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December 1, 2014

Office of Inspector General  
Department of Health and Human Services  
Attn: OIG-403-P  
Cohen Building  
330 Independence Avenue S.W., Room 5269  
Washington, DC 20201

Submitted via [www.regulations.gov](http://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:

Bi-State Primary Care Association 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 (DHHS) on October 3, 2014 (79 Fed. Reg. 59717) (the NPRM).

Established in 1986, Bi-State is a nonpartisan, nonprofit 501(c)(3) charitable organization that promotes access to effective and affordable primary care and preventive services for all, with special emphasis on underserved populations in Vermont and New Hampshire. Bi-State works with federal, state and regional health policy organizations, foundations and payers to develop strategies, policies and programs that provide and support community-based primary health care services in medically-underserved areas. Our members include Community Health Centers, which include Federally Qualified Health Centers (hereinafter interchangeably referred to as health centers or FQHCs); Rural Health Clinics; private and hospital-supported primary care practices; Community Action Programs; Health Care for the Homeless programs; Area Health Education Centers; Clinics for the Uninsured, and social service agencies.

Bi-State fully endorses the National Association of Community Health Center's letter that will be submitted before the OIG's deadline. Our letter reflects their comments and concerns.

As we understand, the NPRM would:

- Revise the Medicare and Medicaid safe harbors under the Anti-Kickback Statute;
- Amend the Civil Monetary Penalties (CMP) rules pertaining to beneficiary inducement and gain sharing;
- Codify protection for certain cost-sharing waivers related to pharmacy services provided to financially needy Medicare Part D beneficiaries;
- Codify protection for remuneration between Medicare Advantage organizations and FQHCs;
- Codify protection for free or discounted local transportation services that meet specified criteria;
- Amend the definition of "remuneration" in the CMP regulations related to the prohibition against inducements; and
- 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.

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Our greatest concern is that the NPRM as proposed would impact 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.

Last, the NPRM would extend protections to free items offered by health centers that promote the health, well-being and safety of their patients.

In general, Bi-State 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 (PHS 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**

Nationally, there are almost 1,300 health centers with more than 9,300 sites serving more than 22 million patients nationwide. In Vermont and New Hampshire, 22 health centers serve over 227,000 patients through their 81 sites. Most of these health centers receive federal grants under Section 330 of the PHS 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) 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 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. Nationally, ~39% of health center patients are Medicaid recipients, ~36% are uninsured, and ~15% are privately insured. In New Hampshire, 22% of health center patients are Medicaid recipients, 29% are uninsured and 34% are privately insured while in Vermont, 27% of health center patients are Medicaid recipients, 10% are uninsured and 45% 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 PHS Act to reduce social, economic, and cultural barriers to accessing care, and their locations in medically underserved rural and urban

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areas, health centers function at the intersection of the health care safety net and public health in communities across America.

Bi-State recommends several revisions to the NPRM in order to reduce legal barriers to health centers effectively carrying out their public purposes.

With regard to revisions in the NPRM to protect the reduction or waiver by pharmacies of any cost-sharing obligations imposed under Medicare Part D, Bi-State suggests that OIG provide additional guidance:

- To ensure that required health center communications about sliding fee discount programs do not constitute “advertising” under the safe harbor;
- To 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
- To 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), Bi-State recommends that OIG clarify that this safe harbor provides protection for four specific types of remuneration between a health center and an MA organization:

- Compensation to health centers that exceeds fair market value;
- Donation of free space by health centers to MA organizations;
- Financial support of health centers community outreach activities, information technology; infrastructure costs; and
- Arrangements in which provider networks stand in the shoes of MA organizations.

Similarly, Bi-State supports addition of a new safe harbor to protect free or discounted local transportation services to Federal health care program beneficiaries. However, Bi-State recommends that OIG expand the safe harbor to protect the provision of services to new and established patients; shield arrangements among care collaboration partners; and include entities exploring delivery system reforms. Additionally, Bi-State 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, Bi-State 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, Bi-State 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, Bi-State 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)**

Bi-State 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, Bi-State 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 individualized determinations of financial need.

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**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% FPL), then conditions (2) and (3) above are not required for protection under the safe harbor. *Id.* § 1128B(b)(3)(G).

**Comment:** Bi-State supports the addition of a safe harbor for the reduction of cost-sharing imposed by Medicare Part D. As such, Bi-State'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% FPL) 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, this statutory safe harbor is limited to services paid under Part B of Medicare (though the regulatory safe harbor extends the safe harbor also to services paid by State health care programs, i.e., Medicaid). *Id.* Therefore, the existing safe harbor creates an unfortunate gap that does not protect waivers of cost-sharing obligations for services paid under Medicare Part D. Bi-State asks that OIG clarify that certain health center activities described below fit comfortably within the new safe harbor.

First, health centers 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 PHS 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 applies to individuals who meet eligibility requirements with third-party coverage when the individual cannot afford cost-sharing. *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 would include 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. **Bi-State 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, health centers 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 cannot afford cost-sharing, including those individuals who have third party coverage. HRSA 2014-02. Eligibility for the sliding fee discount program is set by HRSA and based on patients' income and family size. *Id.* Approximately 93% of health center patients have incomes at or below 200% of the Federal Poverty Line.<sup>1</sup> Consequently, most health center patients are eligible for a sliding fee discount and therefore waivers of cost-sharing obligations occur frequently. **Bi-State requests that OIG clarify that waivers or reductions in cost-sharing obligations under Part D, despite occurring frequently as a result of the population served by health centers, would not be construed as a “routine” waiver under the proposed safe harbor.**

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<sup>1</sup> 2012 Uniform Data System, BPHC, HRSA, DHHS.

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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. 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.* Consequently, health centers perform these eligibility assessments on an annual basis and not on each occasion that a patient receives services. **Bi-State 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, Bi-State supports adding § 1001.952(z) to protect remuneration between a health center and a MA organization pursuant to a written agreement described in § 1853(a)(4) of the SSA. 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 exclude 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:** Bi-State 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, **Bi-State requests that OIG confirm that remuneration between an MA organization and a health center is protected without regard to fair market value.**

Second, **Bi-State requests OIG confirm that the provision of free space to the MA organization would be protected remuneration under the proposed safe harbor.**

Third, **Bi-State 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, **Bi-State 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.**

As currently proposed, the safe harbor is unclear as to whether or not certain arrangements would fit within the proposed safe harbor. This uncertainty will impede beneficial arrangements Congress sought to protect between MA organizations and health centers. Bi-State recommends that OIG clarify that the proposed safe harbor protects the forms of remuneration between health centers and MA organizations described above.

**C. Proposed 42 C.F.R. § 1001.952(bb)**

In general, Bi-State supports the addition of a new safe harbor to protect free or discounted local transportation services to Federal health care program beneficiaries. However, Bi-State would suggest that OIG to expand the safe harbor to include new and established patients; collaboration partners; and entities exploring delivery

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system reforms. Additionally, Bi-State 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:** Bi-State supports inclusion of a safe harbor for discounted transportation services. However, Bi-State recommends that OIG: (1) expand the safe harbor to include transportation offered to new patients as well as established patients; (2) clarify that collaboration partners may transport patients between sites; (3) apply the safe harbor to organizations exploring delivery system reforms such as Accountable Care Organizations (ACOs); and (4) 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, Bi-State urges the OIG to expand the safe harbor to protect transportation furnished to both new and established patients of health centers.**

**Second, Bi-State suggests that transportation furnished under coordinated care programs be explicitly included in this safe harbor.**

**Third, Bi-State urges OIG to include transportation furnished by ACOs or under delivery system reform models under the protections afforded by the safe harbor.**

**Fourth, Bi-State 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.**

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

In general, Bi-State 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 ACA added four new statutory exceptions protecting certain charitable and other programs. ACA § 6402(d)(2)(B). Bi-State limits its comments to two of these exceptions described in the NPRM. First, Bi-State 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, Bi-State 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, Bi-State 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, Bi-State 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:** Bi-State 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 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. Bi-State, 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. In the health center context, FQHCs 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. 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. Bi-State 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 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

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enrollment activities or case management, may not constitute medical care. However, health centers are required to care for the entire patient as well as serve the broader community.

Section 330 of the PHS Act requires health centers to provide required primary health services, including “enabling services.” 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. Enabling services include case management, referrals, translation/interpretation, transportation, eligibility assistance, health education, environmental health risk reduction, health literacy, and outreach.” *See* HRSA, Health Center Program Terms and Definitions.<sup>2</sup> Enabling services and other health center activities, such as education of patients and the general population, are critical to the mission of health centers. Bi-State supports holistic approaches to health. **As such, Bi-State strongly urges OIG to broadly interpret this safe harbor and allow providers maximum freedom to address non-clinical aspects of patient health.**

**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 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:** Bi-State supports a safe harbor for providing items or services to recipients in financial need. However, Bi-State requests that OIG clarify how conditions will be applied to health centers and suggests that OIG extensively interpret the reasonable connection between free or discounted items and services and medical care.

**First, With regard to the previously described concerns, Bi-State requests the OIG clarify that such communications do not constitute advertising that fall outside the proposed safe harbor.**

**Second, 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 include discounts provided by health centers.**

**Third, Bi-State suggests that OIG expansively approach 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

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<sup>2</sup> *See* <http://www.hrsa.gov/grants/apply/assistance/Buckets/definitions.pdf>



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described earlier, Bi-State suggests that this safeguard still should allow for remuneration that is non-clinical but related to medical care, such as social services. **Additionally, Bi-State 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, Bi-State approves of deeming remuneration 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 on to say that "financial need" is not the same as "indigence" and can include any reasonable measure of hardship. *Id.* OIG asks for comments as to whether or not they can require documentation of financial need.

Bi-State supports the NPRM's interpretation of a good faith determination of financial need. Still, Bi-State requests that OIG affirm that health center's assessment of patients' ability to pay under the sliding fee discount schedule requirements is a sufficient, individualized determination of financial need under this safe harbor. Health centers must discount the sliding fee schedule for individuals below 200% FPL. *See* HRSA PIN 2014-02. **Bi-State requests that OIG confirm these determinations of financial need or sufficient for the safe harbor.**

\* \* \*

Thank you for the opportunity to comment on this Proposed Rule. Please do not hesitate to contact me at (603) 228-2830 or via e-mail at [tkuennig@bistatepca.org](mailto:tkuennig@bistatepca.org) if you require any clarification on the comments presented above.

Sincerely,



Tess Stack Kuenning, CNS, MS, RN  
President and Chief Executive Officer