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December 31, 2019

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

VIA ELECTRONIC SUBMISSION

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 Principal Deputy Inspector General Chiedi:

The Medicare Rights Center (Medicare Rights) appreciates the opportunity to comment on the Office of the Inspector General's (OIG's) **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**. Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Medicare Rights provides services and resources to three million people with Medicare, family caregivers, and professionals each year.

### General Comments

Changes in the way Medicare providers deliver care are an important aspect of the switch to value-based care. The penalties for violating some current anti-kickback and self-referral laws and regulations can be severe, from criminal and civil monetary penalties (CMPs) to denial of participation in Medicare. It is possible that fear of these repercussions could potentially hamstring providers who seek innovative partnerships, incentives, or strategies to reduce costs and increase beneficiary engagement or adherence to treatment.

We are pleased the Office of the Inspector General (OIG) has included important consumer protections in the proposed provisions. Such protections can help to ensure that beneficiaries are not penalized through higher costs, underutilization, unnecessary care, or other circumstances that reduce the quality, accessibility,

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convenience, transparency, or affordability of their care. OIG appropriately acknowledges the need for smart design, robust oversight, and strict enforcement of beneficiary protections to ensure both the program and the people who need it are safe. Ultimately, people with Medicare suffer when loopholes and poor incentives are permitted.

### **III. PROVISIONS OF THE PROPOSED RULE: ANTI-KICKBACK STATUTE SAFE HARBORS**

#### **B. Proposed Value-Based Terminology (1001.952(ee))**

##### **1. Value-Based Enterprise (VBE)**

###### **c. Accountable Body**

OIG solicits comments on whether a Value-Based Enterprise (VBE) or its participants should be required to have a compliance program that covers at least those value-based arrangements for which safe harbor protection is sought and whether an accountable body or person should have responsibility for the compliance program. OIG also seeks comments on whether such an accountable body should be affirmatively recognized by all VBE participants who explicitly agree to cooperate with its oversight efforts, and whether such a body should be either independent or have a required duty of loyalty as a criterion of the definition of the body or as a safe harbor requirement.

We support these requirements. Because the arrangements protected by the proposed safe harbors would not have the benefit of programmatic oversight comparable to CMS-sponsored models, there is a need for oversight mechanisms to ensure such arrangements are aligned with value-based purposes and not misused for steering, stinting on care, providing care that is not medically necessary, or infringing on patient choice. We support this accountable body's specific oversight responsibilities including utilization of items and services, cost, quality of care, patient experience, adoption of technology, and the quality, integrity, privacy, and security of data related to the arrangement (such as outcomes, quality, and payment data), and we also support reporting requirements to ensure the bodies have access to and can verify VBE participant data.

The inclusion of an explicit agreement by all VBE participants will ideally eliminate disputes and confusion, and will provide written confirmation that the VBE has contemplated the need for such a body. In addition, we support establishing a duty of loyalty for the accountable body.

##### **3. Target Patient Population**

OIG proposes to define the target patient population using legitimate and verifiable criteria that are set out in writing to ensure the selection process is transparent and based on objective criteria. We support such a definition and are pleased that it will exclude arrangements that are facially discriminatory or that build cherry picking into the selection process. While no rule can completely eliminate this and other bad behavior, requiring objective criteria that are consistent with the goals of a properly structured value-based arrangement should help prevent it.

##### **4. Value-Based Activity**

OIG seeks comments on whether to interpret "reasonably designed" to mean that the value-based activities are expected to further the purpose of the arrangement based on an evidence-based process. OIG also is considering expressly excluding from the definition of "value-based activity" any activity that results in information blocking. We support these definitional requirements.

##### **6. Value-Based Purpose**

OIG solicits input on whether a value-based purpose for appropriately reducing the costs to or growth in expenditures of payors should include circumstances where this is achieved without reducing the quality of care for a target patient population, or whether it should only be so defined if there is improvement in patient quality of care or the parties are maintaining an improved level of care. We support the latter definition. A reduction in costs alone is not true value. The improvement of care should be the first priority and such improvement is less likely to involve underutilization or stinting on care.

**C. Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor (42 CFR 1001.952(ee))**

**1. Outcome Measures**

OIG proposes to require that parties to a value-based arrangement establish one or more specific evidence-based, valid outcome measures against which the recipient of remuneration will be measured, and which the parties reasonably anticipate will advance the coordination and management of care of the target patient population. OIG is also considering an express requirement that outcome measures be designed to drive meaningful improvements in quality, health outcomes, or efficiencies in care delivery, not a nominal improvement. We support this proposal and encourage OIG to include the express requirement for meaningful improvements. This would maintain options for VBE participants without creating a free-for-all environment with no objective measurement or criteria.

OIG also proposes that the parties to the arrangement be required to include a description of the outcome measure(s) in a signed writing, and that the accountable body monitor and assess the recipient's progress toward achieving the outcome measure. If there is no progress or there are material deficiencies in quality of care, the parties must terminate the arrangement. We support the requirement that there be a signed writing that lays out the applicable outcome measures, and that the accountable body must monitor progress. We suggest that there should be a distinction between arrangements that are not making progress and those that are causing harm. The former may be permitted to terminate within 60 days. The latter should be terminated immediately upon determination that there is harm.

**2. Commercial Reasonableness**

OIG proposes to require that value-based arrangements are commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE. We support this requirement.

**3. Writing**

OIG proposes a requirement that any value-based arrangement be set forth in a writing to include the value-based activities to be undertaken by the parties to the value-based arrangement; the term of the value-based arrangement; the target patient population; a description of the remuneration; the offeror's cost for the remuneration; the percentage of the offeror's costs contributed by the recipient; if applicable, the frequency with which the recipient will make payments for ongoing costs; and the specific evidence-based, valid outcome measures against which the recipient would be measured. We support this requirement, along with the requirement that the writing include an affirmative recognition of the oversight role of the established accountable body, and an explicit agreement to cooperate with its oversight efforts, plus reporting requirements for their VBE participants or mechanisms for obtaining access to, and verifying, VBE participant data concerning performance under any value-based arrangement.

**4. Limitations on Remuneration**

**a. In-Kind Remuneration**

OIG proposes, under this safe harbor, to protect only in-kind, non-monetary remuneration. We support this limitation. Monetary remuneration creates additional risk of fraud, abuse, steering, and other negative consequences.

**b. Primarily Engaged in Value-Based Activities**

OIG proposes that any remuneration provided by, or shared among, VBE participants be used primarily to engage in value-based activities that are directly connected to the coordination and management of care of the target patient and should not include the making of a referral. We support this proposal.

**c. No Furnishing of Medically Unnecessary Items or Services or Reduction in Medically Necessary Items or Services**

OIG proposes to require that the remuneration exchanged not induce the parties to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient. We strongly support these proposals and consider any inducement for over- or underutilization to be contrary to the goals of this rule, as well as to the Medicare program.

**d. No Remuneration From Individuals or Entities Outside the Applicable VBE**

OIG proposes that the safe harbor not protect any remuneration funded by, or otherwise resulting from, the contributions of an individual or entity outside of the applicable VBE. We support this limitation.

**5. The Offeror Does Not Take Into Account the Volume or Value of, or Condition Remuneration on, Business or Patients Not Covered Under the Value-Based Arrangement**

OIG proposes to exclude safe harbor protection for any remuneration that is explicitly or implicitly offered, paid, solicited, or received in return for, or to induce or reward, any referrals or other business generated outside of the value-based arrangement. Alternatively, OIG is considering a requirement that the aggregate compensation paid by the offeror not be determined in a manner that takes into account the volume or value of referrals or business generated between the parties for which payment may be made by a federal health program. We support the latter proposal as a better beneficiary protection.

**7. Requirements of a Value-Based Arrangement**

**a. Direct Connection to the Coordination and Management of Care**

OIG proposes that the value-based arrangement exclude remuneration to receive referrals or to be included in a “preferred provider network” (i.e., “pay-to-play” arrangements). We support this limitation.

**b. No Limitation on Decision Making; Restrictions on Directing or Restricting Referrals**

OIG proposes that value-based arrangements not limit parties’ ability to make decisions in the best interests of their patients and that VBE participants maintain their independent, medical, or other professional judgment. OIG also proposes that value-based arrangements not direct or restrict referrals if a patient expresses a preference for a different practitioner, provider, or supplier; the patient’s payor determines the provider, practitioner, or supplier; or such direction or restriction is contrary to applicable law or regulations. We support these exclusions and urge OIG to provide consumer-tested templates for VBEs to communicate with patients that they retain their rights to choose providers.

**c. No Marketing of Items or Services or Patient Recruitment Activities**

OIG proposes to exclude safe harbor protection for value-based arrangements that include marketing items or services to patients or patient recruitment activities. Specifically, OIG would restrict any party to a value-based arrangement, or such party's agent, from marketing or engaging in patient recruitment activities related to any items or services offered or provided to patients in the target patient population under a value-based arrangement. We strongly support this proposal. Beneficiaries must not find themselves targeted by marketing attempts to sway their choice of provider.

## **8. Monitoring and Assessment**

OIG proposes to require a VBE or the VBE's accountable body to monitor and assess the coordination and management of care for the target population in the value-based arrangement, any deficiencies in the delivery of quality care under the value-based arrangement, and progress toward achieving the evidence-based, valid outcome measures. We support this requirement and urge that the monitoring include utilization, referral patterns, and expenditure data to ensure that abuse is curtailed and gaming reduced. We again urge OIG to separate out arrangements that are failing to provide improved care from those that are resulting in material deficiencies in quality of care. The latter must be terminated as soon as possible to ensure that beneficiaries are not being harmed. While remediation may be permissible for arrangements that are failing to improve care, it must not be permitted for material deficiencies.

OIG is consider requiring VBEs to submit certain data to the Department that would identify the VBE, VBE participants, and value-based arrangements, as a requirement for safe harbor protection. We support this requirement to ensure that VBEs are held accountable. This reporting should include the formal writings establishing the VBE and should be used by the Department to assess VBE arrangements, including trends, outlier utilization, or demographics that may point to cherry picking or steering.

## **10. Materials and Records**

OIG proposes that the VBE make available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this safe harbor and seeks comments on requiring parties to maintain materials sufficient to establish compliance with the conditions of this safe harbor for a set period of time. We support this proposal and urge a set period of time for record retention of at least 6 years.

## **11. Possible Additional Safeguards**

### **a. Bona Fide Determination**

OIG is considering requiring two bona fide determinations with respect to the value-based arrangement of the VBE's accountable body. We support this requirement.

### **b. Cost-Shifting Prohibition**

OIG seeks comments on prohibiting VBEs or VBE participants from billing federal health care programs, other payors, or individuals for the remuneration; claiming the value of the remuneration as a bad debt for payment purposes under a Federal health care program; or otherwise shifting costs to a federal health care program, other payors, or individuals. We support such a prohibition. The VBE's decision to offer remuneration in the context of the arrangement should not put other parties on the hook for such payments.

## **D. Value-Based Arrangements With Financial Risk (1001.952(ff))**

OIG proposes that the remuneration must not induce limitations on, or reductions of, medically necessary items or services furnished to any patient and is considering for the final rule additional conditions to safeguard against risks of cherry-picking patients, which could affect the quality of care patients receive. We very strongly support

forbidding remuneration that encourages or induces stinting on care and cherry picking or steering of beneficiaries.

Where we have supported proposals and considerations above, we explicitly incorporate that support for value-based arrangements with financial risk. We again urge the creation of an accountable body; a clear writing about that body, including an agreement to cooperate with oversight; an immediate dissolution of the arrangement if material harm is occurring; and templates laying out beneficiary rights to choice of provider.

### **E. Value-Based Arrangements With Full Financial Risk (1001.952(gg))**

OIG proposes that remuneration exchanged must: be used primarily to engage in the value-based activities set forth in the parties' signed writing; be directly connected to one or more of the VBE's value-based purpose(s), at least one of which must be the coordination and management of care for the target patient population; and not induce the VBE or VBE participants to reduce or limit medically necessary items or services furnished to any patient. We support these requirements.

Where we have supported proposals and considerations above, we explicitly incorporate that support for value-based arrangements with full financial risk. We again urge the creation of an accountable body; an explicit writing about that body, including an agreement to cooperate with oversight; an immediate dissolution of the arrangement if material harm is occurring; and templates laying out beneficiary rights to choice of provider.

OIG proposes to require that the VBE provide or arrange for an operational utilization review program and a quality assurance program that protects against underutilization and specifies patient goals, including measurable outcomes, where appropriate. We support this proposal.

### **F. Arrangements For Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency (1001.952(hh))**

#### **1. Limitations on Offerors**

OIG proposes to limit safe harbor protection to VBE participants. We agree with this proposal because of the protections, assurances, and writings that are to be required from VBE participants.

#### **3. Limitations on Type of Remuneration**

OIG proposes to limit a patient engagement "tool or support" to in-kind, preventive items, goods, or services, or items, goods, or services excluding gift cards, cash, and any cash equivalent. We support this limitation. Monetary benefits for beneficiaries are especially fraught with risk that could be used to commodify health services in an inappropriate way. Many Medicare beneficiaries live on fixed or low incomes and may not perceive monetary-type incentives as optional. For people with chronic conditions, incentives or discounts that accrue for provider visits, for example, could add up quickly into sums that patients might not feel they can afford to miss.

##### **a. Cash and Cash Equivalent Incentives**

OIG identifies significant concerns with allowing providers to offer cash or cash equivalents to patients, including identify theft, inappropriate utilization, and improper steering. OIG seeks comments on whether to protect patient incentives and supports in the form of cash and cash equivalents in certain circumstances. We strongly oppose this idea. As we note above, monetary incentives can quickly become coercive for patients who have low or fixed incomes, which would include many Medicare beneficiaries. For people with multiple provider touchpoints, such incentives or discounts could add up quickly into sums that patients might not feel they can afford to miss.

##### **b. Waiver or Reduction of Cost-Sharing Obligations**

OIG seeks comments on offering reduced cost-sharing protections under certain circumstances. While these waivers are less troubling than cash incentives, we still urge caution because of the potential for steering and cherry picking.

#### **c. Gift Cards**

OIG is considering whether to include protection for gift cards in limited circumstances for the purpose of effecting behavioral change. As with cash incentives, we urge extreme caution when it comes to gift cards, which similarly have the potential to unduly coerce some beneficiaries.

### **4. Additional Proposed Conditions**

#### **a. Furnished Directly to the Patient**

OIG seeks comments on whether the VBE should be required to provide a written notice describing the remuneration's source and purpose. If such a notice is required, we urge OIG to consider the development of consumer-tested templates to convey this information in an objective, easily understood way that will not mislead beneficiaries or create false expectations or reliance on incentives.

#### **b. Funding Limitations**

OIG proposes to prohibit the VBE from using third parties to fund its patient engagement tools, supports, or both. We support this limitation as a necessary check on steering and undue influence.

#### **c. Prohibition on Marketing and Patient Recruitment**

OIG seeks comments on preventing remuneration from being used for patient recruitment or for the marketing of items or services to patients. We strongly support this prohibition. VBEs must not be permitted to use these incentives to lure patients.

#### **d. Direct Connection**

OIG seeks comment on allowing the tool or support furnished to the patient to have a "reasonable connection" rather than a "direct connection" to the coordination and management of care for the patient. We do not support this change and urge that the value-based purpose of the tool or support have a direct connection specifically to the coordination and management of the patient's care.

#### **e. Medical Necessity**

OIG proposes that the tool or support furnished to the patient must not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a federal health care program. We strongly agree.

#### **f. Nature of the Remuneration**

OIG seeks comments on including safeguards that require VBEs to demonstrate and document the desired adherence to a treatment regimen, adherence to a drug regimen, adherence to a follow-up care plan, management of a disease or condition, improvement in measurable health outcomes, or patient safety; and a monitoring requirement to ensure that the patient engagement tools and supports do not result in diminished quality of care or patient harm. We strongly support these considerations as they are necessary to protect beneficiary safety, health, and well-being.

#### **j. Materials and Records**

OIG seeks comments on requiring that VBE participants retain materials and records sufficient to establish compliance with the conditions of this safe harbor for a set period of time. We support this requirement.

## **5. Potential Safeguards**

### **a. Prohibition on Cost-Shifting**

OIG seeks comments on prohibiting VBEs or VBE participants from billing federal health care programs, other payors, or individuals for the remuneration; claiming the value of the remuneration as a bad debt for payment purposes under a federal health care program; or otherwise shifting costs to a federal health care program, other payors, or individuals. We support such a prohibition. The VBE's decision to offer remuneration in the context of the arrangement should not put other parties on the hook for such payments.

### **b. Consistent Provision of Patient Incentives**

OIG seeks comment on whether to require VBE participants to provide the same patient engagement tools or supports to an entire target patient population or otherwise consistently offer tools and supports to all patients satisfying specified, uniform criteria. We support the inclusion of this requirement. This would eliminate some forms of gaming and allow beneficiaries to better understand their eligibility for supports.

### **e. Advertising**

OIG seeks comments on a condition that would prevent the VBE participant from publicly advertising the patient engagement tool or support to patients or others who are potential referral sources. This would prohibit advertising in the media or posting information for public display or on Web sites about the availability of free items or services. We strongly support this prohibition.

### **c. Monitoring Effectiveness**

OIG seeks comments on requiring VBE participants to use "reasonable efforts" to monitor the effectiveness of the tool or support in achieving the intended coordination and management of care for the patient and on requiring the VBE or the VBE participant to have policies and procedures in place to address any identified material deficiencies. We strongly urge OIG to include such requirements and to have a stringent oversight practice as well as a very short time frame to end programs that are causing patient harm.

### **L. Local Transportation (1001.952(bb))**

OIG proposes to modify the existing safe harbor for local transportation to expand the distance which residents of rural areas may be transported and to remove any mileage limit on transportation of a patient from a health care facility from which the patient has been discharged to the patient's residence. We support these modifications. Rural residents face unique risks regarding access to care due to lack of transportation, but even beneficiaries in non-rural areas should have access to safe, reliable transportation to ensure they can access appropriate care.

## **Conclusion**

The importance of protections against steering, stinting on care, and other forms of inappropriate medical decision-making cannot be overstated. Because of this, we urge OIG and all of HHS to investigate closely any proposed changes for their potential to burden or unduly influence people with Medicare. We look forward to working together to advance policies that consider and balance the needs of all stakeholders while promoting high-value and high-quality care. For additional information, please contact Lindsey Copeland, Federal Policy Director at [LCopeland@medicarerights.org](mailto:LCopeland@medicarerights.org) or 202-637-0961 or Julie Carter, Senior Federal Policy Associate, at [JCarter@medicarerights.org](mailto:JCarter@medicarerights.org) or 202-637-0962.



Sincerely,

A handwritten signature in black ink that reads "Lindsey Copeland". The signature is written in a cursive style with a small flourish at the end.

Lindsey Copeland  
Federal Policy Director  
Medicare Rights Center