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Social Supports in the Provider Setting: Anti–Kickback and Beneficiary Inducement Safe Harbors

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Health care organizations are increasingly engaging with individual-level social needs that impact health (health-related social needs or HRSN). The momentum is buoyed by U.S. Department of Health and Human Services' use of rulemaking and other authorities to advance regulatory mandates, incentives, and flexibilities that promote the integration of HRSN services and supports into health care delivery and financing. By way of some recent examples, in 2022, the Centers for Medicare and Medicaid Services (CMS) finalized rules introducing social determinants of health screening into the Inpatient Prospective Payment System and Special Needs Plan Health Risk Assessments.[1] In 2023, CMS issued a long-awaited informational bulletin detailing coverage pathways for HRSN services and supports in Medicaid and CHIP.[2] And as of the start of this year, new codes make health-related social needs risk assessments, as well as community health worker services and patient navigation services (both of which help patients connect to resources that address unmet HRSN) reimbursable under Medicare Part B.[3]

Recent developments notwithstanding, providers still face regulatory hurdles to implementing responsive HRSN interventions. One such barrier is the ability to design a program that directly provides an item or service for free (or for less than market value) without running afoul of the federal anti-kickback statute (AKS) or beneficiary inducements (BIS) prohibition of the civil monetary penalties law (CMPL). While understandable, concern about fraud and abuse compliance need not preclude the pursuit of meaningful programming to address patients' HRSN. And in practice, institutional responses to patients experiencing food insecurity, housing instability, technology access issues, and barriers to transportation—among other social needs—are growing in complexity, number, and scale.

AKS Safe Harbors and BIS Exceptions for Items and Services that Support HRSN

There is no single, one-size-fits-all safe harbor or exception that health care providers can rely on to provide food, transportation services, housing-related resources, and other social supports to Medicare and Medicaid beneficiaries. Instead, several safe harbors and exceptions, many of which have been codified or amended within the past 10 years, may be leveraged to enable some forms of direct support in particular circumstances and subject to applicable conditions. Relevant provisions include:

- The 2016 AKS safe harbor for local transportation[4]
- The 2020 AKS safe harbor for arrangements for patient engagement and support[5]

- BIS exceptions for items and services that promote access to care, improve uptake of certain preventive services, or are based on financial need.[6]

The "Financial Need Based Exception," at 42 C.F.R. § 1003.110(8), is of particular significance to programming in which a hospital, clinic, or other provider is looking to address, directly or through collaborative partnerships with community-based organizations and other vendors, the unmet HRSN of their patients. At least in part, this is because the exception allows for more flexible programming; other safe harbors target narrower goals (e.g., facilitating access to care, supporting patients of a value-based entity, etc.). The conditions of the Financial Need Based Exception are also informative for organizations working outside of the exception—relying on a facts and circumstances analysis—and looking for promising guardrails.

The Financial Need Based Exception

The Financial Need Based Exception provides that, for purposes of the CMPL beneficiary inducements prohibition, the term "remuneration" does not apply to the offer or transfer of items or services for free or less than fair market value if:

(i) the items or services are not offered as part of any advertisement or solicitation;
(ii) the items or services are not tied to the provision of other services reimbursed in whole or in part by Medicare or Medicaid;
(iii) there is a reasonable connection between the items or services and the medical care of the individual; and
(iv) the items or services are provided after determining in good faith that the individual is in financial need.

Preamble commentary to relevant rulemaking and Office of Inspector General (OIG) Advisory Opinions (of which there are only two to date) provide some valuable guidance for compliance with the Financial Need Based Exception.

(i) The items/services are not offered as part of any advertisement or solicitation

This condition of the exception does not create any insurmountable barriers to programming. OIG generally prohibits advertising assistance programs because of concerns that it will steer or coerce people towards other, reimbursable services. Although "whether a particular means of communication constitutes an advertisement or solicitation will depend on the facts and circumstances,"[7] OIG recognizes that providing basic information relating to available supports does not violate marketing prohibitions.[8] OIG explains that it is therefore acceptable, for example, for a hospital-based food pantry to post its hours of operation without compromising marketing restrictions.[9]

(ii) The items/services are not tied to the provision of other services reimbursed in whole or in part by Medicare or Medicaid

OIG interprets this requirement as prohibiting offers or transfers of items/services conditioned on a patient's use of other, reimbursable services.[10] For example, whether or not a patient needs transportation or lodging support to undergo a procedure is tied to whether or not they are undergoing a procedure. That program is not protected under the Financial Need Based Exception.[11] (Remember, however, that other safe harbors or exceptions, such as the transportation safe harbor, may apply.) Similarly, in Advisory Opinion No. 23-08, OIG applied the exception to a proposal involving the offer of a free hearing aid to patients that get a cochlear implant. The OIG opined that the Financial Need Based Exception "would not be met because the free [hearing aid] would be conditioned on the purchase of the [cochlear implant], which is an item reimbursable by Medicare and Medicaid."[12]

OIG has clarified that this condition does not necessarily prohibit supports from being offered to existing patients.[13] There is a cognizable difference between offering patients who have asthma an air conditioner for their home and offering patients an air purifier if they consent to receiving asthma chronic care management services.

(iii) There is a reasonable connection between the item/services and the medical care of an individual

This condition has two parts. The item or service must be reasonable from both a medical perspective and a financial perspective.

Reasonable from a medical perspective: There are two aspects of this condition that are especially worth noting for programming involving HRSN services and supports. First, who determines that there is a reasonable medical connection? For this purpose, OIG recognizes members of a care management team in addition to physicians, pharmacists, and other "generally accepted professional practice" as "medical professionals" authorized to make a determination.[14] This flexibility is noteworthy because it may be sensible, from an operational perspective, for staff members other than a physician to conduct the screening.

Second, what does a reasonable connection to medical care look like? OIG has indicated that it interprets the phrase broadly.[15] Many health-related social supports, including many food- and housing-related interventions, are able to point to an array of research that demonstrate the pertinence of the support to a patient's medical care.[16]

OIG stresses that what really fall outside of the exception are items and services that are "essentially for entertainment and other nonmedical purposes."[17] Moreover, In Advisory Opinion No. 18-05, a health center requestor proposed to provide or arrange for various services for people in the community who care for adults with chronic medical conditions. OIG took issue with the remuneration's reasonable connection to the care recipient's medical care. "Although many of the services Requestor offers under the Arrangement may relate to Caregivers' general health and well-being, the services are not connected to either the Caregivers' or the Care Recipients' medical care."[18] In so reasoning, the OIG recognizes but is not swayed by there being an indirect impact on care recipients.

Reasonable from a financial perspective: OIG treats this prong as sort of a cost-benefit analysis, where the cost of the intervention is measured against the medical benefit to the patient. In order to be financially reasonable, the value of the support must not be disproportionately large compared to the medical benefit.[19] OIG provides neither a method for calculating values, nor any exact ratio to identify something that is disproportionately large. In the absence of bright-line rules for HRSN supports, analysis is further complicated by OIG's inclusion of two vague food-related examples as illustration of the parameter. Paying for a subscription to a "long-term" meal preparation and delivery service for a patient with diabetes would not be reasonable from a financial perspective; but providing meal deliveries for a "limited period of time" after a patient is discharged after a debilitating procedure might be reasonable from a financial perspective.[20]

This condition is subjective and one of the most challenging to navigate. Even in pursuit of a food-related intervention, gray areas remain. What is "long-term?" How does one extrapolate the illustration to "long-term" produce vouchers redeemable at a local grocery store as opposed to meal preparation and delivery?

(iv) There is a good faith, individualized determination of financial need

Medical professionals are not required to use any specific basis for determining need—health care organizations explicitly have the flexibility to determine the appropriate policy for their own patient populations—but a set (i.e., documented), uniformly applied policy is required.[21] Notably, patient statement of need may be solely relied upon where the medical professional can be reasonably comfortable accepting only a patient's statement of need (e.g., the patient is on Medicaid, the professional is located in a low-income area and generally serves low-income

patients, etc.).[22] This flexibility is important because, from an operational perspective, burdensome financial need screenings are likely to prevent participation in the program by some otherwise eligible, vulnerable patients.

Leveraging a Facts and Circumstances Analysis

The Financial Need Based Exception is a valuable tool for health care providers who want to do more than simply screen patients for HRSN or screen and then refer patients to generally available (and potentially overburdened) community resources. The exception is also complex and involves navigating some subjective terms. Strategies for meeting certain conditions, unless thoughtfully approached in the design and implementation phases, may negatively impact the effectiveness, reach, and scalability of the intervention. The same is true for other BIS exceptions and AKS safe harbors. Thus, while recent regulatory activity has offered some safeguards, social programming continues to be offered at the risk of the provider.

Compliance therefore continues to invoke analysis of the specific facts and circumstances, with the Financial Need Based Exception and others as a guide. Utilizing the recommended analysis, providers should become increasingly comfortable pursuing their own HRSN programming. The level of risk can be greatly reduced with a clear understanding of the regulations, exceptions, and guardrails coupled with an iterative approach to programming analysis risk exposure.

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[1] *See* Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term-Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation, 87 Fed. Reg. 48780 (2022); Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 87 Fed. Reg. 27704 (2022).
[2] Ctrs. For Medicare & Medicaid Servs., CMCS Informational Bulletin re: Coverage of Services and Supports to Address Health-Related Social Needs in Medicaid and the Children's Health Insurance Program (Nov. 16, 2023), https://www.medicaid.gov/sites/default/files/2023-11/cib11162023.pdf.
[3] Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program, 88 Fed. Reg. 78818 (2023).
[4] 42 C.F.R. § 1001.952(bb).
[5] 42 C.F.R. § 1001.952(hh).
[6] 42 C.F.R. § 1003.110(6), 42 C.F.R. § 1003.110(5), and 42 C.F.R. § 1003.110(8).
[7] Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368, 88373 (Dec. 7, 2016).
[8] Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77684, 77797 (Dec. 2, 2020). *See also* OIG Advisory Opinion 18-05 (2018) (helping to distinguish marketing from other communications where OIG explains, "Requestor certified that it does not actively market the Arrangement. Requestor provides information about the Center on its website, on its social media pages, and in brochures but does not advertise in the media or on billboards and does not engage in other active advertising.").
[9] *Id.*

[10] *See supra*, note 7 at 81 Fed. Reg. 88402.
[11] *Id.*
[12] Advisory Opinion No. 23-08, https://oig.hhs.gov/documents/advisory-opinions/1133/AO-23-08.pdf.
[13] *See supra*, note 7 at 81 Fed. Reg. 88403. ("In other words, we recognize that providers or suppliers may have ongoing relationships with the patients to whom they may give free or discounted items or services under this exception. What this limitation prohibits is tying the purchase of a reimbursable item or service to the offer of the free item or service.").
[14] *Id.* ("Commenters urged us to deem remuneration to be reasonably connected to medical care when a medical professional (*e.g.,* a pharmacist, physician, care management team, or a generally accepted professional practice) determines it is connected to medical care, is important to patient success, or would benefit treatment or adherence to treatment. . . . We agree that a medical professional is generally in the best position to determine that an item or service is reasonably connected to the care that professional is providing, including achieving a favorable treatment outcome.").
[15] *See supra*, note 7 at 81 Fed. Reg. 88404.
[16] *See, e.g.*, Wang L, Lauren BN, Hager K, et al. Health and economic impacts of implementing produce prescription programs for diabetes in the United States: a microsimulation study. *J Am Heart Assoc*. 2023;0:e029215, https://doi.org/10.1161/JAHA.122.029215.
[17] *See supra*, note 7 at 81 Fed. Reg. 88404.
[18] Advisory Opinion No. 18-05, https://oig.hhs.gov/documents/advisory-opinions/748/AO-18-05.pdf.
[19] *See supra*, note 7 at 81 Fed. Reg. 88404.
[20] *Id.*
[21] *See supra*, note 7 at 81 Fed. Reg. 88405.
[22] *Id.* ("A statement of inability to pay coinsurance may suffice for a Medicaid patient, because Medicaid patients have been screened for financial eligibility by the state. A provider may have other reasons to be comfortable in accepting a patient's own statement of financial need, such as being located in a low-income area and generally serving a financially needy patient population, or knowing that a particular family has very high medical expenses. However, a provider or supplier should not rely solely on a representation by the patient that he or she is in financial need, unless the provider or supplier has some independent basis for belief that such a representation is reliable.").

