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December 2, 2014

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Office of Inspector General

Department of Health and Human Services

Attention: OIG–403-P3

Cohen Building, Room 5269

330 Independence Avenue SW

Washington, DC 20201

**RE: OIG–403–P3: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing.**

1. **Introduction.**

I write on behalf of the Tribal Technical Advisory Group (TTAG) of the Centers for Medicare & Medicaid Services (CMS) to comment on the Notice of Proposed Rulemaking (Notice) issued by the Office of the Inspector General (OIG) concerning the OIG’s proposed amendments to the safe harbors to the civil monetary penalty (CMP) rules[[1]](#footnote-2) and anti-kickback statute (AKS).[[2]](#footnote-3) The TTAG advises CMS on Indian health policy issues involving 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 under the health programs of the Indian Health Service (IHS), Indian Tribes, Tribal organizations, and urban Indian organizations (collectively I/T/Us). Thank you for the opportunity to respond to the Notice.

The TTAG generally supports the proposals set out in the Notice, although we believe that certain changes are necessary to maximize their effectiveness. First, the TTAG supports the OIG’s proposed safe harbor for local transportation, and proposes several amendments to ensure that the safe harbor adequately protects rural providers like I/T/Us. Second, we believe that the OIG should explicitly include nominal incentives for keeping preventive service appointments and achieving health milestones in its proposed safe harbor for promoting access to care. Third, the TTAG supports the proposed safe harbors in instances where I/T/U-operated pharmacies waive cost-sharing, and support the expansion of this safe harbor to other federal health programs such as Medicaid. Similarly, we support the proposed safe harbor for waiving cost sharing for emergency ambulance services, although we believe certain changes are needed to recognize that tribal health organizations are governmentally authorized by federally recognized tribes and should be included in the scope of the safe harbor. Finally, we believe that the requirement prohibiting facilities from advertising the existence of these safe harbors is counterproductive and should be eliminated. We set out our comments below.

1. **Discussion.**
	1. **The Local Transportation Services Safe Harbor Should Apply to Transportation to the Nearest Facility and Without an Established Patient Requirement.**

The OIG proposes a new safe harbor that would protect free or discounted local transportation in order to assist patients (and, if needed, a person to assist the patient) in obtaining medically necessary items and services.[[3]](#footnote-4) Among other things, the OIG seeks comment on whether (1) the safe harbor should be limited to transportation not exceeding twenty-five miles;[[4]](#footnote-5) and (2) whether the proposal should be limited to beneficiaries visiting a facility at which he or she is already an “established patient.”[[5]](#footnote-6)

 In light of the very remote location of many I/T/U facilities, the TTAG strongly supports this proposed safe harbor. Indeed, as the OIG has explicitly noted:

Geographically isolated tribes often do not attempt to contract [with the Indian Health Service], because it is very difficult for them to recruit providers and they face almost insurmountable transportation problems. Remote locations also make it difficult for tribes to form consortiums with other tribes and to participate in 638 contracting meetings and training. Some tribes are located in such remote areas as the bottom of the Grand Canyon and the northern slope of Alaska.[[6]](#footnote-7)

We believe that a transportation-based safe harbor will encourage individuals to seek care that might have otherwise been unavailable due to the transportation-related cost concerns noted above, and that such access can improve health outcomes accordingly.

However, the proposed twenty-five mile limitation appears geared towards localized transportation in urban centers: for example, shuttling residents from a city suburb to a specialist located downtown. By comparison, and as the OIG[[7]](#footnote-8) and other federal agencies[[8]](#footnote-9) have recognized, residents of reservations and Alaska Native Villages must often travel much farther than twenty-five miles to obtain health services. A twenty-five mile geographical limitation will essentially disqualify many I/T/Us and AI/AN patients, and other rural facilities and individuals, from taking advantage of this safe harbor.

We therefore support the OIG’s alternative proposal to authorize transportation under the safe harbor to “the nearest facility capable of providing medically necessary items and services.”[[9]](#footnote-10) This will more appropriately focus on finding a facility that can treat the patient’s medical condition, rather than applying an arbitrary geographical metric (whether twenty-five miles or otherwise). Nor do we believe that this change would risk an overutilization of federal health care programs. If a patient is isolated or impoverished to the point that he or she cannot attend a health care appointment absent transportation assistance, it seems very unlikely the patient would use the (still burdensome, even if discounted) safe-harbored transportation as an excuse to overuse health care services.[[10]](#footnote-11) Rather, we believe that replacing the “twenty-five miles” standard with a “nearest capable facility” standard will better calibrate the safe harbor towards rural, and not just urban, health care facilities.

We also believe that the OIG should explicitly recognize in the Final Rule that in the case of IHS beneficiaries, the safe harbor should also extend to non-emergency transportation to the nearest capable I/T/U facility, even if there is a closer non-I/T/U available. As Congress has recognized, “Federal health services to maintain and improve the health of the Indians are consonant with and required by the Federal Government’s historical and unique legal relationship with, and resulting responsibility to, the American Indian people,”[[11]](#footnote-12) and AI/ANs accordingly have a right to obtain health services at I/T/U facilities free of charge to the individual patient. Many AI/ANs accordingly prefer to use I/T/Us for their health care, as not only are they not personally responsible for payment, but I/T/Us are often the only place that they can receive culturally competent care. The OIG should recognize this aspect of the trust responsibility by extending the safe harbor to the nearest I/T/U for AI/AN patients.

The OIG similarly seeks comment on whether a patient should have to be “established” with their provider in order for the safe harbor to apply.[[12]](#footnote-13) It describes this requirement as follows: “once a patient has selected an oncology practice and has attended an appointment with a physician in the group” the discounted transportation would apply in order to assist “the patient who might have trouble reliably attending appointments for chemotherapy.”[[13]](#footnote-14)

We believe that the safe harbor should apply regardless of patient status. In the scenario set out above, there is no reason to believe that such patients, who will likely be isolated, impoverished, elderly, etc., would not experience the same difficulty in making and keeping the initial oncology appointment(s) as they would in keeping the subsequent chemotherapy sessions. And many such individuals will not have an established primary care physician, let alone any necessary specialists. So, rather than safeguarding against unscrupulous physicians luring new Medicare patients for unnecessary services through promises of free van rides, the “established patient” standard instead will act as a barrier between AI/AN and other Medicare beneficiaries and basic health care.

As discussed in further depth *infra*, it is often difficult to encourage AI/ANs to make and keep initial appointments, particularly when the patient is forced outside of the I/T/U system for specialty or other care. Blocking such patients from the transportation safe harbor will compound existing difficulty among rural and low-income individuals in obtaining primary and preventive services. The TTAG therefore does not believe that the OIG should include an “established patient” standard in its Final Rule.

* 1. **The Access to Care Promotion Safe Harbor Should Protect Incentives for Keeping Primary and Preventive Care Appointments and Achieving Health Milestones.**

The OIG proposes a safe harbor to exempt any “remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs” from the list of prohibited anti-kickbacks.[[14]](#footnote-15) The OIG reasoned that “in some circumstances, patients might be offered incentives to encourage them to engage in arrangements that lower health care costs (without compromising quality) or that promote their own wellness and health care, for example, by participating fully in appropriate prescribed treatment, achieving appropriate treatment milestones, or following up with medically necessary appointments,” and accordingly seeks comment on “whether otherwise prohibited incentives for compliance with treatment regimens should be permitted under this exception and if so, what limitations or safeguards should be required.”[[15]](#footnote-16)

The TTAG supports this exemption and appreciate the OIG’s recognition of the need to promote health care access. AI/ANs suffer the highest health disparities of any ethnic group in the United States and are disproportionately likely to be uninsured.[[16]](#footnote-17) Tribal advocates are particularly concerned with and interested in developing strategies to encourage AI/ANs to make and keep primary care appointments and to engage in preventive services designed to, for example, help diabetes patients manage their conditions to avoid serious complications like amputations. This has historically been difficult for I/T/Us in light of such factors as the remote nature of many I/T/U facilities, the reliance of many AI/ANs on subsistence activities that require long stretches away from home, and the discomfort that many AI/ANs experience when seeking non-traditional medical treatment or visiting non-AI/AN providers.

In other contexts, such as encouraging voting in Alaska Native Corporation shareholder elections and enrolling in Affordable Care Act Marketplace plans, Tribes and Tribal organizations have found that offering incentives is an extremely effective way to encourage participation.[[17]](#footnote-18) This is exactly the type of activity that the OIG describes in the Notice that could encourage the promotion of health care while potentially saving federal health care programs tens of thousands of dollars:[[18]](#footnote-19) a $10 gift certificate could encourage a Medicare or Medicaid patient to seek primary care that could prevent strep throat from becoming scarlet fever or an infection from becoming sepsis, or which could diagnose cancer at a far more manageable stage. Not only do these greatly improve health outcomes, but they also ensure that CMS or IHS are not ultimately responsible for the cost of treating expensive, end-stage or otherwise intensive care. Similar incentives could be offered for achieving “health milestones” such as maintaining certain blood pressure or blood sugar levels across multiple visits, demonstrating tobacco or alcohol cessation, etc.

We do not believe that authorizing such rewards “influence the recipients to order or receive from a particular source items or services paid for by Medicare or Medicaid,” inspire patients “to seek unnecessary or poor quality care to obtain the rewards,” or inspire providers and suppliers to “order or seek orders for additional items or services to recoup the costs of giving the rewards.”[[19]](#footnote-20) Although we do not think modest rewards would induce such negative or abusive behavior, any risk they might can be mitigated by limiting the safe harbor, rather than rejecting it altogether. For example, the OIG could limit the safe harbor to patients at I/T/U providers, federally-qualified health centers, rural health centers, and other facilities that serve a significant proportion of low income or rural patients. This would help ensure that providers who serve comparatively “advantaged” individuals do not use the incentives to “poach” patients from their competitors, and that entities like Medicaid Managed Care organizations do not use the promise of gift cards or similar items to “lure” patients away from the I/T/U system. The OIG could also require any remuneration to be in-kind (such as Native foods or gift certificates) rather than in cash, or limit the total gift value on an individual or annual basis.[[20]](#footnote-21) In any event, we believe that the significant potential savings and positive health outcomes associated with encouraging preventive and primary care make these types of incentives a net positive for CMS.

In light of the effectiveness of current non-medical AI/AN incentive programs and the difficulty that I/T/U facilities face in encouraging patients to keep appointments and maintain medical regimens, we suggest that the OIG consult with the TTAG and other Indian health providers in developing standards that will protect federal health programs while still encouraging access to primary and preventive care. This will ensure that the OIG can take advantage of I/T/U experience in this area and fashion standards that will allow I/T/U and similar providers flexibility in designing incentive programs on a facility-by-facility basis.

* 1. **We Support Proposed Safe Harbors for Emergency Ambulance and Pharmacy Cost-Sharing Reductions and Support their Expansion to Medicaid.**

The OIG has proposed two safe harbors authorizing providers to waive cost-sharing amounts for which a patient would be personally responsible:[[21]](#footnote-22) the first for pharmacies (including those operated by an I/T/U) that waive Medicare Part D cost-sharing, and the second for cost-sharing associated with emergency ambulance services for ambulance suppliers owned and operated by a State, political subdivision of a State, or a federally-recognized Indian Tribe.[[22]](#footnote-23) The OIG seeks comment on “whether to include reductions or waivers of costsharing amounts owed under other Federal health care programs (e.g., Medicaid) in the safe harbor.”[[23]](#footnote-24)

The TTAG supports the both proposed safe harbors (albeit with some concerns that we discuss below). Although IHS facilities are prohibited from charging cost-sharing to AI/ANs,[[24]](#footnote-25) and Tribal health programs do not charge such amounts to AI/ANs as a matter of policy, certain I/T/U facilities do serve non-IHS beneficiaries to whom cost-sharing might otherwise apply. We appreciate the opportunity for I/T/Us to elect to waive cost-sharing for these patients pursuant to the procedures outlined in the Notice, which will grant these programs more flexibility in ensuring access to care for low-income patients.

More specifically, we have the following three suggestions regarding the cost-sharing safe harbors.

*Emergency Ambulance.* The OIG proposes to limit the emergency ambulance safe harbor to ambulance services owned and operated by State, political subdivision of a State, or “a federally recognized Indian tribe.”[[25]](#footnote-26) This would exclude ambulance services operated by tribal organizations authorized by federally recognized Indian tribes to carry out health programs on their behalf. The Indian Self-Determination and Education Assistance Act (ISDEAA) explicitly permits Indian Tribes to authorize Tribal organizations and inter-Tribal consortiums to carry out ISDEAA functions,[[26]](#footnote-27) which in some instances include the ambulance services described in the Notice. In many areas, for reasons of economy or to overcome impossible geographic challenges, Tribal organizations that have entered into agreements with the Indian Health Service pursuant to the ISDEAA under the authority of federally recognized tribes are the only Indian health programs offering health services of any kind. As drafted, then, the ambulance safe harbor would lead to situations in which Tribal health organizations might be the only available provider of ambulance or other services in a Tribal area, but would be categorically excluded from the safe harbor for no other reason than they are not technically an “Indian Tribe.”

 This interpretation undercuts defined Tribal ISDEAA rights and has the potential to greatly diminish Tribal access to this safe harbor. In order to avoid this result, we suggest that the Final Rule extend the ambulance safe harbor to Tribal organizations as well. In order to do so, all references to ambulance services “owned and operated by a State or political subdivision of a State” should be amended to read as either:

Alternative (1): “owned and operated by a State or political subdivision of a State, or a federally recognized Indian tribe, or a tribal organization as that term is defined in Section 4 of the Indian Health Care Improvement Act [25 U.S.C. § 1603].”

OR

Alternative (2): “owned and operated by a State or political subdivision of a State, or tribal health program, as that term is defined in Section 4 of the Indian Health Care Improvement Act [25 U.S.C. § 1603].”

The latter is slightly broader in that it would include Alaska Native Village and Regional Corporations that are entitled to contract or compact to carry out IHS programs pursuant to the ISDEAA.

We also note that in the paragraph at the end of page 59,720 and beginning of page 59,721 of the preamble to the Notice, the OIG seems to indicate that the ambulance safe harbor is limited to providers and suppliers that are “owned and operated by a State or a political subdivision of a State and that was the Medicare Part B provider or supplier of the emergency ambulance services,” and does not mention Tribes at all. We hope this is inadvertent given the other language in the notice, but we request a clarification that the omission of these programs in the preamble was unintentional.

*Extension to Medicaid.* Second, we support the OIG’s proposal to expand both safe harbors to other federal health care programs like Medicaid. As is the case with many of the safe harbors in the Notice, these protections will primarily benefit low-income patients who might be unable to obtain services if they were personally responsible for cost-sharing. In terms of total patient population, it is more likely that this will apply to Medicaid patients than to Medicare patients. We therefore believe that it will be beneficial to include the Medicaid program within the scope of the safe harbor.

*Application of Cost Sharing.* Third, and as noted, while IHS facilities are statutorily prohibited from charging cost-sharing to AI/ANs, Tribal health programs simply do not charge such amounts to AI/ANs on principle even though they are technically authorized to do so. The fact that the OIG proposes to expressly include certain ambulance services and pharmacies operated by operated variously by I/T/U facilities (depending on the particular safe harbor) within the scope of the safe harbor could potentially lead to an argument that Tribal health programs are violating the AKS if they (rightfully) waive AI/AN cost-sharing amounts in other contexts. In order to foreclose this reasoning, we suggest that the OIG include the following clause in both of its final cost-sharing regulations:

Nothing in this provision shall require any facility operated by the Indian Health Service, an Indian tribe, a tribal organization, or an urban Indian organization to collect any cost-sharing amount from any individual eligible to receive services from the Indian Health Service as a condition of satisfying Section 1128B(b) of the Act.

We believe that this clarification, which should apply universally to any cost sharing waiver, will ensure that I/T/Us are not inadvertently charged with violation of the AKS by virtue of their unique place within the American health care delivery system.

* 1. **The Prohibitions on Advertising for Safe Harbor Services are Counterproductive.**

Several of the proposed safe harbors in the Notice are conditioned on the fact that the safe harbor “not [be] advertised or part of a solicitation.”[[27]](#footnote-28) The OIG presumably believes that authorizing such advertisements will either lead to an overutilization of federal health services or else be used by providers to take advantage of the applicable programs or to steal patients from competitors.

We recognize the inherent risk of fraud associated with allowing providers to advertise discounts that are designed to increase participation in Medicare and other programs. We also agree with the OIG that there should be limits on the ability to provide notice about these discounts and reductions – for example, any such authorization should require that the advertisement be done in a good faith attempt to promote access to care, and not as a naked advertisement of “free services” solely to encourage patients to switch to a new provider.

But with that said, the majority of the proposed safe harbors in this Notice are specifically geared towards aiding low-income individuals in making and keeping appointments, traveling to facilities, and obtaining basic services. Not only are these types of patients more likely to go without services altogether rather than overuse federal health dollars, but they also tend to be geographically isolated, elderly, and may have limited (if any) access to internet or phone services (particularly in Indian country),[[28]](#footnote-29) thus making them inherently difficult to contact under any circumstances.

The proposed prohibitions on advertising or solicitation therefore eliminates what may well be the single opportunity for I/T/U and other rural facilities to inform the target patient population that there is an option through which they can afford to obtain primary and preventive services. For example, the ambiguous language used in the proposed regulations could be interpreted as prohibiting I/T/U websites from posting a link entitled “Do You Need Help With Transportation to Keep Your Visit?” or including similar information on a patient appointment reminder mailing. At the very least, we suggest that the OIG adopt some variation of the following clause in any final regulation in which the OIG prohibits making the safe harbor a part of any “advertisement or solicitation”:

For the purposes of this provision, ‘advertisements’ and ‘solicitations’ does not include information provided to a patient in person from a provider, a notice of patient rights on a facility website discussion of charity care, the rights of Indian Health Service beneficiaries, or similar opportunities to waive or reduce patient responsibilities, or any information transmitted directly to a patient as part of a reminder of upcoming appointments or a statement of benefits and coverage.

We believe that this will strike a more appropriate balance between prohibiting unscrupulous “advertising” for reduced-cost services to inflate patient volume while recognizing the legitimate need for providers to notify low-information patients of care options. We also invite the OIG to consult with the TTAG concerning strategies for encouraging access to care while simultaneously preventing financially-minded patient solicitation.

1. **Conclusion.**

The TTAG generally supports the OIG’s proposals set out in the Notice. In particular, the local transportation, cost-sharing waivers, and health care outcome improvement provisions have a real potential to help I/T/Us and their AI/AN patients. We believe that implementing the suggestions set out in this comment will be particularly beneficial towards such facilities and individuals.

The TTAG appreciates the opportunity to comment on the Notice and looks forward to a continued open dialogue with the OIG concerning the AKS and safe harbor provisions generally. 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, TTAG

1. 42 U.S.C. § 1320a-7a. [↑](#footnote-ref-2)
2. 42 U.S.C. § 1320a-7b. [↑](#footnote-ref-3)
3. 79 Fed. Reg. at 59,721. [↑](#footnote-ref-4)
4. *Id.* at 59,724. [↑](#footnote-ref-5)
5. *Id.* at 59,722. [↑](#footnote-ref-6)
6. United States Department of Health and Human Services, Office of Inspector General, Tribal Contracting for Indian Health Services 7 (Mar. 1996). [↑](#footnote-ref-7)
7. United States Department of Health and Human Services, Office of Inspector General, Access to Kidney Dialysis Services at Indian Health Service and Tribal Facilities 12 (Sept. 2011) (noting that AI/AN patients must often travel between 45 and 75 miles for the nearest dialysis facility). [↑](#footnote-ref-8)
8. U.S. Department of Health and Human Services, National Institutes of Health, Facing Cancer in Indian Country: The Yakama Nation and Pacific Northwest Tribes iii (2002) (“In addition, many reservation residents live far from the nearest IHS or tribal primary health facility, and the near­est cancer care is often hundreds of miles away. Some tribes have no health facilities at all.”). [↑](#footnote-ref-9)
9. 79 Fed. Reg. at 59,724. [↑](#footnote-ref-10)
10. We also note that the majority of any transportation under this safe harbor will most likely fall within twenty-five miles anyway. [↑](#footnote-ref-11)
11. 25 U.S.C. § 1601(1). [↑](#footnote-ref-12)
12. 79 Fed. Reg. at 59,722. [↑](#footnote-ref-13)
13. *Id.* [↑](#footnote-ref-14)
14. *Id.* at 59,725. [↑](#footnote-ref-15)
15. *Id.* at 59,726. [↑](#footnote-ref-16)
16. *See generally* Samantha Artiga et al., Henry J. Kaiser Family Foundation, Health Coverage and Care for American Indians and Alaska Natives(2013), *available at* http://kff.org/disparities-policy/issue-brief/health-coverage-and-care-for-american-indians-and-alaska-natives/ (last visited Nov. 27, 2014). [↑](#footnote-ref-17)
17. These “rewards” include things like berry baskets, salmon strips, and other traditional Native foods, raffle entries, gift cards for groceries or gasoline, etc. [↑](#footnote-ref-18)
18. Unless specifically designed to do so, we assume that regulations promulgated under this provision would add to, and not replace, the safe harbors outlined in the OIG’s August 2002 Special Advisory Bulletin entitled “Offering Gifts and Other Inducements to Beneficiaries,” and the current OIG Advisory Opinions that have outlined certain grounds under which the OIG has permitted providers to offer gift cards as incentives for keeping appointments (OIG Advisory Opinion No. 12-21 (Dec. 27, 2012) and OIG Advisory Opinion No. 08-07 (June 27, 2008)). [↑](#footnote-ref-19)
19. 79 Fed. Reg. 59,726. [↑](#footnote-ref-20)
20. While the OIG noted in its 2002 Special Advisory Bulletin that “any gifts or free services to beneficiaries should not exceed the $10 per item and $50 annual [per beneficiary] limits,” in light of the extremely high cost of living in many AI/AN territories (particularly rural Alaska), we request that the OIG consult with THE TTAG before establishing any regulations or otherwise enacting any formulas capping the total frequency or amount of allowable incentives. [↑](#footnote-ref-21)
21. Both exemptions are subject to various conditions about which we do not comment. [↑](#footnote-ref-22)
22. 79 Fed. Reg.at 59,720. [↑](#footnote-ref-23)
23. *Id.* at 59,721. [↑](#footnote-ref-24)
24. *See, e.g.*, 25 U.S.C. § 458aaa-14(c). [↑](#footnote-ref-25)
25. *Id.* [↑](#footnote-ref-26)
26. *See, e.g.*, 25 U.S.C. §§ 450b(j) and (*l*); 458aaa(b); *see also* 25 U.S.C. § 1603(25) (defining “Tribal health program” as ““tribal health program” means an Indian tribe or tribal organization that operates any health program, service, function, activity, or facility funded, in whole or part, by the Service through, or provided for in, a contract or compact with the Service under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450 et seq.)”). [↑](#footnote-ref-27)
27. *See, e.g.*, 79 Fed. Reg. 59,720 (pharmacy cost-sharing waiver); *id.* at 59,724 (local transportation safe harbor). [↑](#footnote-ref-28)
28. *See, e.g.*, Bryan Brewer,Indian Country Today, “Internet Access Will Be a Game-Changer for Indian Country” (Nov. 24, 2014), *available at* http://indiancountrytodaymedianetwork.com/2014/11/24/internet-access-will-be-game-changer-indian-country (noting low levels of reservation internet services and difficulties with obtaining services in rural areas generally). [↑](#footnote-ref-29)