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Office of Inspector General
Department of Health and Human Services
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Cohen Building
330 Independence Avenue S.W.
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Submitted via www.regulations.gov

Re: OIG-403-P3, 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 and Gainsharing

To Whom It May Concern:

The National Association of Community Health Centers, Inc. (NACHC) is pleased to respond to the above-referenced Notice of Proposed Rulemaking published by the Office of Inspector General ("OIG"), Department of Health and Human Services on October 3, 2014 (79 Fed. Reg. 59717) ("the NPRM"). NACHC is the national membership organization for federally qualified health centers (hereinafter interchangeably referred to as "health centers" or "FQHCs") throughout the country, and is a Section 501(c)(3) tax-exempt organization.

The NPRM would revise the Medicare and Medicaid safe harbors under the Anti-Kickback Statute and amends the Civil Monetary Penalty rules pertaining to beneficiary inducement and gainsharing. Among the revisions to the existing safe harbors to the Anti-Kickback Statute, the NPRM would codify protection for certain cost-sharing waivers related to pharmacy services provided to financially needy Medicare Part D beneficiaries, protection for remuneration between Medicare Advantage organizations and FQHCs, and protection for free or discounted local transportation services that meet specified criteria.

In addition, the NPRM would amend the definition of "remuneration" in the Civil Monetary Penalties ("CMP") regulations related to the prohibition against inducements. Among the changes to the existing regulations, the OIG would extend protection to certain remuneration that promotes access to care and to certain remuneration to financially needy individuals. The OIG has specifically requested examples of remuneration to beneficiaries that would promote access to care while posing low risk of harm to Medicare and Medicaid beneficiaries and programs.

The NPRM is of particular concern to health centers because it impacts the ability of health centers to carry out their missions without risking significant financial liabilities and penalties. Two of the proposed safe harbors would protect situations in which health centers offer price reductions under the Medicare program, which are necessary to ensure that no patient is denied services based on the inability to pay. A third proposed safe harbor would protect free or discounted transportation services offered by health centers that enable low-income individuals to access to care in medically underserved areas. Lastly, the NPRM would extend protections to free items offered by health centers that promote the health, well-being and safety of their patients.

Generally, NACHC is supportive of the NPRM. However, we propose important revisions and clarifications to ensure that the regulations do not inhibit beneficial arrangements that permit health centers to fulfill their legal obligations and advance important public purposes established under Section 330 of the Public Health Service Act. To fulfill the goals of the Patient Protection and Affordable Care Act ("ACA"), we believe that the OIG can make changes to the proposed regulations while still protecting Federal health care programs and beneficiaries from potential risk of harm.

I. Background on Health Centers

There are, at present, almost 1,300 health centers with more than 9,300 sites serving more than 22 million patients nationwide. Most of these health centers receive Federal grants under Section 330 of the Public Health Service Act ("PHS Act"), 42 U.S.C. § 254b, from the Bureau of Primary Health Care ("BPHC"), within HRSA. Under this authority, health centers fall into four general categories: (1) those centers serving medically underserved areas, (2) those serving homeless populations within a particular community or geographic area, (3) those serving migrant or seasonal farmworker populations within similar community or geographic areas, and (4) those serving residents of public housing.

To qualify as a Section 330 grantee, a health center must be serving a designated medically underserved area or a medically underserved population. In addition, a health center's board of directors must be made up of at least fifty-one percent (51%) users of the health center and the health center must offer services to all persons in its area, regardless of one's ability to pay. BPHC's grants are intended to provide funds to assist health centers in covering the otherwise uncompensated costs of providing comprehensive preventive and primary care and enabling services to uninsured and underinsured indigent patients, as well as to maintain the health center's infrastructure. Patients from eligible communities, who are not indigent and are able to pay or who have insurance, whether public or private, are expected to pay for the services rendered. Approximately 39 percent of health center patients are Medicaid recipients, approximately 36 percent are uninsured, and approximately 15 percent are privately insured.

II. Comments

Health centers play a unique role among public-funded health insurance programs. Due to the large number of low-income individuals they serve, their statutory mandate under Section 330 of the PHSA to reduce social, economic, and cultural barriers to accessing care, and their locations in medically underserved rural and urban areas, health centers function at the intersection of the health care safety net and public health in communities across America.

NACHC recommends several revisions to the NPRM in order to reduce legal barriers to health centers effectively carrying out their public purposes. In summary, NACHC's comments are as follows:

- In regard to revisions in the NPRM to protect the reduction or waiver by pharmacies of any cost-sharing obligations imposed under Medicare Part D, NACHC suggests that OIG provide additional guidance to: (1) ensure that required health center communications

about sliding fee discount programs do not constitute "advertising" under the safe harbor; (2) clarify that frequent waivers of cost-sharing obligations due to the population served by health centers do not constitute "routine" waivers of cost-sharing; and (3) confirm that annual eligibility determinations for a health center's sliding fee discount program is sufficient for determining financial need prior to waiver or reduction of cost-sharing obligations.

- As to proposed revisions to protect remuneration between a health center and a Medicare Advantage (MA) organization pursuant to a written agreement described in § 1853(a)(4) of the Social Security Act (SSA), NACHC recommends that OIG clarify that this safe harbor provides protection for four specific types of remuneration between a health center and an MA organization: (1) compensation to health centers that exceeds fair market value; (2) donation of free space by health centers to MA organizations; (3) financial support of health centers community outreach activities, information technology, infrastructure costs; and (4) arrangements in which provider networks stand in the shoes of MA organizations.
- NACHC supports addition of a new safe harbor to protect free or discounted local transportation services to Federal health care program beneficiaries. However, NACHC recommends that OIG expand the safe harbor to: protect the provision of services to new and established patients; permit air transportation when it is a usual and customary form of travel; shield arrangements among care collaboration partners; and include entities exploring delivery system reforms. Additionally, NACHC encourages OIG to increase the mileage for local transportation and exempt entities that serve medically underserved populations from meeting the mileage standard.
- With regard to adding statutory exceptions to the definition of remuneration under the CMP regulations to permit certain arrangements that may improve or increase access to care with low risk to beneficiaries or Federal health programs, NACHC recommends that OIG broadly implement the exception to allow for maximum flexibility in engaging patients and providing non-clinical items or services that improve medical care. Similarly, NACHC approves of adding an exception for an offer or transfer of items or services for free or less than fair market value when the recipient is in financial need. However, NACHC requests clarifications on how conditions of the safe harbor will apply to health centers and suggests that OIG broadly interpret certain provisions to allow for additional flexibility.

A. Proposed 42 C.F.R. §1001.952(k)(3)

NACHC supports amending § 1001.952(k) by adding a new subparagraph that protects reductions or waivers by pharmacies of any cost-sharing obligations imposed under Medicare Part D. However, NACHC suggests that OIG provide additional guidance to clarify that health center communications to existing and potential patients about the availability of sliding fees does not fall within the ambit of the meaning of "advertising", that frequent waivers of cost-sharing obligations to patients qualifying for sliding fees do not constitute "routine" waivers of cost-sharing, and that annual determinations of eligibility for sliding fee programs satisfy the requirement for individualized determinations of financial need.

Proposed provisions: The proposed rule would amend § 1001.952(k) to reflect exceptions to the Anti-Kickback Statute as set forth in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003(MMA). MMA amended § 1128B(b)(3) of the Anti-Kickback Statute by creating a safe harbor

from liability for pharmacies that waive or reduce cost-sharing imposed under Medicare Part D, as long as certain conditions are met. MMA § 101(e). The conditions for meeting the safe harbor require that: (1) the waiver or reduction of cost-sharing is not advertised; (2) the pharmacy cannot routinely waive the cost-sharing; and (3) the pharmacy determines in good faith the beneficiary has a financial need or the pharmacy fails to collect the cost-sharing after making reasonable effort to do so. SSA § 1128B(b)(3)(G). If, however, the waiver or reduction of cost-sharing is made on behalf of a subsidy-eligible individual (i.e., individuals with incomes at or below 150% of the Federal Poverty Level), then conditions (2) and (3) above are not required for protection under the safe harbor. *Id.* § 1128B(b)(3)(G).

Comment: NACHC supports the addition of a safe harbor for the reduction of cost-sharing imposed by Medicare Part D. As such, NACHC's comments focus on several areas of concern that relate to how OIG will apply the safe harbor to health centers. At present, waivers of Medicare cost-sharing obligations for individuals who qualify for a health center's sliding fee scale (e.g., individuals with incomes at or below 200% of the Federal Poverty Level) are protected under a safe harbor established under § 1128B(b)(3)(D) of the Social Security Act and codified under § 1001.952(k)(2). However, that statutory safe harbor is limited to services paid under Part B of Medicare and the implementing regulations extend that safe harbor only to services paid by State health care programs, i.e., Medicaid. *Id.* Consequently, the existing safe harbor creates an unfortunate gap that does not protect waivers of cost-sharing obligations for services paid under Medicare Part D. NACHC asks that OIG clarify that certain health center activities described below fit comfortably within the new safe harbor.

First, health centers routinely inform patients of the availability of a sliding fee schedule based on an individual's ability to pay, as required under Section 330 of the Public Health Service Act. *See* 42 U.S.C. § 254b(k)(3)(G)(i). HRSA requires health centers to utilize multiple methods for informing patients of the sliding fee discount program, such as signage, written materials, and communications to patients during the registration process. *See* HRSA Policy Information Notice ("PIN") 2014-02. Recently, HRSA clarified that the sliding fee discount program also applies to individuals with third-party coverage when an individual cannot afford cost-sharing amounts. *Id.* Additionally, health centers must educate patients and the general population on the availability of health services, 42 U.S.C. § 254b(b)(1)(A)(v), and meaningful education about the availability of health services necessarily includes information about the health center's sliding fee discount program. However, these required activities could be construed as advertising the availability of waivers or discounts on Part D cost-sharing obligations. **NACHC requests that OIG clarify that communications about a health center's sliding fee discount program – including its application to patients with third-party coverage, such as Medicare Part D – would not be construed as "advertising or as part of a solicitation" under the proposed safe harbor.**

Second, Federal law requires health centers to provide services to individuals regardless of their insurance status or ability to pay. *See* 42 U.S.C. § 254b(k)(3)(G)(iii). As mentioned above, health centers are required to provide sliding fee discounts to patients who have qualifying incomes at or below 200% of the Federal Poverty Level, including those individuals who have cost-sharing obligations under third party coverage. HRSA 2014-02. Approximately 93% of health center patients have incomes at or below 200% of the Federal Poverty Line.[1] Consequently, most health center patients are eligible for a sliding fee discount and therefore waivers of cost-sharing obligations occur frequently. **NACHC requests that OIG clarify that waivers or reductions in cost-sharing obligations under Part D, despite occurring frequently as a consequence of serving a low-income population, would not be construed as a "routine" waiver under the proposed safe harbor.**

[1] 2013 Uniform Data System, Bureau of Primary Health Care, HRSA, DHHS.

Third, health centers currently assess eligibility for their sliding fee scale programs on an annual basis. Health centers must have supporting processes or operating procedures for assessing income and household size for all patients both for the sliding fee discount program and for other health center program reporting requirements. *See* HRSA PIN 2014-02. Health centers must conduct the eligibility determination process in an efficient, respectful, and culturally appropriate manner to assure that administrative procedures are not a barrier to care. *See Id.* Therefore, health centers perform eligibility assessments on an annual basis and not on each occasion that a patient receives services, which would be impractical administratively and pose a barrier to care. **NACHC requests that OIG clarify that a health center's annual assessment of an individual's eligibility for its sliding fee discount program, reflecting an individual's financial need, would be consistent with the requirements of the proposed safe harbor.**

B. Proposed 42 C.F.R. § 1001.952(z)

Generally NACHC supports adding § 1001.952(z) to protect remuneration between a health center and a Medicare Advantage (MA) organization pursuant to a written agreement described in § 1853(a)(4) of the Social Security Act. However, the proposed text of the safe harbor does not go beyond the statutory text and offers little guidance to health centers of the OIG's interpretation of the circumstances in which remuneration between a health center and an MA organization would be protected under the safe harbor.

Proposed provisions: The NPRM would amend the regulations to add § 1001.952(z) which would excludes any remuneration between a health center and an MA organization pursuant to a written agreement described in SSA § 1853(a)(4) from the definition of remuneration under the Anti-Kickback Statute. This regulatory safe harbor incorporates a statutory exception to the Anti-Kickback Statute added by Section 235 of MMA.

Comments: NACHC supports the addition of this safe harbor but requests confirmation that certain examples of remuneration described below between a health center and an MA organization would be protected under the proposed safe harbor.

First, as part of the written agreement between the MA organization and health center, the MA organization might offer compensation to a health center that exceeds amounts typically paid to a non-health center for similar services. As noted by the NPRM, Section 235 of the MMA required that the written agreement between the two entities specifically provide that the MA organization will pay the contracting FQHC no less than the level and amount of payment that the plan would make for the same services if the services were furnished by another type of entity. The preamble to the safe harbor does not indicate whether an MA organization's payment to the health center of a cost-based rate established by Medicaid or Medicare (and reflecting the broad range of services furnished by the health center) – which may be well above amounts typically paid to non-health centers by the MA organization for similar services – would be protected under the safe harbor. Furthermore, in the calculation of supplemental ("wrap-around") payments to FQHCs, Medicare excludes payments received under the written agreement for financial incentives such as risk pool payments, bonuses, or withholds. SSA § 1833(a)(3)(B)(ii). The preamble does not indicate whether the safe harbor protects financial incentives of any amount made by an MA organization to a health center. **NACHC requests that OIG confirm that all remuneration between an MA organization and a health center is protected without regard to amounts typically paid to other providers or fair market value.**

Second, subject to the Medicare Marketing Guidelines established by the Centers for Medicare and Medicaid services, as part of the written agreement between the MA organization and health center, health centers might provide use of conference room space without charge to the MA

organization to offer sale presentations to potential enrollees**.** Given that the purpose of such sales presentations are to enroll beneficiaries in an MA organization, the provision of donated space could have a direct impact on beneficiaries enrolling with the MA organization, and the value of payments made to the health center by the MA organization for the provision of services covered under the written agreement. **NACHC requests OIG confirm that the provision of free space to the MA organization would be protected remuneration under the proposed safe harbor.**

Third, as part of the written agreement between the MA organization and health center, a MA organization might provide financial support for conducting outreach activities, purchasing health information technology (such as devices that monitor weight, activity levels, glucose levels, and blood pressure), and funding infrastructure costs to implement quality improvement projects. In order to distribute that financial support equitably among health centers, a MA organization might desire to provide the financial support on a per member per month basis, as opposed to a lump sum basis. The good-will created by a MA organization's financial support of a health center, particularly when acknowledged by the health center in communications to patients and the community, might lead to an increase in the volume of beneficiaries enrolling with the MA organization. **NACHC requests OIG confirm that financial support, even when based on the number of health center patients enrolled in the MA organization, would be protected remuneration under the proposed safe harbor.**

Fourth, a health center may contract with an MA organization "indirectly" through an agreement with an Independent Practice Association ("IPA") and subsequently claim supplemental payments from Medicare. Pursuant to federal regulation, these indirect contracting arrangements satisfy the requirement for a written agreement under SSA § 1853(a)(4), entitling FQHCs to the supplemental payments. *See* 42 C.F.R. § 405.2469. Prior to the MMA, the OIG had established a safe harbor under § 1001.952(t) for price reductions offered to eligible managed care organizations, which was defined to include both Medicare and Medicaid managed care organizations. That safe harbor protects "first tier contractors" that are FQHCs when claiming supplemental payments from a Federal health care program. At the time, the OIG was not willing to extend safe harbor protection to "second tier contractors" that were FQHCs claiming supplemental payments from a Federal health care program. Under Section 237 of the MMA, Congress provided for supplemental payments to FQHCs that contract with MA organizations. Subsequent to passage of the MMA, CMS established implementing regulations that interpreted "a written agreement described in section 1853(a)(4)" to mean both direct and indirect contracts with MA organizations. 42 C.F.R. § 405.2469. **NACHC requests OIG confirm that safe harbor protection extends to remuneration between a health center and IPA when the IPA stands in the shoes of the MA organization pursuant to an indirect contract arrangement between a health center and MA organization recognized by CMS regulations.**

The preamble is unclear as to whether or not the above arrangements would fit within the proposed safe harbor. This uncertainty may impede the beneficial arrangements Congress sought to protect between MA organizations and health centers. NACHC recommends that OIG clarify that the proposed safe harbor protects the forms of remuneration between health centers and MA organizations described in the examples above.

C. Proposed 42 C.F.R. § 1001.952(bb)

In general**,** NACHC supports addition of a new safe harbor to protect free or discounted local transportation services to Federal health care program beneficiaries. However, NACHC would suggest that OIG to expand the safe harbor to include: new and established patients; air travel; collaboration partners; and entities exploring delivery system reforms. Additionally, NACHC encourages OIG to increase the mileage for local transportation and exempt entities that serve medically underserved populations from meeting this condition of the safe harbor.

Proposed provision: Pursuant to OIG authority under § 1128B(b)(3)(E) of the Anti-Kickback Statute, the NPRM creates a safe harbor for free and discounted local transportation that meet certain conditions. *See* 79 FR 59721. Previously, OIG has considered a safe harbor that would have allowed for complimentary local transportation of a "nominal value", defined as no more than ten dollars per item or service or fifty dollars in the aggregate over the course of the year. *Id.* OIG was concerned that the "nominal value" in the context of complimentary transportation would be too restrictive. 79 FR 59722. Ultimately, OIG never enacted the safe harbor. *Id.* OIG is now proposing a safe harbor that allows for free or discounted local transportation provided that certain criteria are met.

Among the conditions under the safe harbor, the NPRM requires that: (1) the free or discounted local transportation services be available only to established patients and be determined in a manner unrelated to past or anticipated business; (2) the form of transportation does not include air, luxury, or ambulance-level transportation; (3) the transportation is not a means for providers and suppliers to recruit patients; (4) the transportation is provided only to the patient or those assisting the patient and within the service area of the health care provider or supplier; and (5) the transportation is "local" which is defined as not more than 25 miles. 79 FR 59723-4.

In regard to the third condition, the NPRM identifies three specific activities that would create an inference that the complimentary transportation constitutes patient recruitment and would not be protected under the safe harbor. 79 FR 59724. First, transportation services cannot be advertised or marketed. *Id.* Second, transportation employees cannot be paid based on the volume of beneficiaries transported. *Id.* Third, other health care items or services cannot be marketed during the transport. *Id.*

Comment: NACHC supports inclusion of a safe harbor for discounted transportation services. However, NACHC recommends that OIG: (1) expand the safe harbor to include transportation offered to new patients as well as established patients; (2) expand the form of permissible transportation to include air travel so long as it is not luxurious; (3) clarify that collaboration partners may transport patients between sites; (4) apply the safe harbor to organizations exploring delivery system reforms such as Accountable Care Organizations (ACOs); and (5) increase the mileage for local transport and exempt providers serving medically underserved populations and in medically underserved areas from having to comply with the mileage standard.

First, NACHC urges OIG to expand the safe harbor to include both new and established patients of health centers. Under Section 330 of the PHSA, health centers are required to provide certain primary health services to medically underserved populations. 42 U.S.C. § 254b(a)(1). The required primary health services include "services that enable individuals to use the services of the health center (*including outreach and transportation services*)". Id. § 254b(b)(1)(A)(iv)(emphasis added); see also 42 C.F.R. § 51c.102(h)(5). Moreover, HRSA has issued implementing regulations that require a health center to provide primary health services to all residents of its catchment area. § 51c.102(c)(1)(i). Consequently, health centers could not condition transportation services on the basis of whether individuals in the catchment area were established patients. Moreover, certain health centers specifically serve "migratory and seasonal agricultural workers, the homeless, and residents of public housing." *Id.* These special populations are even more likely to lack a regular source of primary and preventive care and transportation to new patients would greatly benefit this population.

Furthermore, limiting the safe harbor to transportation for established health center patients will create undesirable barriers to primary and preventive care for new patients in medically underserved areas and fail to provide safe harbor protection to enabling services that health centers are required to provide to new patients. For instance, if the safe harbor did not include free or discounted transportation to new patients, it might discourage an established patient from bringing a new infant who is in need of care or persuading a family member who is in need of care -- neither of whom would

be established patients—to the health center. In weighing the benefits of expanding the safe harbor to include new patients against risk of harm to Federal programs and beneficiaries, OIG should consider that the risk of overutilization of primary and preventive services is extremely low. Numerous studies have documented the underuse of primary and preventive care, resulting in lost lives, unnecessary poor health, and higher costs.[2] **Accordingly, NACHC urges the OIG to expand the safe harbor to protect transportation furnished to both new and established patients of health centers.**

Second, NACHC recommends removing air travel from the forms of transportation not permitted under the proposed safe harbor. In geographically-isolated island communities, air travel by small aircraft or helicopter may be the only practical means of transportation from one location to another. Such air travel would not be considered in these communities to be luxurious but more aptly described as ordinary, economical and modest. Especially if the OIG's proposed mileage limitation is increased or providers in underserved communities are categorically exempt, as NACHC recommends below, the exclusion of air travel from transportation protected under the safe harbor may create an unintended barrier to accessing health services for island communities. **NACHC urges the OIG to include air transportation as a permissible form of transportation when air travel is the usual and customary means of transportation in a community.**

Third, NACHC recommends that OIG clarify that the safe harbor applies to providers with established care coordination arrangements. Health centers frequently work with hospitals to coordinate care to improve outcomes and reduce costs. For instance, emergency department diversion programs divert non-emergent care from hospital emergency rooms to outpatient primary care settings. Typically, the hospital and the health center are located in close proximity to one another. However, even minor transportation costs (or hassles) may dissuade patients from seeking care at an outpatient primary care setting. In care coordination programs, the provision of free or discounted local transportation to patients is vital for motivating changes to established patient patterns, improving health outcomes, and reducing costs. **NACHC suggests that transportation furnished under coordinated care programs be explicitly included in this safe harbor.**

Fourth, NACHC suggests that the safe harbor should apply to organizations pursuing delivery system reforms such as ACOs. Care coordination requires a multi-faceted approach to treatment. ACOs and other delivery system reform models enhance care coordination and improve the management of chronic conditions. Transportation can pose barriers to regular patient care (especially for patients whose chronic conditions require frequent visits), follow-up with referrals to specialty care, and adherence to treatment regimes. Given the complexities of care coordination and the importance of delivery system reform, the safe harbor should protect entities engaged in new models of care delivery. **NACHC urges OIG to include transportation furnished by ACOs or under delivery system reform models under the protections afforded by the safe harbor.**

Fifth, NACHC requests that OIG increase the mileage definition for what is considered local transportation and categorically exempt providers in underserved communities from having to meet this condition. Health centers operate in medically underserved areas. *See* 42 U.S.C. § 254b(a)(1). "Medically underserved population" means populations of an urban or rural area designated as having a shortage of health services or a population group designated as having a shortage of such services. *See* 42 U.S.C. § 254b(b)(3)(A). Because health center patients may be unable to access certain needed

[2] See National Association of Community Health Centers, "Health Wanted: The State of Unmet Need for Primary Health Care in America," March 2012, *available at* https://www.nachc.com/client//HealthWanted.pdf (Dec. 2, 2014).

services within their own locality, geography and transportation difficulties are a significant barrier to care for health center patients. This is particularly true for accessing specialty services, hospital services, dental services, mental health services, and substance abuse disorder and addiction services. Furthermore, a mileage limitation of twenty-five miles would render the safe harbor meaningless in many rural, frontier, and island communities, where patients routinely travel hundreds of miles to access needed health services. **NACHC recommends that OIG increase the allowable mileage for local transport under the safe harbor and categorically exempt providers who serve medically underserved communities from having to meet a mileage-based condition.**

D. Proposed 42 C.F.R. Part 1003

In general, NACHC agrees with adding statutory exceptions to the definition of remuneration under the CMP regulations that permits certain arrangements that may improve or increase access to care and care coordination for beneficiaries. The Patient Protection and Affordable Care Act (ACA) added four new statutory exceptions protecting certain charitable and other programs. ACA § 6402(d)(2)(B). NACHC limits its comments to two of these exceptions described in the NPRM. First, NACHC supports an exception to the definition of remuneration that protects remuneration as part of programs that promote access to care with a low risk of harm to the Medicare and Medicaid programs. However, NACHC recommends that OIG broadly implement the exception to allow for maximum flexibility in engaging patients and providing non-clinical items or services that improve medical care. Similarly, NACHC supports adding an exception to the definition of remuneration for an offer or transfer of items or services for free or less than fair market value after a determination that the recipient is in financial need. However, NACHC requests clarifications on how conditions of the safe harbor will apply to health centers and suggests that OIG broadly interpret certain provisions to allow for innovation.

1. Safe Harbor for Remuneration that Promotes Access to Care with Low Risk of Harm

Proposed Provision: The NPRM proposes adding an exception to the definition of remuneration for any remuneration that promotes access to care and poses a low risk of harm to patients and Federal health care programs as described in the ACA. The NPRM interprets remuneration that "promotes access to care" to mean that "remuneration provided improves a particularly beneficiary's ability to obtain medically necessary health care items and services." 79 FR 59725. The NPRM interprets "low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs" to mean remuneration that: "(1) is unlikely to interfere with, or skew, clinical decision-making; (2) is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) does not raise patient-safety or quality-of-care concerns." 79 FR 59725. The NPRM does not provide regulatory text but solicits proposals for language and examples of the types of remuneration to beneficiaries that would implement these principles.

Comment: NACHC recommends that OIG broadly interpret the phrase "promotes access to care" to ensure flexibility for reforms aimed at coordinating and integrating care through patient engagement and to include remuneration that is non-clinical but relates to medical care, such as social and legal services.

The NPRM asks a number of questions concerning what limitations or safeguards should be in place with regard to this safe harbor. The NPRM suggests that dollar limits on the remuneration or reporting requirements for providers on patient milestones and quality could be viable safeguards. NACHC, however, would discourage these particular limitations. At this time, if OIG set dollar limits or reporting requirements under this safe harbor, the restrictions would be entirely arbitrary given the

breadth of the types of remuneration that could promote access to care and the potential for innovation.

To respond to the chronic conditions of its patient population, health centers need flexibility to provide patients with technology that monitors weight, activity levels, glucose levels, and blood pressure. Additionally, some patients may require more intensive or long-term, sustained dietary interventions. Moreover, many patients face substantial social and legal obstacles to adhering to treatment and maintaining their health, such as lack of adequate health insurance, inadequate or unstable income and housing, obstacles to education, lack of job protections, discrimination, problems in the workplace, or lack of legal immigration status. Legal and social services to address these obstacles are critical to patient health. Although in principle these activities could be quantified in terms of cost and patient progress, much of the duration, intensity, and success of the intervention will depend on the starting point of the patient. As health centers care for a disproportionate share of indigent and uninsured patients, restrictions on how to promote access to care are problematic.

Similarly, the NPRM asks whether a safeguard should be in place that limits protected remuneration to interventions that have a reasonable connection to medical care. NACHC suggests that, if OIG pursues this safeguard, it should be tailored to allow for remuneration that is non-clinical but related to medical care, such as social and legal services. As described further below, health centers provide a wide array of items and services that are vital to the health of patients and the communities they serve. Many of these activities, such as outreach and enrollment activities and legal interventions that ensure access to medical care and address social determinants of health (*e.g.,* income stability, education and housing) may not constitute medical care. However, health centers are required to care for the entire patient as well as serve the broader community.

In determining the meaning of the phrase ”promotes access to care,” NACHC urges OIG to consider HRSA’s interpretation of “enabling services” which health centers are required to provide as part of primary health services under Section 330 of the Public Health Service Act. HRSA defines enabling services as “non-clinical services that do not include direct patient services that *enable individuals to access health care and improve health outcomes*.[3] Specifically, enabling services include case management, referrals, translation/interpretation, transportation, eligibility assistance, health education, environmental health risk reduction, health literacy, and outreach.”[4] In addition, HRSA recently clarified that enabling services include "child care, food banks/meals, employment and education counseling, [and] legal services/legal aid."[5] Such enabling services, critical to the mission of health centers, pose little risk of harm to beneficiaries or federal health care programs. **As such, NACHC strongly urges OIG to broadly interpret the phrase “promotes access to care” consistent with HRSA’s definition of “enabling services”, thereby encompassing non-clinical services such as social and legal services that enable individuals to access health care and improve health outcomes.**

2. Safe Harbor for Remuneration Provided to Recipient with Financial Need

Proposed Provision: The NPRM adds a statutory exception to the definition of remuneration for the offer or transfer of items or services for free or at less than fair market value after a determination

[3] *See* HRSA, Health Center Program Terms and Definitions*, available at* www.hrsa.gov/grants/apply/assistance/Buckets/definitions.pdf

[4] *Id.*

[5] *See* HRSA, Service Descriptors for Form SA: Services Provided, "Additional Enabling/Supportive Services”, *available at* bphc.hrsa.gov/about/requirements/scope/form5aservicedescriptors.pdf.

that the recipient is in financial need and meets certain other criteria as articulated in the ACA. Certain other criteria include that: (1) the protected items or services may not be offered as part of any advertisement or solicitation; (2) the offer of the items or services cannot be tied to the provision of other items or services reimbursed under Medicare or Medicaid; (3) there is a reasonable connection between the items or services and the medical care of the individual; and (4) the items or services are provided after determining in good faith that the individual is in financial need. 79 FR 59727-8. The NPRM explains that "items or services" do not include cash or instruments convertible to cash. 79 FR 59727.

Comment: NACHC supports a safe harbor for providing items or services to recipients in financial need. However, NACHC requests that OIG clarify how conditions will be applied to health centers and suggests that OIG clarify its expectations for the reasonable connection between free or discounted items and services and medical care.

First, as similarly described earlier in these comments, health centers must communicate the sliding fee discount program to patients. *See* Section II.A above. **With regard to the previously described concerns, NACHC requests that OIG clarify that such communications do not constitute advertising that fall outside the proposed safe harbor.**

Second, the NPRM states that an item or service is "tied" to reimbursement under Medicare or Medicaid if the provider conditions the offer or transfer of the item or service on the patient's use of other services from the provider reimbursed under Medicare or Medicaid. 79 FR 59727. The NPRM indicates that this condition does not require complete severance of the offer from the medical care of the individual. However, NACHC requests OIG clarify that this provision does not prevent providers from continuing to treat patients after having provided items or services for free or below fair market value. As described earlier in these comments, FQHCs must provide services to individuals regardless of their insurance status or ability to pay. *See* 42 U.S.C. § 254b(k)(3)(G)(iii). Additionally, health centers must provide discounts on fees or payments based on an individual's ability to pay. *See* 42 U.S.C. § 254b(k)(3)(G)(i). **Given the requirements for health centers to discount services, including to patients with third-party insurance covered, OIG should clarify that being "tied" to other items or services reimbursable under Federal programs does not bar health centers from furnishing additional services that are reimbursable under federal health care programs.**

Third, the NPRM describes the term "medical care" in the third condition as referring to the treatment and management of illness or injury and the preservation of health through services offered by medical, dental, pharmacy, nursing, and allied health professionals. 79 FR 59728. The NPRM states that a whether a "reasonable connection" exists will depend on specific facts and circumstances, and require analysis from both a financial and medical perspective. A reasonable connection to medical care from a medical perspective requires the item or service to benefit or advance medical care or treatment for the patient. *Id.* For example, the NPRM indicates that in the right context providing bike helmets to hemophiliac children would be reasonably connected to care. *Id.* However, providing bike helmets to financially needy children being treated in the emergency department may not be related to medical care. *Id.* A reasonable connection from a financial perspective exists if remuneration is disproportionately large compared with medical benefits conferred on the patient. *Id.* Such an imbalance will give rise to an inference that the transfer is being provided to induce beneficiaries to obtain additional services from the provider and would not be covered under the exception. *Id.*

NACHC suggests that OIG clarify what constitutes a reasonable connection to medical care. As described previously, health centers play an important and unique role in their community. Health centers provide the full spectrum of care services and innovate in care coordination. As part of this effort, health centers seek to provide a wide variety of items and/or services under this safe harbor,

including: items for expecting parents such as baby car seats, strollers, diapers, baby formula; items appropriate for children and families such as school supplies and toys; and items appropriate for all financially needy individuals such as food, clothing, books, weight monitors, glucose monitors, or gas cards in rural areas.

The NPRM asks if OIG can, or should, identify specific conditions under which remuneration would be deemed to be "reasonably connected" to patient's medical care, and solicits suggestions for possible conditions under which remuneration would be deemed to be "reasonably connected" to medical care. 79 FR 59727—8**. As described earlier, NACHC suggests that this safeguard still should allow for remuneration that is non-clinical but related to medical care, such as social and legal services. Additionally, NACHC supports deeming remuneration as reasonably connected to medical care under conditions that take into account the unique circumstances of the patient, in terms of physical, behavioral and financial circumstances. Additionally, NACHC urges deeming remuneration reasonably connected to medical care when identified by treating professionals as important to patient success and adherence to treatment.**

Finally, with regard to the fourth condition, items or services may only be provided after a good faith determination the individual is in financial need. The NPRM interprets this to require a good faith, individualized assessment of the patient's financial need on a case-by-case basis. 79 FR 59728. A good faith assessment would require, among other things, use of income guidelines with uniform application. *Id.* The NPRM goes onto say that "financial need" is not the same as "indigence" and can include any reasonable measure of hardship. *Id.*

NACHC supports the NPRM's interpretation of a good faith determination of financial need on a case-by-case basis so long as it does not require assessing need on each occasion that a patient receives services, which would be administratively impractical and pose a barrier to care. **NACHC requests that OIG confirm that health centers' annual determinations of patient financial need qualify as a good faith determination that the individual is in financial need under the safe harbor.**

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Thank you for the opportunity to comment on the NPRM. Please do not hesitate to contact me by telephone at (202) 296-0158 or by e-mail at rschwartz@nachc.org if you require any clarification on the comments presented above.

Sincerely,

Roger Schwartz
Associate Vice President of Executive Branch Liaison