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Office of Inspector General
Department of Health and Human Services
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**RE: Solicitation of New Safe Harbors and Special Fraud Alerts, 74 Fed. Reg. 68762,
et.seq. (December 29, 2009)**

To Whom It May Concern:

The National Association of Community Health Centers (NACHC) is pleased to respond to the above-cited solicitation from the Office of Inspector General (OIG) within the Department of Health and Human Services (HHS) for the promulgation of a new safe harbor under the anti-kickback statute [Section 1128B(b) of the Social Security Act; 42 U.S.C. §1320a-7b(b)]. NACHC is the national membership organization for federally-supported and federally recognized health centers (hereinafter interchangeably referred to as “health centers” or FQHCs) throughout the country, and is an Internal Revenue Code Section 501(c)(3) organization. NACHC also serves as a source of information, analysis, research, education, training, and advocacy regarding medically underserved people and communities.

Background

There are, at present, approximately 1,250 health center entities nationwide, which serve as the health care homes to twenty (20) million persons at more than 7,500 sites located in all fifty (50) states, Puerto Rico, the District of Columbia, the U.S. Virgin Islands and the Pacific Islands. Most of these health centers receive federal grants under Section 330 of the Public Health Service Act (42 U.S.C. §254b) from the Bureau of Primary Health Care (BPHC), within the Health Resources and Services Administration (HRSA). Under this authority, health centers fall into four general categories: (1) centers serving medically underserved areas and/or populations (invariably poor communities); (2) centers serving homeless populations within a particular community or geographic area; (3) centers serving migrant or seasonal farm worker populations within a particular community or geographic area; and (4) centers serving residents of public housing projects. Although there are some slight differences in the grant requirements for each of these four program types, for all intents and purposes, the ways in which these health centers operate are identical.

To qualify for a Section 330 grant or an FQHC look-alike designation¹, a health center must (among other requirements) be located in or serve a federally-designated Medically Underserved Area (MUA) or Medically Underserved Population (MUP). Nearly 70% of health center patients live in poverty. Patients from eligible communities who are not low-income or who have insurance (whether public or private) are expected to pay for the services rendered. Approximately 36% of the patients served by health centers are Medicaid/SCHIP recipients, approximately 8% are Medicare beneficiaries, and approximately 38% are uninsured.

FQHCs are required to make services available to all residents of their service areas. *See* 42 U.S.C. §§ 254b(a)(1).² In providing a comprehensive continuum of care, FQHCs are required to furnish a wide array of required primary health services, including, among other things, basic primary care services (*e.g.*, family medicine, internal medicine, pediatrics, obstetrics and gynecology) and preventive health services, including prenatal and perinatal services; cancer screenings; well-child services; immunizations; screenings for elevated blood lead levels, communicable diseases and cholesterol; pediatric eye, ear and dental screenings; voluntary family planning services; and preventive dental services. *See* 42 U.S.C. §§ 254b(b)(1)(A)(i)(I) & (III). FQHCs also are required to provide various support services to ensure patients have the ability to access all required health care services, such as referrals, case management, enabling services (*e.g.*, transportation, translation), and patient education / health promotion. *See* 42 USC §§ 254b(b)(1)(A)(ii) – (v).

The Section 330 grant funds are intended to support the costs of providing this comprehensive array of preventive and primary care and enabling services to uninsured and underinsured low-income patients. As a result of furnishing these services, health centers save the national health care system between \$9.9 billion and \$17.6 billion a year by helping patients avoid emergency rooms and making better use of preventive services including screening, diagnosis and management of chronic illnesses such as diabetes, asthma, heart and lung disease, depression, cancer and HIV/AIDS. Both infant mortality and rates of low birth weight are reduced in communities served by a health center – sometimes by as much as 40%.

Proposed Safe Harbor to Protect Incentives Provided to Health Center Patients

NACHC proposes the promulgation a new safe harbor to protect certain motivational incentives provided to health center patients (hereinafter, the “Proposed Health Center Patient Incentive Safe Harbor”), which could otherwise violate the federal anti-kickback statute set forth in Section 1128B(b) of the Social Security Act and/or the beneficiary inducement prohibition set forth in section 1128A(a)(5) of the Social Security Act. Consistent with the primary mission of the health center program, the purpose of the Proposed Health Center Patient Incentive Safe Harbor is to increase access to, and the quality of, primary and preventive care to medically underserved, vulnerable populations and communities, and to reduce the costs of providing such care, by offering low-income patients motivational incentives to seek the appropriate level of low-cost preventive and primary care in advance of the development of costly chronic conditions

¹ In addition to those health centers receiving grant funds pursuant to one or more of the Section 330 funding programs, there are certain entities that are designated by the Centers for Medicare and Medicaid Services (CMS) as FQHCs, by virtue of the fact that they meet all of the requirements to receive a Section 330 grant, but do not receive funding from HRSA. For purposes of this comment, unless otherwise noted, we do not distinguish between grantees and FQHC look-alike entities, collectively referring to both types of organizations as “FQHCs” or “health centers.”

² There are certain exceptions to this requirement for health centers that receive grant funds solely to serve migrant and seasonal farmworkers, homeless individuals and families, and/or residents of public housing.

and, for patients with chronic conditions to increase compliance with necessary treatment regimens.

NACHC recognizes the concerns raised by offering incentives to patients. As stated in the OIG Special Advisory Bulletin “Offering Gifts and Other Inducements to Beneficiaries,” (August 2002), “[O]ffering valuable gifts to beneficiaries to influence their choice of a Medicare or Medicaid provider raises quality and cost concerns. Providers may have an economic incentive to offset the additional costs attributable to the giveaway by providing unnecessary services or by substituting cheaper or lower quality services.” However, given the primary mission of the health center program – to increase access to, and the quality of, care while reducing the associated costs – such concerns are minimal. As discussed below, health centers are nationally recognized for furnishing high quality, efficient and cost-effective care, which in turn, reduces or eliminates the need for more costly care (such as emergency room visits and avoidable hospital stays) and, thus, generates significant savings to the entire health care system. Offering motivational incentives to patients is an effective and successful method by which health centers are able to encourage their patients to seek such care – thus achieving results that are beneficial to the health center’s patients and its underserved community as well as to the health care system overall.

The OIG Special Advisory Bulletin lists several circumstances under which providers are allowed to offer gifts to patients without running afoul of the law, including:

- Inexpensive gifts or services, which are defined as gifts or services that have a retail value of no more than \$10 individually and no more than \$50 in the aggregate annually per patient, provided that the gifts or services are not in the form of cash or cash equivalents.
- More expensive items or services that fit within one of five statutory exceptions:
 - Unadvertised, non-routine waivers of cost-sharing amounts based on individualized determinations of financial need and/or exhaustion of reasonable collection efforts.
 - Properly disclosed co-payment differentials in health plans.
 - Incentives to promote the delivery of certain preventive care items or services (provided that the items or services are covered by Medicare/Medicaid, the incentives are not in the form of cash or cash equivalents, and the incentives are not disproportionate to the value of the items/services provided).
 - Any practice permitted under the federal anti-kickback statute pursuant to 42 CFR 1001.952.
 - Waivers of hospital outpatient co-payments in excess of the minimum co-payment amounts.

Some gifts and motivational incentives provided by health centers to encourage patients to seek timely and appropriate low-cost preventive and primary and to comply with necessary treatment regimens meet these requirements. However, due to the very nature of particular incentives, many are unable to do so. For example, one of the most effective ways in which to encourage compliance with children’s immunization schedules is to provide parents with gifts cards for back to school items or other items related to the child’s well-being. Similarly, providing

diapers, formula, gift cards for baby items, and car seats have proven effective in encouraging compliance with pre-natal regimens. Providing “every-day” necessities that are connected to either the patient’s condition or the particular service or treatment he or she receives, and that are necessary for the general well-being of the patients and their families often alleviates the need for low-income patients to choose between receiving necessary health care services or obtaining other necessities. Notwithstanding their proven effectiveness in encouraging the appropriate level of care provided on a timely basis, arrangements to offer these types of incentives are not protected from prosecution without seeking an individual advisory opinion.

Accordingly, NACHC proposes the promulgation of a new safe harbor to protect arrangements under which health centers offer certain motivational incentives to encourage patients to seek appropriate, necessary and timely care. To minimize the possibility of unnecessary or excessive expenditures of federal funds while offering a critical community benefit, namely, the delivery and enhancement of health care services to the poor and uninsured, NACHC proposes that certain conditions or safeguards be built into the Proposed Health Center Patient Incentive Safe Harbor:

- The health center will be required to demonstrate that the motivational incentive will be provided for one of the following reasons: (1) to encourage patients to obtain services, treatment plans or clinical programs that are appropriate and medically necessary based upon a clinician’s determination; (2) as a means to reward compliance with a treatment plan or other clinical program; or (3) as a means to reward the achievement of pre-defined treatment-related goals and/or good health outcomes.
- The health center will be required to demonstrate that the motivational incentive is connected to either the patient’s condition or the particular service, treatment plan or clinical program he or she receives (similar to the aforementioned examples).
- The motivational incentive is not advertised; rather, it is discussed with the patient subsequent to the clinical determination that the patient should obtain the recommended service, treatment plan or clinical program.
- The motivational incentive will be awarded upon the patient’s completion of the recommended service, treatment plan or clinical program (or an appropriate, pre-determined portion thereof), or upon meeting certain predefined clinical goals / health outcomes or other appropriate milestones.
- The health center will be prohibited from using the motivational incentive for marketing or promotional purposes.
- The health center will be prohibited from providing a motivational incentive that can be redeemed for cash or for services or items provided by the health center.
- The health center will be prohibited from providing a motivational incentive that can be redeemed at stores or with vendors operated by or related to other health

care providers or that contain health care goods and services (such as pharmacies) OR the health center will limit the ability of patients to redeem the motivational incentive to the non-health care related departments within the store or vendor.

- The health center will be required to advise patients of their freedom to choose a provider other than the health center, subject to valid limitations imposed by a managed care arrangement.
- The clinical items/services furnished by the health center (the receipt of which formed the underlying basis for providing the motivational incentive) must be included in or related to the health center's federally-approved scope of project.
- The provision of the motivational incentive will not offer any financial benefit to the health center and/or its clinicians which could influence the purchase or order of health care items or services or the generation of other business paid for, in whole or in part, by federal health care programs.

Evaluation Criteria

In its solicitation, the OIG listed several criteria it will consider in reviewing and evaluating proposals for new and modified safe harbors. The Proposed Health Center Patient Incentive Safe Harbor advances all of the criteria relevant to the circumstances of the proposed type of arrangement.

Increased Access to Health Care Services

The arrangements protected under the Proposed Health Center Patient Incentive Safe Harbor will increase access to health care services for underserved populations and communities. As noted above, the primary mission of the health center program is to improve access to, and the quality of, primary and preventive care services furnished to vulnerable populations that would otherwise not have access to these services. Because health centers focus their efforts on underserved populations, low income, uninsured health center patients are much more likely to have a usual source of care than the uninsured nationally. Further, uninsured people living within close proximity to a health center are less likely to have an unmet medical need, less likely to visit the emergency room or have a hospital stay, and more likely to have had a general medical visit compared to other uninsured.

One of the ways in which health centers enhance access to care is by engaging in outreach activities and educating existing and potential patients about the importance of seeking the appropriate level of care on a timely basis, rather than waiting until serious conditions arise requiring costly urgent, emergent and/or specialty care, or more intensive treatment. Notwithstanding, the low-income, indigent populations served by health centers often must make difficult choices regarding how to use their scarce financial resources, which could hinder or preclude the seeking of such care. Providing motivational incentives to ensure that patients initially obtain and continue to receive necessary primary, preventive and well care services is a key component of the outreach and educational processes.

For example, it is well-documented that compliance with certain prenatal treatment regimens (*i.e.*, prenatal vitamins, timely office visits, appropriate testing, *etc.*) plays a vital role in decreasing the rates of infant mortality and low birth weight as well as generally ensuring the health and well-being of both mothers and their infants. However, it is often difficult for low-income women to follow such regimens due to various barriers to care, including inability to keep appointments and choosing to expend limited resources on other necessities required by their families. By offering applicable incentives to obtain appropriate prenatal care (*e.g.*, diapers, formula, car seats, gift cards to baby stores), many of these women will not be required to make these difficult choices and thus, access to pre-natal care for low-income women is increased.

The same can be said for health center patients with chronic conditions, such as diabetes, cardiovascular disease, asthma, depression, cancer, and HIV. A common thread among these conditions is the amount of time and resources required to obtain appropriate treatment. By offering motivational incentives that are connected to either the patient's condition or the particular service or treatment he or she receives, patients will not have to make the difficult choice between obtaining necessary care and ensuring compliance with treatment regimens and access to care will be increased (and, as discussed below, the costs of treatment will be reduced).

Enhanced Quality of Health Care Services

The arrangements protected under the Proposed Health Center Patient Incentives Safe Harbor will enhance the quality of health care services provided to health center patients. In general, studies have found that the quality of care provided at health centers is equal to or greater than the quality of care provided elsewhere. Moreover, 99% of surveyed patients report that they were satisfied with the care they receive at health centers. As discussed above, health centers are nationally recognized for providing care at the appropriate level – patients receive timely preventive and primary care, thereby avoiding the need for hospital and specialty care. Timely treatment at the appropriate level care which is delivered in the community where the patient resides also translates into the delivery of quality health services.

Health centers have been recognized as meeting or exceeding nationally accepted practice standards for the treatment of chronic conditions such as diabetes, cardiovascular disease, asthma, depression, cancer, and HIV. Both the Institute of Medicine and the Government Accountability Office have recognized health centers as models for screening, diagnosing, and managing chronic conditions and that health centers' efforts have led to improved health outcomes for their patients.

However, if health center patients choose not to obtain timely and appropriate primary and preventive care, these results cannot be achieved. Providing appropriate incentives to patients can be a powerful and successful tool in encouraging patients to receive (and to continue to receive) the primary and preventive care required to ensure improved health outcomes and enhanced quality of care overall.

Reduced Costs to Federal Health Care Programs

The arrangements protected under the Proposed Health Center Patient Incentive Safe Harbor will reduce the costs of care and thus, the costs to federal health care programs such as Medicaid and Medicare (payments from which comprise approximately 44% of health center revenues). As

noted above, health centers provide a huge benefit to communities throughout this nation by furnishing efficient and cost-effective primary and preventive care, which in turn, reduces or eliminates the need for more costly care (such as non-urgent emergency room visits and unnecessary, avoidable hospital stays) and, thus, generates significant savings to the entire health care system. Care received at health centers is ranked among the most cost-effective. Two recent reports found that total patient care costs are 24-50% lower than those served in other settings, producing up to \$24 billion in annual health system savings. This includes \$6.7 billion in savings for the federal share of the Medicaid program, and is driven by lower utilization of costly specialty care, emergency departments, and hospitals.

In addition to comprehensive primary care, health centers furnish preventive care, including screening, diagnosis and management of chronic illnesses, that reduces the risk of new health care problems thus lowering the cost of treating patients with chronic diseases. By focusing on increasing the availability of relatively low-cost preventive and primary care services and by creating alternatives to costly non-urgent emergency room visits and/or specialty care, the overall potential cost of care are lowered as well.

Unless, however, health center patients choose to obtain timely low-cost primary and preventive care services, these cost savings cannot be achieved. Thus, providing appropriate motivational incentives not only enhances access to and improves the quality of care, but also assists in keeping the costs of health care (and thus federal health care costs) to a minimum by encouraging patients to obtain low-cost primary and preventive care.

Minimal Potential for Over-Utilization of Health Care Services

The arrangements protected under the Proposed Health Center Patient Incentive Safe Harbor are not likely to result in over-utilization of health care services. The key problem faced by populations served by health centers is lack of health care access. Consequently, expansion of services to this population fills a current unmet need rather than establishing a base for the delivery of unnecessary or duplicative care.

Moreover, health centers are not-for-profit or public grantees of the federal government whose sources of income are strictly scrutinized and tightly-regulated through the federal grant application process, regular oversight, and annual audits, as well as by the Medicaid and Medicare programs. As noted above, approximately 36% of the patients served by health centers are Medicaid/SCHIP recipients, approximately 8% are Medicare beneficiaries, and approximately 38% are uninsured. Thus, in addition to being continually scrutinized by various federal programs (minimizing the potential for abuse or private "enrichment"), health centers have neither the capacity nor the financial incentive to allow for over-utilization of services. Finally, as discussed above, health center services reduce the need for costly hospital and specialty referrals, thereby minimizing the opportunity for over-utilization.

Greater Ability to Provide Services in Medically Underserved Areas or to Medically Underserved Populations

The arrangements protected under the Proposed Health Center Patient Incentive Safe Harbor will offer a greater ability to provide services in Medically Underserved Areas (MUAs) or to Medically Underserved Populations (MUPs). As discussed above, to qualify for Section 330

February 8, 2011

Page 8 of 8

grant funds or FQHC look-alike designation, health centers must be located in or serve an MUA/MUP. As such, by definition, the Proposed Health Center Patient Incentive Safe Harbor protects arrangements that would increase the ability of health centers to provide services in MUAs and MUPs as well as the effectiveness of such services.

No Adverse Impact on Patient Freedom of Choice or Competition among Health care Providers

The arrangements protected under the Proposed Health Center Patient Incentive Safe Harbor will not adversely impact patient freedom of choice or competition among health care providers in the community. As noted above, the health center will be required to advise patients of their freedom to choose a provider other than the health center, subject to valid limitations imposed by a managed care arrangement. Further, because health centers must be located in or serving an MUA/MUP, by definition the centers are operating in areas where there is a shortage of health professionals and thus, no or little competition to promote. Establishing or maintaining access to services is the primary challenge in these areas.

Conclusion

Based on the foregoing, NACHC believes that arrangements protected under the Proposed Health Center Patient Incentive Safe Harbor will help achieve the goals of the Section 330 grant program (as well as the Medicaid and Medicare programs) of maintaining and improving access to, and the quality of, health care services provided to low-income and vulnerable populations, without creating opportunities for fraudulent or abusive expenditures of federal health care funds.

Thank you for the opportunity to respond to the above-referenced solicitation for new safe harbors and special fraud alerts. We look forward to the opportunity to further discuss with this proposal for the promulgation of a new Health Center Patient Incentive Safe Harbor. If you have any questions about the contents of this document or the proposal itself, please call or email me at 202-296-0158 or rschwartz@nachc.com.

Sincerely,



Roger Schwartz
Associate Vice President of Executive Branch Liaison