The National Alliance to Impact the Social Determinants of Health

AN ALLIANCE CONVENED BY LEAVITT PARTNERS

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

INTRODUCTION

On behalf of the National Alliance to Impact the Social Determinants of Health (NASDOH), we commend the Department of Health and Human Services (HHS) for addressing the social determinants of health (SDOH) in the Regulatory Sprint to Coordinated Care. We are pleased to provide comments on the Office of Inspector General (OIG)'s proposed rule (NPRM) to revise the safe harbor protections under the Federal antikickback statute.

NASDOH is a group of stakeholders co-convened by former HHS Secretary Mike Leavitt and Dr. Karen DeSalvo, working to systematically and pragmatically build a common understanding of the importance of addressing social needs as part of an overall approach to health improvement. NASDOH brings together health care, public health and social services expertise, local community experience, community-convening competence, business and financial insight, technology innovation, data and analytics competencies, policy and advocacy acumen to assess and address current regulatory frameworks, funding environments and opportunities, and practical challenges to implementing and sustaining social determinants of health efforts. We seek to make a material improvement in the health of individuals and communities and, through multi-sector partnerships throughout the nation, advance holistic, value-based, person-centered health care that can successfully impact the social determinants of health.

We commend your objective to "remove potential barriers to more effective coordination and management of patient care and delivery of value-based care that improves quality of care, health outcomes, and efficiency".[1] One of the guiding principles of NASDOH is the belief that "Successfully transforming to a value-based health care system requires care and payment models that address the social determinants of health."[2] NASDOH co-conveners Leavitt and DeSalvo wrote "While there is increasing awareness that what creates health is more than clinical excellence, there is still much work to do. Just like examining social well-being shifted economics, we believe addressing social determinants of health will continue to transform the delivery of healthcare and improve health.[3]

NASDOH appreciates the ongoing efforts of HHS to address social determinants through Medicare Advantage Supplemental Benefits for Chronically Ill Enrollees, Medicaid flexibility, potential Innovation Center pilot projects,

[1] 84 FR 55694
[2] http://www.nasdoh.org/about-us/#guiding-principles
[3] https://www.modernhealthcare.com/article/20170923/NEWS/170929957/guest-commentary-value-based-care-s-success-hinges-on-attention-to-social-determinants

and other approaches. We believe the inclusion of safe harbors that have the potential to protect interventions to address the social determinants of health from violations under the Federal anti-kickback statute is an important next step.

NASDOH agrees with the OIG that increased regulatory flexibility could increase the risk of harms associated with fraud and abuse and supports adequate safeguards to protect program integrity.

For all the safe harbors mentioned below, NASDOH members believe that the OIG should issue sub-regulatory guidance (without the need for a formal Advisory Opinion) to provide needed clarity to encourage more providers and health plans to participate in activities to address SDOH. We recommend that the OIG expedite and regularly update "Frequently Asked Questions" (FAQ) documents in response to recurrent questions regarding common provider and health plan circumstances.

RESPONSES

In this document, we offer a perspective based on the multi-sectoral viewpoints from NASDOH as we respond specifically to your questions related to the social determinants of health within three specific safe harbors:

1. The proposed new safe harbor (1001.952(hh)) for certain tools and supports furnished under patient engagement and support arrangements to improve quality, health outcomes, and efficiency;
2. The proposed new safe harbor (1001.952(ii)) for certain remuneration provided in connection with a CMS-sponsored model, which should reduce the need for OIG to issue separate and distinct fraud and abuse waivers for new CMS sponsored models; and
3. The proposed modifications to the existing safe harbor for local transportation (1001.952(bb)) to expand and modify mileage limits for rural areas and for transportation for discharged patients.

1. Patient Engagement and Support Safe Harbor

The NPRM includes a proposed new safe harbor to protect "***tools or supports"*** provided by a "***VBE participant"*** to a patient in the "***target patient population"***.[4] As proposed, this new safe harbor has the potential to cover a number of interventions to address the social determinants of health when performed by a member of a network of individuals and entities that collaborate together to achieve one or more value-based purposes, known as a "value based enterprise" or "VBE". The extent to which this proposed safe harbor will spur additional activity to address social needs will depend in part on how several definitions are resolved in the final rule.

"Tools or supports"

As proposed in 1001.952(hh)(3)(i), (ii) and (iii), the NPRM would limit a patient engagement ***"tool or support"*** to in-kind, preventive items, goods, or services, or items, goods, or services such as health-related technology, patient health-related monitoring tools and services, or ***supports and services designed to identify and address a patient's social determinants of health***, that have a direct connection to the coordination and management of care of the target patient population.[5]

NASDOH agrees with the OIG's assertion that "Evidence indicates that efforts that target home and neighborhood-level factors, such as healthcare accessibility for low-income individuals, physical and environmental obstructions to healthy living, and housing and case management, can lead to improved health

[4] 84 FR 55694
[5] Ibid.

outcomes for people of all ages. These improved health outcomes include decreased mortality, delay or prevention of preventable and chronic diseases, and lowered healthcare utilization, indicating a higher quality of life."[6] NASDOH also agrees that addressing social needs must be a part of a comprehensive approach to achieving better health outcomes.

The OIG notes that while all social determinants have the potential to impact health outcomes, "some social determinants may be more specifically aligned with preventive care and the coordination and management of care for patients (e.g., transportation to medical appointments, nutrition to address clinical conditions, safe housing for patients discharged to their homes) than others (e.g., a more general need for income through employment)."[7] "The OIG seeks public input on which social determinants are most crucial to improving care coordination and transitioning to value-based care and payment, with respect both to needed arrangements between providers or others in a position to generate Federal health care program referrals between them, and needed arrangements between beneficiaries and providers or others in a position to influence the selection of providers, practitioners, and suppliers."[8]

Specifically, the OIG solicits comments on whether the categories of patient engagement tools and supports that would receive protection (i.e., health-related technology, patient health related monitoring tools and services, or supports and services designed to identify and address a patient's social determinants of health) are sufficiently flexible but also sufficiently targeted to protect against the risks of fraud and abuse associated with providing inappropriate remuneration to patients or whether the final rule should specify tools and supports that would be permissible, including whether to base such a list on the types of tools and supports described in CMS guidance for the Medicare and Medicaid programs.

NASDOH believes that the categories of patient engagement tools and supports included in the final rule must explicitly include "supports and services designed to identify and address a patient's social determinants of health" to give health plans, providers, social service organizations and other individuals and entities necessary legal clarity that non-clinical needs may be met. The evidence-base suggests that the non-medical issues which impact health the most include housing, food, transportation and the risk of experiencing interpersonal violence.[9] While these specific social determinants are not comprehensive, they are areas where evidence indicates an opportunity to significantly impact health. Recent research conducted by Leavitt Partners indicated that "60 percent of consumers surveyed reported that they were adversely affected by at least one SDOH, but they report being screened for SDOH at low rates." Further, SDOH program implementation is unevenly distributed; physicians most likely to address SDOH have more Medicaid patients or participate in value-based payment arrangements.[10] More physicians and other healthcare sector participants will be more likely to provide supports and services designed to address SDOH if those supports and services are explicitly included in the safe harbor.

While it is important that the regulation itself remains flexible to allow for new approaches, partnerships, and interventions, NASDOH recommends that upon finalization of the proposed rule, HHS release implementation guidance on the Patient Engagement and Support Safe Harbor to include an illustrative list of SDOH-related tools and supports that can adapt as HHS decision-making on its programs evolves. For example, HHS could make

[6] 84 FR 55694
[7] Ibid.
[8] Ibid.
[9] Hinton, Elizabeth, et al. "Section 1115 Medicaid Demonstration Waivers: the current landscape of approved and pending waivers." Henry J. Kaiser Family Foundation Issue Brief (2019).
[10] Edwards, Kerstin, et al. "Taking Action on Social Determinants of Health" Report. Leavitt Partners (2019). Available at: https://leavittpartners.com/press/leavitt-partners-releases-taking-action-on-social-determinants-of-health-report/

public, through an accessible website, a description of the following, which would be deemed to be allowable tools or supports under the safe harbor:

- Initiatives approved by CMS for the Medicare and Medicaid programs, including the Innovation Center, Medicare Shared Savings Program, and Medicare ACOs;
- Initiatives approved to be utilized in a Medicaid Section 1115 Waiver or State Plan Amendment;
- Allowable Supplemental Benefits for Chronically Ill Enrollees under Medicare Advantage.

This would allow for more rapid dissemination of examples by HHS than would be possible with updates to regulations and provide for a more rapid uptake of effective interventions by value-based enterprises. More generally, NASDOH supports efforts by HHS to provide for expedited scaling and adoption of initiatives that HHS may have approved under waivers or other mechanisms with narrow applicability. NASDOH acknowledges that whether a tool or support would, in fact, be protected under the safe harbor when offered by a VBE participant to a patient in a target patient population would depend on the facts and circumstances and whether all safe harbor conditions were satisfied.

"VBE Participant"

In order to make use of the Patient Engagement and Support Safe Harbor, the supports and services designed to identify and address a patient's social determinants of health must be provided by a "VBE participant", defined as "an individual or entity that engages in at least one value-based activity as part of a value-based enterprise."[11] The establishment of a value-based enterprise requires compliance with formal organization and reporting rules, which may be a barrier to community based organizations and providers of social services.

NASDOH recommends that in the final rule, the OIG create a new term, "**VBE partners,"** to designate individuals and entities that provide SDOH supports and services at the direction of a VBE or VBE participant but are not themselves part of the VBE. The rationale for this additional designation is that many SDOH service providers (rideshare companies, social service organizations, foodbanks) already have direct partnerships with a VBE participant and should not need to become a full participant in a VBE in order to continue to provide such services under the safe harbor. This designation would also give service providers outside a formal VBE arrangement clarity about how they can support patients' social needs within the context of the Federal antikickback statute.

"Target patient population"

In order to make use of the Patient Engagement and Support Safe Harbor, the supports and services designed to identify and address a patient's social determinants of health must be provided to a "**target patient population**", defined as "an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that: (A) are set out in writing in advance of the commencement of the value-based arrangement; and (B) further the value-based enterprise's value-based purpose(s)."[12]

The OIG notes that it is considering for the final rule limiting the definition of "target patient population" to patients with a chronic condition, or alternatively, limiting any or all of the proposed safe harbors that use the target patient population definition to value-based arrangements for patients with a chronic condition.[13] NASDOH believes that the VBE should have the flexibility to define its "target patient population "and that it should not be limited to patients with a chronic condition. The social determinants of health impact a much

[11] 84 FR 55694
[12] 84 FR 55694
[13] Ibid.

broader population than just individuals with chronic conditions. For example, substandard housing may result in acute respiratory infections, elevated lead levels, or other non-chronic conditions. Similarly, older individuals may have social needs that inhibit care for costly acute conditions such as falls or need transportation to obtain high-value clinical preventive services (including those that prevent acute illness). In addition, the definition should allow greater flexibility for changes in the target patient population over time.

If the OIG were to narrow the scope to "patients with a chronic condition", NASDOH would request that the OIG align its definitions and approaches with those used by Medicare Advantage for Supplemental Benefits for Chronically Ill Enrollees and other similar federal programs.

The OIG also solicited comments on whether to extend safe harbor protection to a broader universe of patients. NASDOH believes the safe harbor protection should be applicable broadly because some tools and supports cannot be tailored perfectly to benefit only patients in the target population and VBE participants might not be able to prospectively determine whether an individual is in the target patient population. The OIG proposed extending the protection to "tools and supports furnished by VBE participants to any patient, so long as the tools and supports predominantly address needs of the target patient population and the tools and supports have a direct connection to the coordination and management of care for the patient." NASDOH supports this proposal with one addition: the tools and supports should be directly connected to the coordination and management of care for the patient *or designed to identify or address social determinants of health*.

2. CMS-Sponsored Model Safe Harbor

This new safe harbor would permit remuneration between and among parties to arrangements (e.g., distribution of capitated payments, shared savings or losses distributions) under a CMS model. CMS models include a model or other initiative being tested or expanded by the Innovation Center, the Medicare Shared Savings Program, and Medicare ACOs.[14]

NASDOH supports the objective of the proposed safe harbor to standardize and simplify anti-kickback statute compliance for CMS-sponsored model participants. The Innovation Center provides several opportunities to test both individual and community-level interventions to address the social determinants of health, such as pursuing pooled funding models. Pooled funding is used generally to describe the aggregation of funding from disparate sources to reduce the financial barriers to spreading and scaling successful multi-sectoral models to address SDOH. In this context, pooling acts as a mechanism to align incentives across sectors - e.g. housing, transportation, social care and health care - and removes barriers to multi-sectoral collaboration to address SDOH.

The lack of clarity on opportunities to pool disparate sources of funds, both public and private, can be a barrier to this financing approach and the scale of community-level interventions to address SDOH. CMS uses its existing authority under The Innovation Center to test a broad array of Medicare Advantage service delivery and/or payment approaches to increase choice, lower cost, and improve the quality of care for Medicare beneficiaries. NASDOH recommends that HHS use its current authority and resources under The Innovation Center to support pooled funding for SDOH interventions.

[14] Ibid.

In addition, NASDOH encourages the OIG to expand the scope of this safe harbor to include tools and supports approved by CMS to be utilized in a Medicaid Section 1115 Waiver or State Plan Amendment or allowed as a Supplemental Benefit for Chronically Ill Enrollees under Medicare Advantage.

3. Transportation Safe Harbor

The NPRM makes changes to the existing transportation safe harbor; including increasing mileage for rural patients.

Additionally, the OIG also seeks comment on whether to open the transportation safe harbor to include transportation for "health-related, non-medical purposes" in the final rule. The OIG notes "Such transportation might be to food stores or food banks, social services facilities (such as to apply for food stamps or housing assistance), exercise facilities, or chronic disease support groups, for example."[15] The OIG also seeks comment on 1) whether such an expansion should be limited to specific populations, such as those with chronic conditions, and 2) whether the transportation must be provided as part of a VBE.

NASDOH believes that the OIG should include transportation for "health-related, non-medical purposes" in the safe harbor when the transportation is necessary to identify and address a patient's social determinants of health. For example, a patient with asthma may need transportation to a housing agency to access a mold-free apartment.

As we state in our comments to the Patient Engagement and Support Safe Harbor, we believe that such services should not be limited to individuals with chronic conditions. Additionally, requiring transportation services to be provided by a party to a VBE may be a deterrent as many direct arrangements between the health sector and transportation services already exist.

CONCLUSIONS

On behalf of the National Alliance to Impact the Social Determinants of Health (NASDOH), we thank the Department of Health and Human Services (HHS) for addressing the social determinants of health (SDOH) in the Regulatory Sprint to Coordinated Care. We look forward to serving as a resource to the Office of Inspector General (OIG)'s as it finalizes its revisions to the safe harbor protections under the Federal antikickback statute.

Sincerely,

Vince Ventimiglia
President, Leavitt Partners Collaborative Advocates and Advisor to NASDOH

[15] Ibid.