criteria. The safe harbors vary based on the level of financial risk assumed by an entity, with conditions and requirements generally decreasing as entities assume greater downside risk.

At several points throughout the proposed rule, the OIG notes that it worked closely with CMS to ensure alignment between their respective proposed regulations, most notably on the value-based definitions. Premier appreciates efforts to align policies; however, we are concerned that the two regulations diverge in critical ways that may make it even more challenging for entities to navigate these protections. For example, both regulations utilize different metrics for determining downside financial risk and may require different conditions or standards for the corresponding exceptions and safe harbors, which are discussed in more detail below.

Lack of alignment will create additional administrative burden for providers as they manage compliance against two different metrics. Additionally, providers are highly risk adverse in the face of uncertainty of whether an arrangement will be covered, 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, as providers are likely to abide by the most stringent requirements. While we recognize that both the Stark Law and Anti-Kickback Statute have two different statutory intents, **we encourage CMS and the OIG to align these policies to the fullest extent possible under law.**

PROPOSED VALUE-BASED TERMINOLOGY

The OIG and CMS attempt to align policies by proposing similar definitions related to value-based care. These definitions provide the foundation for the proposed exceptions and safe harbors.

Premier supports these definitions, which are applicable to a broad range of innovative value-based arrangements. However, we are concerned that a few of the definitions lack clarity and may require additional guidance, which we have detailed below. While we appreciate the OIG and CMS proposing broad definitions, we are concerned that a lack of clarity around these definitions may leave 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 CMPs, criminal charges, and exclusion from federal health programs.

In several places, the OIG considers further refinements to its definitions beyond what is proposed by CMS. For example, the OIG is considering additional requirements for the value-based entity (VBE) accountable body or person, such as requiring VBE participants to acknowledge the role of the accountable body and agree in writing to cooperate with oversight efforts. As noted in the proposed rule, the OIG seeks to reduce barriers to healthcare innovation. **The OIG should consider what additional benefits are gained by these prescriptive requirements and if they outweigh the associated burden**. For example, it is unclear how requiring participants to acknowledge the oversight role of the VBE accountable body reduces any potential risk of fraud and abuse. The OIG proposes several other requirements in the proposed safe harbors that are more effective at addressing program integrity risk.

Finally, the OIG is considering additional restrictions for arrangements between entities that have common ownership, citing its interest in protecting patients against abusive cycling for financial gain among commonly owned entities. The OIG notes that these modifications, if finalized, would preclude protection for care coordination arrangement among entities in integrated health systems. **Premier opposes this limitation as it will impede the movement to value-based care and will unfairly target integrated systems**. While there may be rare instances where common ownership may result in abuses, many integrated systems have been leaders in the movement to value-based care and have been effective at driving better outcomes in healthcare. We also seek clarification on what is meant by common ownership in this instance, as many commonly-owned entities are already protected against the Anti-Kickback Statute.

Target Patient Population

The OIG and CMS propose to define the target patient population as one selected based on legitimate and verifiable criteria that are established in writing prior to the start of the arrangement. The OIG also seeks comment on whether to replace “legitimate and verifiable criteria” with “evidence-based criteria.” **We encourage the OIG and CMS to provide additional guidance on the criteria for defining the target patient population**. While both definitions lack clarity, “evidence-based” provides a more tangible framework. At a minimum, we recommend that the OIG and CMS utilize “evidence-based criteria” to define the population.

Additionally, the OIG is considering whether to limit the definition of target patient population to patients with chronic conditions and/or shared disease states, noting that it believes this population would benefit most from care coordination. The OIG also seeks comment on how to define chronic conditions.

We believe this limitation is unnecessary and may hinder innovation in healthcare delivery. The OIG should maintain flexibility in this definition to allow providers to develop value-based arrangements that are in the best interest of the patient based on providers’ clinical expertise. The OIG propose several other safeguards that will help ensure providers are utilizing these flexibilities to support arrangements that are high-value and beneficial.

Value-based activity

The OIG and CMS propose to define a value-based activity as "reasonably designed" to achieve at least one value-based purpose. The OIG attempts to further clarify by seeking comment on whether to interpret reasonably designed to mean that the activities are expected to further the value-based purpose. This definition does not provide any additional clarity as expectations are still subjective to the entity making the determination.

The OIG also seeks comment on whether it should require VBE participants to engage in an evidence-based process to design value-based activities that will further value-based purpose(s). This requirement is overly prescriptive and would create an unnecessarily burdensome process. It is unclear what additional safeguards would be gained through this requirement, since the definitions already require the activity to be designed to meet certain value-based purposes.

The OIG should clarify the requirements for an activity to be considered value-based but should maintain flexibility around the process that VBEs use to design value-based arrangements to meet those requirements.

Finally, the OIG states that a value-based activity "does not include the making of a referral." Many value-based arrangements utilize provider networks to improve quality and reduce unnecessary care. We are concerned that the OIG's statement could be interpreted as prohibiting value-based arrangements that may tie remunerations in part to referrals made within a care network. **We encourage the OIG to provide greater clarity and to not define value-based activities in a way that would prohibit participants from incorporating provider networks into their value-based arrangements.**

VBE Participants

The OIG proposes that the definition of a VBE participant would specifically exclude pharmaceutical manufacturers, durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS) suppliers and manufacturers and laboratories. Citing past oversight experience with these entities, OIG is concerned that because these entities are heavily dependent on practitioner prescriptions and referrals, they might misuse the proposed safe harbors as a way to remunerate practitioners and patients to market their products.

Premier encourages CMS and the OIG to include pharmaceutical manufacturers, device manufacturers, physicians, laboratories, DMEPOS manufacturers, pharmacy benefit managers, payers, group purchasing organizations, pharmacies and wholesale distributors in the definition of a VBE participant. These are critical entities to the movement towards value and therefore should be included in the definition of a VBE participant. While value-based contracts (VBCs) are not a silver bullet to addressing rising healthcare costs and may not be appropriate for all drugs and devices, they are an important tool that warrants further exploration to determine their effectiveness in helping to lower healthcare prices and hold manufacturers responsible for the clinical outcomes associated with their product. While Premier has been successful in implementing several VBCs for drugs and devices, concerns with violating anti-kickback and self-referral laws have inhibited our ability to aggressively pursue VBCs as a robust strategy for lowering healthcare costs.

VBCs are typically structured in one of four ways:

- Evidence-based care discount – Manufacturer discount aligned with provider's execution or standardization of an evidence-based care practice.

- 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.
- 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.
- Risk share by alternative payment model – Shared upside/downside risk between a healthcare system and manufacturer.

Under the current legal infrastructure and constraints with anti-kickback and Stark, most VBCs are structured as evidence-based care discounts. Modernization of these barriers is necessary to permit VBCs 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 arrangements that are currently not permissible under the existing legal infrastructure:

- Scenario 1 - A medical device manufacturer and payer enter into a VBC. 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 only covers the cost of replacing the device. The payment of costs associated with re-hospitalization would be considered remuneration. However, the proposed rule would extend the applicability of the warranty safe harbor and allow for "bundled warranties" that cover certain services in addition to items, if the items and services are reimbursed by the same federal health program (ex – same DRG group). HHS and OIG should provide additional clarity on how this would be operationalized.
- Scenario 2 - A manufacturer and provider enter into a VBC. The manufacturer will provide EHR software and analytic support to assist in tracking of relevant clinical outcome data.
    - This arrangement would not be permissible as the OIG would likely consider the EHR software to be renumeration that could induce the provider to purchase the manufacturer's drug. Receipt of technology may not be conditioned on doing business with the manufacturer.
- Scenario 3 - A manufacturer and payer enter into a VBC. 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 4 - A medical device manufacturer and provider enter into a VBC. 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 VBC 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 VBCs, it is critical that CMS and OIG expand the definition of a VBE.

Should CMS and OIG have hesitations with expanding the definition of VBE, **Premier offers 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 OIG oversight to protect from unintended consequences.**

First, **Premier recommends that OIG study, over the course of at least five years, the implementation of VBCs.** This will provide an opportunity for entities to enter into VBCs and truly test the ability of VBCs to lower healthcare costs while still providing OIG oversight to determine if VBCs 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 CMS and OIG are not willing to expand the definition of VBE, then Premier recommends that OIG expand the applicability of OIG advisory opinions**. Currently, entities wishing to enter into a VBC that may evoke anti-kickback or Stark 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 OIG. While not ideal and expanding the definition of VBE is preferred, a potential interim compromise may be to expand the applicability of OIG advisory opinions to beyond the parties named. This would allow additional entities who wish to enter into a VBC that is structured similarly to an arrangement already reviewed and approved by OIG to do so without seeking an additional opinion. This model would still provide OIG with the oversight to review and approve VBCs but would also expand the feasibility of others to enter into similar agreements.

Value-based purpose

The OIG and CMS propose to 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 we appreciate how broadly the OIG and CMS define value-based purpose, we are concerned that the definitions are too vague. As noted above, the penalties associated with lack of compliance are so steep that providers will unlikely utilize these new flexibilities in the face of uncertainty. For example, The OIG and CMS do not define what would be considered a payment mechanism as providers transition to new healthcare delivery systems.

The OIG and CMS should also expand the goal of “appropriately reducing costs” beyond just payors to also include VBE participants. All appropriate cost reductions within the framework of a value-based arrangement should be allowed.

Additionally, the OIG and CMS provides 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.

We agree that additional criteria need to be established, but caution whether to tie those boundaries to achievement of certain metrics, which may not be known prospectively. 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 define 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.

The OIG is considering limiting the purpose related to appropriately reducing costs to situations where there is an improvement in patient quality or care or maintenance in an improved level of care. We believe this limitation is overly prescriptive and could hinder healthcare innovation. For example, the alternative definition does not define what would be considered an improved level of care. Since quality improvement will vary based on the value-based arrangement, this revised definition adds further complexity to an already complex framework and would be challenging for participants to assess. We do not recommend that the OIG adopt this alternative definition.

Care Coordination and Management

The OIG proposes to define care coordination as the deliberate organization of patient care activities and information sharing between VBE participants and/or patients tailored to improve the health outcomes of the target population.

For each of its safe harbors, the OIG proposes that at least one of the value-based activities must be connected to care coordination and management. This differs from the CMS exceptions, which only require participants to include an activity that meets one of four core goals, of which one is related to care coordination and management. The OIG's proposal is overly prescriptive and will hinder innovations in healthcare delivery. While care coordination and management is a critical component to value-based care, it is not the only intervention. The OIG should maintain flexibility to allow VBE participants to determine which of the value-based purposes best meet the needs of their patient population.

Premier strongly encourages the OIG to not require all safe harbors to have an activity related to care coordination and management and to align its policies with CMS' proposed exceptions.

CARE COORDINATION ARRANGEMENTS TO IMPROVE QUALITY, HEALTH OUTCOMES, AND EFFICIENCY SAFE HARBOR

The OIG's proposed care coordination arrangement safe harbor would not require VBE participants to bear or assume downside financial risk and includes several conditions and restrictions, which will likely make the safe harbor challenging to utilize. Additionally, lack of alignment with CMS' value-based arrangement exception will also create operational challenges and may result in entities not utilizing the CMS exception to its fullest potential. **Premier encourages the OIG to work with CMS to develop consistent parameters across their respective safe harbor and exception and consider refinements to the proposed care coordination safe harbor to ensure it does not hinder healthcare innovation.** We have included several suggestions in the following section.

The OIG proposes to limit 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 the 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 specific to exception. **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. **Premier encourages the OIG to allow monetary remuneration under this proposed safe harbor.**

Under the proposal, VBE participants would be required to 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. The OIG notes that patient satisfaction data could not be used because it may not reflect actual improvements in quality, outcomes, or efficiency. The OIG is also considering whether to require the measures to be rebased periodically or annually and seeks input on the timing of rebasing and specific requirements. The OIG is also considering incorporating CMS Quality Payment Program (QPP) measures into the requirements to establish outcome measures.

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 and making rebasing optional**.

Additionally, **we do not recommend that the OIG require use of the QPP measures for this safe harbor.** In the CY 2020 QPP rulemaking, CMS acknowledged some of the challenges with existing QPP measures, including the lack of measures for certain specialties. The OIG could encourage participants to utilize the criteria for the QPP measures as a framework for establishing outcome measures. However, as we note above, the OIG should maintain as much as flexibility as possible around outcome measurement.

The OIG is also requiring that the arrangements be commercially reasonable, which the OIG is considering to define as an arrangement as that would make commercial sense if entered into by reasonable entities of similar type and size, even without the potential for referrals. The OIG is also considering including a fair market value requirement and disallowing participants from taking into consideration any volume or value of referrals or other business generated, including referrals or business related to the valued-based arrangement.

If finalized, these requirements would be inconsistent with CMS' proposed exception, which does not include requirements related to fair market value, commercial reasonableness, and volume or value of referrals. 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 strongly opposes applying fair market value, commercial reasonableness, and the volume or value standards to the proposed safe harbor.**

The OIG also proposes to require recipients to pay at least 15 percent of the offers' cost of the in-kind contribution, noting that the contribution would ensure the remuneration would actually be used for care coordination and management. The OIG seeks comment on whether certain entities should pay a lower contribution or no contribution at all and what the appropriate level of contribution should be. 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 contribution**. 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. 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.

Finally, the OIG proposes that the value-based arrangement must be terminated within 60 days of the entity determining that the arrangement is unlikely to further care coordination or achieve the outcome measures. **The OIG should consider specifying a curative period in which participants would have the opportunity to correct any compliance issues**. Additionally, we are concerned that the timing may not be sufficient for entities to adjust care practices and arrangements and encourage the OIG to consider a longer termination period. The OIG and CMS should coordinate to establish a consistent process and timeline for corrective actions and termination.

VALUE-BASED ARRANGEMENTS WITH SUBSTANTIAL DOWNSIDE FINANCIAL RISK

Under this new proposed safe harbor, VBEs would be required to take on substantial downside financial risk and participants would be required to meaningfully share in the downside financial risk. The OIG proposes to define substantial downside risk as:

- shared savings with a repayment obligation to the payor of at least 40 percent of any shared losses;
- a repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 percent of any total loss;
- a prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population; or,
- a partial capitated payment from the payor for a set of items and services for the target patient population.

Additionally, the OIG proposes that a VBE participant would be considered to meaningfully share in downside risk if the participant met one of the following:

- A risk-sharing payment under which the VBE participant is at risk for 8 percent of the amount for which the VBE is at risk under its agreement with the applicable payor;
- A partial or full capitation payment, or similar payment methodology; or,
- In the case of a physician VBE participant, a payment that meets the requirements for CMS' proposed meaningful downside financial risk exception

We are concerned that the parameters for this safe harbor may be set too high based on the current state of value transformation progress. We understand the OIG's intentions to align this safe harbor with the nominal risk levels utilized in the Quality Payment Program (QPP). However, the purpose of this safe harbor differs from the QPP, which is focused on providing bonuses to clinicians. We would encourage the OIG to consider more modest parameters that would be more realistic and inclusive of additional arrangements, such as requiring VBE participants to assume risk at 2 percent and/or partial capitation.

The safe harbor would protect both in-kind and monetary remuneration. Additionally, the safe harbor would apply for the six months leading up to the arrangement. We are supportive of the OIG's proposal to provide protection in the pre-participation period for value-based arrangement. We would encourage OIG to consider lengthening the time for at least up to one year to ensure that participants have sufficient time to prepare for the arrangement. Additional flexibilities would be particularly useful for small or rural providers who may lack sufficient experience with value-based arrangements and may need a more gradual glide path to assuming financial risk.

The OIG is considering a condition that would require remuneration to meet the commercial reasonableness requirement, which would be inconsistent with CMS' proposed exception. As noted above, the movement to value-based care helps eliminate many of the program integrity concerns present in a fee-for-service system that requirements, such as commercial reasonableness, have attempted to mitigate. Providers have historically had challenges with evaluating commercially reasonableness in value-based arrangements. As a result, these requirements could also hinder innovation in healthcare delivery reform, one of the key guiding principles for this proposed regulation.

VALUE-BASED ARRANGEMENTS WITH FULL FINANCIAL RISK

The full financial risk safe harbor would be available for entities that are financially responsible on a prospective basis for the cost of all patient care items and services for the target patient populations. This safe harbor would also provide protections for the six months leading up to the start of the arrangement.

Very few arrangements are at true financial risk. Oftentimes there are carveouts for certain high-cost services or populations (e.g., patients with End-Stage Renal Disease). 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.

As proposed, few entities will be positioned to utilize this exception. **Premier recommends that the OIG modify the Full Financial Risk exception 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, we recommend 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.

We are supportive of the OIG's proposal to provide protection in the pre-participation period for value-based arrangement. As noted above, we would encourage OIG to consider lengthening the time for up to at least one year to ensure that participants have sufficient time to prepare for full risk arrangements.

SAFE HARBOR FOR ARRANGEMENTS FOR PATIENT ENGAGEMENT AND SUPPORT TO IMPROVE QUALITY, HEALTH OUTCOMES, AND EFFICIENCY

This proposed new safe harbor would protect certain patient engagement tools and supports furnished by VBE participants directly to patients in a specified target patient population that improve quality, health outcomes, and efficiency. Tools and supports must be in-kind and would exclude cash, gift cards, or remuneration that duplicate tools and services under a value-based arrangement; OIG would place a cap of $500 annually on the value of protected tools and supports. The safe harbor would apply for purposes of the Anti-Kickback Statute and the beneficiary inducements CMP which currently impact the ability of providers and healthcare practitioners to offer patients tools and supports to assist in their care and improve outcomes.

The OIG proposes several safeguards; these include requirements that there be a direct connection to care coordination as well as that the tools or support must be recommended by the patient's provider to advance stated clinical goals. Additionally, contributions from persons outside the value-based entity would be excluded.

Premier strongly supports the establishment of a safe harbor for patient engagement tools and supports that are designed to improve quality, health outcomes and efficiency; protection under both the Anti-Kickback Statute and the beneficiary inducements CMP is essential. We view this as an important component of care coordination and improvement in care delivery for patients both inside and outside of the physician's office or an institutional provider setting. **We urge the OIG to finalize the proposal with modifications to take into account some specific concerns and recommendations discussed below.**

Limitations on Offerors

Limiting safe harbor protection to VBE participants unnecessarily excludes other providers, such as hospitals or physician group practices, from furnishing patient tools and supports to patients. As long as outside providers and practitioners meet the applicable conditions of the safe harbor, which is designed to encourage efficiency, quality and better health outcomes, the risk of fraud or abuse against patients is very low and the potential benefits are substantial. **We encourage the OIG to remove this limitation**. We agree that this limitation would be likely to exclude potentially beneficial tools and supports for patients due to the size or structure of a particular value-based enterprise and the value-based activities it elects to pursue. Physicians or hospitals outside the VBE should not be prevented from offering a better or more appropriate alternative tool or support to a patient to speed their recovery or better manage their condition as long as it is not duplicative of a tool or support furnished by a VBE participant.

Limitations on Recipients

The proposed limitation that only members of the target patient population of the VBE may be eligible recipients is an unnecessary requirement which may be difficult to implement in certain circumstances. As the OIG acknowledges, some VBEs or VBE participants cannot prospectively identify individual patients in the target patient population; currently some CMS-sponsored ACO models provide for patient assignment either retrospectively or on a preliminary prospective basis. Other proposed safeguards would provide sufficient protection against a significant risk of fraud and abuse, including a requirement that the tools and support predominately meet the needs of the target population and have a direct connection to the coordination and management of care for the patient. OIG should not finalize this requirement.

Limitations on Type of Remuneration

Premier strongly supports the types of tools and supports the OIG proposes to protect under the safe harbor. We are especially gratified to see that supports and services designed to identify and address social determinants of health would be protected under the safe harbor. This can be an especially effective way to ensure better care and care management for vulnerable patients. Vouchers for meals or providing transportation are also very effective tools and supports, and we recommend that these proposals be finalized as well.

In the context of patient engagement tools and supports for preventive services**, we appreciate that the OIG would defer to a medical professional's reasonable medical judgment to determine both the scope of preventive care and the types of tools and supports to encourage preventive care**.

Establishing a definition of preventive care could constrict a medical professional's options as the practice of medicine evolves.

Stakeholders would benefit from greater specificity in the types of tools and supports that would be protected under this safe harbor. As technology advances, it is imperative that patients and their healthcare providers have access to effective means to monitor patient health. This should include a wide variety of tools and supports as well as provide flexibility to accommodate innovation in medical practice. With respect to appropriate tools and supports for social determinants of health, it would be helpful for stakeholders if the OIG would provide examples of those tools and supports as an illustration of its final policy decision; however, the OIG should clarify that those examples do not exclude other tools and supports that in the best medical judgment of the provider are appropriate to maintain and coordinate care for these patients. Healthcare providers require flexibility to adapt tools to particular patients and their circumstances and also require the flexibility to try innovative approaches to assist vulnerable subgroups of the patient population.

Notwithstanding our strong support for this proposal, we have concerns with the proposed exclusion of cash, gift cards and certain remuneration. To give healthcare providers a wider range of tools that they know will benefit certain patients directly, we believe that gift cards or cash should be a permissible tool or support for certain services. For example, ensuring that a patient gets annual influenza vaccinations by providing the patient with cash or a gift card for that purpose is an excellent care management tool that does not run a high risk of fraud or abuse.

As noted above, a transportation voucher for patients for medical appointments is an extremely useful patient support. Many of our patients have difficulty getting to their medical appointments; missed appointments often result in poorer health and health outcomes and complicate efforts to coordinate and manage care. The OIG currently permits the offer of transportation under certain circumstances and has acknowledged the beneficial impact of provider-furnished transportation for patients on care and patient outcomes.

Funding Limitations

The proposed limit on funding or contributing to patient engagement tools and supports to VBE participants is an unnecessary condition. It would preclude funds or free in-kind items or services furnished by any individual or entity outside of the VBE to finance or facilitate patient engagement tools or supports. For example, providers often share a care coordinator and collaborate on how to compensate the coordinator. Under this proposed condition, where a care coordinator is shared by a VBE participant and another entity, instead of being able to simply reimburse the other entity for their share of the coordinator's salary, the VBE participant would have to pay the coordinator directly. This is an unnecessary and burdensome requirement.

Direct Connection

In proposing to require a direct connection to patient care coordination and management, the OIG interprets "direct connection" to mean that the VBE has a good faith expectation that the tool or support will further the coordination and management of care for the patients. It is considering instead requiring a reasonable connection in lieu of a direct connection. Since patient tools and supports are designed to assist in the care coordination and management of patients using the medical provider's clinical judgment, we would support the use of the alternative reasonable connection standard. OIG is also considering requiring the VBE to make bona fide determinations that the VBE participants' arrangements to provide tools and supports are directly connected to care coordination and management. **We believe**

this alternative requirement duplicates the determination a VBE would already undergo in establishing the value-based activities of the VBE and the role of the VBE participants in carrying out those activities. We recommend that this alternative proposal not be finalized.

Recommendation by Patient's Provider

The OIG proposes that the tool or support must be recommended by the patient's licensed healthcare provider. It is also considering whether to require the provider to certify in writing that the particular tool or support is recommended solely to treat a documented chronic condition.

These proposed conditions may be difficult to satisfy. Depending on the complexity and number of VBE participants in a VBE, the patient's actual healthcare provider may not be directly involved at the time the tool or support is provided, and thus cannot not "directly" furnish the tool or support. **We recommend that the OIG provide for flexibility in this safe harbor condition to ensure that a VBE participant is not penalized for an inadvertent violation**; the goal is to ensure patients receive the tools and supports they require based on the best clinical judgement of the VBE participant or provider or pursuant to medically appropriate policies established by the VBE.

Monetary Cap

Insofar as the OIG finalizes its proposal to impose an annual cap on the monetary value of tools and supports that may be provided to the patient population, **we urge that it also finalize its proposal to permit the cap to be exceeded for patients who have complex medical conditions or lack financial resources**. Some of our greatest care challenges are patients who do not have adequate resources; having the flexibility to furnish additional medically necessary tools and supports or perhaps even more costly ones to these patients is essential. We also agree that determinations on financial need could be done on a good faith, individualized, case-by-case basis under a uniform set of guidelines.

Consistent Provision of Patient Incentives

The OIG is considering whether to require VBE participants to provide the same patient engagement tools or supports to an entire target patient population or consistently offer these items to all patients satisfying specified, uniformed criteria. As noted above, providers and practitioners require flexibility to tailor the type of tools and supports to the particular patient. Not all tools and supports may necessarily be beneficial for an entire patient population of a VBE. **We recommend that OIG not include a uniformity requirement on the types of tools and supports that may be provided to patients as a condition of protection under the safe harbor.** To address program integrity concerns that a VBE participant may inappropriately differentiate tools and supports amongst individuals in a target patient population, the OIG should consider requiring participants to establish in advance the criteria that a participant would use to determine which sub-populations would receive specific tools or supports.

Retrieval of Items and Goods

The OIG is considering requiring offerors to engage in reasonable efforts to retrieve an item or good furnished as a tool or support under certain circumstances, such as the patient is no longer in the target population, the VBE no longer exists, or the offeror is no longer a VBE participant.

Retrieval of certain tools and supports may not be practical; efforts to retrieve certain tools and supports may expend greater resources that the value of the tool or support itself**. We do not support a**

requirement to retrieve a patient tool or support, but we recommend that the OIG clarify that VBE participants would retain the right to do so.

If the OIG adds a retrieval requirement, it should be limited to those tools and supports that have substantial value at the time of retrieval. Further, any retrieval requirement should be limited to those tools and supports that are easily recovered. In no case should a VBE participant be required to retrieve a particular tool or support if doing so would cause harm to the patient, as determined by the VBE participant who provided the tool or support.

CMS-SPONSORED MODEL ARRANGEMENTS AND CMS-SPONSORED MODEL PATIENT INCENTIVES

The OIG proposes to standardize protection of CMS-sponsored model arrangements by creating a new safe harbor that would permit 1) remuneration between and among parties to arrangements under CMS-sponsored models and 2) remuneration in the form of incentives and supports provided by model participants to patients covered by the model. The OIG seeks comment on broadening the scope of the proposed CMS-sponsored models safe harbor to protect remuneration between and among parties to arrangements under CMS initiatives beyond those authorized under sections 1115A and 1899 of the Act.

Premier supports the OIG's proposed safe harbor for CMS-sponsored models and patient incentive programs. While the other proposed safe harbors have a broader impact and apply potentially across multiple lines of business, a safe harbor that protects Centers for Medicare & Medicaid Innovation Center (CMMI) models will provide clarity and consistency for participants in those models and obviate the need for the development of specific AKS-related waivers, which are often finalized late in a model development process and therefore impactful on the decisions to participate by health care organizations. **Additionally, we ask the OIG to consider extending this safe harbor to State Innovation Waivers under section 1332.** This will ease burden for providers operating in both federal and state value-based arrangements.

ELECTRONIC HEALTH RECORDS AND CYBERSECURITY

Current regulations provide a safe harbor for certain arrangements involving donation of interoperable EHR software or information technology and training services. The EHR safe harbor expires on December 31, 2021. CMS and the OIG propose changes to the exception and safe harbor.

Interoperability

CMS and the OIG propose to update the existing definitions of "electronic health record" and "interoperable" to reflect terms and provisions of the 21st Century Cures (Cures) Act. **Premier supports the CMS and OIG proposals to align the interoperability definition with the Cures Act.** We believe that using terminology and terms identical to the Cures Act would likely help facilitate compliance with the requirements of the EHR exception. However, we do not believe (as stated in the proposed rules) that changing the definitions will provide any regulatory relief or reduce burden resulting from the differences in the agencies' terminology.

CMS and the OIG propose "two clarifying changes" to the regulatory text about interoperability. The current requirement deems that software is interoperable if at the time it is provided to the physician it has been certified to an edition of the EHR certification criteria identified in the then-applicable version of 45

CFR part 170. **We support the proposal to require that the software be certified at the time it is provided to the physician.**

Cybersecurity

Premier supports the CMS and OIG proposals to clarify that the EHR exception applies to software or IT and training services, including certain cybersecurity software and services, necessary and used predominantly to create, maintain, transmit, receive or protect EHRs if the identified conditions are met. We appreciate the proposed expansion of the EHR exception to clarify that an entity donating EHR software and providing training and other related services may also donate cybersecurity software to protect the EHR.

Both CMS and the OIG have called for excluding hardware from the permitted type of technology which is protected under the cybersecurity donation exception/safe harbor. We are concerned this approach could impede the success of this exception and safe harbor. First, the lines between what is considered hardware and software is increasingly being blurred; by breaking out hardware from the definition of technology it does not account for the pace of innovation. Second, vendors do not typically break out the cost of hardware vs. software. Rather, the price or value is based upon the totality of the device. An example would be a networking device that is running software. **Precluding the donation of hardware, therefore, could create barriers to donations of cybersecurity technology if donors and recipients aren't clear how to disaggregate the two.**

The OIG proposes a new safe harbor to protect donations of certain cybersecurity technology and related services. A new exception to the (CMS) referral prohibition related to compensation arrangements is proposed for certain arrangements involving donation of certain cybersecurity technology and related services ("the cybersecurity exception"). **Premier supports changes that will help ensure that interconnected health information systems are protected from cyberattacks and vulnerabilities.** We support the proposed cybersecurity exception as an approach to promote increased security.

Premier appreciates the Administration's efforts to articulate definitions of "cybersecurity" and "technology". However, as we have stated elsewhere in these comments, Premier believes that is increasingly difficult and ineffective to try to distinguish between what is hardware, software and services. **We urge the Administration to incorporate and consider implications of existing (and contemplated) features, functions and capabilities, including cloud-based and subscription-based products and services.** The recognition of Application Programming Interface (API) technology within the text of the proposed rules—which is neither software nor a service—is a good example of the hardware/software/technology definitional conundrum. Furthermore, **we recommend that the Administration consider the multifunctional nature of various technologies and services including those used to implement, maintain or establish effective cybersecurity and the industry's decreasing use of "stand-alone" technologies and solutions.**

Sunset Provision

The EHR exception/safe harbor was originally adopted in the 2006 and was scheduled to expire on December 31, 2013 and later extended to December 31, 2021. The sunset was included because CMS and the OIG believed that the need for the exception would diminish over time as the use of EHR technology became a standard and expected part of medical practice. CMS and the OIG seek comment on whether a later sunset date should be set instead of making the exception permanent. **Premier strongly supports making the exception permanent.** While EHR technology has become a standard and expected part of medical practice, the technology will continue to evolve. In recognition of the constant evolution the exception/safe harbor should be permanent. Moreover, the exception will help

providers meet the new interoperability requirements as well as assist several provider types (such as nursing homes) that were not included in the Medicare and Medicaid EHR Incentive Program.

15 Percent Contribution

A current condition of the EHR safe harbor/exception is the recipient must pay 15 percent of the donor's cost of the technology. In response to concerns about burden, CMS and the OIG seek comment on eliminating or reducing the contribution, either for all practice or only small and rural organizations. **Premier recommends that the Administration eliminate the 15 percent contribution requirement in the EHR exception for all recipients, including for the initial donation of EHR technology, and subsequent updates and upgrades.** This will help reduce the uncertainty and administrative burden associated with assessing each type of donation and associated contribution.

Replacement technology

CMS and the OIG seek comment on the types of situations in which the donation of replacement technology would be appropriate. Premier believes that given the ongoing evolution and enhancements to technologies it is increasingly difficult if not nearly impossible to clearly distinguish between changes to existing technologies as contrasted with replacement technologies. We urge CMS to carefully consider the unintended consequences of the rapid pace of advancement in EHR technology, aging EHR technology at existing practices, the embedding of modules and functionality within legacy EHRs, modifications to ONC's EHR certification program and emerging/improved technologies and to allow donations of replacement technology. **Premier supports removing the limitation on donating equivalent items or services to allow donations of replacement EHR technology.**

PERSONAL SERVICES AND MANAGEMENT CONTRACTS AND OUTCOMES-BASED PAYMENT ARRANGEMENTS

As part of the modification to the existing personal services and management contracts safe harbor, the OIG proposes to protect outcomes-based payments arrangements outside the context of VBEs. These arrangements would include gainsharing, shared savings payments, episodic payments and pay-for-performance; they would exclude payments only for internal cost savings.

OIG proposes to define 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 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 the methodology for determining the compensation must be set in advance, the actual amount of compensation does not have to be set in advance. The methodology must also be commercially reasonable and be consistent with fair market value; it may not be determined in manner that directly takes into account volume or value of referrals or business otherwise generated for which payment may be made (directly or indirectly) by a federal health care program.

Manufacturers of drugs, medical devices and supplies would be excluded from such arrangements. As noted above, we strongly opposed OIG's proposal exclude these entities from protections under the value-based safe harbors.

Premier appreciates the proposal to protect certain outcomes-based payments by modifying the existing personal services and management contracts safe harbor. We agree with the policy intent behind the proposal; however, we are deeply concerned that as proposed, 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 CMMI payment models. Some of the conditions under the proposal are onerous and may be difficult to achieve.

Under the proposal, 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 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 proposal 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.

We suggest that the OIG 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.

LOCAL TRANSPORTATION

The OIG proposes to increase the limit on transportation of residents in rural communities from 25 to 75 miles of the healthcare provider. **Premier supports the proposed changes which expand the scope of protected local transportation services.** The removal of the mileage limits on hospital discharge transports to a patient's residence is sensible, and the definition of residence should include a custodial care facility, which may be needed on a temporary or permanent basis. We believe the OIG should adopt a similar policy for transports to a sub-acute care facility too. Given the rising importance of addressing social needs, we believe the OIG should add protection of transportation to non-medical facilities that are part of a care coordination plan and/or that address social determinants of health (e.g., access to food, social services, exercise facilities).

ACO BENEFICIARY INCENTIVE PROGRAM

The OIG proposes to codify the statutory exception to the definition of remuneration that accommodates the ACO Beneficiary Incentive. **We support codifying this exception; however, we believe the exception should be broadened to accommodate any future beneficiary incentives covered under CMS-sponsored payment models.** Premier has previously stated that the ACO Beneficiary Incentive is too limited and that CMS should give ACOs (and APMs more broadly) the ability to design beneficiary incentives for subsets of their population (e.g. patients with a certain chronic condition). Accordingly, OIG should create an exception that is flexible to beneficiary incentive options that may be available in future models.

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on the Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements proposed rule. If you have any questions regarding our comments or need more information, please contact Aisha Pittman, Vice President, Policy, at aisha_pittman@premierinc.com or 202.879.8013.

Sincerely,

Blair Childs
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Premier healthcare alliance