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September 9, 2014

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Office of Inspector General
Department of Health and Human Services
Attention: OIG-1271-N
Cohen Building, Room 5296
330 Independence Avenue SW
Washington, DC 20201

RE: Comments on OIG-1271-N: Solicitation of Information and Recommendations for Revising OIG's Non-Binding Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act

I write on behalf of the National Indian Health Board (NIHB) 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 revisions and additions to the Non-Binding Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act (Criteria). The OIG considers the Criteria when determining whether to impose a permissive exclusion for offenses committed under 42 U.S.C. § 1320a-7(b)(7)² or to instead require providers to enter into a Corporate Integrity Agreement as a condition of continued participation.

Established in 1972, the NIHB is an inter-Tribal organization that advocates on behalf of Tribal governments for the provision of quality health care to all American Indians and Alaska Natives. The NIHB is governed by a Board of Directors consisting of a representative from each of the twelve Indian Health Service ("IHS") Areas. Each Area Health Board elects a representative to sit on the NIHB Board of Directors. In areas where there is no Area Health Board, Tribal governments choose a representative who communicates policy information and concerns of the Tribes in that area with the NIHB. Whether Tribes operate their entire health care program through contracts or compacts with IHS under Public Law 93-638, the Indian Self-Determination and

¹ 79 Fed. Reg. 40,114 (July 11, 2014).

² These include predicate offenses for civil monetary penalties and criminal penalties for acts involving federal health care programs, as well as false statements or omissions concerning eligibility for Supplemental Security and certain other federal benefits. *Id.*

³ 62 Fed. Reg. 67,392 (Dec. 24, 1997).

Education Assistance Act ("ISDEAA"), or continue to also rely on IHS for delivery of some, or even most, of their health care, the NIHB is their advocate.

Thank you for the opportunity to respond to the Notice. The NIHB believes that the OIG should edit the Criteria to include consideration of whether a facility is the sole or primary provider of health services in a community. We also believe that Tribal consultation is needed concerning the "Tribal Integrity Agreements" that the OIG has issued to at least one Tribal provider as an alternative to permission exclusion. Finally, we believe that the problems we raise concerning the Tribal Integrity Agreement demonstrate the necessity of a more proactive approach towards ensuring accurate billing practices in I/T/Us. We set out our comments below.

I. Discussion.

1. The OIG Should Add Sole or Primary Community Provider Status to the List of Criteria.

Governing law permits the OIG to waive exclusion altogether in certain specific circumstances when the provider at issue is a community's sole physician or source of essential specialized services.⁴ The Criteria's only comparable provision, entitled "Financial Responsibility," directs the OIG to consider whether a permissive exclusion of a defendant that "is an entity" would prevent the entity from "being able to operate without a real threat of bankruptcy and without a real threat to its ability to provide quality health care items or services." Because an excluded facility can remain financially and functionally viable while still being tremendously burdened by a lack of federal program reimbursement, the NIHB believes that the current standard of whether there is "real threat" (an undefined term) of either bankruptcy or the inability to provide quality health care services is inadequate for its purpose. The NIHB therefore suggests that the OIG add language to the Criteria evaluating whether the facility at issue is the "sole or primary source of health care services in a community."

Evaluating the facility's role in the community is particularly important in the Tribal health context, as Congress authorized Tribes to bill federal health care programs partially out of recognition that "many Indian people, especially those residing in very remote and rural locations, were eligible for but could not access Medicaid and Medicare services without traveling sometimes hundreds of miles to Medicaid and Medicare providers located off reservation." Tribal health programs are also often the only place where AI/ANs can receive culturally competent care. The

September 2, 2014).

⁴ See, e.g., 42 U.S.C. § 1320a-7(b)(14) (default on repayment of HHS scholarships or loans) and (c)(3)(B) (certain mandatory exclusions); 42 C.F.R. § 1001.1801(b) (exclusions stemming from certain criminal offenses) and 1701(a)(3) (billing for assistants during cataract surgery).

⁵ 62 Fed. Reg. at 67,394.

⁶ Indian Health and Medicaid, *available at* http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Indian-Health-and-Medicaid/Indian-Health-Medicaid.html (last visited

exclusion of Tribal and other remote providers is therefore disproportionately likely to interfere with the provision of services that cannot be replaced in the community, often resulting in AI/ANs simply foregoing care rather than visiting a non-Tribal facility.⁷

In light of the key role that Tribal health programs play in providing AI/AN health services, historic and ongoing IHS underfunding,⁸ and the increasing importance of federal health program payments to Tribal health facilities,⁹ virtually any exclusion-related diminution in revenue can have a profound effect on Tribes and the communities they serve. The OIG should accordingly consider whether a provider is the "sole or primary source of health care services in a community" when determining whether to impose a permissive exclusion against a health facility.

2. Tribal Consultation is Necessary to Develop Standards Applicable to Tribal Governments.

As noted above, the OIG uses the Criteria to determine whether to exclude a provider or otherwise require that it enter into a Corporate Integrity Agreement (CIA). Although CIAs are tailored to address the specific facts of a given case, a review of the active CIAs available on the OIG's website indicates that the documents tend to be very similar, and generally modeled from a template that is designed for use with non-governmental health care facilities.¹⁰

By comparison, the OIG has offered at least one Indian Tribe a "Tribal Integrity Agreement" (the Agreement) as a precondition for avoiding exclusion. It appears that the Agreement is essentially the same as the CIA template used with corporate entities, except that "Tribal Council" and similar phrases are substituted for "Board of Directors" and similar phrases. The NIHB is unaware of the OIG undertaking any Tribal consultation prior to authorizing the "Tribal Integrity Agreement" program or developing any language or provisions for these types of agreements. Nor does it appear that the Agreement was drafted with any thought put towards the structural and functional differences between a general health care facility and a health program operated by a sovereign Tribal government.

⁷ This is particularly true given that AI/ANs are disproportionately likely to be uninsured, thus further disincentivizing their seeking treatment in a non-Tribal context. *See generally* SAMANTHA ARTIGA ET.AL., HENRY J. KAISER FAMILY FOUNDATION, HEALTH COVERAGE AND CARE FOR AMERICAN INDIANS AND ALASKA NATIVES (2013).

⁸ IHS is only funded at approximately 56% of need. *See* NATIONAL TRIBAL BUDGET FORMULATION WORKGROUP'S RECOMMENDATIONS ON THE INDIAN HEALTH SERVICE FISCAL YEAR 2015 BUDGET 3 (2013).

⁹ See Edward J. Fox & Verné F. Boerner, Medicaid and Indian Health Programs: Indian Health Finance at 6-7 (Mar. 2009) (discussing increases in Medicare and Medicaid revenues for Tribal health programs).

¹⁰ See generally United States Department of Health and Human Services, Office of the Inspector General, Corporate Integrity Agreements, *available at* https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp (last visited September 2, 2014).

The NIHB is extremely concerned about the terms of the Agreement and the use of comparable agreements with Tribal providers moving forward. Although the Tribal program under scrutiny consists of only a handful of substance abuse and mental health personnel, the Triba estimates that compliance with the Tribal Integrity Agreement could cost as much as half of its total Tribal health care budget per year. Further, the Agreement demonstrates a significant lack of understanding of the nature of Tribal health programs and Tribal governments generally, and is unnecessarily sweeping and punitive. For example, and among other things, the Agreement:

- Requires the Tribe to provide "covered employees" with various types of training, a Code of Conduct, etc, and subjects them to various other requirements. But a "covered employee" is defined as including every Tribal employee, officer and elected Tribal Council member, as well as various independent contractors, regardless of whether they work in the specific health program at issue or even in a health program generally. The Tribe believes this would be functionally impossible to implement.
- Requires the Tribe to provide "Tribal governance" training to all covered employees, including elected Council members. This is a condescending and paternalistic condition that does not respect the government-to-government relationship between the United States and Indian Tribes.
- Requires the Tribe to hire a full-time Agreement compliance officer that does not answer to anyone in the Tribal government. It will be difficult, at best, for any Tribe to find and retain a full-time compliance officer except at extremely high cost, especially in remote areas.
- Requires certain Tribal employees, including elected Council members, to annually certify compliance with the Agreement and all relevant federal program requirements, with penalties of up to \$50,000 for each "false" certification. Tribal health programs suffer from high employee turnover due to their remote locations and other factors, which makes this level of detailed certification inherently difficult to provide. The penalty amount is also disproportionate to the very real potential of good-faith certification errors.
- Requires the Tribe to institute all required reforms within ten to ninety days, an unrealistic expectation that ignores internal Tribal governance structures and legislative and administrative processes.

• Proposes multiple enforcement mechanisms that would likely either be barred by the Tribe's sovereign immunity¹¹ or the Tribal Council's legislative immunity,¹² or require the waiver thereof.

In addition to these examples, the Agreement further specifies that its terms apply to the Tribe itself, and not just the specific health program, thus threatening exclusion of the entire Tribe due to the improper acts of independent contractors at a single Tribal health facility. Excluding a Tribe in its entirety due to the acts of various culpable individuals punishes the innocent Tribal health recipients, who, as noted above, may not have alternate sources of care. And while health facilities are certainly responsible for helping ensure employee and contractor compliance with applicable law, the far-reaching consequences of excluding an entire Tribe (and all of its associated health programs) due to the actions of an individual will almost always be disproportionate.

As currently drafted, this Tribal Integrity Agreement does not provide a meaningful or beneficial alternative from permissive exclusion from federal health care programs. Nor does it recognize or respect the distinction between compliance at the corporate level as compared to the Tribal governmental level, the nature of Tribal governments, or the federal government's trust responsibility to provide AI/ANs with health care. The NIHB therefore requests that the OIG consult with Tribes concerning the terms, scope and application of Tribal Integrity Agreements. Significant changes are needed towards both the document and to the OIG's approach to evaluating Tribal providers in order to ensure continued Tribal participation in federal health programs.

3. Tribal Consultation is Necessary to Develop Strategies for Better Preventing Compliance Issues at I/T/Us.

The problematic issues raised in the Tribal Integrity Agreement demonstrate the difficulties with reactively punishing I/T/Us for billing and compliance issues: risks of error from high staff turnover and the complex I/T/U billing system, costly and onerous integrity plans, further diminution from an already seriously underfunded Indian health system, etc. The NIHB believes that federal health program goals would be better served through a more proactive, preventive approach that could focus on ensuring best practices. For example, CMS should provide I/T/U training regarding federal health care billing processes on a regular basis (at least biannually) and should have staff available to provide technical assistance about subsequent billing issues. Similarly, the OIG should not take enforcement actions based on unintentional compliance issues flagged during preliminary audits of I/T/U programs, but should instead work with the I/T/U to resolve the issues to satisfaction and prevent these types of mistakes moving forward.

¹² See, e.g., Grand Canyon Skywalk Dev., LLC v. Hualapai Indian Tribe of Ariz., 966 F. Supp. 2d 876, 885 (D. Ariz. 2013) (noting that "to the extent the complaint names Tribal Council members for their role in passing the takings ordinance and resolution, they have legislative immunity").

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¹¹ See, e.g., Michigan v. Bay Mills Indian Cmty., 134 S. Ct. 2024, 2032 (2014) ("Unless Congress has authorized [a] suit [against an Indian Tribe], our precedents demand that it be dismissed.").

These are just a few examples of the potential avenues through which to ensure proper I/T/U billing and federal health program integrity through proactive compliance, education, outreach, and troubleshooting, as opposed to post-hoc punishment or sanctioning. Additional Tribal consultation is necessary in order to fully develop these and other program reforms. The NIHB stands ready to work with the OIG and CMS on designing and implementing these changes moving forward.

II. Conclusion.

The NIHB believes that the OIG should add language to the Criteria recognizing the need to evaluate a facility's role in providing community access to health services when considering permissive exclusion. The OIG should also initiate Tribal consultation with the NIHB, Tribes, and Tribal organizations in order to (1) reevaluate the use and terms of Tribal Integrity Agreements and the nature of the relationship between the OIG and Tribal governments and (2) reconsider the approach towards monitoring federal health program compliance at Tribal facilities.

The NIHB appreciates the opportunity to comment on the Criteria and looks forward to a continued open dialogue with the OIG concerning the terms and circumstances surrounding permissive exclusion and federal health care program billing generally.

Sincerely,

Cathy M. Abramson

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Chair, NIHB