Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

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

Dated: December 17, 2019.

Blake M. Ashbee,

Acting Regional Administrator, Region 4.

[FR Doc. 2019–28236 Filed 12–30–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2018–0705; FRL–10003–47–Region 6]

Air Plan Approval; New Mexico; Interstate Transport Requirements for the 2008 Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Environmental Protection Agency (EPA) is extending the comment period for the proposed rule titled ''Air Plan Approval; New Mexico; Interstate Transport Requirements for the 2008 Ozone NAAQS'' that was published in the **Federal Register** on December 3, 2019. The proposal provided for a public comment period ending January 2, 2020. The EPA received a request from the public to extend this comment period. The EPA is extending the comment period to a 45-day public comment period ending January 17, 2020.

DATES: The comment period for the proposed rule published December 3, 2019 (84 FR 66098), is extended. Written comments must be received on or before January 17, 2020.

ADDRESSES: Submit your comments, identified by Docket Number EPA–R06–OAR–2018–0705, at *http://www.regulations.gov* or via email to *fuerst.sherry@epa.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact Sherry Fuerst, 214–665–6454, *fuerst.sherry@epa.gov*. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at the EPA Region 6 Office, 1201 Elm Street, Suite 500, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Sherry Fuerst, 214–665–6454, *fuerst.sherry@epa.gov*. To inspect the hard copy materials, please schedule an appointment with Ms. Fuerst or Mr. Bill Deese at 214–665–7253.

SUPPLEMENTARY INFORMATION: On December 3, 2019, we published in the **Federal Register** ''Air Plan Approval; New Mexico; Interstate Transport Requirements for the 2008 Ozone NAAQS'' addressing ozone interstate transport (84 FR 66098). We received a request for an extension of the comment period and, in response, have decided to allow an additional 15 days. We are extending the comment period to January 17, 2020. This action will allow interested persons additional time to prepare and submit comments.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen Oxides, Ozone.

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

Dated: December 18, 2019.

David Garcia,

Air and Radiation Division Director, Region 6.

[FR Doc. 2019–27865 Filed 12–30–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

Solicitation of New Safe Harbors and Special Fraud Alerts

AGENCY: Office of Inspector General (OIG), HHS.

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 anti-kickback statute), as well as developing new OIG Special Fraud Alerts.

DATES: To ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on March 2, 2020.

ADDRESSES: In commenting, please refer to file code OIG–128–N. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission. You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at *http://www.regulations.gov*.

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Office of Inspector General, Regulatory Affairs, Department of Health and Human Services, Attention: OIG–128–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.

3. *By hand or courier.* If you prefer, you may deliver your written comments by hand or courier before the close of the comment period to the following address: Office of Inspector General, Department of Health and Human Services, Cohen Building, Room 5527, 330 Independence Avenue SW, Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619–0335. For information on the inspection of public comments, please see the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Samantha Flanzer, Office of Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on recommendations for developing new or revised safe harbors and Special Fraud Alerts. Please assist us by referencing the file code OIG–128–N.

Inspection of Public Comments: All comments received before the end of the comment period will be posted on *http://www.regulations.gov* for public viewing.

I. Background

A. OIG Safe Harbor Provisions

Section 1128B(b) of the Act, (42 U.S.C. 1320a–7b(b), the anti-kickback statute), provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward the referral of business 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 fines of up to $100,000 and imprisonment for up to 10 years. Violations of the anti-kickback statute also may result in the imposition of civil monetary penalties (CMP) 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, concern was expressed 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 (section 1128B(b)(3)(E) of the Act; 42 U.S.C. 1320a–7b(b)(3)(E)), which specifically 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 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 have been a series of final regulations published in the **Federal Register** establishing safe harbors protecting 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 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 providers and other entities regarding practices OIG considers to be suspect or of particular concern.[3] The Special Fraud Alerts encourage industry compliance by giving providers guidance that can be applied to their own practices. OIG Special Fraud Alerts are published in the **Federal Register** and on OIG's website and are intended for extensive distribution.

In developing Special Fraud Alerts, OIG relies on a number of sources and consults directly with experts in the subject field, including those within OIG, other agencies of the U.S. Department of Health and Human Services (the Department), 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 the Health Insurance Portability and Accountability Act of 1996 (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 or modifying existing safe harbors to the anti-kickback statute and Special Fraud Alerts.

In developing safe harbors for the anti-kickback statute, OIG, in consultation with the U.S. Department of Justice, thoroughly reviews the range of factual circumstances that may fall within the proposed safe harbor subject area. In doing so, OIG seeks to identify and develop regulatory limitations and controls in order to permit beneficial and innocuous arrangements while, at the same time, protecting Federal health care programs and their beneficiaries from the harms caused by fraud and abuse.

II. Solicitation of Additional New Recommendations and Proposals

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

While OIG welcomes all relevant comments, this solicitation is separate and distinct from both OIG's ''Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP,'' published on August 27, 2018 (RFI),[4] and its notice of proposed rulemaking (NPRM) entitled ''Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements,'' published on October 17, 2019.[5] Commenters need not duplicate comments previously submitted in response to OIG's RFI or NPRM.

A. Criteria for Modifying and Establishing Safe Harbor Provisions

In accordance with section 205 of HIPAA, we will consider a number of factors in reviewing proposals for new or modified safe harbor provisions, such as the extent to which the proposals would affect an increase or decrease in:

[1] *See e.g.,* Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 FR 88368 (Dec. 7, 2016).

[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: Physician-Owned Entities, 79 FR 19271 (Mar. 29, 2013).

[4] Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, 83 FR 43607 (Aug. 27, 2018).

[5] Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 84 FR 55694 (Oct. 17, 2019).

- 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: December 10, 2019.

Joanne M. Chiedi,

Acting Inspector General.

[FR Doc. 2019–27202 Filed 12–30–19; 8:45 am]

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