



December 23, 2019

Joanne M. Chiedi
Acting Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Ave, SW Washington, DC 20201

RE: OIG-0936-AA10-P. Comments on Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements.

Dear Acting Inspector General Chiedi:

The Center for Health Law and Policy Innovation of Harvard Law School (“CHLPI”) appreciates the opportunity to provide comments on the proposed revisions to safe harbors under the Anti-Kickback Statute (“AKS”) and the Civil Monetary Penalty (“CMP”) rules regarding beneficiary inducements. We commend the Office of Inspector General, Department of Health and Human Services (“HHS OIG”) on its initiative to modernize regulations in a manner that recognizes the importance of and seeks to facilitate social determinants of health interventions.

CHLPI advocates for legal, regulatory, and policy reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic illnesses. CHLPI’s Health Law Lab explores, analyzes, and nurtures innovations that address social determinants of health, and examines the legal, regulatory, and policy implications of integrating these interventions into health care delivery and financing. The Health Law Lab divines and disseminates lessons and best practices from health care providers, payers, coalitions, and community-based organizations who are developing and implementing exciting new innovations that make our health system more equitable, outcome-driven, and cost-effective.

We agree with the HHS OIG that “the broad reach of the Federal anti-kickback statute...the “beneficiary inducements CMP,” and...the Stark law...potentially [inhibits] beneficial arrangements that would advance the transition to value-based care and improve the coordination of patient care among providers and across care settings in both the Federal health care programs and commercial sectors.”¹ We have examined these issues as we work to enable collaborations between health care entities and community-based or other external partners that address health-related social needs and broader social determinants of health. We can confirm that uncertainty around the application of anti-kickback, CMP, and Stark provisions to various arrangements and endeavors has a chilling effect on innovation. In some cases, new collaborations that would have, for example, addressed food insecurity among patients with diet-related chronic disease, have been stalled or halted altogether out of an abundance of caution. As noted by HHS OIG, the proposed collaborations, similar to the ones described in these revisions in many respects, may in fact “be protected under existing safe harbors or exceptions to the definition of “remuneration”

¹ Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 84 Fed. Reg. 55694, 55695 (proposed Oct. 17, 2019) (to be codified at 42 C.F.R. § 1001.952).

under the beneficiary inducements CMP.”² However, without more explicit acknowledgement that these arrangements are permitted and given the significant consequences that can result from violation of these laws, health care entities are understandably cautious in green-lighting new endeavors – especially when it comes to actions that address social determinants of health, where the application of the current regulatory regime is least understood.

We believe these proposed revisions will, in addition to enabling more coordinated care overall, encourage more health care entities to address social determinants in their value-based care arrangements. As the rule is finalized, we encourage HHS OIG to consider three guiding principles that are critical to enabling innovation while maintaining safeguards against fraud and abuse.

A. Regulations must recognize the central role of community-based organizations (“CBOs”) in addressing the social determinants of health and facilitate partnerships between health care providers and such entities.

CBOs, such as food banks and housing assistance programs, bring critical expertise, infrastructure, and other capabilities to effective interventions that address social determinants of health. HHS OIG should consider and explicitly address how the safe harbor, and the resulting protection from liability under the beneficiary inducements CMP, affects arrangements between health care providers and such entities. Value-based enterprises (VBEs) that are choosing their target patient populations based either on geographic region or chronic disease state will want to contract with CBOs and other external partners who have expertise and cultural competence in addressing the needs of these particular patients. While it seems that social service organizations are contemplated as potential VBE participants,³ we urge HHS OIG to provide some concrete examples of the role these entities would play in a VBE (assuming that all other requirements for meeting the safe harbor are met).

B. Regulations must enable local solutions to local needs. Interventions to address social determinants of health, like health care, require flexibility to respond to individual and local needs. HHS OIG notes that it seeks “public input on which social determinants are most crucial to improving care coordination and transitioning to value-based care and payment” and “how the final safe harbor should make distinctions among the categories of social determinants, such as protecting some types of tools and supports but not others.”⁴ These types of parameters will inevitably limit innovative and effective interventions to improve health outcomes—and unnecessarily so. Certain other conditions and safeguards proposed, such as the monetary cap and the requirement that supports advance specifically enumerated goals,⁵ lend themselves to a sufficiently targeted intervention and limit the risk of harm associated with a safe harbor that otherwise permits health care providers to address a broad range of unmet health-related social needs with a more flexible toolkit.

However, in the event HHS OIG decides to enumerate a list of social determinant interventions that are most crucial to improving care coordination and transitioning to value-based payment, we suggest explicitly including protection for specific tools and supports and then providing additional flexibility for protection of other services where there is evidence to suggest efficacy of meeting the projected outcome measure for the

² *Id.* at 55708.

³ *Id.* at 55703.

⁴ *Id.* at 55724.

⁵ *Id.* at 55727-28.

target population. With respect to the types of social determinants interventions that should explicitly be protected, we suggest at least the list of services that are included in “allowable uses” of the Massachusetts Medicaid’s Delivery System Reform Incentive Payment Flexible Services Program (broadly divided into Nutrition Sustaining Supports and Tenancy Preservation Supports).⁶

C. Each condition/safeguard put in place as part of the patient engagement and support safe harbor must be nuanced as necessary and appropriate for supports to address the social determinants of health, especially as pertaining to advertising and monetary caps.

There is – or should be – a difference between advertising/marketing and the provision of targeted education/necessary and useful information for patients. A blanket prohibition against advertising⁷ creates a greater barrier to care coordination in an arrangement to provide access to nutritious food through an onsite food pantry—in which, at a minimum, information such as pantry hours of operation must be easily accessible—than an arrangement that involves providing patients with a smart watch.⁸ HHS OIG should also ensure that provisions in the final rule leave enough flexibility that patients can make an informed choice about their care. Patients should be able to understand how their providers are pursuing value and good patient outcomes. Even if a particular service should not be “advertised,” providers should retain the ability to inform patients of the types of social determinant interventions they are using to achieve the best possible patient care, and related items/services available to support patients in achieving improved health outcomes.

With respect to monetary caps for patient engagement tools,⁹ such caps should be dependent on the type of service. A per-occurrence limitation of \$100 would be more appropriate for a tool or service that support needs that are likely to recur (e.g. nutrition needs), but might limit the effectiveness of an arrangement to support a patient who experiences housing instability.¹⁰

We also encourage HHS OIG, as it experiments in this important space, to be cautious of creating opportunities at the exclusion of others, and to clarify that any safe harbor regarding supports to address the social determinants of health will not negatively impact analyses under other AKS safe harbors and exceptions to the beneficiary inducements CMP. In finalizing the local

⁶ Performance Year 3 (PY3) Delivery System Reform Incentive Payment (DSRIP) Flexible Services (FS) Program Guidance Document for MassHealth Accountable Care Organizations and MassHealth Community Partners, Version 1.0 (last revised Aug. 1, 2019), MASS. EXEC. OFFICE OF HEALTH & HUMAN SRVS.

⁷ Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 84 Fed. Reg. 55694, 55730 (proposed Oct. 17, 2019) (to be codified at 42 C.F.R. § 1001.952).

⁸ Zealous compliance with prohibitions on advertising and marketing is a barrier to the provision of basic information to patients, negatively impacting the coordination of and participation in social determinants of health interventions. HHS OIG seemed to recognize this challenge in finalizing the local transportation safe harbor, 42 C.F.R. § 1001.952(bb), which expressly carves out the basic activity of posting necessary route and schedule details from the condition that a shuttle service is not marketed or advertised.

⁹ Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 84 Fed. Reg. 55694, 55728 (proposed Oct. 17, 2019) (to be codified at 42 C.F.R. § 1001.952).

¹⁰ *Id.* at 55729.

transportation safe harbor, HHS OIG portrayed the safe harbor—meeting the conditions set forth thereunder—as paramount. In discussing the beneficiary inducements CMP exception for arrangements that promote access to care and pose a low risk of harm, HHS OIG commented that “[t]his exception should be read in the context of those more specific exceptions and safe harbors.... We have set out conditions in the anti-kickback statute safe harbor for local transportation that we believe are necessary for such transportation to be ‘low risk.’ If a local transportation arrangement did not meet the requirements of the safe harbor (e.g., it would be long-distance transportation, or transportation that is advertised), it would be unlikely to be low risk under this exception.”¹¹ Only a few years later, HHS OIG is considering expansive revisions to the local transportation safe harbor.¹²

In addition to encouraging HHS OIG to finalize the rule in accordance with these principles, we make the following specific comments on smaller points within the proposed rule:

1. **Definition of target population:** HHS OIG has solicited comments on whether it should limit the definition of “target patient population” to patients with a chronic condition.¹³ We believe the definition should not be limited in this way. Pregnant or new mothers, for example, would be excluded from this definition, but are a population that could certainly benefit from more coordinated care. HHS OIG should also not limit the definition to “patients with a shared disease state that would benefit from care coordination.”¹⁴ This definition is also too narrow. Some VBEs may reasonably want to target, for example, all patients with a number of different conditions who had two or more Emergency Room visits in the past few months.
2. **Vouchers satisfy the in-kind requirement:** We strongly support the proposal that a voucher for a particular tool or support, such as a meal or transportation voucher, would satisfy the in-kind requirement under the proposed safe harbor for patient engagement and support arrangements.¹⁵ This flexibility supports partnerships between health care providers and CBOs by permitting a CBO to provide the support itself to a patient.
3. **Pharmacies as VBE participants:** HHS OIG has solicited comments on whether pharmacies should be excluded from the definition of VBE participants.¹⁶ We believe that, in some cases, it may be appropriate for a pharmacy to be a VBE participant. Pharmacies are an important point of care in many communities for reasons including that they may be the most geographically accessible provider and that they may offer the most flexible hours. In addition to dispensing items (primarily medications), pharmacies are increasingly becoming hubs of other services, such as nutrition and disease self-management education. Accordingly, pharmacies can be an effective—and essential—partner in patient engagement and support activities. Under proposed conditions, however, it seems that a pharmacy would have to be a VBE participant in order to be the entity that dispenses, for example, a meal voucher. A blanket exclusion of pharmacies

¹¹ Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368, 88390-91 (Dec. 12, 2016).

¹² Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 84 Fed. Reg. 55694, 55750 (proposed Oct. 17, 2019) (to be codified at 42 C.F.R. § 1001.952).

¹³ *Id.* at 55702.

¹⁴ *Id.*

¹⁵ *Id.* at 55694, 55724.

¹⁶ *Id.* at 55704.

from eligibility as a VBE participant therefore undermines both access to these interventions and care coordination.

4. **Care management and remote monitoring cost-sharing waivers:** HHS OIG has solicited comment on whether there should be safe harbor protections for waiving cost-sharing amounts for care management and remote monitoring.¹⁷ We believe there should be safe harbor protections for such waivers; we have heard from partners that patients have in some cases refused to allow their providers to engage in services that do not take place during in-person visits or from which they do not see immediate benefit due to cost-sharing. Cost-sharing waivers for such activities, therefore, can enable more effective care coordination and promote good outcomes for patients by enabling providers to engage in critical case management and remote monitoring activities.

5. **Determination of financial need:** HHS OIG proposes that the aggregate retail value of a patient engagement tools or supports may exceed \$500 per year if “furnished to a patient based on good-faith, individualized determination of the patient’s financial need.”¹⁸ We suggest that use of validated social need screening tools that pertain to the appropriateness of a potential patient engagement tool or support is a reasonable method to satisfy the determination of financial need. The Hunger Vital SignTM, for example, is a validated tool for identifying risk for food insecurity among youth, adolescents, and adults.¹⁹ The two-question tool is widely used among health care providers and community-based organizations. Together with similar screening tools relating to housing, transportation, and utility help needs, the Hunger Vital SignTM was incorporated into the Centers for Medicare and Medicaid Services’ Accountable Health Communities Screening Tool in 2017.²⁰ The Hunger Vital SignTM should therefore be recognized as a valid way to determine financial need with respect to a patient who has a need for nutrition-related support.

6. **Proposed revisions to the transportation safe harbor:** CHLPI commends HHS OIG’s initiative to modify the local transportation safe harbor.²¹ Each year, millions of Americans encounter transportation barriers that prevent them from accessing the medical and non-medical services they need to heal and thrive. As a result, these individuals may struggle to prevent or manage serious health conditions, resulting in worsening health outcomes and rising health care costs. The local transportation safe harbor has the potential to encourage innovative solutions to this pernicious issue; we strongly support HHS OIG’s proposal to relax existing restrictions through, among other revisions, eliminating the mileage limit on transportation for discharged patients.

With respect to rural mileage limits, transportation-related barriers to care are especially acute in rural areas and we do not believe that the objectives of the safe harbor would be furthered by imposing a demonstration of need requirement to protect transportation in

¹⁷ *Id.* at 55725.

¹⁸ *Id.* at 55728.

¹⁹ See Erin R. Hager et al., *Development and Validity of a 2-Item Screen to Identify Families at Risk for Food Insecurity*, 126 PEDIATRICS 26-32 (2010).

²⁰ See Alexander Billioux et al., *Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool*, NAT’L ACAD. OF MED. PERSP. 1-9 (2017).

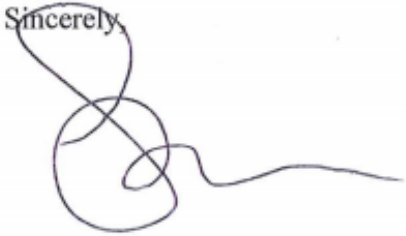
²¹ Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 84 Fed. Reg. 55694, 55750 (proposed Oct. 17, 2019) (to be codified at 42 C.F.R. § 1001.952).

excess of current mileage limits. In the event, however, that HHS OIG determines it necessary to impose such a condition, HHS OIG should recognize a range of assessment tools, including tools validated to screen for transportation needs (such as that incorporated in the Accountable Health Communities Screening Tool and the PRAPARE assessment tool).²²

Finally, we encourage expansion of the safe harbor to protect transportation to non-medical services in a manner consistent with our other comments set forth above. Comprised of relatively straightforward conditions, explicit protection for transportation to a series of specific, clearly defined services within this safe harbor would facilitate the adoption of such arrangements to the benefit of vulnerable patients across the country.

Again, we appreciate HHS OIG's recognition of the value in addressing social determinants of health as part of the Regulatory Sprint to Coordinated Care. Protections for arrangements that support social determinants have the potential to profoundly impact federal health care program beneficiaries and others, and to help health care providers succeed in achieving value-based care. We would be happy to work with HHS OIG to incorporate CHLPI's guiding principles and other comments provided above.

Sincerely,

A handwritten signature in blue ink, appearing to be 'Sarah Downer', written over the word 'Sincerely,'.

Sarah Downer
Associate Director, Whole Person Care
Clinical Instructor

on behalf of

The Center for Health Law and Policy Innovation
Harvard Law School
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²² For more information about the PRAPARE assessment tool, please visit: <http://www.nachc.org/research-and-data/prapare/>.