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Office of Inspector General
Department of Health and Human Services
Attention: OIG–0936–AA10–P
Room 5521
Cohen Building
330 Independence Ave. SW
Washington, DC 20201

Re: 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 [OIG–0936–AA10–P]

To Whom It May Concern:

The U.S. Chamber of Commerce (the "Chamber") submits these comments in response to the recently published proposed rule regarding revisions to the safe harbor protections under the Federal Anti-Kickback Statute (the "Proposed Rule").[1] The Chamber applauds efforts by the U.S. Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") to reduce regulatory burdens that can inhibit innovative arrangements to promote value-based care. We believe these proposed changes are a vital step in advancing the transition to value-based care and the coordination of care.

Furthermore, the Chamber supports the alignment between the Centers for Medicare & Medicaid Services ("CMS") and OIG in proposing changes to regulations implementing the physician self-referral law (the "Stark Law") and the Anti-Kickback Statute. Consistency among the Stark Law exceptions and the Anti-Kickback Statute safe harbors should help establish a clear regulatory framework in which the health care industry can coordinate to improve patient care while lowering costs. The Chamber encourages CMS and OIG to continue to look for ways to more closely align the Stark Law and Anti-Kickback Statute regulatory frameworks.

The Chamber strongly supports the establishment of Stark Law exceptions and Anti-Kickback Statute safe harbors that allow health care entities to work together to improve patient outcomes. Value-based arrangements developed under these new safe harbors have the potential to improve the quality and affordability of patient care across specialties, geographic areas, and disease

[1] 84 Fed. Reg. 55,694 (Oct. 17, 2019), *available at* https://www.govinfo.gov/content/pkg/FR-2019-10-17/pdf/2019-22027.pdf.

types. Further, the Chamber appreciates OIG's efforts to impose safeguards to prevent these safe harbors from limiting medically necessary care.

In these comments, the Chamber urges OIG to continue to streamline and modernize the Anti-Kickback Statute regulations such that health care providers and payors, among others, can focus on delivering high-quality patient care in an efficient manner. Additionally, we encourage OIG to adopt a framework based in principled self-regulation, with appropriate safeguards. Our comments also support aspects of the Proposed Rule that reduce unnecessary complexity and provide suggestions for how OIG can further refine its proposals.

PROPOSED DEFINITIONS

Accountability for "Value-Based Enterprise"

In the Proposed Rule, OIG stipulates that a value-based enterprise ("VBE") should be required to maintain an accountable body or person responsible for the financial and operational oversight of the VBE.[2] The Chamber supports this proposal. We agree with OIG that the accountable body or responsible person would be well positioned to identify any program integrity issues and take appropriate action to address them.

However, the Chamber recommends that OIG not mandate that the VBE have a compliance program for the safe harbor protections that it is seeking. Rather, we suggest that OIG make clear that the accountable body or person is responsible for oversight and compliance with the applicable safe harbors. This approach would allow the accountable body or person the flexibility to self-regulate in a manner tailored to the specific VBE, its participants, the related value-based activities, and the target patient population. For example, a relatively large and complicated VBE with many participants undertaking value-based activities directed towards a large target patient population over many years may require a formal compliance program. Conversely, a smaller VBE with only two participants and advancing value-based care for a more limited population over a briefer period of time may not. Each VBE should decide for itself the best approach to compliance.

The Proposed Rule also solicits comments on whether VBEs should be required to implement reporting requirements for their VBE participants or other mechanisms for obtaining access to, and verifying, VBE participant data under any value-based arrangement.[3] The Chamber agrees with OIG that VBE participants should be required to periodically assess and verify performance under the VBE, but we urge the agency to grant discretion to VBEs as to how this assessment occurs, is documented, and is verified by the accountable body or person. These requirements will vary based on the size, scope, and breadth of the VBE and its value-based arrangements.

Definition of "Target Patient Population"

In the Proposed Rule, OIG defines "target patient population" as "an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that: (A) [a]re set out in writing in advance of the commencement of the value-based

[2] *Id.* at 55,701.

[3] *Id.*

arrangement; and (B) further the VBE's value-based purpose(s)."[4] We support OIG's suggestion that "legitimate and verifiable criteria" may include health characteristics, geographic characteristics, payor status, or other defining characteristics. This interpretation gives VBE participants appropriate flexibility in designing value-based arrangements tailored closely to the target patient population's needs.

The finalized Anti-Kickback Statute safe harbors, however, should allow VBE participants sufficient discretion to determine the most appropriate target patient population for the specific goals of the program and the degree of risk that parties wish to undertake from the payor. The payor, if not part of the VBE, should be able to participate in defining "target patient population," especially as a payor and a VBE need to agree on which patients are in the subject population.

We agree with the agency's approach of allowing enterprises to think creatively as to how to better serve certain patient populations, within the general parameters that the criteria be "legitimate and verifiable," but the Chamber would not support OIG's suggestion that "target patient population" may be limited to patients with chronic diseases. Rather, "target patient population" should also include patients with acute conditions, patients seeking emergency or preventative care, patients within specified geographic zones, or patients that meet some other defined and documented set of characteristics. Limiting the scope of "target patient population" (and, thus, certain safe harbor protections for value-based arrangements) to only chronic conditions will hamper value-based arrangements, fail to incentivize value-based arrangements that improve quality outcomes for patients without chronic conditions, and minimize potential cost savings. For example, a target patient population might consist of patients requiring certain orthopedic surgical interventions (e.g., joint replacement) to address medical needs not necessarily related to a chronic condition.

Further, the Chamber requests that OIG avoid defining target patient population so narrowly or restrictively as to limit a VBE's ability to adjust target populations over time and during the lifespan of a value-based arrangement.

Excluding Certain Entities from the Definition of "VBE Participant"

The Chamber urges OIG not to exclude pharmaceutical manufacturers, suppliers of durable medical equipment, prosthetics/orthotics, and supplies ("suppliers of DMEPOS"), laboratories, pharmacies, medical device companies, pharmacy benefit managers, or any other entities from the definition of "VBE participant."[5] We share OIG's concern regarding arrangements or behaviors that could give rise to a risk of program or patient abuse. However, to address this concern, OIG should focus on limiting or prohibiting the types of behavior or relationships that it finds to be abusive. It should not distinguish between health care entities based on product or service type.

For the industry-wide move to value-based care to be successful, all entities along the continuum of health care delivery should be eligible for protection under these rules so as to encourage their participation in value-based arrangements. We fear that excluding certain entities, such as pharmaceutical manufacturers or laboratories, based on the belief that they play a minimal role in

[4] *Id.* at 55,702.

[5] *See id.* at 55,703–04.

patient care coordination or value-based arrangements would be short-sighted. As OIG acknowledges in the Proposed Rule, pharmaceutical companies, suppliers of DMEPOS, medical device companies, and laboratories offer a variety of technologies and programs that benefit care coordination.[6] Disallowing these entities from participating in VBEs under the proposed safe harbors would be a missed opportunity to expand protections for innovative patient care models. Failing to grant all types of health care entities protection under these new rules could chill future innovation in the move to value-based care, which would undermine the agency's main objective in proposing these revisions to the Anti-Kickback Statute safe harbors.

In the Proposed Rule, OIG states that its historical enforcement and oversight experience gives rise to its concern that pharmaceutical manufacturers, suppliers of DMEPOS, medical device companies, and laboratories might misuse the proposed safe harbors.[7] OIG provides examples of potential abusive behaviors that these entities could engage in, but does not explain whether or how its historical enforcement concerns are unique to these types of health care entities.

To prevent program abuse, we urge OIG to enhance the safeguards associated with the proposed safe harbors, such as by clearly prohibiting certain types of behavior, rather than limiting the types of entities that can receive safe harbor protection for appropriate, beneficial value-based arrangements.

PROPOSED VALUE-BASED SAFE HARBORS

Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency

In the Proposed Rule, OIG establishes a safe harbor to protect in-kind remuneration exchanged between qualifying VBE participants with value-based arrangements that satisfy certain requirements.[8] This safe harbor would include a requirement that the VBE participants establish evidence-based outcome measures related to patient care against which the recipient of remuneration would be measured. The Chamber supports this proposal.[9]

In particular, we agree with OIG's reasoning that the selected outcome measures should have a close nexus to the value-based activities of the value-based arrangement and the needs of the target patient population.[10] We would support an express requirement in the final rule that outcome measures be designed to drive meaningful improvements in quality, health outcomes, or

[6] *Id.* at 55,705.

[7] *Id.* at 55,703–05.

[8] *Id.* at 55,708.

[9] Additionally, OIG is considering whether or not to protect from Anti-Kickback Statute liability value-based arrangements and outcomes-based payments that include exclusivity requirements—i.e. requiring that a VBE participant is the exclusive provider of care coordination items or the exclusive provider of reimbursable items. *Id.* at 55,704, 55,706. The Chamber does not support such a position. Many arrangements may depend upon measurable quality improvements as a result of the use of a particular product or service (for example, a specific type of patient monitoring device). The Chamber does support a requirement that value-based arrangements that include product exclusivity must also permit the use of items that are deemed to be in the best interest of patients by a patient's provider.

[10] *Id.*

efficiencies in care delivery, as long as appropriate flexibility is granted to VBEs to design measures tailored to their specific value-based purposes.

OIG solicits comments on whether it should require VBE participants to rebase the outcome measures (*i.e.*, reset the benchmark used to determine whether the outcome measure was achieved) when feasible.[11] The Chamber encourages OIG to require participants to assess whether rebasing is feasible, and, if so, rebase the outcome measures, pursuant to a specified timeframe, such as every year. Rebasing will encourage VBEs to ensure that they continue to make meaningful improvements in patient care or cost of care delivery throughout the life of the enterprise. Rather than prescribing the timeframe, however, OIG should allow VBEs to determine how often rebasing would be appropriate given the specifics of the value-based arrangement. Importantly, if a VBE has already achieved optimal quality outcomes based on appropriate measures, it should not be required to further rebase those measures.

OIG proposes that this safe harbor would not protect remuneration funded by, or otherwise resulting from the contributions of, an individual or entity outside of the VBE.[12] The Chamber is concerned that this limitation could potentially prevent plan sponsors from making legitimate contributions to a value-based arrangement simply because they are not VBE participants. Accordingly, we recommend that this safe harbor protect remuneration from certain entities outside of the VBE, such as plan sponsors, with safeguards in place to protect against program abuse. Further, as described above, we urge OIG not to exclude any health care entities from the definition of VBE participant. All types of health care entities should be permitted to participate in a VBE, and thus exchange in-kind remuneration as appropriate under this proposed safe harbor.

The Chamber also supports OIG's proposal to require the recipient of in-kind remuneration under this safe harbor to contribute at least 15 percent of the offeror's cost. We agree with OIG that requiring financial participation by the recipient will make it more likely that the recipient will make full use of the care coordination items and services and promote the recipient's commitment to achieving the intended purpose of the value-based arrangement.[13] A financial contribution requirement incentivizes the recipient's full participation in the value-based arrangement.

Notably, however, we encourage OIG to allow health care providers with limited financial resources, such as rural providers, small providers, and providers that serve underserved populations, to be exempt from the contribution requirement or pay a lower contribution percentage. As OIG noted in the Proposed Rule, this approach would allow flexibility for parties with fewer financial resources to engage in value-based arrangements.[14]

The Chamber encourages OIG to coordinate with CMS on aligning the Anti-Kickback Statute regulatory framework as closely as possible to the Stark Law regulatory framework. The

[11] *Id.* at 55,708–09.

[12] *Id.* at 55,710.

[13] *Id.* at 55,711.

[14] *Id.*

Chamber also encourages OIG to make clear that upfront or initial investments in these types of value-based arrangements would also be protected from Anti-Kickback Statute liability.

Value-Based Arrangements with Full Financial Risk

OIG proposes to add a new safe harbor for VBEs that have assumed "full financial risk" for a target patient population.[15] OIG proposes that a VBE would be at full financial risk for the cost of care of a target patient population if the entity is "financially responsible for the cost of *all items and services* covered by the applicable payor for each patient in the target patient population and is prospectively paid by the applicable payor."[16] To truly incentivize innovation, we recommend that this safe harbor is broadened to also include VBEs that have assumed full financial risk for only a certain defined set of patient care items and services (*e.g.*, all costs associated with knee replacement surgery).

As proposed, the full financial risk safe harbor is too narrow—it will likely apply to only a small number of arrangements. Although this safe harbor will provide the appropriate protections for structures based on capitation payments or global budget payments, it will not offer protection for more limited arrangements in which VBE participants still take on full financial risk. Like broader arrangements, value-based payment models for a defined set of patient care services have the potential to improve the quality of patient care while reducing costs. They also carry a low risk of patient or program abuse by creating an incentive for providers to limit the volume of services provided. Accordingly, the full financial risk safe harbor should be broadened to value-based payment arrangements for a defined set of items or services.

Additionally, this safe harbor should only include minimum time periods that are appropriate for the defined set of patient care items and services that are at risk. For example, a value-based arrangement in which a provider takes on financial risk associated with all items and services required for a knee replacement could have a minimum time period of six months. Minimum time periods for a participant to take on full financial risk should be based on the target patient population and included items and services. Limiting the application of this safe harbor to a single minimum period of time applied across the board would impose an unnecessary obstacle to potentially beneficial innovation.

The Chamber supports OIG's proposal to protect value-based arrangements entered into in preparation for the implementation of the VBE's full financial risk payor contract where the VBE is contractually obligated to assume full financial risk but has not yet done so.[17] The Chamber urges OIG to provide this protection for at least one year prior to the assumption of full financial risk. This protection will allow VBE participants needed time to prepare for the assumption of full financial risk. The Chamber is concerned that a shorter period of time, such as six months, would be insufficient for participants to adequately prepare for the implementation of the arrangement and could hinder its success.

[15] *Id.* at 55,719.

[16] *Id.* (emphasis added).

[17] *Id.* at 55,720.

The Chamber supports OIG's proposal that "full financial risk" would not prohibit a VBE participant from entering into arrangements, such as reinsurance, to protect against catastrophic losses.[18] We encourage OIG to clarify that such arrangements are also allowed for entities who seek to satisfy the safe harbor for substantial downside financial risk. Reinsurance is an important mechanism through which VBE participants can become comfortable taking on downside financial risk. Further, VBEs should be permitted to source any reinsurance internally, as appropriate.

Lastly, the Chamber appreciates the coordination between OIG and CMS in developing this safe harbor and the corresponding Stark exception for full financial risk. The Chamber requests that OIG and CMS continue to work together to ensure maximum alignment between each of the proposed new safe harbors and exceptions. In particular, the Chamber is concerned that the differing proposed standards for assuming a threshold of downside risk—whether "substantial" or "meaningful"—will be confusing and will pose a potential barrier to greater engagement in VBAs. To the extent that OIG and CMS can simplify and align their terminology, the easier it will be for entities to take advantage of these new protections and enter into innovative arrangements to improve patient care.

Arrangements for Patient Engagement & Support to Improve Quality, Health Outcomes, and Efficiency

We support OIG's proposal to establish a new safe harbor for certain arrangements for patient engagement tools and supports furnished by VBE participants to improve quality, health outcomes, and efficiency.[19] However, the Chamber recommends that OIG permit pharmaceutical companies, suppliers of DMEPOS, pharmacy benefit managers, medical device companies, and others to participate and obtain protection under this safe harbor.

Excluding these entities from the definition of "VBE participant" and thus from the protections offered by this safe harbor will limit the provision of beneficial tools and supports to patients. Entities within these sectors currently offer valuable tools for patient engagement that improve the quality of patient care, including tools that encourage drug adherence. Furthermore, many of these health care entities are working to develop additional patient support tools that have the potential to improve care and reduce costs. By excluding them from eligibility for this safe harbor, OIG risks limiting patient access to valuable support and stifling innovation in this area.

Instead of excluding specific entities from the definition of "VBE participant," and thus protection under this safe harbor, OIG could prohibit specific behavior about which it has concerns (*e.g.*, inappropriately using patient engagement tools to market a product or diverting patients from a more clinically appropriate item or service).

If OIG declines to extend this safe harbor to pharmaceutical manufacturers, pharmacy benefit managers, suppliers of DMEPOS, and laboratories, we recommend that OIG develop alternative

[18] *Id.* at 55,720.

[19] While the Chamber is generally supportive of this proposal, we request that OIG provide additional information, including examples, regarding the types of patient engagement tools that would be included in this safe harbor.

safe harbors or other accommodations that allow these entities to contribute to and participate in value-based arrangements under the Anti-Kickback Statute.[20]

In the Proposed Rule, OIG solicits comment on whether the agency should require offerors to engage in reasonable efforts to retrieve an item or good furnished as a tool or support under certain circumstances, such as when the patient is no longer in the target patient population.[21] The Chamber urges OIG not to implement such a requirement. Once an item has been given to a patient, it should remain with the patient. It would be administratively difficult to retrieve items from patients at a later point in time. Furthermore, most of these tools do not carry a high dollar value. Accordingly, there is low risk that, without retrieval of the item, this safe harbor would be misused to protect inducements to beneficiaries that do not promote value.

Cybersecurity Technology & Related Services

We support the agency's proposal to create a new safe harbor to protect arrangements involving the donation of certain cybersecurity technology and related services, including the proposal to exclude hardware from the definition of "technology."[22] The Chamber urges OIG not to limit the types of entities that can make cybersecurity donations under this exception.[23] Such a restriction could stifle advances in patient care coordination or health information security in the future.

Furthermore, we encourage OIG to require that there be a clear nexus between the cybersecurity donation and the business relationship. In other words, the cybersecurity technology should be necessary for the provision of the services involved. For example, a hospital could be permitted to donate cybersecurity technology to a physician if it would secure the transfer of personal health information between the two entities and thus improve care coordination for shared patients. This exception should not allow cybersecurity technology to be used as a way to entice new business for entities providing services unrelated to information technology.

Clarify Protection for Tools to Monitor Quality and Outcomes

The Chamber urges OIG to clarify that the proposed safe harbors would include protections that would allow VBE participants to provide the enterprise or one another, at free or reduced cost, tools and infrastructure necessary to monitor quality and outcomes. These tools could include collection and analysis of data, software, equipment, information, and services reasonably necessary or appropriate for operationalizing the arrangement and optimizing the efficacy of the services subject to the arrangement.

Significantly, the HHS press release announcing the CMS and OIG proposed rules provided a number of examples of arrangements that could potentially be protected by the proposed value-

[20] We support the agency's suggestion that it may consider a future rulemaking to address protection for value-based and outcomes-based contracting for makers of pharmaceuticals and medical devices, and we encourage OIG to expedite any such future rulemaking, especially if it concludes that the present Proposed Rule excludes these industries from protection under the new value-based safe harbors. *See id.* at 55,704–05.

[21] *Id.* at 55,729.

[22] *Id.* at 55,733–39.

[23] *Id.* at 55,737.

based exceptions and safe harbors including "a specialty physician practice [ ] shar[ing] data analytics services with a primary care practice;" hospital-provided care coordinators and data analytics systems "to help physicians ensure that their patients are achieving better health outcomes;" hospital-provided remote monitoring technology to alert physicians when a patient needs healthcare intervention; dialysis facility-provided data analytics software to nephrologists "to help them monitor patients' health outcomes."[24] Unfortunately, these examples were not included in the Proposed Rule. The Chamber requests that OIG clarify that such tools and services may be eligible for protection under the finalized rule.

PROPOSED REVISIONS TO EXISTING SAFE HARBORS

Electronic Health Records Items & Services Safe Harbor

OIG proposed revisions to the existing safe harbor for certain arrangements involving the donation of interoperable electronic health records ("EHR") software or information technology and training services.[25] Specifically, among other things, the agency proposed to eliminate the safe harbor's sunset provision, which is currently set for December 31, 2021.[26] The Chamber supports this proposal.

We agree with the agency's conclusion that the continued availability of this safe harbor provides certainty with respect to the cost of EHR items and services for recipients and thus promotes EHR technology adoption. Furthermore, we agree with OIG's reasoning that the EHR safe harbor encourages EHR adoption by new physicians concerned about the cost of EHR technology and preserves the gains already made in the adoption of interoperable EHR technology.[27] We expect EHR items and services will continue to be of benefit to care coordination and efficiency for many years after 2021.

OIG also solicited comment on eliminating or reducing the 15 percent cost sharing requirement for small and rural practices or, alternatively, for all recipients.[28] We do not believe that OIG should eliminate this cost sharing requirement for all recipients—it serves as a reasonable safeguard to ensure recipients will use the EHR technology and thus reduces wasteful spending. However, the Chamber supports relieving this cost sharing requirement for small and rural practices, rural hospitals, disproportionate share hospitals, and other providers with demonstrable financial need.

Personal Services Safe Harbor

The Chamber supports OIG's proposed changes to the existing safe harbor for personal services and management contracts. Revising the requirement that "aggregate" compensation be set forth

[24] HHS Proposes Stark Law and Anti-Kickback Statute Reforms to Support Value-Based and Coordinated Care (Oct. 9, 2019) *available at* https://www.hhs.gov/about/news/2019/10/09/hhs-proposes-stark-law-anti-kickback-statute-reforms.html.

[25] *Id.* at 55,739–44.

[26] *Id.* at 55,741.

[27] *Id.* at 55,741–42.

[28] *Id.* at 55,743.

in advance so that only payment *methodology* must be set forth in advance, as well as eliminating the requirement that part-time contractual arrangements specify exact interval schedules, allows for greater flexibility in personal services arrangements while continuing to incorporate safeguards that limit potential abuse. Additionally, we appreciate OIG's efforts to implement modifications that align this safe harbor more closely with the personal services arrangements exception to the Stark law.

We also support OIG's proposal to protect outcomes-based payment arrangements in certain circumstances under this safe harbor.[29] However, we again oppose the exclusion of pharmaceutical manufacturers, pharmacy benefit managers, suppliers of DMEPOS, laboratories, or other health care entities from the protection of this safe harbor. Rather than excluding payments by these specific entities from the definition of "outcomes-based payment," OIG should deny protection under this safe harbor for specific behavior—such as using an outcomes-based payment to mask a kickback or to encourage the use of medically unnecessary items—no matter the type of entity involved. OIG should not preclude entire health care industries from participating in this important safe harbor.

The Chamber agrees with OIG that this safe harbor should require the parties to an arrangement to establish one or more specific evidence-based, valid outcome measures that the agent must satisfy to receive the outcomes-based payment.[30] We believe that it also is appropriate to require parties to regularly monitor and assess the agent's performance on each outcome measure, as well as to rebase the outcome measure periodically where feasible. As with our comments on the value-based safe harbors above, rather than prescribing the timeframe for rebasing, OIG should allow entities to determine how often rebasing would be appropriate given the specifics of the outcomes-based payment arrangement.

CONTINUED NEED FOR ADDITIONAL SUB-REGULATORY GUIDANCE

The Chamber requests that OIG issue additional sub-regulatory guidance, including frequently asked questions, regarding how the Anti-Kickback Statute safe harbors apply to common arrangements among health care entities. This guidance can help to address stakeholder questions and ease compliance burdens among members of the health care industry. Specifically, issuing robust and expeditious sub-regulatory guidance regarding the proposed new safe harbors could encourage participation in value-based arrangements by clarifying how the safe harbors apply and providing increased certainty regarding Anti-Kickback Statute protections. Trade associations and other industry organizations, such as the Chamber, could work with OIG to identify common arrangements upon which OIG could issue guidance. Timely and regularly updated sub-regulatory guidance would serve as a valuable resource for health care entities developing and engaging in novel arrangements aimed at reducing inefficiencies and improving patient care. Reliance exclusively on the advisory opinion process as a source of guidance,

[29] *Id.* at 55,745.

[30] *Id.* at 55,746.

however, would be insufficient as such opinions relate only to the requestors and can take excessive time to develop and release (in some cases, years).

CONCLUSION

The Chamber commends OIG's efforts to revise the Anti-Kickback Statute regulations to promote a transition to value-based care across the health care industry. With the modifications described herein, we believe the agency's proposals will foster innovative value-based arrangements that both improve patient outcomes and reduce costs.

Sincerely,

Katie Mahoney
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U.S. Chamber of Commerce