procured 1,600 metric tons of nickel sulfate incorporated into a constituent material for the battery cell production facility, of which 75 percent (1,200/1,600 metric tons) is FEOC-compliant. Since the lithium hydroxide is the least compliant applicable critical mineral or component, M allocates the FEOC-compliant lithium hydroxide mass to 50 percent or 500,000 (50 percent * 1,000,000) of the total battery cells, and to battery cells that contain FEOC-compliant cathode electrodes and have been allocated FEOC-compliant nickel sulfate. Under paragraph (c)(2)(ii)(E) of this section, the quantity of FEOC-compliant battery cells is limited by the applicable critical mineral (lithium hydroxide) that has the lowest percentage (50 percent) of FEOC-compliant supply.

(E) Under paragraph (c)(2) of this section, M must use a serial number or other identification system to track the 500,000 FEOC-compliant battery cells to 500 (500,000/1,000) specific batteries.

(F) Under paragraph (d)(1) of this section, a compliant-battery ledger must be established for calendar year 2025. For purposes of paragraph (d)(2)(i) of this section, M determines that it will manufacture 500 batteries for calendar year 2025 that are FEOC-compliant. Under paragraph (d)(2)(ii) of this section, M attests to the 500 FEOC-compliant batteries and provides the basis for the determination, including attestations, certifications, and documentation demonstrating compliance with paragraphs (b) and (c) of this section. Once the IRS, with analytical assistance from the DOE, has approved the number, a compliant-battery ledger is established with a balance of 500 FEOC-compliant batteries.

(h) *Severability.* The provisions of this section are separate and severable from one another. If any provision of this section is stayed or determined to be invalid, it is the agency's intention that the remaining provisions will continue in effect.

(i) *Applicability date.* This section applies to new clean vehicles placed in service after December 31, 2023.

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2023–26513 Filed 12–1–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 93

RIN 0937–AA12

Public Health Service Policies on Research Misconduct; Extension of Comment Period

AGENCY: U.S. Department of Health and Human Services (HHS).

ACTION: Proposed rule; Extension of comment period.

SUMMARY: The Department of Health and Human Services (HHS), Office of the Secretary, Office of the Assistant Secretary for Health (OASH), Office of Research Integrity (ORI) is extending the comment period by 30 days for the proposed rule entitled ''Public Health Service Policies on Research Misconduct'' published in the **Federal Register** on October 6, 2023. Public comments must be submitted on or before January 4, 2024.

DATES: HHS is extending the comment period by 30 days on the proposed rule published October 6, 2023 at 88 FR 69583. Submit comments on or before January 4, 2024.

ADDRESSES: For efficient management of comments, HHS requests that all comments be submitted electronically to *https://www.regulations.gov* (referred to hereafter as ''*regulations.gov*''). In commenting, please refer to the Regulatory Information Number (RIN) [0937–AA12].

Instructions: Enter the RIN in the search field at *https://www.regulations.gov* and click on ''Search.'' To view the proposed rule, click on the title of the rule. To comment, click on ''Comment'' and follow the instructions. If you are uploading multiple attachments into *regulations.gov*, please number and label all attachments; *https://www.regulations.gov* will not automatically number them. All relevant comments will be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section in the Notice of Proposed Rulemaking published at 88 FR 69583.

Docket: For access to the docket to read comments received, please go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Sheila Garrity, JD, MPH, MBA, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852; telephone 240–453–8200.

SUPPLEMENTARY INFORMATION: The Agency is extending the deadline to comment on the proposed rule entitled ''Public Health Service Policies on Research Misconduct'' published in the **Federal Register** on October 6, 2023 (88 FR 69583), in response to requests for an extension to allow interested persons additional time to submit comments.

Dated: November 29, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–26590 Filed 12–1–23; 8:45 am]

BILLING CODE 4150–31–P

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 February 2, 2024.

ADDRESSES: In commenting, please refer to file code OIG–1123–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–1123–N.

2. *By regular, express, or overnight mail.* You may send written comments to the following address: OIG, Regulatory Affairs, HHS, Attention: OIG–1123–N, Room 5628, 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: Tiana Korley, (240) 935–0776.

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 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.

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

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 28, 2023.

Christi A. Grimm,

Inspector General.

[FR Doc. 2023–26526 Filed 12–1–23; 8:45 am]

BILLING CODE 4152–01–P