

Submitted via email

April 2, 2021

Ms. Christi A. Grimm  
Principal Deputy Inspector General  
Department of Health and Human Services  
Office of Inspector General  
Attention: OIG-1117-N, Room 5527, Cohen Building,  
330 Independence Avenue, SW  
Washington, DC 20201

**Re: Solicitation of New Safe Harbors and Special Fraud Alerts, OIG-128-N**

Dear Ms. Grimm:

On behalf of the CMS Tribal Technical Advisory Group (TTAG), I write to you regarding the Office of Inspector General's (OIG) Solicitation of New Safe Harbors and Special Fraud Alerts. The TTAG advises CMS on Indian health policy issues involving Medicare, Medicaid, the Children's Health Insurance Program, and any other health care programs funded (in whole or part) by CMS. In particular, TTAG focuses on providing policy advice to CMS regarding improving the availability of health care services to American Indians and Alaska Natives (AI/AN) under these federal health care programs, including through providers operating under the health programs of the Indian Health Service (IHS), Tribes, Tribal organizations, and Urban Indian organizations (I/T/Us or Indian health care providers). We appreciate the opportunity to provide information and comments on your request.

**1. OIG Should Create a Indian Health Care Provider (IHCP) Safe Harbor Akin to the FQHC Safe Harbor.**

In its most recent solicitation, OIG has sought information concerning additional or modified safe harbors to the anti-kickback statute (AKS) or exceptions to the definition of "remuneration" under the beneficiary inducements civil monetary penalties (CMP) that may be necessary to protect such arrangements. Under the current AKS and CMP regime, any transfer of remuneration from a health provider to a potential referral source or patient is prohibited if an imputed purpose for the transfer could be to encourage referrals or induce patients to seek services from the provider, unless the transaction fits squarely within an existing AKS safe harbor or CMP exception. The Indian health system is currently—and will continue to be—severely hamstrung by the broad scope of these laws and the severe penalties for violating them -- unless the current fraud and abuse regime is changed to recognize the unique characteristics of the Indian health care system, encourage coordinated care among Indian health care providers (IHCPs), and support efforts to improve access and outcomes for the system's American Indian and Alaska Native beneficiaries, who as a group are medically underserved and have the lowest health status in the nation.

In response, we attach recommendations for new safe harbors for IHCPs. These would build upon and create parity with the existing safe harbor for Federally Qualified Health Centers (FQHCs), with whom IHCPs share key attributes that justify the safe harbors, as we explain below.

*This is not a new or novel request.*

Since 2012, the TTAG and Tribes have requested that the OIG create a safe harbor for IHCPs akin to the safe harbors provided for Federally Qualified Health Centers (FQHCs) at 42 C.F.R. § 1001.952(w). TTAG submitted comprehensive recommendations to OIG's 2012 annual safe harbor comment solicitation, and again in 2014, 2015, and 2018. In 2019, the TTAG submitted the same request once again in its comments on the new safe harbor regulations OIG proposed that year.

The TTAG is disappointed that the OIG has not yet created a safe harbor for IHCPs. It has been nine years since the TTAG's first request. In 2019, the OIG undertook a comprehensive update of its safe harbor regulations in its Regulatory Sprint to Coordinated Care, adding seven new safe harbors and modifying four existing ones. The TTAG requested OIG include the safe harbor for Indian health care providers as part of that Regulatory Sprint, but OIG declined to do so, leaving Indian health care providers behind.

As the TTAG noted in its comments on the proposed rule, none of the new safe harbors are useful to IHCPs. The new safe harbors are based on value-based entities assuming and sharing downside risk. These types of market arrangements do not work for the federally funded Indian health care delivery system, which cannot take on the types of downside risk required to qualify for the Safe Harbor.

What the Indian health system needs is its own safe harbor akin to that for FQHCs. *There is no reason for the OIG to maintain a safe harbor for FQHCs, but not for Indian health care providers.* IHCPs have *all* of the attributes of FQHCs that were cited by the OIG as mitigating against risk of abuse in its final rule establishing the FQHC safe harbor. Like FQHCs, IHCPs are federally funded. 72 Fed. Reg. 56632, 56636 (Oct. 7, 2007). Like FQHCs, IHCPs serve individuals in medically underserved areas. 72 Fed. Reg. at 56633. Like FQHCs, IHCPs have a complex statutory and regulatory framework they must operate under and, among other restrictions, they are statutorily required to apply all their federal funding and program revenue on health care related services. For example, Section 401 of the Indian Health Care Improvement Act (IHCA) requires IHCPs to use Medicare, Medicaid, and CHIP reimbursements to achieve or maintain compliance with Medicare, Medicaid and CHIP requirements or any other health care related purposes. 25 U.S.C. § 1641.

In addition, Section 508(j) of ISDEAA requires all program income to be treated as supplemental funding to a tribe or tribal organization's funding agreement. 25 U.S.C. § 5388(j). This means that any third-party reimbursements—Medicare, Medicaid, CHIP, private insurance, etc.—must be used in furtherance of the Nation's ISDEAA agreement with the IHS. Like FQHCs, IHCPs are

often offered “remuneration” from other providers and suppliers interested in supporting the FQHC’s or IHCP’s mission through, for example, "capital development grants, low cost (or no cost) loans, reduced price services, or in-kind donations of supplies, equipment, or space." 72 Fed. Reg. at 56634.

In the only advisory opinion the OIG has issued with regard to an Indian health care provider, it advised that an arrangement in which a tribally operated health care provider negotiated a 10 percent discount for Medicare patients it referred to a certain hospital, whose care the Indian provider paid for, would not be subject to enforcement under the Anti-Kickback statute, even though the arrangement clearly implicated the AKS. OIG Advisory Opinion 01-03. In doing so, the OIG noted that the proposed arrangement would not result in the expenditure of any additional federal funds, and that it "arises in the context of the unique and historic relationship between the Federal government and the sovereign Indian nations, pursuant to which Congress has promulgated certain health care programs for the benefit of Indian people." The same considerations should inform the OIG here.

American Indians and Alaska Natives make up a large portion of the country’s medically underserved populations and remain predominantly low-income individuals with limited access to care. Indian health care providers need the same option as FQHCs to enter arrangements with hospitals, providers, and suppliers, and establish collaborative relationships, such as capital development grants, low-cost or no-cost loans, reduced price services, and in-kind donations of supplies, equipment or facility space. Having a safe harbor specific to Indian health care providers, mirrored on the one in place for FQHCs, would substantially help these underfunded programs achieve those needs and conserve Indian Health Service and other federal funds, by allowing them to accept goods, items, services, donations or loans from willing providers and suppliers. Outpatient clinics operated by tribes under the Indian Self-Determination and Education Assistance Act (ISDEAA) and urban Indian organizations contracting with IHS under Title V of the Indian Health Care Improvement Act are already defined to be FQHCs under the Social Security Act, but clinics operated by the IHS are not, nor are Indian hospitals operated by tribes or the IHS. Most of the nation's Indian health providers either do not meet the definition of an FQHC (Tribal hospitals, for example) or are not enrolled in Medicare and Medicaid as an FQHC. As a result, the existing FQHC safe harbor is not available to the vast majority of IHCPs.

The coronavirus disease (COVID-19) pandemic has only underscored the need for an Indian specific safe harbor. Indian health care providers—more than ever—need to partner with health care providers and suppliers outside the Indian health care system to work together to address public health crises like COVID-19 and the opioid epidemic.

For example, OIG lists a number of arrangements in its coronavirus FAQs that would technically violate the Anti-Kickback Statute, but which the OIG would not enforce during the Public Health Emergency due to low risk of fraud. One example OIG provides is providers and suppliers such as hospitals, pharmacies, and health systems donating free supplies and services for coronavirus

vaccination purposes. OIG concludes that such activity poses a low risk of fraud and states that it would decline to bring an enforcement action against it even though providing free or discounted goods and services would technically violate the Anti-Kickback statute. The temporary relief this FAQ provides is critically important for IHCPs that received donations to help them with coronavirus vaccination, and for IHCPs that were able to share their supplies with other IHCPs. We note, however, that FQHCs did not have to rely on this OIG non-enforcement statement, because the existing FQHC safe harbor allows FQHCs to accept donations to carry out their mission at any time, and not only during the current pandemic. IHCPs need the same flexibilities. They too must be allowed to partner with other providers in order to fulfill their mission of providing care to one of the most medically underserved populations in the country.

## 2. Conclusion

The TTAG appreciates the opportunity to work together with OIG to refine an Indian Health Care safe harbor, including provisions that would treat Indian health care programs in a manner consistent with FQHCs under the federal health care fraud and abuse laws. It is critical for OIG to understand that the existing safe harbors simply do not work for Indian health care providers. Adopting our recommended safe harbor would provide much needed clarity and give Indian health programs the flexibility to save resources and expand access to quality health care for their patients by, for example, entering into collaborative health care arrangements, referring and paying for specialty services, sharing scarce personnel and resources, improving physician recruitment and retention, accepting donations of goods and services from other providers, and providing beneficiary supports and services – with appropriate safeguards and without fear of violating federal law.

Thank you for the opportunity to respond to your request for information. We look forward to meeting with you and sincerely hope you will incorporate the attached recommendations as you consider issuing new regulations. Please do not hesitate to contact us if you have any questions or comments or would like any additional information.

Sincerely,



W. Ron Allen, Chair,  
Tribal Technical Advisory Group

cc: Melinda Golub, Senior Counsel, Office of Counsel to the Inspector General  
Kitty Marx, Director, CMCS Division of Tribal Affairs, Centers for Medicare and Medicaid Services

Attachment:

- A. TTAG Recommendation for Proposed American Indian and Alaska Native and Indian Health Care Provider Safe Harbors.