February 2, 2024

The Honorable Christi A. Grimm
Inspector General
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue SW
Washington, DC 20201

Submitted via regulations.gov

Re: Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts (88 FR 84116)

Dear Inspector General Grimm:

On behalf of the Centers for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Group (TTAG), I write to provide a response to the “Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts” (88 FR 84116). This has been a longstanding priority for the TTAG for well over a decade, and we hope that this comment takes us a step closer to finding a path forward in partnership with the HHS Office of Inspector General (OIG).

As you know, the Indian health system is currently – and will continue to be – severely hamstrung by the broad scope of the anti-kickback statute, which unnecessarily complicates legitimate resource sharing among Indian health care providers and reduces opportunities to improve access to care for American Indian and Alaska Native (AI/AN) people who are among the most underserved in the country. This exacerbates the severe and chronic underfunding of the Indian health system that persists despite the federal government’s trust responsibility to provide for the health and well-being of AI/AN people. The Indian health system needs 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 IHCPs. IHCPs have all 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.¹ Like FQHCs, IHCPs serve individuals in medically underserved areas.² 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 (IHCIA) requires

² 72 Fed. Reg. at 56633.
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.\(^3\)

AI/ANs make up a large portion of the country’s medically underserved populations with limited access to care. IHCPs 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 IHCPs, like the one in place for FQHCs, would substantially help these underfunded programs achieve those needs and conserve Indian Health Service (IHS) 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 IHCIA are already defined to be FQHCs under the Social Security Act, but clinics operated by the IHS are not, nor are hospitals operated by Tribes or the IHS.

Most IHCPs 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.

Since 2012, the TTAG has requested that the OIG approve its request for an Indian-specific safe harbor. There is no reasoned basis for OIG to allow some Indian health care providers access to an FQHC-type safe harbor but not others.

As a result, the TTAG developed an Indian-specific safe harbor to the anti-kickback statute that is based on the safe harbor for FQHCs. The TTAG has repeatedly requested OIG adopt this safe harbor, but the OIG has declined to do so. In the past, OIG has claimed – without explanation – that existing safe harbors are sufficient but indicated it might consider the topic again in future rulemaking.

We appreciate your consideration of the above comments and recommendations and look forward to engaging further on this important issue.

Sincerely,

W. Ron Allen, CMS TTAG Chair
Jamestown S’Klallam Tribe, Chairman/CEO

\(^3\) 25 U.S.C. § 1641.