

# Tribal Technical Advisory Group

To the Centers for Medicare & Medicaid Services

c/o National Indian Health Board 910 Pennsylvania Avenue, SE Washington, DC 20003 (202) 507-4070 (202) 507-4071 fax

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

December 23, 2019

Office of Inspector General  
Department of Health and Human Services  
Attention: OIG-0936-AA10-P  
Room 5521, Cohen Building  
330 Independence Avenue SW  
Washington, DC 20201

**RE: (OIG-0936-AA10-P) Revisions To Safe Harbors Under the Anti-Kickback Statute, and to Civil Monetary Penalty Rules Regarding Beneficiary Inducements**

On behalf of the Tribal Technical Advisory Group (TTAG) to the Centers for Medicare & Medicaid Services (CMS), I write to comment on the proposed rule issued by the Department of Health and Human Services (HHS) Office of Inspector General (OIG) concerning the proposed modifications to the safe harbors under the civil monetary penalty (CMP) law and the Anti-Kickback Statute (AKS),<sup>1</sup> published October 17, 2019. The TTAG advises CMS on Indian health policy issues concerning Medicare, Medicaid, the Children's Health Insurance Program (CHIP), 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 in the Indian Health Service (IHS), Indian Tribes, Tribal organizations, and Urban Indian Organizations (collectively I/T/Us). We appreciate the opportunity to provide information and comments on the proposed rule.

## **I. Background**

The federal Anti-Kickback Statute (AKS) imposes criminal penalties for giving or receiving anything of value in return for referrals or to generate business when services are paid for by a federal health care program. The offense is a felony crime, punishable by fines up to \$100,000 and imprisonment up to 10 years. Violations of the AKS also may result in the imposition of CMPs under section 1128A(a)(7) of the Social Security Act.<sup>2</sup>

Because the statute is so broad and can hinder potentially beneficial arrangements, Congress enacted a law that specifically requires the development and promulgation of regulations (i.e. safe

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<sup>1</sup> 42 U.S.C. § 1320a-7b.

<sup>2</sup> 42 U.S.C. § 1320a-7a.

harbor provisions) that would specify payment and business practices that would not be subject to sanctions under the Anti-Kickback Statute, even though they may be capable of inducing referrals.<sup>3</sup> Congress delegated to the HHS Secretary the authority to protect certain arrangements and payment practices under the Anti-Kickback Statute. In doing so, Congress intended for the safe harbor regulations to be updated periodically to reflect changing business practices and technologies in the health care industry.<sup>4</sup>

In modifying and establishing safe harbors, the HHS Secretary may consider whether a specified payment practice may impact: access to health care services or quality of health care services; ability of health care facilities to provide services in medically underserved areas or to medically underserved populations; the cost to federal health care programs; or any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in federal health care programs.

The OIG has now proposed seven new safe harbors and four modifications to existing safe harbors to allow for certain beneficial arrangements as part of their “Regulatory Sprint to Coordinated Care.” The proposed rule is intended to remove potential barriers to more effective coordination, management of patient care, and delivery of value-based care that ultimately improves health care quality and outcomes.

Since 2012, the TTAG and Tribes have requested that the OIG create an Indian-specific safe harbor akin to the safe harbors provided for Federally Qualified Health Centers (FQHCs) at 42 C.F.R. § 1001.952(w). TTAG submitted comprehensive recommendations to OIG’s 2012 annual safe harbor comment solicitation, and again in 2014, 2015, and 2018. Tribes have also had several in-person meetings with OIG attorneys – most recently on November 6, 2019. Now, as the office undertakes the most significant revision to the AKS safe harbors since the rules were originally published, we reiterate those Tribal recommendations, and we urge you to incorporate an Indian-specific safe harbor.

#### **A. The Indian Health System is a Federally-Funded System**

The United States has a unique trust responsibility toward American Indian and Alaska Native (AI/AN) people regarding health care, and unique Constitutional authority to fulfill that responsibility that is recognized by the courts. As Congress has declared, “it is the policy of [the U.S.], in fulfillment of its special trust responsibilities and legal obligations to Indians . . . to ensure the highest possible health status for Indians and urban Indians and to provide all resources necessary to effect that policy.”<sup>5</sup> The obligation to carry out the trust responsibility to Indians applies to all agencies and offices of the federal government – including the Department of Health and Human Services (HHS). The Department of Health & Human Services has repeatedly recognized this obligation, including in its Strategic Plan FY 2018-2022.

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<sup>3</sup> Section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93 (section 1128B(b)(3)(E) of the Act; 42 U.S.C. 1320a-7b(b)(3)(E)).

<sup>4</sup> H.R. Rep. No. 100-85, Pt. 2, at 27 (1987).

<sup>5</sup> 25 U.S.C. § 1602(a)(1).

Fulfillment of the trust responsibility to AI/ANs is reflected in the federal budget. The Indian health system receives funding through an annual appropriation to the Indian Health Service (IHS), although underfunding of the IHS has been a longstanding and multigenerational issue. To assist the Indian health system through third party revenue, Congress, in 1976, authorized IHS and Tribal providers to bill Medicare, Medicaid and CHIP for the services they provide to beneficiaries enrolled in those programs. Still, Indian health programs face many challenges, suffer high turnover rates, and must ensure that their limited resources are used to the maximum extent practicable. Indian health programs survive, in part, by devising innovative and collaborative approaches for delivering health services to their generally rural and high-morbidity AI/AN populations.

Our Indian health care providers<sup>6</sup> need to be able to enter into arrangements with hospitals, providers, and suppliers, and to establish collaborative relationships. Arrangements could include: capital development grants; low-cost or no-cost loans; reduced price services; and in-kind donations of supplies, equipment, or facility space. Yet, Tribes are concerned that the broad reach of the Anti-Kickback Statute, and adjoining criminal and civil penalties, could negatively impact Indian health providers should their arrangements come under the scrutiny of the Inspector General, and discourage them from entering into clearly beneficial relationships. To avoid penalties, Tribes could find themselves avoiding or placing counter-productive limitations on relationships between providers and their patients, with other providers, and with vendors. This is why Tribes have requested safe harbors to the Anti-Kickback Statute for Indian health providers; specifically one modeled after the federally qualified “health centers” (FQHC) safe harbor at 42 C.F.R. § 1001.952(w). A safe harbor for Indian health care providers is needed to ensure that Native peoples do not face needless barriers to care coordination or are denied the benefits of sharing of resources, both within the Indian health system and with other providers.

## **B. Safe Harbor for Federally Qualified Health Centers**

The FQHC safe harbor was intended to permit health centers to accept certain remuneration that would otherwise run afoul of the AKS when the remuneration furthers a core purpose of the federal health centers program. That is, to ensure the quality and availability of safety net health care services for underserved populations. FQHCs are ideal candidates to receive safe harbor protections because they 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.”<sup>7</sup> TTAG’s position has long been that the reasoning behind granting FQHCs their own safe harbor as health centers also should apply to all Indian health programs.

In a note to the safe harbor at 1001.952(w), the term “health center” is defined as a Federally Qualified Health Center as defined under section 1905(l)(2)(B)(i) or 1905(l)(2)(B)(ii) of the Social Security Act. Section 1905(l)(2)(B) of the Social Security Act defines FQHC as follows:

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<sup>6</sup> The AI/AN health care delivery system consists of Indian Health Service-operated facilities, Tribally-owned or operated facilities, and Urban Indian Organizations. As referenced herein, the term “Indian Health Care Provider” refers to these facilities.

<sup>7</sup> Safe Harbor for Federally Qualified Health Centers Arrangements Under the Anti-Kickback Statute, 72 Fed. Reg. 56632 (Oct. 4, 2007), <https://oig.hhs.gov/authorities/docs/07/HealthCenterSafeHarbor.pdf>

The term “Federally-qualified health center” means an entity which –

- (i) is receiving a grant under section 330 of the Public Health Service Act
- (ii)(I) is receiving funding from such a grant under a contract with the recipient of such a grant, and
  - (II) meets the requirements to receive a grant under section 330 of such Act,
- (iii) based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant, including requirements of the Secretary that an entity may not be owned, controlled, or operated by another entity, or
- (iv) was treated by the Secretary, for purposes of part B of title XVIII, as a comprehensive federally funded health center as of January 1, 1990;

and includes an outpatient health program or facility operated by a Tribe or Tribal organization under the Indian Self-Determination Act (Public Law 93-638) or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services. In applying clause (ii), the Secretary may waive any requirement referred to in such clause for up to 2 years for good cause shown.

The Health Center/FQHC safe harbor at 1001.952(w) applies to FQHCs as defined in the language above and Tribal outpatient programs are included in that language. To give the agency an idea of the impact of the FQHC designation and the current FQHC safe harbor, there are 36 FQHCs or FQHC “Look-Alike”<sup>8</sup> health centers that self-designate as either Tribal or urban Indian, as of FY 2019. However, most of the nearly 742 Indian health providers<sup>9</sup> 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 Indian health care providers.

## **II. Request for Indian Safe Harbors in the Context of the Regulatory Sprint**

Having a safe harbor specific to Indian health care providers, modeled on the one in place for FQHCs, would substantially help these underfunded programs to address patient needs and conserve Indian Health Service and other federal funds, by allowing them to accept goods, items, services, donations or loans from willing providers and suppliers, and to coordinate their services with one another. The Indian health system is not profit-oriented. Any funds that Tribes save go back into the health system. There would thus be dual benefits to an Indian-specific safe harbor:

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<sup>8</sup> From the Health Resources & Services Administration (HRSA) website (May 2018): “Federally Qualified Health Center Look-Alikes are community-based health care providers that meet the requirements of the HRSA Health Center Program, but do not receive Health Center Program funding. They provide primary care services in underserved areas, provide care on a sliding fee scale based on ability to pay and operate under a governing board that includes patients.” Section 1905(l)(2)(B) of the Social Security Act is the defining legislation, <https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc-look-alikes/index.html>

<sup>9</sup> See Government Accountability Office, IHS: Facilities Reported Expanding Services Following Increases in Health Insurance Coverage and Collections (Sept. 2019), <https://www.gao.gov/assets/710/701133.pdf>

increased patient services through coordination and the reduction of costs overall, as well as savings on federal fiscal resources. Without such a safe harbor, fearful of running afoul of the AKS, Indian health care providers may avoid coordinating care and entering into beneficial arrangements.

Office of Inspector General attorneys responded to TTAG's proposal to include Indian Safe Harbors in the federal fraud and abuse regulations in a letter dated September 27, 2019.<sup>10</sup> Based on a fresh review by OIG of the TTAG's responses to previous comment solicitation, OIG wrote:

"We believe existing safe harbors to the federal anti-kickback statute and exceptions to the beneficiary inducements [civil monetary penalty] CMP may provide the necessary regulatory flexibility and protections for Indian health care providers, without the need for further modification. However, we acknowledge that certain financial arrangements highlighted by the TTAG, e.g., the transfer or sharing of personnel across two or more providers for free or below fair market value, would not be protected under existing regulations."

OIG attorneys offered to review the special circumstances and examples set forth by TTAG in the context of the Regulatory Sprint.

While we appreciate OIG's engagement with Tribes and Indian health care leaders thus far, we are disappointed that the proposed rule does not include the Indian-specific safe harbor that Tribes have consistently recommended. TTAG also remains concerned about the matters listed below.

**Specialty care referrals.** A major concern of the TTAG has been that the Anti-Kickback Statute potentially impedes referrals for specialty care. Specialty services available through IHS-funded facilities are generally limited or vary by hospital. To fill the gaps, many of the larger Tribal health programs could in certain cases provide various kinds of supports for health programs carried out by individual Tribes or smaller Tribal organizations, so long as it does not artificially induce referrals. All of this could occur under the funding agreements entered into by the individual Tribes and Tribal organizations with the Indian Health Service. Similar arrangements exist through the 37 states in which there are Indian health care providers.<sup>11</sup> 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.

In the September 27 letter to TTAG representatives, OIG stated that to the extent specialty care arrangements involve exchange of remuneration as part of care coordination agreements, OIG would consider these in context of the proposed rule. We ask OIG to honor this statement and address specialty referrals for Indian health care providers when it publishes the final rule. The TTAG urges the OIG to renew its support for a 2001 OIG opinion in which it recognized that IHS referral arrangements can result in overall reduced costs to the federal treasury.<sup>12</sup> The principles and conclusions reached in that opinion should be carried forward by the OIG in opining that these

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<sup>10</sup> Attachment 1 to this letter.

<sup>11</sup> See the IHS profile at <https://www.ihs.gov/newsroom/factsheets/ihsprofile/>

<sup>12</sup> HHS Office of the Inspector General, OIG Advisory Opinion No. 01-03 (May 3, 2001), <https://oig.hhs.gov/fraud/docs/advisoryopinions/2001/ao01-03.pdf>

types of sharing and care coordination arrangements do not implicate the AKS for the federally funded Indian health care system.

**Civil monetary penalties.** We also note that the OIG has in several instances in the September 27 letter pointed Tribes to CMP exceptions that it believes would help them to avoid liability for various arrangements.<sup>13</sup> TTAG is confused by the repeated recommendation to seek protection under the listed exceptions, since we understand that the CMPs do not necessarily shield a person or entity from the AKS, even though the opposite is true – that an AKS safe harbor shields a person from the CMP law. Although we appreciate that OIG has provided these recommendations, it is the Indian Safe Harbors that our group has drafted, and which we have included here, that would directly address the distinctiveness of our health system and ultimately provide the protection we are seeking. Our suggestions make sense for the federal government as well.

### **III. Responses and Recommendations to the Proposed Rule**

Each of the proposed safe harbors and exceptions protect remuneration exchanged between a value-based entity and its “value-based participants” pursuant to a “value-based arrangement.” OIG and CMS have proposed to define “value-based enterprise” (VBE), “value-based participant,” and “value-based arrangement” similarly, and HHS and the Centers for Medicare & Medicaid Services (CMS), in its Stark Law revisions, have solicited comments on the definitions.

Unfortunately, the proposed value-based safe harbors, in current form, will not benefit the Indian health system. For this reason, we reiterate our request for OIG to adopt the American Indian and Alaska Native safe harbors that TTAG has proposed, which are attached to these comments.<sup>14</sup>

#### **A. Value-based Safe Harbors**

- Care coordination safe-harbor (42 C.F.R. § 1001.952(ee))

The proposed rule would establish a safe harbor for certain care coordination arrangements within a “value-based enterprise,” or VBE. Under the proposed rule, a VBE would consist of a network of individuals and entities that collaborate together to achieve one or more value-based purposes. The VBE could consist of as little as two physicians, or other entities participating in arrangements eligible for safe harbor protection, if all safe harbor conditions are fully met.

Given its complexity and for various other reasons, we think it is unlikely the safe harbor would be of much help to the Indian health care system. Indeed, several modifications OIG is considering for the final rule would effectively make the safe harbor completely unavailable to Indian health providers, or would dramatically limit its benefits, and we therefore oppose them.

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<sup>13</sup> One example from the letter is related to transportation and lodging, where the OIG states: “the ‘promotes access to care’ exception to the beneficiary inducements CMP may already provide flexibility with respect to the provision of both free or discounted transportation and lodging. This exception, while subject to additional safeguards, shares similar aims to the excerpted provision in the Proposed Safe Harbor.”

<sup>14</sup> Attachment 2 to this letter.

First, OIG states that it is considering prohibiting any remuneration in a VBE from being paid for by a federal program. The Indian health program is a federally funded program, authorized to bill Medicaid, Medicare and CHIP, so making that change would rule out the safe harbor for Indian health care providers. Instead, TTAG recommends that the OIG explicitly include Indian health programs in the definition of a VBE, to avoid excluding Tribes from safe harbor protections.

Second, OIG states that it is considering denying safe harbor protections for arrangements between entities with common ownership. The Indian health care system consists of IHS, Tribal organizations, and Urban Indian Organizations (the I/T/U). Arrangements between entities with common ownership is our reality. If the safe harbor is not available for commonly-owned entities, it will be of limited use to Indian health care providers. Consequently we ask that OIG not prohibit arrangements between common entities, or at least, that it expressly protect arrangements between Indian health care providers.

Third, OIG states that it is considering limiting a VBE's "target population" to only patients with chronic conditions or shared disease states. Such a limitation would be unworkable for many Indian health care programs, which strive to provide comprehensive services for all their patients throughout their life-spans, and to help prevent chronic conditions and diseases before they occur. The limitation would also be inappropriate given the well-documented and extensive unmet health care needs of AI/ANs.

The proposed rule also includes a recipient contribution requirement as a safeguard to help ensure that the use of any remuneration exchanged pursuant to the safe harbor would be for the coordination and management of the target patient population's care. Protection under the safe harbor would be contingent on the recipient's payment of at least 15% of the offeror's cost for the in-kind remuneration. The agency intended this requirement to mirror that set forth in the current electronic health records items and services safe harbor, 1001.952(y). For reasons that we elaborate on at section "E" below, the TTAG recommends that OIG eliminate the contribution requirement for Indian health programs.

- Value-based safe harbors involving downside financial risk (42 C.F.R. § 1001.952(ff), (gg))

The OIG is proposing two safe harbors that would protect both monetary and in-kind remuneration, and offer flexibility in recognition of a VBE's assumption of substantial or full downside financial risk.

As currently drafted, none of the listed arrangements that qualify as substantial downside financial risk or full downside financial risk are payment arrangements that apply to the Indian health care system. So even though IHS and Tribal facilities would benefit from safe harbors that would protect monetary and in-kind remuneration, they are not eligible under the rule. TTAG recommends that OIG extend the protections created by this safe harbor to expressly include Indian health programs.

The OIG proposes the most flexibility for arrangements (including in-kind and monetary remuneration) involving VBEs that have assumed "full financial risk" for a target patient

population. The entities protected under this safe harbor would be able to innovate with respect to coordinated care arrangements to make up for the higher risk that they would assume.

As we have previously discussed, Indian health care is paid for through IHS appropriations and the Medicare, Medicaid and CHIP programs. As a result, Indian health care providers are not risk-bearing entities like those the OIG proposes to protect under the regulations. TTAG believes that Indian health care providers should be able to access the same kind of flexibilities as risk-bearing entities because they require the flexibility that is provided by this statute in order to maintain day-to-day operations. Extending maximum flexibility to Indian health care providers is consistent with, and arguably required by, the federal trust responsibility for Indian health.

#### **B. Patient Engagement and Support (42 C.F.R. § 1001.952(hh))**

Under the proposed safe harbor, in-kind patient engagement tools or supports furnished directly by a VBE participant to a patient in a target patient population would not be considered “remuneration” if directly connected to the coordination and management of care and all other conditions of the safe harbor are met. OIG proposes that the aggregate retail value of the patient engagement tools and supports furnished by a VBE participant to a patient could not exceed \$500 annually, with certain limited exceptions.

TTAG supports the inclusion of this new safe harbor, which could be very beneficial for Indian health care providers seeking to engage and support IHS-eligible patients. If, however, OIG includes language preventing VBE participants from being able to bill a federal health care program for the patient engagement tools and supports that are furnished, then Indian health programs will not be able to use the safe harbor. Indian health programs are federally funded and bill Medicaid, Medicare or CHIP, and therefore this restriction would mean I/T/Us would be prevented from being able to benefit from this safe harbor.

OIG also solicits comment on whether the proposed rule should allow waiver or offset of cost-sharing in connection with certain services. TTAG recommends that OIG allow Indian health programs to provide waivers for cost-sharing as an important patient engagement tool for IHS-eligible individuals.

#### **C. Personal Services and Management Contracts Safe Harbor (42 C.F.R. § 1001.952(d))**

The personal services safe harbor protects referrals when payment exchanged is at fair market value. OIG proposes modifications to the safe harbor that would add flexibility with respect to outcomes-based payments and part-time arrangements. Some outcomes-based payments would be protected, including shared savings payments, gainsharing payments, episodic or bundled payments, and pay-for-performance. Overall, the TTAG welcomes the increased flexibility proposed by changes to this safe harbor, and appreciates OIG’s commitment to facilitating improved care coordination. Below, we elaborate further on the importance of care coordination to the Indian health care system, and our concern with applying the “fair market value” requirement to services received in our facilities.

Care coordination and sharing arrangements are important to the efficiency of the Indian health care system. This is especially true in the rural locations we serve, where low retention of health



providers is the norm. OIG has advised TTAG that the personal services arrangement and management contracts safe harbor<sup>15</sup> may protect shared personnel arrangements utilized by AI/ANs when resources are limited, if each party to the arrangement pays fair market value for the services furnished by the shared personnel (and assuming all other safe harbor criteria are met). Yet in some instances, Indian health care providers cannot pay what might be considered fair market value for services elsewhere. In other instances, contractors may seek to argue that Tribes should pay fair market value, but the fair market value may differ for on-reservation jobs, Indian health system jobs, or others. To address this challenge, we recommend that OIG, in the final rule, indicate that fair market value for Indian health program personnel should be determined by the economic realities of the communities in which the transactions occur, with special consideration to the recruitment and retention challenges endemic in Indian country.

There are other unique issues that arise in Indian country which OIG must consider. For example, due to discrepancies in funding for Indian health as opposed to other federal programs, volunteer providers want to provide free facilities space or services to Tribes for a charitable purpose. These charitable contributions are not meant to induce referrals, but to help facilitate continuity of care. They should be recognized and allowed under the safe harbors, similar to the proposed provision on technology risk assessments. There, OIG has acknowledged that “[m]any organizations cannot afford to retain in-house [personnel], or designate [certain personnel]” with technology-related duties, and thus proposes to allow technology risk assessment to be a “protected donation” service under the safe harbor regulations. We ask that OIG apply this reasoning more broadly to Tribes and Indian health care providers and specifically allow a safe harbor for facilities space or personal services donations to them.

#### **D. Local Transportation Safe Harbor (42 C.F.R. § 1001.952(bb))**

The OIG proposes two modifications to the existing safe harbor for local transportation: expanding the mileage limits for rural areas from the current 50 miles to 75 miles, and eliminating mileage transportation restrictions for patients discharged from inpatient facilities. OIG is also soliciting comments on whether the safe harbor should be expanded to protect transportation for non-medical purposes that will improve or maintain health.

For Indian health care providers, patient transportation is a major challenge. High unemployment and inability to afford a vehicle or alternative mode of transportation are just some of the barriers we face. As well, Tribes are often located in the most rural areas of the country, and patients must often travel even farther than 75 miles for care. While the TTAG welcomes the proposed increase in the mileage limit, we encourage OIG to eliminate the mileage limit for Indian health programs altogether – or to further expand the limit for our health programs. We also ask that OIG consider eliminating or easing the safe harbor’s restrictions when the purpose of the transportation is to access primary or preventive care, with appropriate limitations (such as number of visits per year, for example), to ensure there is no abuse.

TTAG supports OIG’s proposal to eliminate the mileage limit for patients discharged from inpatient facilities. We also support extending the safe harbor to local transportation for health-related, non-medical purposes. Because of the unique transportation challenges that IHS-eligible

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<sup>15</sup> See 42 C.F.R. § 1001.952(d).

people face, extending the safe harbor for health-related non-medical purposes solely for them may be appropriate.

#### **E. Electronic Health Records (EHR) Safe Harbor, 42 C.F.R. § 1001.952(y)**

The rule proposes modifications to the existing safe harbor for electronic health records items and services to add protections for certain related cybersecurity technology; to update provisions regarding interoperability; and to remove the sunset date. The OIG proposes to keep the requirement found in the 2006 Final EHR Safe Harbor Rule (§ 1001.952(y)) that, to address fraud risk in technology donations, the recipient pays 15% of the donor's cost of the technology. Further, the OIG is considering whether to eliminate or reduce the contribution requirement for small or rural hospitals, and asks how “rural practices” should be defined.

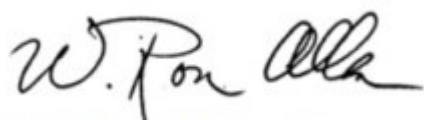
In the September 27 letter to TTAG, HHS OIG acknowledged that the 15% contribution requirement is burdensome for Indian health care providers and may act as a barrier to adoption of EHRs technology, and it offered to take this into account with regard to this proposed rule. We reiterate here that, for Tribes, even the 15% donation is prohibitive. The TTAG therefore recommends that the agency eliminate the contribution requirement for Indian health programs. With respect to modifying definitions, we recommend that OIG include Indian health providers in the definition of “rural practices.” We also recommend the removal of the sun set date.

The rule also proposes to delete the condition that prohibits the donation of equivalent items or services at current section 1001.952(y)(7) to allow donations of replacement electronic health records technology. Because of the financial constraints faced by IHS and Tribally-operated hospitals, TTAG supports this change. The OIG should remove the existing condition that prohibits the donation of equivalent EHR items or services.

#### **IV. Conclusion**

The TTAG appreciates the opportunity to comment on the proposed rule and looks forward to a continued open dialogue with the OIG concerning the AKS and safe harbor provisions. We invite the OIG to consult with the TTAG concerning strategies for encouraging patient access to care. Please feel free to contact us with any questions or comments or if you would like any additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Ron Allen". The signature is fluid and cursive, with the first name "W." and last name "Allen" clearly distinguishable.

W. Ron Allen  
Chair, Tribal Technical Advisory Group

# **ATTACHMENT 1**



DEPARTMENT OF HEALTH AND HUMAN SERVICES

## OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



September 27, 2019

W. Ron Allen, Chair  
Medicare, Medicaid and  
Health Reform Policy Committee  
910 Pennsylvania Avenue, SE  
Washington, DC 20003

Dear Mr. Allen:

Thank you for the opportunity to meet with you and your colleagues on the Medicare, Medicaid and Health Reform Policy Committee on July 23, 2019, to discuss the healthcare needs of American Indians and Alaska Natives and proposals submitted by the Centers for Medicare and Medicaid Services Tribal Technical Advisory Group (TTAG) to update the healthcare fraud and abuse regulations administered by the Office of Inspector General (OIG). We appreciate your comments at our meeting and in writing in response to the Request for Information regarding the anti-kickback statute and beneficiary inducements civil monetary penalty (CMP) law, which OIG published in August 2018.<sup>1</sup> Please accept this letter as a written response to those proposals, which we hope will become part of an ongoing dialogue.

As an initial matter, and based upon our discussion at the MMPC meeting, we believe an additional in-person briefing may be productive, both for OIG to discuss existing regulations and guidance that may be of interest to the TTAG, Tribes, and Tribal organizations, and for OIG to learn more about the specific arrangements Indian healthcare providers would like to undertake to better meet the needs of their patients. We believe such a meeting will facilitate OIG's analysis of any potential regulatory barriers and our evaluation of solutions.

We have carefully reviewed and considered the TTAG's comment letter in response to the RFI, including the recommended American Indian and Alaska Native and Indian Health Care Provider safe harbor. In addition, we have reviewed and analyzed prior TTAG comment letters in response to OIG's annual solicitation of proposals and recommendations for developing new, and modifying existing, safe harbor provisions under the Federal anti-kickback statute. Please find attached to this letter our response to certain examples highlighted by the TTAG in its comment letters to OIG.

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<sup>1</sup> OIG, *Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP*, 83 Fed. Reg. 43,607 (Aug. 27, 2018), available at <https://www.govinfo.gov/content/pkg/FR-2018-08-27/pdf/2018-18519.pdf>.

Based upon our analysis of the examples set forth in the TTAG's comment letters, in some instances, we believe existing safe harbors to the Federal anti-kickback statute and exceptions to the beneficiary inducements CMP may provide the necessary regulatory flexibility and protections for Indian healthcare providers, without the need for further modification. However, we acknowledge that certain financial arrangements highlighted by the TTAG, *e.g.*, the transfer or sharing of personnel across two or more providers for free or below fair market value, would not be protected under existing regulations. Accordingly, we are considering the TTAG's proposals as we work on the Department of Health and Human Services' Regulatory Sprint to Coordinated Care ("Regulatory Sprint"). As we discussed at our meeting on July 23rd, the Regulatory Sprint is a Departmental priority intended to modernize fraud and abuse regulations in order to facilitate care coordination, the transition to value-based care, and enhanced beneficiary engagement. In connection with this initiative, the Office of Management and Budget recently posted a notice of proposed rulemaking on its website, RIN number 0936-AA10.

We are working to ensure that Indian healthcare providers will benefit from the flexibility afforded by any new safe harbors created in connection with the Regulatory Sprint. In doing so, and pursuant to the Indian Health Care Improvement Act, we are cognizant that many Indian tribes and tribal organizations have increased their engagement with the private healthcare sector and may furnish services to either commercial or other Federal health care program beneficiaries.

We share the MMPC's commitment to achieving care coordination, cost-efficiencies, and improved quality of care for the Indian Health Service, Tribes, Tribal organizations, and Urban Indian organizations' health programs. Thank you in advance for a continuing dialogue on the issues raised during our July 23, 2019, meeting, and as highlighted in the TTAG's comment letters. As noted above, please let us know if a briefing by OIG for the TTAG would be helpful. In the meantime, please do not hesitate to contact Samantha Flanzer in our Industry Guidance Branch at (202) 870-3896, or me at (202) 205-9483.

Sincerely,



Robert K. DeConti  
Assistant Inspector General for Legal Affairs



### Attachment 1

- *EHR network:* We understand the Alaska Tribal Health System is in the final stages of implementing a new clinically integrated electronic health record network, requiring substantial financial investment in information systems across all Tribal health providers in the state. To the extent the implementation of the clinically integrated EHR network implicates the anti-kickback statute, beneficiary inducements CMP, or both, the electronic health records items and services safe harbor may offer protection for such shared investments, provided, among other criteria, the recipient pays 15 percent of the donor's costs for the items and services. *See* 42 C.F.R. § 1001.952(y). We are aware that the 15 percent contribution requirement may be burdensome for some Indian healthcare providers and may act as a barrier to adoption of electronic health records technology. We are considering this issue in connection with the Regulatory Sprint.
- *Specialty care referrals:* The TTAG's comment letter in response to OIG's August 2018 RFI expresses concern that the anti-kickback statute "potentially impede[s] referrals for specialty care." The anti-kickback statute governs the exchange of remuneration to induce referrals. Since the anti-kickback statute does not prohibit referral arrangements that do not involve the exchange of remuneration, we would need to know more about the facts of these specialty care referral arrangements to identify any regulatory barriers. OIG's advisory opinion process would be one way for Indian healthcare providers to obtain meaningful advice on the application of the anti-kickback statute to these arrangements. To the extent that the specialty care arrangements highlighted by the TTAG involve the exchange of remuneration as part of care coordination agreements, we are considering this type of arrangement in connection with the Regulatory Sprint.
- *Shared personnel:* We understand that providers serving American Indian and Alaska Native (AI/AN) communities often provide care to patients in remote, medically underserved areas, and therefore it may be essential for such providers to share personnel. The personal services arrangement and management contracts safe harbor (*See* 42 C.F.R. § 1001.952(d)) may protect such shared personnel arrangements, provided each party to the arrangement pays fair market value for the services furnished by the shared personnel (and assuming all other safe harbor criteria are met). To the extent that additional guidance from OIG may be necessary in this area, we are interested in learning more about these arrangements.
- *Furnishing items and services to patients with financial need:* We recognize that Indian healthcare providers frequently serve low-income individuals. Accordingly, we note that the beneficiary inducements CMP includes an exception that permits the waiver of coinsurance and deductible amounts if, among other criteria, the waiver is offered only upon a good faith determination that the beneficiary is in financial need and is not advertised.<sup>2</sup> *See* 42 C.F.R. § 1003.110. In addition, the beneficiary inducements CMP includes a financial-need-based exception that, more broadly, protects the offer or

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<sup>2</sup> We note that upon meeting any exception to the beneficiary inducements CMP, parties to the financial arrangement will also need to conduct a separate analysis under the Federal anti-kickback statute.

transfer of items or services for free or less than fair market value if certain conditions, including an assessment of financial need, are met. *Id.* More specifically, this exception requires that (1) the item or service not be advertised or solicited; (2) the item or service not be tied to the provision of other services reimbursed by Medicare or Medicaid; (3) there be a reasonable connection between the item or service and the individual's medical care; and (4) there be an individualized determination of financial need. *Id.*

- *Transportation and lodging:* The American Indian and Alaska Native and Indian Health Care Provider safe harbor proposed by the TTAG in response to the OIG's August 2018 RFI (Proposed Safe Harbor) includes protection for the exchange of certain remuneration intended to "improv[e] [American Indian and Alaska Native beneficiaries'] access to health care," which may include transportation services and lodging. We note that the existing local transportation safe harbor, 42 C.F.R. § 1001.952(bb) protects the provision of free or discounted local transportation services to providers' established patients within a defined geographic radius, provided, among other criteria, that the services are not advertised. In addition, the "promotes access to care" exception to the beneficiary inducements CMP may already provide flexibility with respect to the provision of both free or discounted transportation and lodging. This exception, while subject to additional safeguards, shares similar aims to the excerpted provision in the Proposed Safe Harbor. It permits the exchange of remuneration for items or services that "improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs." 42 C.F.R. § 1003.110; *see also* 81 Fed. Reg. 88,390 (Dec. 7, 2016). We recognize the important role transportation plays in patient access to care, quality of care, healthcare outcomes, and effective coordination of care for patients, and in connection with the Regulatory Sprint, are considering this issue.
- *Maternal and pediatric care:* We recognize that the provision of maternal and pediatric care items like car seats, lodging to pregnant women while awaiting delivery, and diabetes screening, can be essential tools to facilitating care to, and ensuring good health outcomes for many patients, including AI/AN populations. As noted previously, the "promotes access to care" exception under the beneficiary inducements CMP may already protect such patient engagement tools, provided, among other criteria, that the offer of the item or service will "improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid," and the item or service is not: (1) advertised, (2) tied to the provision of other reimbursable items or services, or (3) offered as a "reward" for receiving care. 42 C.F.R. § 1003.110. Likewise, the beneficiary inducements CMP's financial-need-based and preventive care exceptions may protect the provision of maternal and pediatric care items like care seats, dependent upon the facts and circumstances. *Id.*; *see also* 81 Fed. Reg. 88,404 (Dec. 7, 2016); 65 Fed. Reg. 24,409 (April 26, 2000).

## **ATTACHMENT 2**



**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).