

Tribal Technical Advisory Group

To the Centers for Medicare & Medicaid Services

c/o National Indian Health Board 926 Pennsylvania Avenue, SE Washington, DC 20003 (202) 507-4070 (202) 507-4071 fax

Submitted via <http://www.regulations.gov>.

July 8, 2014

Patrice Drew
Office of Inspector General
Department of Health and Human Services
Attention: OIG-403-P, P2
Cohen Building
330 Independence Avenue SW, Room 5541C
Washington, DC 20201.

RE: Comments on Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General’s Civil Monetary Penalty Rules and Exclusion Authority

I write on behalf of the Tribal Technical Advisory Group (TTAG) of the Centers for Medicare & Medicaid Services (CMS) to comment on two Notices of Proposed Rulemaking issued by the Department of Health and Human Services (HHS) Office of the Inspector General (OIG): Fraud and Abuse; Revisions to the Office of Inspector General’s Civil Monetary Penalty Rules¹ and Fraud and Abuse; Revisions to the Office of Inspector General’s Exclusion Authority² (collectively the Proposed Rules). The TTAG advises 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 in part) by CMS. 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/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.

Thank you for the opportunity to respond to the Proposed Rules. The TTAG appreciates the OIG’s clarification of various aspects of its exclusion and civil monetary penalty (CMP) authority. We also strongly support the OIG’s proposal to authorize “early” reinstatement for excluded providers in certain circumstances. However, we are concerned about the proposed increases in CMPs amounts, the potential disproportionate impacts of federal exclusion on rural patients, and the inclusion of IHS loan repayment programs within the current regulatory exclusion for default on a federal scholarship or loan program. We set out our comments and suggestions below.

I. Discussion.

¹ 79 Fed. Reg. 27,080 (May 12, 2014) [hereinafter “The CMP Rule”].

² 79 Fed. Reg. 26,810 (May 9, 2014) [hereinafter “The Exclusion Rule”].

1. \$10,000 Daily CMPs for Unreturned Overpayments are Not Supported by Statutory Language and are Unduly Punitive.

42 U.S.C. § 1320a-7k(d) requires providers to report and return overpayments by the later of sixty days after the date the overpayment was identified or the date any applicable corresponding cost report is due. Failure to comply with these provisions triggers CMP liability pursuant to 42 U.S.C. § 1320a-7a(a)(10).

As the OIG notes, 42 U.S.C. § 1320a-7a(a)(10) “does not contain a specific penalty amount, but instead uses the default penalty amount in the CMPL, which is up to \$10,000 for each item or service.”³ But citing the sixty day period, the OIG states that “the penalty could be interpreted to attach to each following day that the overpayment is retained.”⁴ The OIG accordingly seeks comment on whether it should impose a CMP of up to \$10,000 for each day that the provider fails to return the overpayment⁵ or whether instead to apply the default penalty of up to \$10,000 to each individual *claim* identified an overpayment, rather than as a cumulative daily penalty.⁶

The TTAG strongly supports the latter penalty as a matter of both statutory interpretation and general policy. First, the plain language of 42 U.S.C. § 1320a-7a(a)(10) states that the offender “shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than \$10,000 *for each item or service*” (emphasis added). By comparison, in the very next sentence of the same statutory section, Congress authorized a penalty of “\$10,000 *for each day* the prohibited relationship occurs” (emphasis added). Reading an unspoken daily penalty into the overpayment provision when Congress explicitly included such a penalty in a separate provision of the same statute violates numerous rules of statutory interpretation.⁷

³ CMP Rule at 27,086.

⁴ *Id.*

⁵ *Id.* at 27,096.

⁶ *Id.* at 27,086.

⁷ See, e.g., *E.P.A. v. EME Homer City Generation, L.P.*, 134 S. Ct. 1584, 1601 (2014) (“We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest.”) (citation omitted); *Mississippi ex rel. Hood v. AU Optronics Corp.*, 134 S. Ct. 736, 742 (2014) (“[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”) (citation omitted); *Roberts v. Sea-Land Servs., Inc.*, 132 S. Ct. 1350, 1362 (2012) (noting the “duty to give effect, if possible, to every clause and word of a statute”) (citations omitted).

From a policy perspective, \$10,000 daily penalties could be ruinously expensive for Tribal health programs, which already struggle with drastic federal underfunding.⁸ Because the term “overpayment” is defined broadly as “any funds that a person receives or retains under subchapter XVIII or XIX of this chapter to which the person, after applicable reconciliation, is not entitled under such subchapter,” these penalties could also apply in circumstances that do not warrant such draconian CMPs.⁹ For example, there are many situations in which a Tribal health program might “identify” such an overpayment within the meaning of the statute but, for whatever reason, fail to return it within the sixty day time period: confusion over whether the funds actually constitute an overpayment, administrative delays, high turnover in billing offices, transition to new billing technology, etc.¹⁰ Even though the health program may nevertheless be technically culpable under the statute, these non-malicious violations should not result in exponentially increased fines.

Neither the statutory language nor basic considerations of equity support the proposed \$10,000 daily penalty for failure to return an overpayment. The TTAG instead requests that the OIG apply the statutorily mandated penalty of up to \$10,000 per overpayment in the Final Rule.

2. The OIG Should Exempt IHS Programs From the Proposed Expansion of the Loan Default Regulations.

42 U.S.C. § 1320a-7(b)(14) and implementing regulations at 42 C.F.R. § 1001.1501 authorize the OIG to exclude providers from federal health care programs if they “default on repayments of scholarship obligations or loans in connection with health professions education made or secured, in whole or in part, by the Secretary.” The OIG proposes in the Exclusion Rule to specify that this exclusion applies to individuals who default on a number of additional federal repayment and loan programs, including those offered by IHS.

The TTAG opposes the inclusion of IHS scholarship and loan repayment programs within the scope of the loan default regulations. Both IHS and Tribal health programs have recently testified before Congress as to the difficulty in retaining qualified staff in Tribal facilities due to remote site locations and other considerations.¹¹ With defaults on student loans skyrocketing due to the ongoing

⁸ The Indian Health Service is only funded at approximately 50% of need to achieve health parity with the non-AI/AN population. *See* NATIONAL TRIBAL BUDGET FORMULATION WORKGROUP’S RECOMMENDATIONS ON THE INDIAN HEALTH SERVICE FISCAL YEAR 2015 BUDGET 3 (May 2013).

⁹ 42 U.S.C. § 1320a-7k(d)(4)(B).

¹⁰ Although the standard for “knowing” of an overpayment requires actual knowledge, deliberate ignorance, or reckless disregard of the existence of an overpayment, *see* 42 U.S.C. § 1320a-7k(d)(4)(A), it is still conceivable that the OIG could find liability in these examples.

¹¹ *See generally Oversight Hearing on the President’s Fiscal Year 2015 Budget for Tribal Programs Before the Sen. Comm. on Indian Affairs*, 113th Cong. (2014) (testimony of National Indian Health Board); *Improving Federal Health Care in Rural America: Developing the Workforce and Building Partnerships Before the Subcomm. on the Efficiency and Effectiveness of Federal Programs and the Federal Workforce of the Sen. Comm. on Homeland Security and Government Affairs*, 113th Cong.

effects of the financial crisis of 2008,¹² filling the employment gaps in Tribal and other rural providers will be made that much more difficult if the OIG expands its exclusion authority for loan default (which generally bears no relationship to provider quality or patient safety).

More specifically, IHS scholarships are largely awarded to Tribal members; indeed, Congress recognized the need for “identifying Indians with a potential for education or training in the health professions” when it authorized various AI/AN grant programs as part of the Indian Health Care Improvement Act.¹³ Excluding AI/ANs from providing desperately-needed health care services in Tribal communities runs directly counter to this goal and to the federal government’s trust responsibility toward AI/ANs.

The TTAG recognizes that there are certain circumstances in which exclusion might be a necessary remedy for a particularly recalcitrant provider, and that there are discretionary safeguards in the statute and regulations designed to protect patients and providers from disproportionate impacts of a loan default exclusion. But given the ongoing financial downturn and funding difficulties among IHS and Tribal health programs, we do not believe that this is a prudent time to add to the OIG’s exclusion authority for non-practice related, personal loan defaults. At the very least, in light of the clear congressional intent toward expanding AI/AN employment and participation in health care fields and the particular health crises in Tribal communities, the Final Rule should exempt IHS scholarship and loan repayment programs from any expansion of the loan default exclusion.

3. Potential Regulation to Protect Rural Patients.

42 U.S.C. § 1395y(e)(2) authorizes CMS to pay claims submitted directly by a Medicare enrollee when (1) the items or services are furnished by an excluded individual and (2) the enrollee does not know or have reason to know of the exclusion.¹⁴ However, CMS notes that in many

(2013) (statement of Dr. Yvette Roubideaux, Director, Indian Health Services).

¹² The federal Consumer Financial Protection Board has recognized that “[d]efault rates have spiked significantly since the financial crisis of 2008,” CONSUMER FINANCIAL PROTECTION BOARD, REPORT TO THE SENATE COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS, THE SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS, THE HOUSE OF REPRESENTATIVES COMMITTEE ON FINANCIAL SERVICES, AND THE HOUSE OF REPRESENTATIVES COMMITTEE ON EDUCATION AND THE WORKFORCE, PRIVATE STUDENT LOANS at 4 (Aug. 29, 2012), while the United States Department of Education’s most current information indicates that close to 15% of all federal borrowers default on their loans. United States Department of Education, “Default Rates Continue to Rise for Federal Student Loans,” *available at* <http://www.ed.gov/news/press-releases/default-rates-continue-rise-federal-student-loans> (Sept. 30, 2013).

¹³ 25 U.S.C. § 1612(a)(1).

¹⁴ CMS promulgated the current implementing regulations before the enactment of Medicare parts C and D, and accordingly proposes to add references to these programs in the regulations. The TTAG supports this proposal.

contexts (particularly Part D), the provider, not the enrollee, submits claims for reimbursement.¹⁵ Because the statute is explicitly limited to situations where the beneficiary submits claims directly, CMS notes that this could result in situations where rural patients are left unable to obtain necessary services due to the exclusion of the only local provider if the provider submits the claim on the beneficiary's behalf. CMS is soliciting comments on how it could craft a regulation that would protect the enrollees in these circumstances.¹⁶

In order to remain within the statutory framework, we suggest that CMS authorize excluded providers to give relevant paperwork to enrollees that the enrollees can submit themselves, either online or at the provider's facility.¹⁷ Additionally, after a beneficiary submits a claim from an excluded provider, the statute requires CMS to notify the enrollee of the exclusion and prohibits additional payments for services provided by the excluded individual or entity after a reasonable time past the notice. Current regulations waive the prohibition in the case of emergency services so long as the claim is "accompanied by a sworn statement of the person furnishing the items or services specifying the nature of the emergency and why the items or services could not have been furnished by an individual or entity eligible to furnish or order such items or services."¹⁸ CMS should extend this exception to any services that the beneficiary cannot reasonably obtain elsewhere, which would protect patients "captured" by a single excluded pharmacy or physician. We therefore suggest the following edits to 42 C.F.R. § 1001.1901(c):¹⁹

42 C.F.R. § 1001.1901(c) Exceptions to paragraph (b)(1) of this section.

(1) If an enrollee of Part B of Medicare submits an otherwise payable claim for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual after the effective date of exclusion, CMS will pay the first claim submitted by the enrollee and immediately notify the enrollee of the exclusion. In cases where the excluded individual or entity's submission of claims would invalidate payment for an emergency item or service or one

¹⁵ Exclusion Rule at 26,817. The exception at 42 U.S.C. § 1395y(e)(2) is explicitly limited to circumstances in which the "individual eligible for benefits" submits the claim for payment, and not the excluded provider.

¹⁶ *Id.*

¹⁷ Many Tribal health programs already offer such services in other contexts in which patients are required to submit paperwork directly: providing assistance in filling out relevant forms and then mailing them on the patient's behalf directly from the provider's facility.

¹⁸ 42 C.F.R. § 1001.1901(c)(5)(i).

¹⁹ Though this regulation currently only applies to Part B enrollees, as noted, CMS proposes to extend it to Parts C and D as well.

that the enrollee cannot reasonably obtain from a non-excluded individual or entity, the provider may assist the enrollee in submitting the claim directly.

...

(5)(i) Notwithstanding the other provisions of this section, payment may be made under Medicare, Medicaid or other Federal health care programs for ~~certain emergency~~ items or services furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician or other authorized individual during the period of exclusion. To be payable, a claim for such ~~emergency~~ items or services must be accompanied by a sworn statement of the person furnishing the items or services specifying ~~the nature of the emergency and why the items or services could not have been furnished by an individual or entity eligible to furnish or order such items or services,~~ whether due to a medical emergency, a patient's geographical or financial inability to obtain medically-necessary services from a non-excluded provider, or other circumstances within the scope of the individual or entity's professional judgment.

We believe that these regulations will better protect AI/ANs and other rural enrollees from situations in which a provider's exclusion essentially cuts off all services in a geographical area. It will also maintain necessary oversight, as the provider must still submit a sworn statement of medical necessity, which would leave the individual or facility subject to permanent exclusion, federal perjury charges, etc. if falsified. This will act as a reasonable deterrent to ensure that these provisions are only utilized in actual medical emergencies or cases of last resort.

4. The TTAG Supports CMS's Proposed "Early Reinstatement" Provisions.

CMS notes that many providers excluded due to adverse licensing determinations often switch health careers or obtain licensure in a different state, reasoning that doing so is more practical than the burden of obtaining reinstatement from the state licensing board.²⁰ But, these individuals remain barred from federal health programs in light of their unresolved adverse action in the prior state. CMS therefore proposes to reinstate such individuals if:

- The excluded individual fully and accurately discloses the circumstances surrounding the licensing action that resulted in exclusion and subsequently obtains either a health care license in another state or a different type of health care license in the original state of exclusion;
- The excluded individual demonstrates that he or she no longer poses a threat to federal health care programs and beneficiaries; or
- The excluded individual regains state health care licensure or three years passes from the date of exclusion, whichever comes first.²¹

²⁰ Exclusion Rule at 26,814.

²¹ *Id.* at 26,814-15.

The TTAG supports this approach. As noted above, the extreme remoteness of many Tribal health facilities and communities makes it particularly difficult for Tribal health programs to retain qualified staff and providers. This is made even more difficult if staff members who have demonstrated that they no longer pose any danger to patients or program integrity remain excluded based on a licensing action that occurred years in the past, under changed circumstances, in a separate jurisdiction, or in instances where it would not make any financial or professional sense to have challenged the adverse determination. We believe that CMS's proposals strike an appropriate balance between patient safety and practical necessity.

II. Conclusion.

The TTAG largely agrees with CMS's approach in the Proposed Rules and believes that its provisions will generally improve providers' understanding of their rights and responsibilities. The additional considerations set out in this comment will further improve the fairness and flexibility of both the exclusion and CMP programs.

The TTAG appreciates the opportunity to comment on the Proposed Rules and looks forward to a continued open dialogue with CMS on the issues discussed above.

Sincerely,

A handwritten signature in black ink, appearing to read "Valerie Davidson", with a long, sweeping flourish extending to the right.

Valerie Davidson
Chair, TTAG