

Tribal Technical Advisory Group

To the Centers for Medicare & Medicaid Services

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Submitted via [regulations.gov](http://www.regulations.gov)

August 17, 2012

Kenneth D. Kraft
Office of Inspector General
Department of Health and Human Services
Attention: OIG-1301-N
Room 5541B, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Re: TTAG Comments on [OIG-1301-N]: Solicitation of Information and Recommendations for Revising OIG's Provider Self-Disclosure Protocol

Dear Inspector General Kraft,

I write on behalf of the Tribal Technical Advisory Group (TTAG) of the Center of Medicare and Medicaid Services (CMS) regarding the attached analysis and recommendations (Comments) to the Office of Inspector General (OIG), Department of Health and Human Services (HHS) in response to the request for comments published June 8, 2012 in the *Federal Register* titled "Solicitation of Information and Recommendations for Revising OIG's Provider Self-Disclosure Protocol (OIG-1301-N or Proposed rule.) We appreciate the opportunity to comment on this Proposed Rule.

The TTAG advises Center of Medicare and Medicaid Services (CMS) on Indian health policy issues involving Medicare, Medicaid, the Children's Health Insurance Program, and any other health care program funded (in whole or part) by CMS.¹ In particular, the 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, Indian Tribes, tribal organizations and urban Indian organizations (I/T/U).²

¹ Sec. 5006(e) of the American Recovery and Reinvestment Act codifies in statute, at sections 1902(a)(73) and 2107(e)(1)(C) of the Social Security Act, the requirement for the Secretary of Health and Human Services to maintain a Tribal Technical Advisory Group within CMS and the requirement that States seek advice from Tribes on a regular and ongoing basis where one or more Indian health program or urban Indian organization furnishes health care services.

² The abbreviation "I/T/U" means the Indian Health Service (IHS), an Indian Tribe, tribal organization or urban Indian organization, and is sometimes referred to collectively as "Indian Health Care Providers". The term "Indian Health Service" means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act (IHCIA), 25 USC §1661. The term "Indian Tribe" has the meaning given that term in Sec. 4 of the IHCIA, 25 USC §1603. The term "tribal organization" has

Introduction

The Indian Health Service (IHS), Indian tribes, tribal organizations, and urban Indian organizations (collectively I/T/Us) supply essential health services to approximately 1.9 million AI/ANs on/near reservations in thirty-five states. An additional 46,000 AI/ANs who do not have access to reservation-based programs receive medical and public health services from thirty four urban Indian organizations supported by Federal funds. On the whole, the I/T/U system serves one of the poorest and most medically-underserved populations in the United States.

These health disparities are worsened by the drastic underfunding of the Indian health system: the National Tribal Budget Formulation Workgroup estimates that the IHS budget requires an extra \$21 billion to achieve health parity between AI/ANs and the general American population. The OIG itself has noted that funding for certain Indian health programs “has failed to keep pace with inflation, resulting in curtailed services to IHS beneficiaries.” While Tribal health programs attempt to make up funding gaps by billing Medicare, Medicaid, third party insurance, etc., AI/ANs are comparatively less likely to enroll in a government or private insurer than members of the general population. This is because the United State owes a special trust responsibility and legal obligation to ensure the highest possible health status for American Indians and Alaska Natives, including the provision of health care at no charge to the individual. Many AI/ANs prefer to receive the government-funded Indian health services to which they are entitled rather than enroll in a third party insurer, making third party collection difficult. Because neither IHS nor Tribal health programs charge AI/ANs for services, this often leaves Tribal health programs at the fiscal mercy of a system that simply cannot support their growing needs.

The combination of drastic underfunding and the high morbidity of the AI/AN patient population places tremendous financial strain on I/T/U providers. We are therefore deeply concerned with the operation of the Protocol, as successful self-disclosures have the ability to mitigate potential penalties and preserve already scarce federal resources. We appreciate this opportunity.

Analysis and Recommendations

1. Clarification regarding disclosure of physician self-referral violations.

In 2006, the OIG published an Open Letter (2006 Letter) promoting the use of the Protocol to resolve matters giving rise to civil monetary penalty (CMP) liability under both the anti-kickback statute and the physician self-referral law (Stark). But, in a 2009 Open Letter (2009 Letter), OIG walked back this policy and stated that it would no longer accept self-disclosure of a matter that involves only liability under the Stark law in the absence of a “colorable anti-kickback statute violation.”

It remains uncertain as to what constitutes a “colorable anti-kickback violation.” Is OIG referring to “colorable” as a legal term of art meaning the “appearance, guise, or semblance” of a violation if the legal basis is generally correct and the facts can be proven in court? Is OIG referring to something less formal, under which a provider should disclose if he or she reasonably believes there has been a

the meaning given that term in Sec. 4 of the IHCIA, 25 USC §1603. The term "urban Indian organization" has the meaning given that term in Sec. 4 of the "IHCIA", 25 USC §1603.

Stark violation? Or is the definition more demanding, and a provider must be certain and/or able to actually prove the existence of a violation?

These examples may seem nebulous or overlapping, but it is extremely important that providers understand the exact contours of the Protocol. The decision to self-disclose can have tremendous financial and professional repercussions and is usually made after the party painstakingly weighs options with colleagues, facility administrators, and legal counsel. The uncertainty surrounding the Protocol's requirements for Stark violations could lead to providers ultimately subjecting themselves to unnecessary liability by failing to self-disclose, or else lead to self-disclosures that fail to satisfy the "colorable" standard and subsequently subject the provider to an unwarranted level of scrutiny. The effects of a mistake in either direction can be devastating in light of the stakes involved. We therefore suggest that the OIG publish a clarification as to the specific definition of a "colorable anti-kickback violation."

2. Minimum settlement and range of penalty multipliers.

In order to "better allocate provider and OIG resources," the 2009 Letter established a minimum \$50,000 settlement amount to resolve any kickback-related submissions accepted under the Protocol. The OIG noted that this minimum amount was "consistent with OIG's statutory authority to impose a penalty of up to \$50,000 for each kickback and an assessment of up to three times the total remuneration. See 42 U.S.C. § 1320a-7a(a)(7)," but said that it would "continue to analyze the facts and circumstances of each disclosure to determine the appropriate settlement amount consistent with our practice . . . of generally resolving the matter near the lower end of the damages continuum, i.e., a multiplier of the value of the financial benefit conferred." We have several comments regarding these policies.

First, 42 U.S.C. § 1320a-7a(a)(7) authorizes a penalty of not more than \$50,000 for each individual kickback. Because self-disclosure should, in theory, reflect a good faith attempt to mitigate potential liability, we are puzzled as to why OIG would characterize a maximum authorized fine as its minimum baseline for settlement and subsequently "resolve the matter near the lower end of the damages continuum." While such a system could benefit parties accused of multiple kickbacks, providers who have only received a single kickback might well be financially dissuaded from self-disclosure if they are certain to face the maximum statutory penalty. We therefore suggest that the minimum settlement be adjusted downward in instances of isolated kickbacks, as well as in cases where providers accept a small number of kickbacks that, under the circumstances, are unlikely to face an aggregate penalty exceeding \$50,000. In light of OIG's stated goal of fact-based penalty assessment, it might also be preferable to simply eliminate the inflexible minimum settlement altogether.

In the 2006 Letter, OIG also noted that "[s]ubject to the facts and circumstances of the case, OIG will generally settle [self-disclosure] matters for an amount near the lower end of this continuum, i.e., a multiplier of the value of the financial benefit conferred by the hospital upon the physician(s)." We seek clarification as to how the OIG uses or plans to use this multiplier: what the potential multiples of the value can be, whether there are certain factual scenarios that will lead to a higher multiplier by default, etc. The fact that this practice can exponentially increase provider liability warrants more definitive context as to its actual operation.

3. Guidance regarding violations surrounding the employment of excluded providers.

Thus far, essentially all of the Federal Register notices and OIG Open Letters outline the applicability of the Protocol essentially only in the contexts of the Stark and anti-kickback laws. But there is equal concern as to the Protocol's applicability of the Protocol in the event that a party contracts, intentionally, or accidentally, with an excluded provider.

For example, we have spoken to providers who are concerned that language from the OIG Exclusion Special Bulletin (Bulletin) and two OIG advisory opinions indicating that excluded providers cannot be reimbursed with any federal funding of any kind may contradict regulatory language indicating that facilities are only prohibited from using federal program payments (as defined) to reimburse an excluded provider. There is similar confusion regarding the patients to whom an excluded provider may offer health services. While the OIG has issued statements indicating that an excluded provider is wholly banned from providing any services to any federal health program beneficiaries, our interpretation of applicable law indicates that the excluded provider may serve such beneficiaries so long as the provider does not bill Medicare, Medicaid, or any other federal health care programs (again, as defined). OIG's interpretation also seems inconsistent with the fact that State health care programs can obtain waivers in certain circumstances that would allow excluded providers to serve federal beneficiaries regardless.

These are just a few examples of the uncertainty that parties face in determining whether they have violated prohibitions on transacting with excluded providers. Compounded by the existing ambiguity as to the scope of the Protocol regarding such transactions, there is a comparatively high level of perceived "risk" in self-disclosing a potential violation regarding interactions with excluded providers. We therefore seek guidance as to whether the Protocol applies to self-disclosure of potential violations involving an excluded provider, and, if it does, we seek similar clarification as to the circumstances that the OIG considers serious enough to warrant self-disclosure.

4. Certification of Compliance Agreements and Corporate Integrity Agreements.

As part of the self-disclosure settlement process, OIG has the option of requiring providers to enter into a Certification of Compliance Agreements (CCA) or a Corporate Integrity Agreement (CIA) as part of the party's resolution settlement. A CCA requires the provider to certify that it is maintaining the essential elements of its compliance program and that the specific problems that gave rise to the compliance issue are addressed. By comparison, a CIA typically lasts much longer and involves strict timelines for bringing the provider's compliance program to a level the OIG believes is sufficient to control risk of false claims. Providers agree that a CIA is far more rigorous than a CCA.

It is our understanding that the OIG generally issues CIAs and rarely, if ever, opts to enter into a CCA. We therefore request a basic assurance that the CCA model is still valid and that OIG still considers CCAs to be a potential settlement option. If so, we seek further clarification as to the factors or circumstances in which OIG believes that one or the other type of agreement is warranted; at the very least, a good faith self-disclosure should be considered a mitigating factor weighing in favor of a CCA, rather than a CIA. We believe that such transparency is necessary as providers weigh whether to submit a self-disclosure under the Protocol.

5. Applicable Timelines.

In 2005, the OIG issued a Compliance Guidance clarifying aspects of the Protocol and other compliance-related issues for hospitals. Unlike the Protocol, the Compliance Guidance sets a specific self-disclosure timeline of “not more than sixty (60) days after determining that there is credible evidence of a violation” in order to “demonstrate the hospital’s good faith and willingness to work with governmental authorities to correct and remedy the problem.”

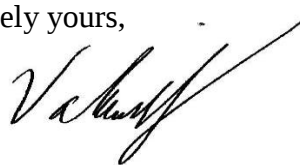
While we appreciate the OIG’s emphasis on prompt reporting, identifying the actual contours and depth of a violation may be an extraordinarily complex endeavor requiring close collaboration between hospital administration, providers, billing specialists, auditors, and/or attorneys. Without such a detailed determination of the actual scope of a violation, providers will simply not have the adequate factual background from which to make an informed determination about whether or not to self-report. This type of inquiry can, and often does, take far longer than the sixty day limitation published in the Compliance Guidance.

We therefore suggest that the OIG clarify that all providers, hospitals or otherwise, may make a full inquiry using standards of due diligence and good faith instead of being tied to what is often an arbitrarily short deadline that results in premature disclosures. While some providers may be able to internally investigate and then report to OIG within the sixty day limit, for those who cannot, softening the deadline will ensure that providers who require additional time may make the necessary effort to do so. This is in accordance with our related suggestion that Tribes be able to reduce their exposure to conflicts of interest by having a process that allows for a more timely consideration and processing of safe harbor submissions. If the ultimate aim of the self-disclosure protocol and safe harbor requests are to ensure that providers work within the parameters of the law, we believe that these suggestions will greatly aid Tribal health programs in achieving that goal.

Conclusion

Thank you in advance for consideration of these recommendations as we jointly work to advance the health status of American Indian and Alaska Native individuals and communities across the United States. TTAG appreciates the opportunity to provide input on this important government-to-government process. If you have any questions, you can email me at vdavidson@anthc.org.

Sincerely yours,



Valerie Davidson
Chair, CMS Tribal Technical Advisory Group

Cc: Dr. Yvette Roubideaux, Director, Indian Health Service
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