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: *Regulations.gov*

October 26, 2018

The Honorable Daniel R. Levinson, Inspector General
U.S. Department of Health and Human Services
Office of Inspector General
Attention: OIG-0803-N
Room 5513, Cohen Building
330 Independence Ave. SW
Washington, DC, 20201

Re: Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP (OIG-0803-N)

Dear Mr. Levinson:

On behalf of the Centers for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Group (TTAG), I write to submit comments on the request for information regarding the *Medicare and State Health Care Programs; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP* (OIG-0803-N). The TTAG advises CMS on Indian health policy issues involving Medicare, Medicaid, the Children's Health Insurance Program, and any other health care programs funded (in whole or part) by CMS. In particular, TTAG focuses on providing policy advice to CMS regarding improving the availability of health care services to American Indians and Alaska Natives (AI/AN) under these federal health care programs, including through providers operating under the health programs of the Indian Health Service (IHS), Tribes, Tribal organizations, and Urban Indian organizations (I/T/Us or Indian health care providers). We appreciate the opportunity to provide information and comments on your request.

Background

The TTAG and Tribes have engaged with OIG on proposed safe harbors for Indian health care providers for a number of years. We submitted comprehensive comments in response to OIG's 2012 annual safe harbor solicitation,[1] as well as recommendations for revising OIG's Provider Self-Disclosure Protocol.[2] Since then the TTAG have also submitted comments in 2014[3] and 2015.[4] We also had several in-person meetings in 2015 that were productive, but since then our dialogue has not continued. Our recommendations have not lost their importance nor has there

[1] *See* TTAG Letter in Response to OIG-120-N, February 27, 2012.
[2] See TTAG Letter in Response to OIG-1301-B, August 12, 2012.
[3] See TTAG Letter in Response to OIG-40-P, P2, July 8, 2014.
[4] See TTAG Letter in Response to OIG-123-N, March 2, 2015.

been adequate progress on their implementation. These safe harbors are needed to overcome needless barriers to care coordination and sharing of resources both within the Indian health system and with other providers. We attach the following updated recommendations from our initial 2012 letter and invite your staff to present at the next TTAG meeting on November 15, 2018 in Washington, DC in order to update the TTAG on your responses to our outstanding recommendation, and so we can answer any questions you may have.

Discussion

In the OIG's RFI, information is sought around additional or modified safe harbors to the anti-kickback statute (AKS) or exceptions to the definition of "remuneration" under the beneficiary inducements civil monetary penalties (CMP) that may be necessary to protect such arrangements. Under the current AKS and CMP regime, any transfer of remuneration from a health provider to a potential referral source (the physicians participating in the value-based delivery model) is prohibited if an imputed purpose for the transfer (coordinated care that improves the health and well-being of a patient or individual) could be to encourage referrals (the choice by a physician to provide her patient the benefit of better outcomes through the value-based model implemented by the health provider). We believe that models for delivering health care cannot effectively be integrated into the Indian health system unless the current fraud and abuse regime is changed to support coordinated care or value-based care to American Indian and Alaska Native beneficiaries within the Indian health system.

Our attached, updated recommendations for new safe harbors for Indian health care providers include provisions that would create parity with the existing safe harbor for Federally Qualified Health Centers (FQHCs). FQHCs and Indian health programs share similar goals and purposes, and similarly serve predominantly low-income individuals, including beneficiaries of the Medicaid and Medicare programs. Indian health care programs likewise primarily use federal funding (*e.g.,* federal funds transferred under the Indian Self-Determination and Education Assistance Act and various federal grants) to carry out their health care programs. While the OIG has responded favorably to development of safe harbors to the AKS and CMP for FQHCs, historically it has not done so for the Indian Health System, despite its similarity to FQHCs as a federal provider of health care and the fact that, as federal providers of care, both FQHCs and the Indian Health System are not motivated by the same financial considerations as private providers and the broader health care system.

Moreover, the dire health care situation for native patients described in our 2012 letter remains a concern: native patients continue to make up a large portion of the country's medically underserved populations and remain predominantly low income individuals with limited access to care. Indian health care providers are vastly underfunded and have a significant need to maximize their available resources. Indian health care providers need an option to enter arrangements with hospitals, providers, and suppliers, and establish collaborative relationships, such as capital development grants, low-cost or no-cost loans, reduced price services, and in-kind donations of supplies, equipment, or facility space. Indian health programs have the same concerns FQHCs

had, before the safe harbor was in place, with trying to enter into such arrangements to further their own missions of care, in order to providing a full range of quality care and safety-net health care services. Having a safe harbor specific to Indian health care providers, mirrored on the one in place for FQHCs, would substantially help these underfunded programs to address those needs and conserve Indian Health Service and other federal funds, by allowing them to accept goods, items, services, donations or loans from willing providers and suppliers. Therefore, the TTAG believes that Indian health programs must have parity with FQHCs under the anti-kickback statute and other federal health care fraud and abuse laws.

In our 2012 recommendations, we included proposed language for a new safe harbor at 42 C.F.R. § 1001.952(z)(4), which we drafted to closely track the FQHC safe harbor, though we built-in some variations based on the unique status of Indian health care within the federal health system. For example, while we retained a statement similar to the FQHC safe harbor regarding a patient's freedom to choose a provider, we did not require that Indian health providers give notice to patients regarding that choice. We did so because of the unique way in which the Indian health care system works, including patient eligibility for services. As another example, the proposed safe harbor would allow for informal processes for competitive bidding given the small pool of possible partners for many Tribal communities.

We continue to believe this safe harbor, and the others proposed in our 2012 submission, would strike an appropriate balance between the administrative burden of compliance and the OIG's need to ensure the integrity of the Medicare and Medicaid system and to prevent fraud, waste, and abuse. We also believe the safe harbor would not risk overutilization of federal health care resources, and any savings realized by Indian health care providers would ultimately accrue to the benefit of the federal government; and is consistent with the federal government's trust responsibility to provide health care to American Indians and Alaska Natives.

The discussion in the Background section of the RFI describes the challenge faced by the IHS, tribes and tribal organizations, and urban Indian organizations on a regular basis. Because statutes are broadly written and violations can result in criminal and civil penalties, they chill even innocuous relationships that could be beneficial to patients, promote efficient and effective care, lower costs, better utilize scare health care resources, and pose little or no threat of abuse. . This is the case for Indian health providers interested in providing care coordination arrangements in order to meet the needs of American Indians and Alaska Natives, who are among the poorest[5] and most medically-underserved populations in the United States.

Many Tribal health programs have expended considerable financial resources to create an efficient system of care that achieves to lower costs and provide higher quality care, with the vision that American Indians and Alaska Native will become the healthiest people in the world.

[5] The 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/brownse.aspx?lvlID=52 (Feb. 26, 2012).

This shared vision and collective accountability among Tribal health partners works to coordinate care, and recognizes innovation and change as critical elements in meeting the demands of the Indian health care system. These are essential elements to build a better health care system – one that controls cost, improves quality, and increases efficiency.

To achieve these goals, the Tribal health programs routinely align their interests and share resources, risks, and rewards. For example, the Alaska Tribal Health System is in the final stages of implementing a new clinically integrated electronic health record (EHR) network on a shared Cerner domain, which requires substantial financial investment in information systems and coordination across all Tribal health providers in the state. This initiative is very similar to the current undertaking of the Veterans Health Administration to move their electronic health record system to a Cerner EHR solution. This allows inter-operability, sharing of patient data for coordination of care, and ultimately improves quality and lowers costs. The Public Health Service and Indian Health Service have a wider range of these types of arrangements when they directly administered Indian health programs that are now the responsibility of Tribes, tribal organizations and urban Indian organizations. The arrangements have been extraordinarily helpful and some continue to be the basis for ensuring certain health care services are available at all in some communities.

The AKS and CMP are substantial impediments to care coordination and innovation as it might be enforced in the Indian health system. For example, they potentially impede referrals for specialty care under existing Purchased/Referred Care agreements, agreements that share specialty care providers and even primary care doctors, and the new care coordination agreements with non-tribal providers in accordance with CMS policy for federal funding for services "received through" an IHS/Tribal facility and furnished to Medicaid-eligible American Indians and Alaska Natives.[6] The implications of the AKS and CMP thwart innovation and the development of care coordination arrangements that could be carried out under these types of arrangements, and that are vital to changing and improving efficiency and quality of the health care delivery system.

As a result, we recommend safe harbors that exempt the Indian health system from certain transactions in which an Indian health program is one of the parties, similar to those afforded FQHCs, that would help fulfill the Federal trust responsibility, the mission of the Indian Health Service, and needs of AN/AI people.

Conclusion

The TTAG welcomes an opportunity to work together with OIG to refine an Indian Health Care safe harbor, including provisions that would treat Indian health care programs in a manner consistent with FQHCs under the federal health care fraud and abuse laws. Having such a safe

[6] *See* Dear State Health Official Letter Re: Federal Funding for Services "Received Through" an IHS/Tribal Facility and Furnished to Medicaid-Eligible American Indians and Alaska Natives, SHO #16-002 (February 26, 2016).

harbor in place would not only provide much needed clarity; it would also give Indian health programs the flexibility to enter into collaborative health care arrangements that will save resources and greatly expand access to quality health care for their patients—without fear of violating federal law.

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

Sincerely,

W. Ron Allen, Chair,
Tribal Technical Advisory Group

cc:

Melinda Golub, Senior Counsel, Office of Counsel to the Inspector General

Kitty Marx, Director, CMCS Division of Tribal Affairs, Centers for Medicare and Medicaid Services

Attachment:

1. TTAG Recommendation for Proposed American Indian and Alaska Native and Indian Health Care Provider Safe Harbors, Updated October 26, 2018

Attachment

Proposed American Indian and Alaska Native and Indian Health Care Provider Safe Harbors, updated October 26, 2018

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

(cc) 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 (cc):

(1) An exchange or transfer or any goods, items, services, supplies, equipment, space, personnel, donations or loans (whether the donation or loan is 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, or a waiver of the obligation to pay copayment, coinsurance, deductible or other cost-sharing payments, but only if the exchange–

(i) is for the purpose of improving the individual's access to health care, including for example–

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

(B) 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; or

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

(ii) consists of an item or service–

(A) that is provided as a reasonable incentive to secure timely and appropriate preventive and other items and services, or to encourage or improve the individual's compliance with a treatment plan or regimen;

(B) 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; or

(C) 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, supplies, 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 or among Indian health care providers, or between or among Indian health care providers and another health care provider or a non-profit or governmental provider of social, legal, housing, educational, or training services, for the benefit of patients or other individual receiving or eligible to receive services from an Indian health care provider, including agreements or arrangements authorized by 42 U.S.C. 254a.

(4) The transfer of any goods, items, services, supplies, equipment, space, personnel, 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, supplies, equipment, space, personnel, donations, or loans to an Indian health care provider (as defined in this paragraph), as long as the following standards are met—

(i) The transfer is made pursuant to a written agreement or an arrangement that is memorialized in writing that describes the amount of, all goods, items, services, supplies, equipment, space, personnel, donations, or loans to be provided by the individual or entity to the Indian health care provider.

(ii) The amount of goods, items, services, supplies, equipment, space, personnel, donations, or loans may not be conditioned on the volume or value of Federal health care program business generated between the parties.

(iii) The goods, items, services, supplies, equipment, space, personnel, 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 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 Secretary of Health and Social Services through or in conjunction with the Indian Health Service, another governmental agency, or an Indian health provider; including, by way of example, billing services, technology support and enabling services, such as case management, transportation, child care, patient lodging, or translation services.

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

(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, supplies, equipment, space, personnel, or services without charge or at a reduced charge to the Indian health care provider must furnish such goods, items, supplies, equipment, or services to all individuals from the Indian health care provider who clinically or programmatically qualify for them, 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, supplies, equipment, 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, supplies, equipment, space, personnel, 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.

(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 (cc)(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 (cc)(4) available to the Secretary upon request.

For purposes of this paragraph (cc), the term "Indian health care provider" means (A) The Indian Health Service, (B) Any health program of an Indian tribe, tribal organization (as such terms are defined in section 4 of the Indian Health Care Improvement Act), or inter-tribal consortium, 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, an Agreement with the Secretary 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).