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December 23, 2019

Joanne M. Chiedi
Acting Inspector General
Office of the Inspector General
U.S. Department of Health and Human Services
ATTN: OIG-0936-AA10-P
Room 5521, Cohen Building
330 Independence Avenue SW,
Washington, DC 20201

Re: (OIG-0936-AA10-P) Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute (AKS), and Civil Monetary Penalty (CMP) Rules Regarding Beneficiary Inducements

Dear Acting Inspector General Chiedi:

On behalf of the Northwest Portland Area Indian Health Board (NPAIHB), I submit the following comments on the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG) proposed rule regarding safe harbors under the federal Anti-Kickback Statute (AKS) and the Civil Monetary Penalties (CMP) law, published in the Federal Register on October 17, 2019. Established in 1972, the NPAIHB is tribal organization under the Indian Self-Determination and Education Assistance Act (ISDEAA), P.L. 93-638, representing the 43 federally-recognized Indian Tribes in Idaho, Oregon, and Washington on specific health care issues. NPAIHB works closely with the Indian Health Service (IHS) Portland Area Office, operating a variety of important health programs on behalf of our member tribes, including the Northwest Tribal Epidemiology Center.[1]

We appreciate the opportunity to provide comments and recommendations on the new proposed safe harbors to the AKS and CMP law. However, we are disappointed that despite constant tribal engagement with OIG, and the clear tribal implications of the proposed rule, that tribal consultation did not occur prior to the drafting of the proposed rule.

Further, we believe that the proposed safe harbors will not support the needs of the Portland Area Tribes and the Indian health system, and that further attention must be directed towards tribes and American Indians and Alaska Natives (AI/ANs).

I. BACKGROUND

The Anti-Kickback Statute (AKS) (42 U.S.C. § 1320a-7b(b)) is a federal law that generally prohibits the knowing and willful payment of anything of value ("remuneration") for, or to reward for patient referrals or the generation of business

[1] A "tribal organization" is recognized under the Indian Self-Determination Education Assistance Act (P.L. 93-638; 25 U.S.C. § 450b(1)) as follows: "[T]he recognized governing body of any Indian tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities."

involving items or services payable by federal health care programs. Consequences for violating the AKS may result in a felony punishable by up to $100,000 in fines or 10 years in prison. Additionally, violations of the AKS can lead to penalties under the Civil and Monetary Penalty (CMP) law (1128A(a)(7) of 42 U.S.C. § 1320a-7a(a)(7)) if a beneficiary of a state health program (i.e. Medicaid) is incentivized to see a particular provider or supplier.

Congress enacted a law that specifically requires the development of provisions (i.e. safe harbors) that would not be subject to sanctions under the AKS.[2] Health care providers and others may voluntarily seek to comply with statutory and regulatory safe harbors so that they have the assurance that their business practices will not be subject to any AKS enforcement actions. Arrangements that do not fit in a safe harbor are analyzed on a case-by-case basis, including whether the parties had the requisite criminal intent. Congress delegated to the Secretary of HHS the authority to periodically update the safe harbor regulations to reflect the changing practices and technologies of the health care industry.

OIG has 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 and management of patient care and delivery of value-based care that ultimately improves quality of care, health outcomes, and efficiency. NPAIHB believes that protections must be enacted to not hinder beneficial arrangements toward value-based care and care coordination for tribes and Indian health care providers (IHCPs).

II. GENERAL COMMENTS

A. Tribes and the Indian Health System

The United States has consistently acknowledged the government-to-government relationship with tribes and its special trust responsibility to provide health care services to AI/ANs. This unique responsibility and relationship with AI/ANs and tribal governments is the direct result of treaties between the United States and Indian tribes, and has been reaffirmed by judicial decisions, executive orders, memoranda, and Acts of Congress.

The Indian health system receives funding through IHS appropriations, but IHS is chronically underfunded. The Indian health system is a unique federal health program that has been authorized by Congress to bill other federal health programs, including Medicare, Medicaid and Children's Health Insurance Program (CHIP) for services it provides to its beneficiaries. Needless to say, IHS and tribal health facilities rely on this federal funding.

In order to address the disproportionate health disparities in Indian Country with limited federal funding, Indian health programs must be able to enter into arrangements with other providers. This includes: monetary and in-kind donations of supplies, equipment, or facility space, no-cost or low-cost loans, and reduced shared services. However, we are concerned with how the AKS and penalties could discourage or negatively impact care coordination arrangements with Indian health facilities. Tribes need to be able to maximize care coordination and resources sharing to provide increased quality care to AI/AN patients.

[2] 42 U.S.C. 1320a-7b(b)(3)(E)); section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987.

B. Request for American Indian and Alaska Native Safe Harbor

Since 2012, the Centers for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Group (TTAG) and tribes have engaged with OIG on proposed AI/AN-specific safe harbors. NPAIHB recommends amending 42 C.F.R. § 1001.952 with the new subsection highlighted in the October 26, 2018 CMS TTAG proposed AI/AN and IHCP Safe Harbors (Attachment A) modeled after the safe harbors for Federally Qualified Health Centers (FQHCs).

There are exceptions and safe harbors to the AKS designed specifically for FQHCs to ensure quality and availability of safety net health care services for underserved populations. For example, contributions of goods, donations, loans, and services to an FQHC that would otherwise implicate the purpose of the AKS, provide a safe harbor to increase availability or enhanced quality of health care to underserved communities. According to OIG, 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."[3]

A safe harbor specific to Indian health care providers, modeled on the FQHC safe harbor, would substantially help these underfunded programs to address patient needs and conserve IHS and other federal funds, by allowing tribes to accept goods, services, supplies, donations or loans from willing providers and suppliers, and to coordinate services. The Indian health system is not profit-oriented and funds that tribes save go directly back into the Indian health system. Thus, there would be dual benefits to an AI/AN safe harbor: increased patient services through coordination and the reduction of costs overall, and savings on federal fiscal resources.

III. SPECIFIC COMMENTS

A. Three New Value-Based Safe Harbors

The proposed rule creates three new value-based safe harbors: (1) a safe harbor for care coordination arrangements; (2) a safe harbor for value-based arrangements with substantial downside financial risk; and (3) a safe harbor for value-based arrangements with full financial risk. OIG must include flexibility for value-based safe harbors because Indian health programs will unlikely use these current safe harbors.

1. Coordinated Care Arrangements (42 C.F.R. § 1001.952(ee))

IHS Portland Area Tribes experience a significant shortage and low retainment of health care providers. Additionally, the IHS Portland Area does not have any IHS or tribal hospitals, therefore all AI/AN patients in need of specialty care services are referred out. Therefore, care coordination and sharing arrangements are key to the Indian health system. We urge 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.[4]

The proposed rule creates a new safe harbor for "value-based arrangements" that would protect certain care coordination agreements designed to improve quality, health outcomes, and efficiency.

[3] Safe Harbor for Federally Qualified Health Centers Arrangements Under the Anti-Kickback Statute, 72 Fed. Reg. 56632 (Oct. 4, 2007).
[4] HHS Office of the Inspector General, OIG Advisory Opinion No. 01-03 (May 3, 2001).

The arrangement would exist between a value-based entity (VBE) and one of its participants or between participants in a VBE network collaborating to achieve at least one value-based purpose. We are unsure whether Indian health facilities in the IHS Portland Area would meet the definition of a VBE and any additional requirements to meet the definition would exclude tribes from participating. Tribes are sovereign nations that will not enter into agreements with another entity with authority over the tribe. NPAIHB recommends for the inclusion of Indian health care providers in the definition of a VBE because Indian health facilities are governed by tribes and are constantly engaged in value-based care to provide exceptional quality care to all AI/AN patients. NPAIHB requests that this safe harbor be expanded to include monetary remuneration for Indian health programs. We support the CMS TTAG request for OIG to consider specialty care arrangements involving the exchange of remuneration be included alongside care coordination agreements.

Certain restrictions apply, including the need for participants to establish evidence-based outcome measures, implement monitoring and assessment requirements, have a written agreement, and the recipient would have to contribute at least 15% of the offeror's cost in furnishing the remuneration. We are concerned that these requirements will exclude Indian health programs from being able to use this safe harbor. NPAIHB strongly recommends elimination of the contribution requirement for tribes and IHCPs. Tribes are not able to afford the contribution requirements.

The safe harbor requires that care coordination be measured against concrete outcome measures. However, we believe the outcome measures would not be aligned with already reported tribal outcome measures, becoming an unnecessary administrative burden for understaffed Indian health facilities. We request that OIG include Indian health facilities as value-based entities (VBEs) who provide fee-for-service care to truly protect and encourage value-based care.

Additionally, OIG is considering prohibiting VBEs or VBE participants from billing federal health care programs for remuneration, otherwise shifting costs to a federal health care program. NPAIHB believes that Indian health programs will not be able to meet the terms of the proposed care coordination arrangement safe harbor if OIG prevents remuneration from federal health care programs. Allowing remuneration from federal health care programs is designed to improve care coordination results in overall savings to the federal government even if it results in additional referrals or payments by Medicare and Medicaid.

2. Value-Based Care: Substantial Downside Financial Risk (42 C.F.R. § 1001.952(ff))

The proposed rule would create a safe harbor for value-based arrangements involving VBEs that assume "substantial downside financial risk." It would allow VBEs to enter into shared savings agreements including: (1) shared savings with a repayment obligation of at least 40% of any shared losses; (2) a repayment obligation under an episodic or bundled payment arrangement of at least 20% of any total loss; (3) receiving a prospectively paid population-based payment for a defined subset of the total cost of care of a target population; or (4) receiving a partial capitated payment for a set of items and services at a discount of at least 60% of the total expected fee-for-service payments for the same items or services. Indian health care providers are mostly paid under fee-for-service arrangements which do not allow for shared savings, episodic or bundled payments, or capitated payments. Therefore, tribes will not be able to assume the risk associated with this safe harbor. NPAIHB requests authorization for Indian health care providers to access the same kind of

flexibilities as risk-bearing entities because we require the flexibility provided by this statute in order to maintain day-to-day operations.

3. Value-Based Care: Full Financial Risk (42 C.F.R. § 1001.952(gg))

The proposed rule includes a new safe harbor for arrangements in which the recipient of remuneration assumes full financial risk. For AI/AN patients, payment is provided in full through the federal obligation and tribes do not enter into arrangements with a financial loss risk, therefore there is no downside financial risk.

NPAIHB believes Indian health facilities would not want to or be able to qualify for either of these payment arrangements for this safe harbor because tribes do not participate in value-based risk models. We request OIG extend the same protections and flexibilities involving a downside financial risk to Indian health facilities and IHCPs.

B. Additional New Safe Harbors

1. Patient Engagement and Support Safe Harbor (42 C.F.R. § 1001.952(hh))

The proposed rule creates a new safe harbor to protect a VBE provider furnishing certain tools or supports to target population patients in order to improve quality, health outcomes, and efficiency. NPAIHB recommends that Indian health facilities be automatically designated as value-based entities (VBEs).

The rule would allow certain patient engagement tools or supports up to an aggregate retail to not exceed $500 annually, directly connected to the coordination and management of care. Included would be preventative items, health-related technology services and monitoring tools, and services designed to address the social determinants of health. NPAIHB supports this new safe harbor for tribes and Indian health facilities to utilize for care coordination.

The proposed rule limits eligible recipients to beneficiaries of federal health programs. We strongly oppose the prohibition of VBE participants from billing federal health care programs for certain tools or supports because this would eliminate all Indian health facilities from being eligible for this safe harbor.

The proposed rule would not permit routine waivers of cost-sharing obligations under Medicare and Medicaid. The rule seeks comment on whether such waiver or offset of obligations should be permitted under the safe harbors applying to value-based arrangements. NPAIHB strongly disagrees with the proposed cost-sharing obligations under federal health care programs because AI/ANs are entitled to health care at no cost, therefore tribes should be eligible for a waiver for cost-sharing obligations.

C. Proposed Revisions to Existing Safe Harbors

1. Electronic Health Records (EHR) Safe Harbor (42 C.F.R. § 1001.952(y))

OIG proposes modifying the existing safe harbor for EHR items and services to allow certain nonmonetary remuneration related to cybersecurity technology that is included under an EHR arrangement and updating the existing safe harbor's provision regarding interoperability.

The safe harbor includes a proposal 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 percent of the donor's cost of the cybersecurity technology. OIG has acknowledged that a 15 percent contribution requirement is burdensome to some recipients and acts as a barrier to adoption of EHR technology. OIG solicits feedback on alternatives to the contribution requirement for small and rural practices, all practices, or for upgrades and updates.

The 15 percent contribution is extremely burdensome for Indian health care facilities with already extremely expensive EHR systems. A significant number of IHS Portland Area Tribes have used their own tribal dollars separate from federal funding to purchase an EHR system because the IHS Resource Patient Management System (RPMS) was inadequate for their provider and patient needs. We recommend to include all tribes and IHCPs in the small and rural definitions. NPAIHB recommends that OIG eliminate the contribution requirement for all tribes and Indian health providers.

OIG proposes to remove the existing December 31, 2021 sunset date and is considering an extension of the sunset date for the final rule. OIG requests comment on whether a later sunset date should be selected instead of making the safe harbor permanent, and if so, what that date should be. NPAIHB concurs with the elimination of the sunset provision and recommends removing an expiration date altogether.

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

The proposed rule would modify the existing safe harbor for personal services and management contracts to allow additional use of part-time arrangements and value-based care at fair market value. Outcome-based payments including shared savings payments, gainsharing payments, episodic or bundled payments, and pay-for-performance would be protected under this safe harbor.

Overall, NPAIHB appreciates and supports the increased flexibility for personal services arrangements and management contracts, which may protect arrangements by Indian health facilities. Part-time arrangements can be an important way for Indian health programs in the IHS Portland Area to fill vacancies and increase capacity. However, we are concerned that tribes will be unable to utilize this safe harbor because of the requirement for each party in the arrangement pay the fair market value for services. The fair market value for Indian health facility jobs and services may not align with the fair market value elsewhere. We recommend that the fair market value for Indian health facilities be lowered and relate more to the economic realities of provider recruitment and retention in tribal communities.

OIG highlights that many organizations are unable to afford in-house personnel or designate personnel with technology-related duties. The proposed rule allows technology risk assessment to be a "protected donation" service under the safe harbor regulations. NPAIHB requests that OIG apply this rationalization more broadly to tribes and allow a safe harbor for facility space or personal services donations to tribes.

3. Local Transportation Safe Harbor (42 C.F.R. § 1001.952(bb))

The proposed revision to the local transportation safe harbor would increase the mileage limit for rural areas from 50 to 75 miles. The revision does not change the types of services covered by the safe harbor, and therefore would not expand to include emergency transportation or air transport.

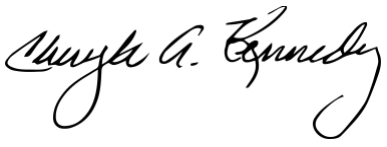
OIG solicits feedback on whether the proposed mileage increase is sufficient and whether the safe harbor should be expanded to protection non-medical health related transportation. AI/AN patient access to transportation is a major barrier to health care services for all tribes and Indian health facilities due to high unemployment and the inability to afford a vehicle or other mode of transportation. NPAIHB generally supports the proposed increased mileage limit for rural areas. However, we believe that all tribes and Indian health facilities should be included in the definition of rural and should not be subject to any mileage limitations for the cost of transportation. NPAIHB recommends the inclusion of emergency transportation and air transport for Indian health facilities because tribes are authorized to use federal funding to provide transportation using federal funding for patient travel costs.[5] We support the need for non-medical health related transportation to be available for Indian health facilities. Non-medical transportation to get quality healthy food or obtain social services is vital for preventative efforts for our patients to overcome day-to-day barriers.

The proposed rule includes eliminating mileage transportation restrictions for patients discharged from inpatient facilities. NPAIHB strongly supports this change as it would allow AI/AN patients much-needed transportation back to the tribal community after discharge.

IV. CONCLUSION

We appreciate the opportunity to provide comments on the HHS OIG proposed safe harbors under the Anti-Kickback Statute. We look forward to working with OIG to achieve better care coordination, cost-efficiencies, and improved quality care for our people, while guarding against fraud and abuse. NPAIHB believes that the AI/AN-specific safe harbors are the most effective way to meet these goals and we hope OIG considers these in the final regulations. Thank you for considering our written comments. For additional information please contact Laura Platero, Government Affairs/Policy Director at (503) 407-4082 or by email to lplatero@npaihb.org or Sarah Sullivan, Health Policy Analyst at (503) 228-4185 or by email to ssullivan@npaihb.org.

Sincerely,



Cheryle A Kennedy
Vice Chair, Northwest Portland Area Indian Health Board
Chair, Confederated Tribes of Grande Ronde

[5] Indian Health Care Improvement Act, Section 213.