

Tribal Technical Advisory Group

To the Centers for Medicare & Medicaid Services

c/o National Indian Health Board 926 Pennsylvania Avenue, SE Washington, DC 20003 (202) 507-4070 (202) 507-4071 fax

Submitted via e-mail: Dan.Levinson@oig.hhs.gov

June 26, 2015

Daniel R. Levinson
Director, Office of the Inspector General
Department of Health and Human Services
330 Independence Ave., SW
Washington, D.C. 20201

RE: Status Update on TTAG's Proposed Indian-Specific Safe Harbors to the Federal Anti-Kickback Statute

Dear Director Levinson:

I am writing on behalf of the Tribal Technical Advisory Group (TTAG) to the Centers for Medicare and Medicaid Services (CMS) to request that the Department of Health and Human Services' Office of the Inspector General (OIG) participate in the TTAG's next face-to-face meeting on Wednesday, July 15, 2015, at the Museum of the American Indian in Washington, D.C.¹ Specifically, we seek a dialogue with the OIG concerning the status of the TTAG's proposed Indian-specific safe harbors to the federal anti-kickback statute.

On February 27, 2012, the TTAG submitted comments on the OIG's annual solicitation for proposals to develop or modify safe harbor provisions under the anti-kickback statute (OIG-120-N),² in which the TTAG suggested a number of new Tribal safe harbors. In its Fall 2012 semi-annual report, the OIG noted that the agency was "considering whether to promulgate a safe harbor that would address the concerns described in this [the TTAG] proposal." The TTAG has subsequently met twice with OIG staff to try to address any questions that might be a barrier to formal action on the recommendations, and resubmitted its 2012 comments to the OIG on March 2, 2015, in response to the OIG's most recent solicitation (OIG-123-N).³ Although we have been repeatedly assured that the OIG is working on addressing the TTAG's 2012 proposals, nothing tangible has occurred in the nearly three and a half years since their submission.

¹ The TTAG advises CMS on Indian health policy issues involving Medicare, Medicaid, the Children's Health Insurance Program, and any other health care program funded (in whole or part) by CMS. In particular, the TTAG focuses on providing policy advice to CMS regarding improving the availability of health care services to American Indians and Alaska Natives (AI/ANs) under these federal health care programs, including through providers operating under the health programs of the Indian Health Service, Indian Tribes, tribal organizations and urban Indian organizations.

² Solicitation of New Safe Harbors and Special Fraud Alerts, 76 Fed. Reg. 81,904 (Dec. 29, 2011).

³ Solicitation of New Safe Harbors and Special Fraud Alerts, 79 Fed. Reg. 78,376 (Dec. 30, 2014). A copy of our 2012 comments and our 2015 resubmission are attached to this letter. We also note that the TTAG requested in its 2015 resubmission that the OIG attend the TTAG's July 2015 meeting, but have not yet received a response.

RE: Status Update on Indian-Specific Safe Harbors Anti-Kickback Statute June 26, 2015

This delay has been tremendously problematic for Tribes, and it is critically important that the OIG provide direction as soon as possible as to whether and how the agency intends to adopt the TTAG's proposals. As perhaps the only truly integrated health system in the United States, Tribal health programs have devised innovative and collaborative approaches for delivering health services to what is generally a rural, underserved, and high-morbidity AI/AN population. But uncertainty concerning the anti-kickback statute's broad statutory limitations on relationships among providers and their patients, other providers, and vendors makes it difficult to achieve such innovations. Meanwhile, the threat of criminal and civil penalties under the anti-kickback rules are so broad, and potentially so devastating to the underfunded Indian health system, that they discourage Tribal providers from entering into innocuous relationships that could even potentially implicate the statute. Simply put, the lack of a definitive response from the OIG on these matters directly impedes the provision of health care to AI/ANs.

We accordingly reiterate our request that the OIG attend our July meeting to provide a meaningful status update on the TTAG's 2012 proposals. We also request that the OIG remain available to answer questions and receive feedback from the TTAG concerning its suggested safe harbors, to strategize as to how this particular safe harbor request can be moved forward, and to discuss how the OIG can maintain an ongoing dialogue with the TTAG and with Indian Country generally to prevent these types of years-long delays in communication moving forward.

The TTAG greatly appreciates any help that you can provide to help us resolve this issue, and we look forward to discussing this critically important matter with you at our July meeting. Please do not hesitate to contact me with any questions.

Sincerely,



W. Ron Allen,
Tribal Chairman and CEO, Jamestown S'Klallam Tribe
Chairman, Tribal Technical Advisory Group

Attachments: 2

cc: Dee Sabattus, Co-Chair, Tribal Technical Advisory Group
Kitty Marx, Director, Centers for Medicare and Medicaid Services Tribal Affairs Group

Tribal Technical Advisory Group

To the Centers for Medicare & Medicaid Services

c/o National Indian Health Board 926 Pennsylvania Avenue, SE Washington, DC 20003 (202) 507-4070 (202) 507-4071 fax

Submitted at <http://www.regulations.gov>

February 27, 2012

Office of the Inspector General
Congressional and Regulatory Affairs
Department of Health and Human Services
Attention: OIG-120-N
Room 5541, Cohen Building
330 Independence Avenue SW
Washington DC 20201

Dear Inspector General:

In response to the December 29, 2011, Department of Health and Human Services (“HHS”) Office of the Inspector General (“OIG”) annual solicitation for proposals to develop or modify safe harbor provisions under the Federal anti-kickback statute (OIG-120-N),¹ the Tribal Technical Advisory Group (TTAG) to the Centers for Medicare and Medicaid Services (CMS) proposes the addition of one or more safe harbors to exempt certain transactions in which an Indian health program is one of the parties.

TTAG advises CMS on Indian health policy issues involving Medicare, Medicaid, the Children’s Health Insurance Program, and any other health care program 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, Indian Tribes, tribal organizations and urban Indian organizations (I/T/U).

1. Introduction and Background

The Indian health system is arguably the only truly integrated health system in the United States. It is comprised of the Indian Health Service, tribal health programs, and urban Indian organizations (“Indian health care providers”).² Indian health care providers work to fulfill the Nation’s special trust responsibilities and legal obligations to Indians—

¹Solicitation of New Safe Harbors and Special Fraud Alerts, 76 Fed. Reg. 81,904 (Dec. 29, 2011) [hereinafter “Safe Harbor Solicitation”].

²Throughout this request, the term “Indian health care provider” shall have the meaning given that term in 42 C.F.R. § 447.50(b)(2), where that term is defined to mean “a health care program operated by the Indian Health Service (IHS) or by an Indian Tribe, Tribal Organization, or Urban Indian Organization (otherwise known as an I/T/U) as those terms are defined in section 4 of the Indian Health Care Improvement Act, (25 U.S.C. 1603).”

(1) to ensure the highest possible health status for Indians and urban Indians and to provide all resources necessary to effect that policy;

(2) to raise the health status of Indians and urban Indians to at least the levels set forth in the goals contained within the Healthy People 2010 initiative or successor objectives;

(3) to ensure maximum Indian participation in the direction of health care services so as to render the persons administering such services and the services themselves more responsive to the needs and desires of Indian communities;

...

(6) to ensure that the United States and Indian tribes work in a government-to-government relationship to ensure quality health care for all tribal members; . . .³

Despite severe underfunding, the Indian health system strives to provide not only direct health care services (including behavioral health services), but also to provide public health services, health promotion and disease and injury prevention, safe water and sanitation, health facilities, emergency response, and all of the other components of a true system in order to achieve health status improvements among AI/ANs. IHS and tribally-operated programs supply essential health services to approximately 1.9 million AI/ANs⁴ on/near reservations in thirty five states. An additional 46,000 AI/ANs who do not have access to reservation-based programs receive medical and public health services from thirty four urban Indian organizations supported by Federal funds.⁵ As shown in the table below, the Indian health system is comprised of a total of only 45 hospitals and barely more than 600 non-hospital facilities.⁶

	Hospitals	Health Centers	Alaska Village Clinics	Health Stations	School Health Centers
IHS	28	58	N/A	31	2
Tribal	17	235	166	92	13
Urban		36			

To fulfill the objectives set out in the IHCA through these widely dispersed facilities stretched over 35 states with extremely limited resources, every possible efficiency must be achieved.

³/Section 3 of the IHCA, codified at 25 U.S.C. § 1602.

⁴/Indian Health Service, *Fiscal Year 2012 Budget Justification*, CJ-1, available at <http://www.ihs.gov/nonmedicalprograms/budgetformulation/documents/FY%202012%20Budget%20Justification.pdf>.

⁵/Id. at CJ-112.

⁶/Id. at CJ-182.

Reliance on referrals and care purchased through the contract health services program are essential even for minimum care since vast regions of the Indian health system have no hospitals at all and in other regions the hospitals must serve communities not even connected to them by a road system through clinics that in some cases lack even running water.

Unfortunately, the uncertainties created by the extremely broad statutory limitations on certain relationships among health providers and their patients, other providers, and vendors makes achievement of such efficiencies extremely difficult. The discussion of OIG Safe Harbor provisions in the Background section of the Safe Harbor Solicitation describes the dilemma faced by the IHS, tribes and tribal organizations, and urban Indian organizations on a regular basis. The application of and potential criminal and civil penalties under the anti-kickback statutes⁷ are so broad and potentially devastating to a health care provider that they chill even innocuous relationships that could benefit Indian health providers seeking to meet the needs of AI/ANs who are among the poorest⁸ and most medically-underserved populations in the United States.

The same Office of Minority Health profile of AI/ANs states:

It is significant to note that American Indians/Alaska Natives frequently contend with issues that prevent them from receiving quality medical care. These issues include cultural barriers, geographic isolation, inadequate sewage disposal, and low income.

Some of the leading diseases and causes of death among AI/ANs are heart disease, cancer, unintentional injuries (accidents), diabetes, and stroke. American Indians/Alaska Natives also have a high prevalence and risk factors for mental health and suicide, obesity, substance abuse, sudden infant death syndrome (SIDS), teenage pregnancy, liver disease, and hepatitis.

Other Health Concerns. American Indians and Alaska Natives have an infant death rate 60 percent higher than the rate for Caucasians. AI/ANs are twice as likely to have diabetes as Caucasians. An example is the Pima of Arizona, who have one of the highest diabetes rates in the world. AI/ANs also have disproportionately high death rates from unintentional injuries and suicide. In 2010, the tuberculosis rate for AI/ANs was 5.8, as compared to 2.0 for the White population.⁹

⁷/42 U.S.C. §§ 1320a-7a and 1320a-7b.

⁸The Department of Health and Human Services (“HHS”) estimates that twenty-eight percent of AI/ANs live at or below poverty level. U.S. Department of Health and Human Services, Office of Minority Health, “American Indian/Alaska Native Profile,” *available at* <http://minorityhealth.hhs.gov/templates/browse.aspx?lvlID=52> (Feb. 26, 2012).

⁹*Also see*, U.S. Department of Health and Human Services, National Tribal Budget Recommendations for the Indian Health Service, Fiscal Year 2013 Budget 11, *available at*

These health disparities are worsened by the drastic underfunding of the Indian health system. The National Tribal Budget Formulation Workgroup estimates that the IHS budget requires an extra 21 billion dollars to achieve health parity between AI/ANs and the general American population.¹⁰ The OIG itself has noted that funding for certain Indian health programs “has failed to keep pace with inflation, resulting in curtailed services to IHS beneficiaries.”¹¹

Accordingly, in response to the Safe Harbor Solicitation, we propose amendment of an existing safe harbor and the addition of four new safe harbors specific to Indian health care providers. *See*, attached “Proposed American Indian and Alaska Native and Indian Health Care Provider Safe Harbors.” By implementing these safe harbors, which we discuss in more detail below, we believe the OIG can increase the access to and quality of health care and other related services provided to AI/ANs, while still maintaining the integrity of Federal health programs.

2. Description of Proposed Safe Harbors

42 C.F.R. § 1001.952(k). Waiver of beneficiary coinsurance and deductible amounts.

There is currently a safe harbor for reduction or waiver of Medicare or State health care program beneficiary’s obligation to pay coinsurance or deductibles.¹² Such a safe harbor encourages access to health care that an individual might otherwise forego. We believe this safe harbor should be extended to AI/ANs eligible for IHS services. Doing so is consistent with the Federal trust responsibility and furthers the objectives Congress sought to achieve when it adopted a protection for Indians (as that term is used in 42 C.F.R. § 447.50(b)(1)) from enrollment fees, premiums, copayment, cost sharing, and similar charges if the individual is referred for care through contract health services¹³ and similar special protections in the Patient Protection and Affordable Care Act (“ACA”) for AI/ANs.¹⁴

http://www.nihb.org/docs/03282011/FY%202013%20National%20Tribal%20Budget%20Recommendations_Final.pdf [hereinafter “HHS 2013 Budget”] (AI/ANs have the highest rate of diabetes in the United States: in some communities, up to 60% of all adults are diabetic; *Id.* at 12 (AI/ANs also have a higher mortality rate than the general population from specific cancers and have more devastating outcomes after diagnosis.); U.S. Department of Health and Human Services, Indian Health Service, “Disparities Fact Sheet,” January 2011, *available at* <http://info.ihs.gov/Disparities.asp> [hereinafter “Disparities Fact Sheet”] (AI/ANs die at higher rates than other Americans from tuberculosis (500% higher), alcoholism (514% higher), diabetes (177% higher), unintentional injuries (140% higher), homicide (92% higher) and suicide (82% higher).

¹⁰/FY 2013 Tribal Budget Recommendations to the U.S. Department of Health & Human Services (Mar. 4, 2011), *available at*

http://www.nihb.org/docs/03282011/FY%202013%20National_Tribal_Budget_Recommendations_for_IHS_FINAL.pdf.

¹¹/OIG Advisory Op. 01-03 at 3, n. 5 (citing, “Review of the Indian Health Service’s Contract Health Services Program,” Office of the Inspector General (A-15-97-50001)).

¹²/42 C.F.R. § 1001.952(k).

¹³/Section 5006(a) of the American Recovery and Reinvestment Act, codified at 42 U.S.C. § 1396o(j).

¹⁴/ACA Sections 1402(d) (codified at 42 U.S.C. § 18071(d)) and 1411 (codified at 42 U.S.C. §

The effect of extending this safe harbor would be to improve access for individual AI/ANs, which may help avoid costly delays in obtaining necessary health care services, but also in more immediate savings to the extent the individual was eligible for contract health services (“CHS”) from an Indian health care provider. While Indian health programs are payors of last resort,¹⁵ CHS is responsible to pay any copayments or deductibles for those AI/ANs that it refers to care.¹⁶ To the extent health care providers are protected by a safe harbor and will extend discounts or waivers, immediate savings may be achieved in Indian health care provider CHS programs with no risk of a shift of costs to other health care payers.

42 C.F.R. § 1001.952(z). New Safe Harbor for Indian health care providers. Four new safe harbors are provided for under this new paragraph.

New 42 C.F.R. § 1001.952(z)(1) Exchanges among Indian health care providers. The first safe harbor directed at Indian health care providers is aimed at authorizing exchanges or transfer of value among Indian health care providers. As discussed in Section 1 of this letter, in many Areas of the Indian Health Service system, Indian health care providers provide various kinds of support for each other, including sharing specialists and even primary care providers, accepting referrals, providing training, and so on. This is particularly true in the Alaska Area where the Alaska Native Medical Center (“ANMC”) acts as both the regional Alaska Native hospital for the Anchorage Service unit, which includes the vast expanse of land from the tip of the Aleutian Chain, Kodiak Island, the Kenai Peninsula, and all throughout Southcentral Alaska, and is also the tertiary care hospital in the tribal health system in Alaska for Alaska Natives living throughout the balance of the State from Barrow to Metlakatla. By design and by law it is intended to provide various supports for the other health programs – small and large. But, ANMC is not the only example even within Alaska. Virtually all of the larger tribal health programs are providing various kinds of supports for health programs carried out by individual tribes or smaller tribal organizations. All of this occurs under the funding agreements entered into by the individual tribes and tribal organizations with the Indian Health Service. Similar arrangements exist through the remaining 34 states in which there are Indian health care providers.

While it is not at all clear to us that a safe harbor is needed for these arrangements, given the breadth of the anti-kickback provisions, we believe one should be established or the OIG should opine that one is not needed.

18081. *Also see*, 25 U.S.C. § 1623(a).

15/25 U.S.C. § 1623(b).

16/42 C.F.R. § 36.61 (CHS is a supplemental payer) and 25 U.S.C. § 1621u (individuals eligible for CHS-approved services are exempt from liability for charges and costs associated with such services, including Medicare copayments and deductibles). *Also see*, OIG Advisory Opinion No. 01-03, p. 3.

New 42 C.F.R. § 1001.952(z)(2). Transfers from an Indian health care provider to an Indian eligible for or receiving the services of that provider. As discussed in the introduction, the Indian health system is truly that. As a system it is committed to assuring access and to encouraging and promoting prevention through a wide variety of means. Only visiting areas of Indian country can truly create an understanding of the vastness of the areas for which Indian health care providers are responsible and the challenges the people they serve often have accessing care.

For example, the Tanana Chiefs Conference, a tribal consortium of forty-two tribes and tribal organizations in Alaska, serves as the primary provider of health care and other services to AI/ANs in Alaska's Interior Region, a service area of 235,000 square miles that represents about 37% of the entire state. This includes forty seven villages with populations ranging from twenty to almost 1,000 people, virtually all of which are medically underserved areas. It provides these services through a central clinic in Fairbanks and village clinics throughout the region (mostly staffed only by community health aides). The nearest tribally operated hospital is ANMC in Anchorage. Air ambulances are an essential part of assuring access to either the non-Indian hospital in Fairbanks (where CHS will likely have to contribute to the cost of care) and to ANMC.

Once AI/ANs arrive in a Native health care hub, their challenges are just beginning since they obviously cannot return home each night. One of the major improvements in health status in Alaska was achieved by development of pre-maternal homes in which pregnant women and sometimes their young children can stay while awaiting delivery. Pre-maternal homes can be credited with a meaningful reduction in infant mortality. This care and other patient housing are essential to make access to care affordable by the AI/ANs who otherwise would often delay or avoid care because the cost of transportation or lodging would be outside their means.

Prevention is also central to the improvements in health status that the United States has committed to support and that are so desperately needed among AI/ANs. Prevention is encouraged through a wide variety of means: from handing out berry buckets as an incentive to encourage well child examinations or diabetes screening (and, not incidentally, more reliance on healthier subsistence foods), to providing car seats in those locations where there are roads, to free float coats and, if there is a pool in the community, swimming lessons, to try to reduce deaths by drowning. Improvements in housing to make it possible for an elder to continue to live in the village or other accommodations are also central to sustaining a system.

The items and services described in this proposed safe harbor range in value from insignificant to much more. However, all of the exchanges are intended solely to improve access and to achieve health promotion and disease and injury prevention. Again, since these activities are carried out under agreements with the IHS pursuant to the ISDEAA and IHCA, it is not clear that they require safe harbors. However, the activities that occur are exactly those that are often in the news or addressed in compliance as implicating anti-kickback provisions of the law. It is neither feasible, nor a good use of scarce resources, to try to obtain an advisory opinion about each of the myriad such arrangements. Either the creation of a safe harbor or an OIG opinion that a safe harbor is not needed for such arrangements is needed.

New 42 C.F.R. § 1001.952(z)(3). Sharing Arrangements. The proposed safe harbor regarding sharing arrangements is intended to ensure that sharing medical care facilities and resources among Indian health care providers and other health care providers is encouraged. It is modeled after 42 U.S.C. 254a and focuses on improving quality of care and minimizing duplicative and, therefore often, wasteful, expenditures.

New 42 C.F.R. § 1001.952(z)(4). Support of Indian health care providers. This safe harbor, which is fleshed out in the greatest detail, is modeled after the safe harbor provided to Federally Qualified Health Centers ("FQHCs") in 42 C.F.R. § 1001.952(w).

As the OIG noted in the FQHC Final Rule, the FQHC safe harbor was “intended to permit health centers to accept certain remuneration that would otherwise implicate the anti-kickback statute when the remuneration furthers a core purpose of the Federal health centers program: ensuring the availability and quality of safety net health care services to otherwise underserved populations.”¹⁷ As the OIG also highlighted some of the beneficial aspects of FQHCs made them ideal candidates for a safe harbor, including:

FQHCs are designed to assist the large number of individuals living in medically underserved areas, as well as the growing number of special populations with limited access to preventive and primary health care.

- FQHCs play a vital role in the health care safety net, providing cost effective care for communities with limited access to health care resources.
- FQHCs serve predominantly low-income individuals, including some beneficiaries of the Medicare and Medicaid programs as well as a substantial and growing number of uninsured patients.¹⁸

The Indian health system is a real-world embodiment of the FQHC mission as articulated by the OIG. Indian health care providers provide cost effective care to low-income individuals who are often uninsured and are part of a medically underserved population. Beyond merely providing services in communities with limited access to health care, Indian health care providers are often the *only* health care provider in an AI/AN community.

In light of AI/ANs’ heavy reliance on the I/T/U system for their health care, there cannot be any question that AI/ANs are a medically underserved population that suffer greatly from the underfunding of the I/T/U program. For example, in 2004, the United States Commission on Civil Rights found that there is a “dire health care situation facing Native Americans,” and that in addition to “disturbingly high mortality rates,” Native Americans

¹⁷FQHC Final Rule, at 56,634.

¹⁸*Id.* at 56,633.

suffer “significantly lower health status and disproportionate rates of disease”¹⁹ The Commission also found that Federal funding of health care is insufficient, explaining “IHS funding levels are inadequate by every applicable standard of measurement and in every area of health service delivery within IHS.”²⁰ In a separate report, the Commission found that “IHS’s real spending per Native American, after adjusting for inflation and population growth, has fallen over time, despite funding increases,”²¹ that “a large and expanding gap exists between needed and available services, or unmet needs, in Native American communities,”²² and that IHS operates at approximately 59% capacity to provide adequate health care.²³

All savings achieved through safe harbors for Indian health care providers ultimately accrue to the benefit of the Federal government: first, by helping it achieve its special trust responsibility to AI/ANs, and secondly, by achieving actual savings in the cost of health care delivery.

As noted this safe harbor was closely modeled after the FQHC safe harbor. But, it is not identical. We attempted to streamline it in recognition that Indian health care providers are unique and governed by very different statutory rules than the 330 community health centers. We also tried to balance the administrative burden of compliance with the important integrity concerns of the OIG.

We note a few of the issues that we know are of particular concern.

Patient freedom of choice among health care providers. As discussed above, many AI/ANs independently choose to obtain their health care from an Indian health care provider in light of the Federal government’s special trust responsibility to provide health care at no cost to the them and the greater cultural competence and familiarity often present in these settings. Patient freedom of choice, then, may not be as much of a concern as it would be with different patient populations. Also, many of the arrangements that Indian health care providers would enter into under the safe harbor would be for emergency or highly specialized services in remote areas, thus making the question of patient choice that much less of a focus than, for example, a choice of primary physicians in a major urban area.

That said, all AI/ANs ultimately have the choice to seek out another provider. We have retained the express statement of that right and the duty to respond to questions. We did not include the express requirement of notice about choice, which we believe would be very confusing for AI/ANs who use Indian health care providers as a matter of right.

¹⁹U.S. Comm’n on Civil Rights, *Broken Promises: Evaluating the Native American Health Care System* iii (Sept. 2004), available at <http://www.usccr.gov/pubs/nahealth/nabroken.pdf>.

²⁰*Id.* at 120.

²¹U.S. Comm’n on Civil Rights, *A Quiet Crisis: Federal Funding and Unmet Needs in Indian Country* 43 (July 2004), available at <http://www.usccr.gov/pubs/na0703/na0731.pdf>.

²²*Id.* at 42

²³*Id.* at 43.

Competition among health care providers. Many Indian health care providers that seek to enter into arrangements with outside providers will offer a request for proposals designed to ensure a competitive bidding process. However, much more informal processes are also relied upon due to the small pool of potential partners from whom to obtain necessary services.

The potential overutilization of health care services. AI/AN are arguably the most medically underserved population in the United States, and many Indian health care providers face a daily struggle to provide even basic health services to their patients. Even with the flexibility afforded by a safe harbor, I/T/Us will still face dramatic financial shortfalls and will not suddenly begin authorizing or performing frivolous or unnecessary procedures upon receiving a safe harbor. Further, many, if not most, arrangements entered into under a safe harbor would involve services through the CHS program, which contains internal safeguards on the medical necessity of covered services.

The existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may take into account their decisions whether to (1) order a health care item or service or (2) arrange for a referral of health care items or services to a particular practitioner or provider. The agreements entered into pursuant to the safe harbor would benefit each Indian health care provider tasked with the efficient provision of health care throughout its jurisdiction and to its patient population, by granting additional financial and administrative flexibility. As the OIG has itself cited as a factor supporting the legitimacy of favorable contract terms for Tribal health programs, these types of agreements arise 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” and are “fully consistent with IHS policy encouraging tribes to be prudent purchasers”²⁴ Rather than sparking unseemly quid pro quo remuneration, the safe harbor would help fulfill the Federal trust responsibility, the goals of the FQHC program, and the requirements of the CHS program.

Obviously much more could be said about the details in the attached proposed safe harbor. However, we believe much of it to be self-explanatory. But, more importantly, we believe it is incumbent on the OIG to interact with the Tribal Technical Advisory Group to CMS and to hold consultation pursuant to the HHS and CMS Tribal Consultation Policies and Executive Order 13175. Such interactions will provide an opportunity for a more specific and focused discussion of the critical provisions.

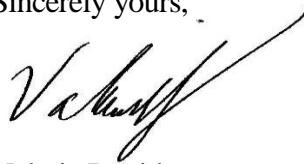
²⁴OIG Advisory Op. 01-03 at 7.

3. Conclusion

On behalf of Tribal Technical Advisory Group (TTAG) to the Centers for Medicare and Medicaid Services (CMS), I thank you for considering our proposal for Indian health care provider-specific safe harbors to the anti-kickback statute. Providing adequate health care to our remote service areas is a constant challenge considering IHS's inadequate budget. The safe harbor will be tremendously beneficial to the chronically underserved, overwhelmingly low-income patient population, and will provide financial benefits to numerous Federal health programs. We do not believe that implementing the safe harbor will increase the risk of violating any Federal laws, or otherwise jeopardizing the integrity of any Federal health care program. Rather, it will further the Federal government's trust responsibility towards providing health services to AI/ANs.

Please let us know if there is any other information CMS TTAG can provide to assist your analysis of this matter.

Sincerely yours, .



Valerie Davidson
Chair, CMS Tribal Technical Advisory Group

Cc: Dr. Yvette Roubideaux, Director, Indian Health Service
Kitty Marx, Director, CMS Tribal Affairs Group

**Proposed American Indian and Alaska Native and
Indian Health Care Provider Safe Harbors**

Amend 42 C.F.R. § 1001.952(k), as follows:

(k) *Waiver of beneficiary coinsurance and deductible amounts.* As used in section 1128B of the Act, “remuneration” does not include any reduction or waiver of a Medicare or a State health care program beneficiary's or an Indian’s (as that term is used in 42 C.F.R. § 447.50(b)(1)) obligation to pay coinsurance or deductible amounts as long as all of the standards are met within either of the following two categories of health care providers:

. . .

(2) If the coinsurance or deductible amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under titles V or XIX of the Act to a federally qualified health care center or other health care facility under any Public Health Services Act grant program or under title V of the Act, or is an Indian as that term is used in 42 C.F.R. § 447.50(b)(1), the health care center or facility may reduce or waive the coinsurance or deductible amounts for items or services for which payment may be made in whole or in part under part B of Medicare or a State health care program.

Amend 42 C.F.R. § 1001.952 by adding a new subsection (z), as follows:

(z) *Indian health care provider.* For purposes of applying section 1128B(b) of the Social Security Act, the exchange of anything of value between or among the following shall not be treated as remuneration if the exchange arises from or relates to exchanges provided for under subparagraphs (1), (2), (3) or (4) of this paragraph (z).

(1) An exchange or transfer or any goods, items, services, donations or loans (whether the donation or loan in cash or in-kind) between or among entities that fall within the definition of an Indian health care provider (as defined in this paragraph) or a referral of a patient or other individual receiving or eligible to receive services from an Indian health care provider.

(2) An exchange between an Indian health care provider and any individual served or eligible for service from such provider, but only if—

(i) the individual receiving the benefit of the exchange receives services or is eligible to receive services—

(A) from an Indian tribe or tribal organization under a funding agreement entered into with the Indian Health Service pursuant to the Indian Self-Determination and Education Assistance Act, Pub. L. 93-638, as amended, a tribal health program and the Indian Health Service as those terms are defined in section 4 of the Indian Health Care Improvement Act, or

(B) from an urban Indian organization that has entered into a contract with or received a grant from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act, Pub. L. 94-437, as amended; and

(ii) the exchange is—

(A) for the purpose of ensuring the individual has meaningful access to health care, including for example—

(1) transporting the individual (and escort, if needed) for the provision of health care items or services;

(2) providing housing to the individual (including a pregnant individual) and immediate family members or an escort incidental to assuring the timely provision of health care items and services to the individual;

(3) is for the purpose of paying premiums, copayments, deductibles, or other cost sharing on behalf of such individuals; or

(B) consists of an item or service—

(1) of small value that is provided as a reasonable incentive to secure timely and appropriate preventive and other items and services;

(2) that is reasonably calculated to minimize the risk of injury or disease to an individual or the individual's caretaker, such as a float coat or other water safety device or an infant or child car seat or housing accommodation such as a ramp or lift;

(3) that is authorized under the Indian Health Care Improvement Act, as amended.

(3) An agreement or arrangement for the exchange, transfer or sharing of any scarce or specialized health resource, including facilities, equipment, space, services, or personnel, which, because of cost, limited availability, or unusual nature, are either unique or scarce in the health care community or are subject to maximum utilization only through mutual use, between an Indian health care provider and other providers or suppliers in the health care community for the benefit of patients or other individual receiving or eligible to receive services from an Indian health care provider.

(4) The transfer of any goods, items, services, donations or loans (whether the donation or loan is in cash or in-kind), or combination thereof from an individual or entity provider or supplier that provides or supplies such goods, items, services, donations, or loans to an Indian health care provider (as defined in this paragraph), as long as the following standards are met—

(i)(A) The transfer is made pursuant to a written contract, lease, grant, loan, or other agreement that describes the amount of, all goods, items, services, donations, or loans to be provided by the individual or entity to the Indian health care provider.

(B) The amount of goods, items, services, donations, or loans specified in the agreement in accordance with paragraph (z)(4)(i)(A)(3) of this section may be a fixed sum, fixed percentage, or set forth by a fixed methodology. The amount may not be conditioned on the volume or value of Federal health care program business generated between the parties. The written agreement will be deemed to cover all goods, items, services, donations, or loans provided by the individual or entity to the Indian health care provider as required by paragraph (z)(4)(i)(A)(3) of this section if all separate agreements between the individual or entity and the Indian health care provider incorporate each other by reference or if they cross-reference a master list of agreements that is maintained centrally, is kept up to date, and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of arrangements.

(ii) The goods, items, services, donations, or loans are medical or clinical in nature or reasonably relate to services provided by the Indian health care provider pursuant to or under—

(A) the Snyder Act, the Indian Health Care Improvement Act, or any other legislation authorizing programs, services, functions or activities that may be carried out by the Indian Health Service; provided that in the case of—

(1) a tribal health program as that term is defined in Section 4 of the Indian Health Care Improvement Act, its compact or contract and funding agreement entered into pursuant to the Indian Self-Determination and Education Assistance Act; or

(2) an urban Indian organization, its contract or grant agreement pursuant to Title V of the Indian Health Care Improvement Act;

(B) including, by way of example, billing services, technology support and enabling services, such as case management, transportation or translations services.

(iii) The Indian health care provider reasonably expects the arrangement to contribute meaningfully to the Indian health care provider's ability to maintain or increase the availability, or enhance the quality, of services provided to eligible individuals or individuals served by the Indian health care provider.

(iv) The Indian health care provider must re-evaluate the arrangement at reasonable intervals to ensure that the arrangement is expected to continue to satisfy the standard set forth in paragraph (z)(4)(iii) of this section, and must document the re-evaluation. Arrangements must not be renewed or renegotiated unless the Indian health care provider reasonably expects the standard set forth in paragraph (z)(4)(iii) of this section to be satisfied in the next agreement term. Renewed or renegotiated agreements must comply with the requirements

of paragraph (z)(4)(iii) of this section.

(v) The individual or entity does not

(A) require the Indian health care provider (or its affiliated employees) to refer patients to a particular individual or entity, or

(B) restrict the Indian health care provider (or its affiliated employees) from referring patients to any individual or entity.

(vi) Individuals and entities that offer to furnish goods, items, or services without charge or at a reduced charge to the Indian health care provider must furnish such goods, items, or services to all individuals from the Indian health care provider who clinically or programmatically qualify for the goods, items, or services, regardless of the patient's payor status or ability to pay. The individual or entity may impose reasonable limits on the aggregate volume or value of the goods, items, or services furnished under the arrangement with the Indian health care provider, provided such limits do not take into account an individual's payor status or ability to pay.

(vii) The agreement must not restrict the Indian health care provider's ability, if it chooses, to enter into agreements with other providers or suppliers of comparable goods, items, or services, or with other lenders or donors or from using a reasonable methodology to select the providers or suppliers that best meet its needs. In making these determinations, the Indian health care provider should look to the procurement standards applicable to it under applicable law.

(viii) The Indian health care provider will not hinder individuals from exercising their freedom to choose any willing provider or supplier. In addition, the Indian health care provider must disclose the existence and nature of an agreement under paragraph (z)(4)(i) of this section to any such individual who inquires.

(ix) The Indian health care provider may, at its option, elect to require that an individual or entity charge an individual referred by the Indian health care provider the same rate it charges other similarly situated individuals not referred by the Indian health care provider or that the individual or entity charges an individual referred by the Indian health care provider a reduced rate (where the discount applies to the total charge and not just to the cost sharing portion owed by an insured patient).

(x) The Indian health care provider will make documentation related to any transfer subject to paragraph (z)(4) available to the Secretary upon request.

For purposes of this paragraph (z), the term "Indian health care provider" means (A) The Indian Health Service, (B) Any health program of an Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Health Care Improvement Act) that operates any health program, service, function, activity, or facility funded, in whole or part, by

the Indian Health Service through, or provided for in, a Funding Agreement with the Indian Health Service under the Indian Self-Determination and Education Assistance Act, or (C) Any Urban Indian Organization (as such term is defined in section 4 of the Indian Health Care Improvement Act).

Tribal Technical Advisory Group

To the Centers for Medicare & Medicaid Services

c/o National Indian Health Board 926 Pennsylvania Avenue, SE Washington, DC 20003 (202) 507-4070 (202) 507-4071 fax

Submitted via <http://www.regulations.gov>.

March 2, 2015

Patrice Drew
Office of Inspector General
Department of Health and Human Services
Attention: OIG-123-N
Cohen Building, Room 5269
330 Independence Avenue SW
Washington, DC 20201

RE: OIG-123-N: Solicitation of New Safe Harbors and Special Fraud Alerts

Dear Ms. Drew,

I write on behalf of the Tribal Technical Advisory Group (TTAG) of the Centers for Medicare & Medicaid Services (CMS)¹ to comment on the Notice of Proposed Rulemaking (Notice) issued by the Office of the Inspector General (OIG) concerning the OIG's annual solicitation for proposals and recommendations for developing new and modifying existing safe harbor provisions under the federal anti-kickback statute (AKS),² as well as developing new OIG Special Fraud Alerts.³ Thank you for the opportunity to provide feedback.

The TTAG (and many individual tribes and tribal organizations) submitted comprehensive comments (attached) in response to the OIG's 2012 annual safe harbor solicitation. Since then, members of the TTAG have met twice with OIG staff to discuss the interests that Indian health providers are trying to address and to try to respond to any questions that might be a barrier to formal action on the recommendations. Although we have been assured that the OIG is working on addressing them, nothing tangible has occurred in the three years since the comments were submitted.

¹ The TTAG advises CMS on Indian health policy issues involving Medicare, Medicaid, the Children's Health Insurance Program, and any other health care program funded (in whole or in part) by CMS. In particular, the TTAG focuses on providing policy advice designed to improve the availability of health care services to American Indians and Alaska Natives (AI/ANs) under these federal health care programs, including through providers operating under the health programs of the Indian Health Service (IHS), Indian Tribes, Tribal organizations, and urban Indian organizations (collectively I/T/Us).

² 42 U.S.C. § 1320a-7b.

³ 79 Fed. Reg. 78,376 (Dec. 30, 2014).

The TTAG proposed that the OIG:

- Extend the current safe harbor for a reduction or waiver of a Medicare or State health care program beneficiary's obligation to pay coinsurance or deductibles to AI/ANs eligible for IHS services.
- Create a new safe harbor, modeled after the existing harbor authorizing Federally Qualified Health Centers "to accept certain remuneration that would otherwise implicate the anti-kickback statute when the remuneration furthers a core purpose of the Federal health centers program: ensuring the availability and quality of safety net health care services to otherwise underserved populations,"⁴ that is specific to I/T/U providers.
- Create a new safe harbor authorizing exchanges or transfers of value among and between Indian health care providers.
- Create a new safe harbor authorizing Indian health care providers to share other resources, including practitioner services and facility space, among one another.
- Create a new safe harbor authorizing Indian health care providers to offer free or reduced-cost goods or services to IHS-eligible individuals that encourage healthy lifestyle choices and the use of preventive care, improve public safety, facilitate patients' keeping health care appointments, etc.

To our knowledge, the OIG has not since adopted any of the suggested safe harbors set out in the TTAG's 2012 transmittal. These proposals have not lost their urgency in the interim, and the federal government has not adequately addressed the underlying factors necessitating their enactment. The TTAG is therefore incorporating by reference and resubmitting its 2012 suggestions in response to OIG-123-N.⁵ We believe that the safe harbors represent an important step in targeting the funding inadequacies endemic to the Indian health system and combating the AI/AN community's disproportionate morbidity and low health outcomes and literacy.

The TTAG appreciates the opportunity to comment on the Notice. We would also like to invite your staff to present at the next TTAG meeting on July 15, 2015, in Washington, D.C., in order to update the TTAG on the process and discuss when action can be expected. In the intervening period, we would be happy to have our subject matter experts meet with your staff to respond to questions or work with them to identify the most straightforward ways to overcome the operational challenges these proposed safe harbors are intended to address. We truly appreciate the magnitude

⁴ Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Federally Qualified Health Centers Arrangements Under the Anti-Kickback Statute, 72 Fed. Reg. 56,632, 56,634 (Oct. 4, 2007).

⁵ These comments are attached to this memorandum.

of the work your office faces. Unfortunately, having these matters unresolved adds to the cost and risks of administering Indian health programs.

Thank you so much for your consideration of the renewed recommendations and the request for more direct communication between your staff and the TTAG.

Sincerely,

A handwritten signature in cursive script that reads "W. Ron Allen".

W. Ron Allen
Chair, TTAG

Cc: Kitty Marx, Director, CMS Division of Tribal Affairs

Attachment:

Tribal Technical Advisory Group

To the Centers for Medicare & Medicaid Services

c/o National Indian Health Board 926 Pennsylvania Avenue, SE Washington, DC 20003 (202) 507-4070 (202) 507-4071 fax

Submitted at <http://www.regulations.gov>

February 27, 2012

Office of the Inspector General
Congressional and Regulatory Affairs
Department of Health and Human Services
Attention: OIG-120-N
Room 5541, Cohen Building
330 Independence Avenue SW
Washington DC 20201

Dear Inspector General:

In response to the December 29, 2011, Department of Health and Human Services (“HHS”) Office of the Inspector General (“OIG”) annual solicitation for proposals to develop or modify safe harbor provisions under the Federal anti-kickback statute (OIG-120-N),¹ the Tribal Technical Advisory Group (TTAG) to the Centers for Medicare and Medicaid Services (CMS) proposes the addition of one or more safe harbors to exempt certain transactions in which an Indian health program is one of the parties.

TTAG advises CMS on Indian health policy issues involving Medicare, Medicaid, the Children’s Health Insurance Program, and any other health care program 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, Indian Tribes, tribal organizations and urban Indian organizations (I/T/U).

1. Introduction and Background

The Indian health system is arguably the only truly integrated health system in the United States. It is comprised of the Indian Health Service, tribal health programs, and urban Indian organizations (“Indian health care providers”).² Indian health care providers work to fulfill the Nation’s special trust responsibilities and legal obligations to Indians—

¹Solicitation of New Safe Harbors and Special Fraud Alerts, 76 Fed. Reg. 81,904 (Dec. 29, 2011) [hereinafter “Safe Harbor Solicitation”].

²Throughout this request, the term “Indian health care provider” shall have the meaning given that term in 42 C.F.R. § 447.50(b)(2), where that term is defined to mean “a health care program operated by the Indian Health Service (IHS) or by an Indian Tribe, Tribal Organization, or Urban Indian Organization (otherwise known as an I/T/U) as those terms are defined in section 4 of the Indian Health Care Improvement Act, (25 U.S.C. 1603).”

(1) to ensure the highest possible health status for Indians and urban Indians and to provide all resources necessary to effect that policy;

(2) to raise the health status of Indians and urban Indians to at least the levels set forth in the goals contained within the Healthy People 2010 initiative or successor objectives;

(3) to ensure maximum Indian participation in the direction of health care services so as to render the persons administering such services and the services themselves more responsive to the needs and desires of Indian communities;

...

(6) to ensure that the United States and Indian tribes work in a government-to-government relationship to ensure quality health care for all tribal members; . . .³

Despite severe underfunding, the Indian health system strives to provide not only direct health care services (including behavioral health services), but also to provide public health services, health promotion and disease and injury prevention, safe water and sanitation, health facilities, emergency response, and all of the other components of a true system in order to achieve health status improvements among AI/ANs. IHS and tribally-operated programs supply essential health services to approximately 1.9 million AI/ANs⁴ on/near reservations in thirty five states. An additional 46,000 AI/ANs who do not have access to reservation-based programs receive medical and public health services from thirty four urban Indian organizations supported by Federal funds.⁵ As shown in the table below, the Indian health system is comprised of a total of only 45 hospitals and barely more than 600 non-hospital facilities.⁶

	Hospitals	Health Centers	Alaska Village Clinics	Health Stations	School Health Centers
IHS	28	58	N/A	31	2
Tribal	17	235	166	92	13
Urban		36			

To fulfill the objectives set out in the IHCA through these widely dispersed facilities stretched over 35 states with extremely limited resources, every possible efficiency must be achieved.

³/Section 3 of the IHCA, codified at 25 U.S.C. § 1602.

⁴/Indian Health Service, *Fiscal Year 2012 Budget Justification*, CJ-1, available at <http://www.ihs.gov/nonmedicalprograms/budgetformulation/documents/FY%202012%20Budget%20Justification.pdf>.

⁵/Id. at CJ-112.

⁶/Id. at CJ-182.

Reliance on referrals and care purchased through the contract health services program are essential even for minimum care since vast regions of the Indian health system have no hospitals at all and in other regions the hospitals must serve communities not even connected to them by a road system through clinics that in some cases lack even running water.

Unfortunately, the uncertainties created by the extremely broad statutory limitations on certain relationships among health providers and their patients, other providers, and vendors makes achievement of such efficiencies extremely difficult. The discussion of OIG Safe Harbor provisions in the Background section of the Safe Harbor Solicitation describes the dilemma faced by the IHS, tribes and tribal organizations, and urban Indian organizations on a regular basis. The application of and potential criminal and civil penalties under the anti-kickback statutes⁷ are so broad and potentially devastating to a health care provider that they chill even innocuous relationships that could benefit Indian health providers seeking to meet the needs of AI/ANs who are among the poorest⁸ and most medically-underserved populations in the United States.

The same Office of Minority Health profile of AI/ANs states:

It is significant to note that American Indians/Alaska Natives frequently contend with issues that prevent them from receiving quality medical care. These issues include cultural barriers, geographic isolation, inadequate sewage disposal, and low income.

Some of the leading diseases and causes of death among AI/ANs are heart disease, cancer, unintentional injuries (accidents), diabetes, and stroke. American Indians/Alaska Natives also have a high prevalence and risk factors for mental health and suicide, obesity, substance abuse, sudden infant death syndrome (SIDS), teenage pregnancy, liver disease, and hepatitis.

Other Health Concerns. American Indians and Alaska Natives have an infant death rate 60 percent higher than the rate for Caucasians. AI/ANs are twice as likely to have diabetes as Caucasians. An example is the Pima of Arizona, who have one of the highest diabetes rates in the world. AI/ANs also have disproportionately high death rates from unintentional injuries and suicide. In 2010, the tuberculosis rate for AI/ANs was 5.8, as compared to 2.0 for the White population.⁹

⁷42 U.S.C. §§ 1320a-7a and 1320a-7b.

⁸The Department of Health and Human Services (“HHS”) estimates that twenty-eight percent of AI/ANs live at or below poverty level. U.S. Department of Health and Human Services, Office of Minority Health, “American Indian/Alaska Native Profile,” *available at* <http://minorityhealth.hhs.gov/templates/browse.aspx?lvlID=52> (Feb. 26, 2012).

⁹*Also see*, U.S. Department of Health and Human Services, National Tribal Budget Recommendations for the Indian Health Service, Fiscal Year 2013 Budget 11, *available at*

These health disparities are worsened by the drastic underfunding of the Indian health system. The National Tribal Budget Formulation Workgroup estimates that the IHS budget requires an extra 21 billion dollars to achieve health parity between AI/ANs and the general American population.¹⁰ The OIG itself has noted that funding for certain Indian health programs “has failed to keep pace with inflation, resulting in curtailed services to IHS beneficiaries.”¹¹

Accordingly, in response to the Safe Harbor Solicitation, we propose amendment of an existing safe harbor and the addition of four new safe harbors specific to Indian health care providers. *See*, attached “Proposed American Indian and Alaska Native and Indian Health Care Provider Safe Harbors.” By implementing these safe harbors, which we discuss in more detail below, we believe the OIG can increase the access to and quality of health care and other related services provided to AI/ANs, while still maintaining the integrity of Federal health programs.

2. Description of Proposed Safe Harbors

42 C.F.R. § 1001.952(k). Waiver of beneficiary coinsurance and deductible amounts.

There is currently a safe harbor for reduction or waiver of Medicare or State health care program beneficiary’s obligation to pay coinsurance or deductibles.¹² Such a safe harbor encourages access to health care that an individual might otherwise forego. We believe this safe harbor should be extended to AI/ANs eligible for IHS services. Doing so is consistent with the Federal trust responsibility and furthers the objectives Congress sought to achieve when it adopted a protection for Indians (as that term is used in 42 C.F.R. § 447.50(b)(1)) from enrollment fees, premiums, copayment, cost sharing, and similar charges if the individual is referred for care through contract health services¹³ and similar special protections in the Patient Protection and Affordable Care Act (“ACA”) for AI/ANs.¹⁴

http://www.nihb.org/docs/03282011/FY%202013%20National%20Tribal%20Budget%20Recommendations_Final.pdf [hereinafter “HHS 2013 Budget”] (AI/ANs have the highest rate of diabetes in the United States: in some communities, up to 60% of all adults are diabetic; *Id.* at 12 (AI/ANs also have a higher mortality rate than the general population from specific cancers and have more devastating outcomes after diagnosis.); U.S. Department of Health and Human Services, Indian Health Service, “Disparities Fact Sheet,” January 2011, *available at* <http://info.ihs.gov/Disparities.asp> [hereinafter “Disparities Fact Sheet”] (AI/ANs die at higher rates than other Americans from tuberculosis (500% higher), alcoholism (514% higher), diabetes (177% higher), unintentional injuries (140% higher), homicide (92% higher) and suicide (82% higher).

¹⁰/FY 2013 Tribal Budget Recommendations to the U.S. Department of Health & Human Services (Mar. 4, 2011), *available at*

http://www.nihb.org/docs/03282011/FY%202013%20National_Tribal_Budget_Recommendations_for_IHS_FINAL.pdf.

¹¹/OIG Advisory Op. 01-03 at 3, n. 5 (citing, “Review of the Indian Health Service’s Contract Health Services Program,” Office of the Inspector General (A-15-97-50001)).

¹²/42 C.F.R. § 1001.952(k).

¹³/Section 5006(a) of the American Recovery and Reinvestment Act, codified at 42 U.S.C. § 1396o(j).

¹⁴/ACA Sections 1402(d) (codified at 42 U.S.C. § 18071(d)) and 1411 (codified at 42 U.S.C. §

The effect of extending this safe harbor would be to improve access for individual AI/ANs, which may help avoid costly delays in obtaining necessary health care services, but also in more immediate savings to the extent the individual was eligible for contract health services (“CHS”) from an Indian health care provider. While Indian health programs are payors of last resort,¹⁵ CHS is responsible to pay any copayments or deductibles for those AI/ANs that it refers to care.¹⁶ To the extent health care providers are protected by a safe harbor and will extend discounts or waivers, immediate savings may be achieved in Indian health care provider CHS programs with no risk of a shift of costs to other health care payers.

42 C.F.R. § 1001.952(z). New Safe Harbor for Indian health care providers. Four new safe harbors are provided for under this new paragraph.

New 42 C.F.R. § 1001.952(z)(1) Exchanges among Indian health care providers. The first safe harbor directed at Indian health care providers is aimed at authorizing exchanges or transfer of value among Indian health care providers. As discussed in Section 1 of this letter, in many Areas of the Indian Health Service system, Indian health care providers provide various kinds of support for each other, including sharing specialists and even primary care providers, accepting referrals, providing training, and so on. This is particularly true in the Alaska Area where the Alaska Native Medical Center (“ANMC”) acts as both the regional Alaska Native hospital for the Anchorage Service unit, which includes the vast expanse of land from the tip of the Aleutian Chain, Kodiak Island, the Kenai Peninsula, and all throughout Southcentral Alaska, and is also the tertiary care hospital in the tribal health system in Alaska for Alaska Natives living throughout the balance of the State from Barrow to Metlakatla. By design and by law it is intended to provide various supports for the other health programs – small and large. But, ANMC is not the only example even within Alaska. Virtually all of the larger tribal health programs are providing various kinds of supports for health programs carried out by individual tribes or smaller tribal organizations. All of this occurs under the funding agreements entered into by the individual tribes and tribal organizations with the Indian Health Service. Similar arrangements exist through the remaining 34 states in which there are Indian health care providers.

While it is not at all clear to us that a safe harbor is needed for these arrangements, given the breadth of the anti-kickback provisions, we believe one should be established or the OIG should opine that one is not needed.

18081. *Also see*, 25 U.S.C. § 1623(a).

15/25 U.S.C. § 1623(b).

16/42 C.F.R. § 36.61 (CHS is a supplemental payer) and 25 U.S.C. § 1621u (individuals eligible for CHS-approved services are exempt from liability for charges and costs associated with such services, including Medicare copayments and deductibles). *Also see*, OIG Advisory Opinion No. 01-03, p. 3.

New 42 C.F.R. § 1001.952(z)(2). Transfers from an Indian health care provider to an Indian eligible for or receiving the services of that provider. As discussed in the introduction, the Indian health system is truly that. As a system it is committed to assuring access and to encouraging and promoting prevention through a wide variety of means. Only visiting areas of Indian country can truly create an understanding of the vastness of the areas for which Indian health care providers are responsible and the challenges the people they serve often have accessing care.

For example, the Tanana Chiefs Conference, a tribal consortium of forty-two tribes and tribal organizations in Alaska, serves as the primary provider of health care and other services to AI/ANs in Alaska's Interior Region, a service area of 235,000 square miles that represents about 37% of the entire state. This includes forty seven villages with populations ranging from twenty to almost 1,000 people, virtually all of which are medically underserved areas. It provides these services through a central clinic in Fairbanks and village clinics throughout the region (mostly staffed only by community health aides). The nearest tribally operated hospital is ANMC in Anchorage. Air ambulances are an essential part of assuring access to either the non-Indian hospital in Fairbanks (where CHS will likely have to contribute to the cost of care) and to ANMC.

Once AI/ANs arrive in a Native health care hub, their challenges are just beginning since they obviously cannot return home each night. One of the major improvements in health status in Alaska was achieved by development of pre-maternal homes in which pregnant women and sometimes their young children can stay while awaiting delivery. Pre-maternal homes can be credited with a meaningful reduction in infant mortality. This care and other patient housing are essential to make access to care affordable by the AI/ANs who otherwise would often delay or avoid care because the cost of transportation or lodging would be outside their means.

Prevention is also central to the improvements in health status that the United States has committed to support and that are so desperately needed among AI/ANs. Prevention is encouraged through a wide variety of means: from handing out berry buckets as an incentive to encourage well child examinations or diabetes screening (and, not incidentally, more reliance on healthier subsistence foods), to providing car seats in those locations where there are roads, to free float coats and, if there is a pool in the community, swimming lessons, to try to reduce deaths by drowning. Improvements in housing to make it possible for an elder to continue to live in the village or other accommodations are also central to sustaining a system.

The items and services described in this proposed safe harbor range in value from insignificant to much more. However, all of the exchanges are intended solely to improve access and to achieve health promotion and disease and injury prevention. Again, since these activities are carried out under agreements with the IHS pursuant to the ISDEAA and IHCA, it is not clear that they require safe harbors. However, the activities that occur are exactly those that are often in the news or addressed in compliance as implicating anti-kickback provisions of the law. It is neither feasible, nor a good use of scarce resources, to try to obtain an advisory opinion about each of the myriad such arrangements. Either the creation of a safe harbor or an OIG opinion that a safe harbor is not needed for such arrangements is needed.

New 42 C.F.R. § 1001.952(z)(3). Sharing Arrangements. The proposed safe harbor regarding sharing arrangements is intended to ensure that sharing medical care facilities and resources among Indian health care providers and other health care providers is encouraged. It is modeled after 42 U.S.C. 254a and focuses on improving quality of care and minimizing duplicative and, therefore often, wasteful, expenditures.

New 42 C.F.R. § 1001.952(z)(4). Support of Indian health care providers. This safe harbor, which is fleshed out in the greatest detail, is modeled after the safe harbor provided to Federally Qualified Health Centers ("FQHCs") in 42 C.F.R. § 1001.952(w).

As the OIG noted in the FQHC Final Rule, the FQHC safe harbor was “intended to permit health centers to accept certain remuneration that would otherwise implicate the anti-kickback statute when the remuneration furthers a core purpose of the Federal health centers program: ensuring the availability and quality of safety net health care services to otherwise underserved populations.”¹⁷ As the OIG also highlighted some of the beneficial aspects of FQHCs made them ideal candidates for a safe harbor, including:

FQHCs are designed to assist the large number of individuals living in medically underserved areas, as well as the growing number of special populations with limited access to preventive and primary health care.

- FQHCs play a vital role in the health care safety net, providing cost effective care for communities with limited access to health care resources.
- FQHCs serve predominantly low-income individuals, including some beneficiaries of the Medicare and Medicaid programs as well as a substantial and growing number of uninsured patients.¹⁸

The Indian health system is a real-world embodiment of the FQHC mission as articulated by the OIG. Indian health care providers provide cost effective care to low-income individuals who are often uninsured and are part of a medically underserved population. Beyond merely providing services in communities with limited access to health care, Indian health care providers are often the *only* health care provider in an AI/AN community.

In light of AI/ANs’ heavy reliance on the I/T/U system for their health care, there cannot be any question that AI/ANs are a medically underserved population that suffer greatly from the underfunding of the I/T/U program. For example, in 2004, the United States Commission on Civil Rights found that there is a “dire health care situation facing Native Americans,” and that in addition to “disturbingly high mortality rates,” Native Americans

¹⁷FQHC Final Rule, at 56,634.

¹⁸*Id.* at 56,633.

suffer “significantly lower health status and disproportionate rates of disease”¹⁹ The Commission also found that Federal funding of health care is insufficient, explaining “IHS funding levels are inadequate by every applicable standard of measurement and in every area of health service delivery within IHS.”²⁰ In a separate report, the Commission found that “IHS’s real spending per Native American, after adjusting for inflation and population growth, has fallen over time, despite funding increases,”²¹ that “a large and expanding gap exists between needed and available services, or unmet needs, in Native American communities,”²² and that IHS operates at approximately 59% capacity to provide adequate health care.²³

All savings achieved through safe harbors for Indian health care providers ultimately accrue to the benefit of the Federal government: first, by helping it achieve its special trust responsibility to AI/ANs, and secondly, by achieving actual savings in the cost of health care delivery.

As noted this safe harbor was closely modeled after the FQHC safe harbor. But, it is not identical. We attempted to streamline it in recognition that Indian health care providers are unique and governed by very different statutory rules than the 330 community health centers. We also tried to balance the administrative burden of compliance with the important integrity concerns of the OIG.

We note a few of the issues that we know are of particular concern.

Patient freedom of choice among health care providers. As discussed above, many AI/ANs independently choose to obtain their health care from an Indian health care provider in light of the Federal government’s special trust responsibility to provide health care at no cost to the them and the greater cultural competence and familiarity often present in these settings. Patient freedom of choice, then, may not be as much of a concern as it would be with different patient populations. Also, many of the arrangements that Indian health care providers would enter into under the safe harbor would be for emergency or highly specialized services in remote areas, thus making the question of patient choice that much less of a focus than, for example, a choice of primary physicians in a major urban area.

That said, all AI/ANs ultimately have the choice to seek out another provider. We have retained the express statement of that right and the duty to respond to questions. We did not include the express requirement of notice about choice, which we believe would be very confusing for AI/ANs who use Indian health care providers as a matter of right.

¹⁹U.S. Comm’n on Civil Rights, *Broken Promises: Evaluating the Native American Health Care System* iii (Sept. 2004), available at <http://www.usccr.gov/pubs/nahealth/nabroken.pdf>.

²⁰*Id.* at 120.

²¹U.S. Comm’n on Civil Rights, *A Quiet Crisis: Federal Funding and Unmet Needs in Indian Country* 43 (July 2004), available at <http://www.usccr.gov/pubs/na0703/na0731.pdf>.

²²*Id.* at 42

²³*Id.* at 43.

Competition among health care providers. Many Indian health care providers that seek to enter into arrangements with outside providers will offer a request for proposals designed to ensure a competitive bidding process. However, much more informal processes are also relied upon due to the small pool of potential partners from whom to obtain necessary services.

The potential overutilization of health care services. AI/AN are arguably the most medically underserved population in the United States, and many Indian health care providers face a daily struggle to provide even basic health services to their patients. Even with the flexibility afforded by a safe harbor, I/T/Us will still face dramatic financial shortfalls and will not suddenly begin authorizing or performing frivolous or unnecessary procedures upon receiving a safe harbor. Further, many, if not most, arrangements entered into under a safe harbor would involve services through the CHS program, which contains internal safeguards on the medical necessity of covered services.

The existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may take into account their decisions whether to (1) order a health care item or service or (2) arrange for a referral of health care items or services to a particular practitioner or provider. The agreements entered into pursuant to the safe harbor would benefit each Indian health care provider tasked with the efficient provision of health care throughout its jurisdiction and to its patient population, by granting additional financial and administrative flexibility. As the OIG has itself cited as a factor supporting the legitimacy of favorable contract terms for Tribal health programs, these types of agreements arise 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” and are “fully consistent with IHS policy encouraging tribes to be prudent purchasers”²⁴ Rather than sparking unseemly quid pro quo remuneration, the safe harbor would help fulfill the Federal trust responsibility, the goals of the FQHC program, and the requirements of the CHS program.

Obviously much more could be said about the details in the attached proposed safe harbor. However, we believe much of it to be self-explanatory. But, more importantly, we believe it is incumbent on the OIG to interact with the Tribal Technical Advisory Group to CMS and to hold consultation pursuant to the HHS and CMS Tribal Consultation Policies and Executive Order 13175. Such interactions will provide an opportunity for a more specific and focused discussion of the critical provisions.

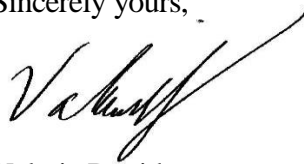
²⁴OIG Advisory Op. 01-03 at 7.

3. Conclusion

On behalf of Tribal Technical Advisory Group (TTAG) to the Centers for Medicare and Medicaid Services (CMS), I thank you for considering our proposal for Indian health care provider-specific safe harbors to the anti-kickback statute. Providing adequate health care to our remote service areas is a constant challenge considering IHS's inadequate budget. The safe harbor will be tremendously beneficial to the chronically underserved, overwhelmingly low-income patient population, and will provide financial benefits to numerous Federal health programs. We do not believe that implementing the safe harbor will increase the risk of violating any Federal laws, or otherwise jeopardizing the integrity of any Federal health care program. Rather, it will further the Federal government's trust responsibility towards providing health services to AI/ANs.

Please let us know if there is any other information CMS TTAG can provide to assist your analysis of this matter.

Sincerely yours, .



Valerie Davidson
Chair, CMS Tribal Technical Advisory Group

Cc: Dr. Yvette Roubideaux, Director, Indian Health Service
Kitty Marx, Director, CMS Tribal Affairs Group

**Proposed American Indian and Alaska Native and
Indian Health Care Provider Safe Harbors**

Amend 42 C.F.R. § 1001.952(k), as follows:

(k) *Waiver of beneficiary coinsurance and deductible amounts.* As used in section 1128B of the Act, “remuneration” does not include any reduction or waiver of a Medicare or a State health care program beneficiary's or an Indian’s (as that term is used in 42 C.F.R. § 447.50(b)(1)) obligation to pay coinsurance or deductible amounts as long as all of the standards are met within either of the following two categories of health care providers:

. . .

(2) If the coinsurance or deductible amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under titles V or XIX of the Act to a federally qualified health care center or other health care facility under any Public Health Services Act grant program or under title V of the Act, or is an Indian as that term is used in 42 C.F.R. § 447.50(b)(1), the health care center or facility may reduce or waive the coinsurance or deductible amounts for items or services for which payment may be made in whole or in part under part B of Medicare or a State health care program.

Amend 42 C.F.R. § 1001.952 by adding a new subsection (z), as follows:

(z) *Indian health care provider.* For purposes of applying section 1128B(b) of the Social Security Act, the exchange of anything of value between or among the following shall not be treated as remuneration if the exchange arises from or relates to exchanges provided for under subparagraphs (1), (2), (3) or (4) of this paragraph (z).

(1) An exchange or transfer or any goods, items, services, donations or loans (whether the donation or loan in cash or in-kind) between or among entities that fall within the definition of an Indian health care provider (as defined in this paragraph) or a referral of a patient or other individual receiving or eligible to receive services from an Indian health care provider.

(2) An exchange between an Indian health care provider and any individual served or eligible for service from such provider, but only if—

(i) the individual receiving the benefit of the exchange receives services or is eligible to receive services—

(A) from an Indian tribe or tribal organization under a funding agreement entered into with the Indian Health Service pursuant to the Indian Self-Determination and Education Assistance Act, Pub. L. 93-638, as amended, a tribal health program and the Indian Health Service as those terms are defined in section 4 of the Indian Health Care Improvement Act, or

(B) from an urban Indian organization that has entered into a contract with or received a grant from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act, Pub. L. 94-437, as amended; and

(ii) the exchange is—

(A) for the purpose of ensuring the individual has meaningful access to health care, including for example—

(1) transporting the individual (and escort, if needed) for the provision of health care items or services;

(2) providing housing to the individual (including a pregnant individual) and immediate family members or an escort incidental to assuring the timely provision of health care items and services to the individual;

(3) is for the purpose of paying premiums, copayments, deductibles, or other cost sharing on behalf of such individuals; or

(B) consists of an item or service—

(1) of small value that is provided as a reasonable incentive to secure timely and appropriate preventive and other items and services;

(2) that is reasonably calculated to minimize the risk of injury or disease to an individual or the individual's caretaker, such as a float coat or other water safety device or an infant or child car seat or housing accommodation such as a ramp or lift;

(3) that is authorized under the Indian Health Care Improvement Act, as amended.

(3) An agreement or arrangement for the exchange, transfer or sharing of any scarce or specialized health resource, including facilities, equipment, space, services, or personnel, which, because of cost, limited availability, or unusual nature, are either unique or scarce in the health care community or are subject to maximum utilization only through mutual use, between an Indian health care provider and other providers or suppliers in the health care community for the benefit of patients or other individual receiving or eligible to receive services from an Indian health care provider.

(4) The transfer of any goods, items, services, donations or loans (whether the donation or loan is in cash or in-kind), or combination thereof from an individual or entity provider or supplier that provides or supplies such goods, items, services, donations, or loans to an Indian health care provider (as defined in this paragraph), as long as the following standards are met—

(i)(A) The transfer is made pursuant to a written contract, lease, grant, loan, or other agreement that describes the amount of, all goods, items, services, donations, or loans to be provided by the individual or entity to the Indian health care provider.

(B) The amount of goods, items, services, donations, or loans specified in the agreement in accordance with paragraph (z)(4)(i)(A)(3) of this section may be a fixed sum, fixed percentage, or set forth by a fixed methodology. The amount may not be conditioned on the volume or value of Federal health care program business generated between the parties. The written agreement will be deemed to cover all goods, items, services, donations, or loans provided by the individual or entity to the Indian health care provider as required by paragraph (z)(4)(i)(A)(3) of this section if all separate agreements between the individual or entity and the Indian health care provider incorporate each other by reference or if they cross-reference a master list of agreements that is maintained centrally, is kept up to date, and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of arrangements.

(ii) The goods, items, services, donations, or loans are medical or clinical in nature or reasonably relate to services provided by the Indian health care provider pursuant to or under—

(A) the Snyder Act, the Indian Health Care Improvement Act, or any other legislation authorizing programs, services, functions or activities that may be carried out by the Indian Health Service; provided that in the case of—

(1) a tribal health program as that term is defined in Section 4 of the Indian Health Care Improvement Act, its compact or contract and funding agreement entered into pursuant to the Indian Self-Determination and Education Assistance Act; or

(2) an urban Indian organization, its contract or grant agreement pursuant to Title V of the Indian Health Care Improvement Act;

(B) including, by way of example, billing services, technology support and enabling services, such as case management, transportation or translations services.

(iii) The Indian health care provider reasonably expects the arrangement to contribute meaningfully to the Indian health care provider's ability to maintain or increase the availability, or enhance the quality, of services provided to eligible individuals or individuals served by the Indian health care provider.

(iv) The Indian health care provider must re-evaluate the arrangement at reasonable intervals to ensure that the arrangement is expected to continue to satisfy the standard set forth in paragraph (z)(4)(iii) of this section, and must document the re-evaluation. Arrangements must not be renewed or renegotiated unless the Indian health care provider reasonably expects the standard set forth in paragraph (z)(4)(iii) of this section to be satisfied in the next agreement term. Renewed or renegotiated agreements must comply with the requirements

of paragraph (z)(4)(iii) of this section.

(v) The individual or entity does not

(A) require the Indian health care provider (or its affiliated employees) to refer patients to a particular individual or entity, or

(B) restrict the Indian health care provider (or its affiliated employees) from referring patients to any individual or entity.

(vi) Individuals and entities that offer to furnish goods, items, or services without charge or at a reduced charge to the Indian health care provider must furnish such goods, items, or services to all individuals from the Indian health care provider who clinically or programmatically qualify for the goods, items, or services, regardless of the patient's payor status or ability to pay. The individual or entity may impose reasonable limits on the aggregate volume or value of the goods, items, or services furnished under the arrangement with the Indian health care provider, provided such limits do not take into account an individual's payor status or ability to pay.

(vii) The agreement must not restrict the Indian health care provider's ability, if it chooses, to enter into agreements with other providers or suppliers of comparable goods, items, or services, or with other lenders or donors or from using a reasonable methodology to select the providers or suppliers that best meet its needs. In making these determinations, the Indian health care provider should look to the procurement standards applicable to it under applicable law.

(viii) The Indian health care provider will not hinder individuals from exercising their freedom to choose any willing provider or supplier. In addition, the Indian health care provider must disclose the existence and nature of an agreement under paragraph (z)(4)(i) of this section to any such individual who inquires.

(ix) The Indian health care provider may, at its option, elect to require that an individual or entity charge an individual referred by the Indian health care provider the same rate it charges other similarly situated individuals not referred by the Indian health care provider or that the individual or entity charges an individual referred by the Indian health care provider a reduced rate (where the discount applies to the total charge and not just to the cost sharing portion owed by an insured patient).

(x) The Indian health care provider will make documentation related to any transfer subject to paragraph (z)(4) available to the Secretary upon request.

For purposes of this paragraph (z), the term "Indian health care provider" means (A) The Indian Health Service, (B) Any health program of an Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Health Care Improvement Act) that operates any health program, service, function, activity, or facility funded, in whole or part, by

the Indian Health Service through, or provided for in, a Funding Agreement with the Indian Health Service under the Indian Self-Determination and Education Assistance Act, or (C) Any Urban Indian Organization (as such term is defined in section 4 of the Indian Health Care Improvement Act).