

and Conflict of Interest and Disclosure requirements.

**DATES:** Written comments should be received on or before January 27, 2017.

**ADDRESSES:** Submit your comments, identified by EPA-R06-OAR-2014-0513, at <http://www.regulations.gov> or via email to [Donaldson.tracie@epa.gov](mailto:Donaldson.tracie@epa.gov). For additional information on how to submit comments see the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Tracie Donaldson, (214) 665-6633, [Donaldson.tracie@epa.gov](mailto:Donaldson.tracie@epa.gov).

**SUPPLEMENTARY INFORMATION:** In the final rules section of this **Federal Register**, the EPA is approving the State's SIP submittal as a direct rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action no further activity is contemplated. If the EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

Dated: December 21, 2016.

**Samuel Coleman,**

*Acting Regional Administrator, Region 6.*

[FR Doc. 2016-31331 Filed 12-27-16; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 80

[EPA-HQ-OAR-2016-0544; FRL-9957-46-OAR]

#### Change the RFS Point of Obligation; Extension of Comment Period

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Extension of public comment period.

**SUMMARY:** On November 22, 2016, the U.S. Environmental Protection Agency ("EPA") published a Notice of its proposed denial of several petitions requesting that EPA initiate a rulemaking process to reconsider or

change its regulations that identify refiners and importers of gasoline and diesel fuel as the entities responsible for complying with the annual percentage standards adopted under the Renewable Fuel Standard (RFS) program. The Notice invited public comment on this proposal by January 23, 2017—60 days after publication of the Notice in the **Federal Register**. On December 13, 2016, the EPA received a request from the Small Retailers Coalition to extend the comment period by 30 days to allow its members to provide thorough comments and data. In light of the importance of this issue, the EPA is extending the deadline for written comments an additional 30 days to February 22, 2017.

**DATES:** Comments must be received on or before February 22, 2017.

**ADDRESSES:** Submit your comments on the EPA's proposed denial of the petitions referenced above, identified by Docket ID No. EPA-HQ-OAR-2016-0544, at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn 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, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION CONTACT:** Julia MacAllister, Office of Transportation and Air Quality, Assessment and Standards Division, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: 734-214-4131; email address: [macallister.julia@epa.gov](mailto:macallister.julia@epa.gov).

**SUPPLEMENTARY INFORMATION:** The EPA proposal noted above was published on November 22, 2016, at 81 FR 83776. For the reasons noted above, the public comment period will now end on February 22, 2017.

Dated: December 20, 2016.

**Christopher Grundler,**

*Director, Office of Transportation and Air Quality.*

[FR Doc. 2016-31259 Filed 12-27-16; 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:** Notice of intent to develop regulations.

**SUMMARY:** In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), this annual notice solicits proposals and recommendations for developing new, and modifying existing, safe harbor provisions under the Federal anti-kickback statute (section 1128B(b) of the Social Security Act), 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 February 27, 2017.

**ADDRESSES:** In commenting, please refer to file code OIG-125-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: Patrice Drew, Office of Inspector General, Regulatory Affairs, Department of Health and Human Services, Attention: OIG-125-N, Room 5541C, 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, by hand or courier, your written comments before the close of the comment period to Patrice Drew, Office of Inspector General, Department of Health and Human Services, Cohen Building, Room 5541C, 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) 619-1368.

For information on viewing public comments, please see the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Patrice Drew, Regulatory Affairs Liaison, Office of Inspector General, (202) 619-1368.

**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-125-N.

*Inspection of Public Comments:* All comments received before the end of the comment period are available for viewing by the public. All comments will be posted on <http://www.regulations.gov> after the closing of the comment period. Comments received timely will also be available for public inspection as they are received at Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201, Monday through Friday from 10 a.m. to 5 p.m. To schedule an appointment to view public comments, phone (202) 619-1368.

## I. Background

### A. OIG Safe Harbor Provisions

Section 1128B(b) of the Social Security Act (the Act) (42 U.S.C. 1320a-7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward business reimbursable under Federal health care programs. The offense is classified as a felony and is punishable by fines of up to \$25,000 and imprisonment for up to 5 years. OIG may also impose civil money penalties, in accordance with section 1128A(a)(7) of the Act (42 U.S.C. 1320a-7a(a)(7)), or exclusion from Federal health care programs, in accordance with section 1128(b)(7) of the Act (42 U.S.C. 1320a-7(b)(7)).

Because the statute, on its face, is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements may be subject to criminal prosecution or administrative sanction. In response to the above concern, section 14 of the Medicare and Medicaid Patient and

Program Protection Act of 1987, Public Law 100-93 section 14, specifically required the development and promulgation of regulations, the so-called "safe harbor" provisions, specifying various payment and business practices that, although potentially capable of inducing referrals of business reimbursable under Federal health care programs, would not be treated as criminal offenses under the anti-kickback statute and would not serve as a basis for administrative sanctions. OIG 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" (56 FR 35952, July 29, 1991). Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices will not be subject to liability under the anti-kickback statute or related administrative authorities. OIG safe harbor regulations are found at 42 CFR part 1001.

### B. OIG Special Fraud Alerts

OIG has also periodically issued Special Fraud Alerts to give continuing guidance to health care providers with respect to practices OIG finds potentially fraudulent or abusive. 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 our Web site and are intended for extensive distribution directly to the health care provider community, as well as to those charged with administering the Federal health care programs.

In developing Special Fraud Alerts, OIG has relied on a number of sources and has consulted directly with experts in the subject field, including those within OIG, other agencies of 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 section 205, the Act, section 1128D, 42 U.S.C. 1320a-7d, requires the Department to develop and publish an annual notice in the **Federal Register** formally soliciting proposals for modifying existing safe harbors to the anti-kickback statute and for developing new safe harbors and Special Fraud Alerts.

In developing safe harbors for a criminal statute, OIG thoroughly reviews the range of factual circumstances that may fall within the proposed safe harbor subject area so as to uncover potential opportunities for fraud and abuse. Only then can OIG determine, in consultation with the Department of Justice, whether it can effectively develop regulatory limitations and controls that will permit beneficial and innocuous arrangements within a subject area while, at the same time, protecting Federal health care programs and their beneficiaries from abusive practices.

## II. Solicitation of Additional New Recommendations and Proposals

In accordance with the requirements of section 205 of HIPAA, OIG last published a **Federal Register** solicitation notice for developing new safe harbors and Special Fraud Alerts on December 23, 2015 (80 FR 79803). As required under section 205, a status report of the proposals OIG received for new and modified safe harbors in response to that solicitation notice is set forth in Appendix F of OIG's Fall 2016 *Semiannual Report to Congress*.<sup>1</sup> OIG is not seeking additional public comment on the proposals listed in Appendix F at this time. Rather, this notice seeks additional recommendations regarding the development of new or modified safe harbor regulations and new Special Fraud Alerts beyond those summarized in Appendix F.

A detailed explanation of justifications for, or empirical data supporting, a suggestion for a safe harbor or 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 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:

- 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

<sup>1</sup> The OIG *Semiannual Report to Congress* can be accessed through the OIG Web site at <http://oig.hhs.gov/publications/semiannual.asp>.

- the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

In addition, we will also consider other factors, including, for example, the existence (or nonexistence) of any potential financial benefit to health care professionals or providers that may take into account their decisions 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 21, 2016.

**Daniel R. Levinson,**  
*Inspector General.*

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## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

#### 49 CFR Parts 531, 533 and 536

[Docket No. NHTSA-2016-0135]

#### Corporate Average Fuel Economy Standards; Credits

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

**ACTION:** Grant of petition for rulemaking.

**SUMMARY:** This notice partially grants a petition for rulemaking submitted by the Alliance of Automobile Manufacturers and the Association of Global Automakers (hereinafter collectively referred to as “Petitioners”) on June 20, 2016, to consider amending various aspects of the light vehicle Corporate Average Fuel Economy (CAFE) regulations. The Petitioners requested that NHTSA issue a direct final rule to implement the requested changes, but NHTSA believes that the issues and questions raised by the Petitioners are worthy of notice and comment. NHTSA will address the changes requested in the Petition in the course of the rulemaking proceeding, in accordance with statutory criteria.

**DATES:** December 21, 2016.

**FOR FURTHER INFORMATION CONTACT:** For technical issues, you may call Mr. James Tamm in the Fuel Economy Division of the Office of Rulemaking at (202) 493-0515. For legal issues, you may call Ms. Rebecca Yoon in the Office of Chief Counsel at (202) 366-2992. You may send mail to these officials at: National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590.

**SUPPLEMENTARY INFORMATION:** On June 20, 2016, the Petitioners submitted a Petition to the National Highway Traffic Safety Administration (NHTSA) and the Environmental Protection Agency (EPA) requesting that the agencies issue a direct final rule to amend various aspects of the Corporate Average Fuel Economy (CAFE) and light-duty greenhouse gas (GHG) regulations. The Petitioners stated that these amendments are necessary to “address various inconsistencies between” NHTSA’s CAFE program and EPA’s GHG emissions program, and to “address additional inefficiencies” in the programs.

Specifically, Petitioners requested that NHTSA (and EPA) <sup>1</sup> modify the CAFE regulations as follows:

(1) Include “off-cycle” credits in the calculation of manufacturers’ fleet fuel economy levels for model years 2010 through 2016;

(2) Include air conditioning efficiency credits in the calculation of manufacturers’ fleet fuel economy levels for model years 2010 through 2016;

(3) Apply the “fuel savings adjustment factor” for all uses of CAFE credits;

(4) Apply the same estimate of Vehicle Miles Traveled for model years 2011 through 2016 that the EPA GHG program uses;

(5) Change the definition of “credit transfer” in 49 CFR part 536 to state that the statutory cap on credit transfers applies at time of transfer rather than at time of use;

(6) Amend regulations to clarify that manufacturers may manage and apply their credits regardless of their origin;

(7) Amend 49 CFR 531(d) so that minimum domestic passenger car standards represent 92 percent of the overall passenger car CAFE standard for the fleet as a whole calculated at the end of each model year, rather than 92 percent of the overall standard as calculated at the time that the standards are/were originally issued;

<sup>1</sup> This decision addresses only those portions of the Petition that are within NHTSA’s jurisdiction and responsibility. It does not address aspects of the Petition that are exclusively under EPA’s jurisdiction.

(8) Adjust the “multiplier” for full electric vehicles, plug-in hybrid electric vehicles, fuel cell vehicles, and compressed natural gas vehicles; and  
(9) “Improve” the off-cycle credit approval process and reaffirm several provisions.

Some aspects of the Petition were directed to NHTSA, some to both NHTSA and EPA, and other requests were directed exclusively to EPA. The sixth item, seeking clarification that manufacturers may manage and apply their credits regardless of their origin, requests a change in an EPA regulation (40 CFR 86.1865(k)(5)) that does not appear applicable or relevant to the CAFE program. Calculation procedures for CAFE compliance are located at 40 CFR 600.510-12. Credits for CAFE over-compliance are determined based on the difference between a manufacturer’s calculated “achieved” CAFE value and the manufacturer’s calculated “required” CAFE value. NHTSA believes that this request was not intended to be directed at the CAFE program, but NHTSA would welcome Petitioners’ clarification if this is incorrect.

Similarly, the eighth item, which addresses the “multiplier” for alternative fuel vehicles, applies exclusively to EPA’s GHG program. NHTSA does not speak for EPA in this decision, and will not address this item in the upcoming rulemaking.

The remaining items will be addressed in conjunction with the Agency’s upcoming proposal for setting future CAFE standards. NHTSA believes that these issues are best considered concurrently with that rulemaking for both procedural and substantive reasons. Procedurally, reducing the number of rulemaking actions increases administrative efficiency and improves the ability to evaluate cumulative program impacts comprehensively. Substantively, while Petitioners’ requests nominally focus on credit and flexibility issues, NHTSA believes that the underlying questions of whether and how to expand compliance flexibilities is closely related to the question of what CAFE standards are maximum feasible in future model years, which NHTSA will determine in the upcoming rulemaking as required by statute. The Petitioners appear to agree with this, as the Petition suggests that if a lack of compliance flexibilities leads manufacturers to pay civil penalties for CAFE non-compliance, the CAFE standards may be beyond maximum feasible levels. While NHTSA does not agree that the fact that *any* manufacturer would face civil penalties alone would suggest that CAFE standards would be