

recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Daniel Blackman,

Regional Administrator, Region 4.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts

AGENCY: Office of Inspector General (OIG), Department of Health and Human Services (HHS or the Department).

ACTION: Notification of intent to develop regulations.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), this annual notification solicits proposals and recommendations for developing new, or modifying existing, safe harbor provisions under section 1128B(b) of the Social Security Act (the Act), the Federal anti-kickback statute, as well as developing new OIG Special Fraud Alerts.

DATES: To ensure consideration, public comments must be received no later than 5 p.m. on January 27, 2023.

ADDRESSES: In commenting, please refer to file code OIG–1122–N. Because of staff and resource limitations, we cannot accept comments by fax transmission. You may submit comments in one of two ways (no duplicates, please):

1. *Electronically.* You may submit comments electronically at <https://www.regulations.gov>. Follow the “Submit a comment” instructions and refer to file code OIG–1122–N.

2. *By regular, express, or overnight mail.* You may send written comments to the following address: OIG, Regulatory Affairs, HHS, Attention: OIG–1122–N, Room 5527, Cohen Building, 330 Independence Avenue SW, Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

For information on viewing public comments, please see the

SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT:

Susan Edwards, (202) 619–0335.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments

received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>.

I. Background

A. OIG Safe Harbor Provisions

Section 1128B(b) of the Act (42 U.S.C. 1320a–7b(b)), the Federal anti-kickback statute, provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward, among other things, referrals for or purchases of items or services reimbursable under any of the Federal health care programs, as defined in section 1128B(f) of the Act (42 U.S.C. 1320a–7b(f)). The offense is classified as a felony and is punishable by a fine of up to \$100,000 and imprisonment for up to 10 years. Violations of the Federal anti-kickback statute also may result in the imposition of civil monetary penalties under section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)), and liability under the False Claims Act (31 U.S.C. 3729–33).

Because of the broad reach of the statute, stakeholders expressed concern that some relatively innocuous business arrangements were covered by the statute and, therefore, potentially subject to criminal prosecution. In response, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93 (note to section 1128B of the Act; 42 U.S.C. 1320a–7b), which requires the development and promulgation of regulations, the so-called safe harbor provisions, that would specify various payment and business practices that would not be subject to sanctions under the Federal anti-kickback statute, even though they potentially may be capable of inducing referrals of business for which payment may be made under a Federal health care program. Since July 29, 1991, there has been a series of final regulations published in the **Federal Register** establishing safe harbors to protect various payment and business practices.¹ These safe harbor provisions

have been developed “to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements.”² Health care providers and others may voluntarily seek to comply with the conditions of an applicable safe harbor so that they have the assurance that their payment or business practice will not be subject to sanctions under the Federal anti-kickback statute. The safe harbor regulations promulgated by OIG are found at 42 CFR part 1001.

B. OIG Special Fraud Alerts

OIG periodically issues Special Fraud Alerts to give continuing guidance to health care industry stakeholders about practices that OIG considers to be suspect or of particular concern.³ Special Fraud Alerts encourage industry compliance by giving stakeholders guidance that can be applied to their own practices. OIG Special Fraud Alerts are published in the **Federal Register**, on OIG’s website, or both, and are intended for extensive distribution.

In developing Special Fraud Alerts, OIG relies on several sources and consults directly with experts in the subject field including those within OIG, other agencies of HHS, other Federal and State agencies, and those in the health care industry.

C. Section 205 of the Health Insurance Portability and Accountability Act of 1996

Section 205 of HIPAA, Public Law 104–191, and section 1128D of the Act (42 U.S.C. 1320a–7d), requires the Department to develop and publish an annual notification in the **Federal Register** formally soliciting proposals for developing additional or modifying existing safe harbors to the Federal anti-kickback statute and for issuing Special Fraud Alerts.

In developing or modifying safe harbors under the Federal anti-kickback statute, and in consultation with the Department of Justice, OIG thoroughly reviews the range of factual circumstances that may receive protection by the proposed or modified safe harbor. In doing so, OIG seeks to identify and develop safe harbors that protect beneficial and innocuous arrangements and safeguard Federal

Monetary Penalty Rules Regarding Beneficiary Inducements, 85 FR 77684 (Dec. 2, 2020).

² Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952, 35958 (July 29, 1991).

³ See, e.g., Special Fraud Alert: OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies (July 20, 2022), <https://oig.hhs.gov/documents/root/1045/sfa-telefraud.pdf>.

¹ See, e.g., Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil

health care programs and their beneficiaries from the harms caused by fraud and abuse.

II. Solicitation of New and Modified Safe Harbor Recommendations and Special Fraud Alert Proposals

OIG seeks recommendations regarding the development of additional or modified safe harbor regulations and the issuance of new Special Fraud Alerts. A detailed explanation of justifications for, or empirical data supporting, a suggestion for a new or modified safe harbor or for the issuance of a new Special Fraud Alert would be helpful and should, if possible, be included in any response to this solicitation.

A. Criteria for Modifying and Establishing Safe Harbor Provisions

In accordance with section 205 of HIPAA, we will consider various factors in reviewing proposals for additional or modified safe harbor provisions, such as the extent to which the proposals may result in an increase or decrease in:

- Access to health care services,
- The quality of health care services,
- Patient freedom of choice among health care providers,
- Competition among health care providers,
- The cost to Federal health care programs,
- The potential overutilization of health care services, and
- The ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

In addition, we will consider other factors including, for example, the existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may influence their decision whether to: (1) order a health care item or service or (2) arrange for a referral of health care items or services to a particular practitioner or provider.

B. Criteria for Developing Special Fraud Alerts

In determining whether to issue additional Special Fraud Alerts, we will consider whether and to what extent the practices that would be identified in a new Special Fraud Alert may result in any of the consequences set forth above, as well as the volume and frequency of the conduct that would be identified in the Special Fraud Alert.

Dated: November 22, 2022.

Christi A. Grimm,
Inspector General.

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 8360

[LLCOS05000 L12200000.DU0000 18X]

Notice of Proposed Supplementary Rule for Travel Management on Public Lands in Montrose, Delta, San Miguel, and Ouray Counties, CO

AGENCY: Bureau of Land Management, Interior.

ACTION: Proposed supplementary rule.

SUMMARY: The Bureau of Land Management (BLM) is proposing to establish a supplementary rule to make enforceable travel management decisions for mechanized vehicles in the Dry Creek Travel Management Plan (TMP) issued December 1, 2009; the Ridgway TMP issued May 10, 2013; and the Norwood-Burn Canyon TMP issued November 14, 2014. The proposed supplementary rule (proposed rule) would apply to public lands in Montrose, Delta, San Miguel, and Ouray counties, Colorado, administered by the BLM Uncompahgre Field Office.

DATES: Please send comments by January 27, 2023. Comments postmarked or received in person or by electronic mail after this date may not be considered in the development of the final supplementary rule.

ADDRESSES: You may submit comments by one of the following methods: mail or hand deliver to Proposed Supplementary Rule, Attention: Caroline Kilbane, Outdoor Recreation Planner, BLM Uncompahgre Field Office, 2505 S Townsend Ave., Montrose, CO 81401. You may also submit comments via email to ckilbane@blm.gov (include "Proposed Supplementary Rule" in the subject line).

FOR FURTHER INFORMATION CONTACT:

Caroline Kilbane, Outdoor Recreation Planner at (970) 240-5300 or by email at ckilbane@blm.gov. Individuals in the United States who are deaf, deafblind, hard of hearing or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

Written comments on the proposed rule should be specific, confined to

issues pertinent to the proposed rule, and explain the reason for any recommended change. Where possible, comments should reference the specific section or paragraph of the proposed rule that the comment is addressing. The BLM is not obligated to consider or include in the Administrative Record for the final supplementary rule, comments delivered to an address other than those listed earlier (See **ADDRESSES**) or comments that the BLM receives after the close of the comment period (See **DATES**), unless they are postmarked or electronically dated before the deadline.

Comments, including names, street addresses, and other contact information of respondents, will be available for public review at the address specified in the **ADDRESSES** section above, during regular business hours (8 a.m. to 4:30 p.m. Monday through Friday, except Federal holidays). Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

Prior to 2009, the BLM Uncompahgre Field Office used the 1989 Uncompahgre Basin Resource Management Plan (RMP) and the 1985 San Juan/San Miguel Resource Area RMP to manage travel on BLM-managed lands within the Dry Creek, Ridgway, and Norwood-Burn Canyon areas. In March 2007, the BLM published in the **Federal Register** a Notice of Intent to Amend the Uncompahgre Basin and San Juan/San Miguel RMPs and prepare the Dry Creek Comprehensive Travel Management Plan, Colorado (72 FR 10243). The RMP amendment, approved in June 2010, changed off-highway vehicle designations in identified areas from "Open or Limited" to "Limited to existing routes year-long or with seasonal restrictions" until further route-by-route planning could be completed. The BLM issued decision records for the Dry Creek TMP on December 1, 2009; the Ridgway TMP on May 13, 2013; and the Norwood-Burn Canyon TMP on November 14, 2014. The BLM approved the TMPs after multiple public comment opportunities and coordination with local government. On April 2, 2020, the BLM approved a revised Uncompahgre RMP that includes the Dry Creek, Ridgway,