Executive Airport, Austin, TX; within 2 miles each side of the 131° bearing from Austin Executive Airport extending from the 6.6-mile (previously 6.3-mile) radius of Austin Executive Airport to 11.2 (decreased from 11.3) miles southeast of the Austin Executive Airport; and within 2 miles each side of the 311° bearing from the Austin Executive Airport extending from the 6.6-mile (previously 6.3-mile) radius of Austin Executive Airport to 10.9 (increased from 10.5) miles northwest of the Austin Executive Airport; Establishing Class E airspace extending upward from 700 feet above the surface within a 7-mile radius of Lago Vista TX/Rusty Allen Airport, Lago Vista, TX;

And establishing Class E airspace extending upward from 700 feet above the surface within a 6.8-mile radius of Lakeway Airport, Lakeway, TX.

This action is the result of biennial airspace reviews and to bring the airspace into compliance with FAA orders and support IFR operations at these airports.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6003 Class E Airspace Areas Designated as an Extension.

* * * * *

ASW TX E3 Austin, TX [Establish]

Austin-Bergstrom International Airport, TX
(Lat 30°11′40″ N, long 97°40′12″ W)
Austin-Bergstrom INTL: RWY 18R–LOC, TX
(Lat 30°11′36″ N, long 97°40′42″ W)

That airspace extending upward from the surface within 2.2 miles each side of the 359° bearing from the Austin-Bergstrom INTL: RWY 18R–LOC extending from the 5-mile radius to 7.1 miles north of the Austin-Bergstrom INTL: RWY 18R–LOC; and within 2 miles each side of the 359° bearing from the Austin-Bergstrom International Airport extending from the 5-mile radius of Austin-Bergstrom International Airport to 6 miles north of the Austin-Bergstrom International Airport.

* * * * *

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW TX E5 Austin, TX [Amended]

Austin-Bergstrom International Airport, TX
(Lat 30°11′40″ N, long 97°40′12″ W)
Austin-Bergstrom INTL: RWY 36R–GS, TX
(Lat 30°10′54″ N, long 97°39′22″ W)
Austin Executive Airport, TX
(Lat 30°23′51″ N, long 97°33′59″ W)

That airspace extending upward from 700 feet above the surface within a 7.5-miles radius of the Austin-Bergstrom International Airport; and within 4 miles either side of the 179° bearing from the Austin-Bergstrom INTL: RWY 36R–GS extending from the 7.5-mile radius of Austin-Bergstrom International Airport to 7.7 miles south of the Austin-Bergstrom INTL: RWY 36R–GS; and within a 6.6-mile radius of Austin Executive Airport; and within 2 miles each side of the 131° bearing from Austin Executive Airport extending from the 6.6-mile radius of Austin Executive Airport to 11.2 miles southeast of Austin Executive Airport; and within 2 miles each side of the 311° bearing from Austin Executive Airport extending from the 6.6-mile radius of Austin Executive Airport to 10.9 miles northwest of Austin Executive Airport.

* * * * *

ASW TX E5 Lago Vista, TX [Establish]

Lago Vista TX/Rusty Allen Airport, TX
(Lat 30°29′55″ N, long 97°58′10″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of the Lago Vista TX/Rusty Allen Airport.

* * * * *

ASW TX E5 Lakeway, TX [Establish]

Lakeway Airpark, TX
(Lat 30°21′27″ N, long 97°59′40″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of the Lakeway Airpark.

* * * * *

Issued in Fort Worth, Texas, on November 26, 2024.

Steven T. Phillips,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2024–28149 Filed 11–29–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1000 and 1001

RIN 0936–AA12

Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Exclusion Authorities

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

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes to amend the regulations relating to exclusion authorities under the authority of the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS or the Department). The proposed rule would codify changes made by the Medicaid Services Investment and Accountability Act of 2019 (MSIAA), that added exclusion authorities related to misclassification and false information about outpatient drugs. The proposed rule would also update and clarify OIG's procedures for excluding individuals and entities from participation in the Federal health care programs, including the factors that will be considered in determining the length of exclusions, the provisions governing notices of exclusions, and certain provisions related to reinstatement into the programs.

DATES: To ensure consideration, public comments must be received no later than 5 p.m. eastern time on January 31, 2025.

ADDRESSES: In commenting, please refer to file code OIG–2401–P. 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–2401–P.

2. *By regular, express, or overnight mail.* You may send written comments to the following address: OIG, Regulatory Affairs, HHS, Attention: OIG–2401–P, Room 5267, 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.

Docket: Go to the Federal eRulemaking Portal at *https://www.regulations.gov* for access to the rulemaking docket, including any background documents and the plain-language summary of the proposed rule of not more than 100 words in length required by the Providing Accountability Through Transparency Act of 2023.

FOR FURTHER INFORMATION CONTACT: David Fuchs, Deputy Branch Chief, Office of Counsel to the Inspector General, at (202) 763–4750.

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 as soon as possible after they have been received on the following website: *https://www.regulations.gov.*

I. Executive Summary

A. Purpose and Need for Regulatory Action

MSIAA expanded OIG's exclusion authority to protect the Federal health care programs from fraud and abuse by allowing OIG to exclude certain individuals and entities that knowingly misclassify a covered outpatient drug, knowingly fail to correct such misclassification, or knowingly provide false information related to drug pricing, drug product information, or data related to drug pricing or drug product information. OIG proposes to update its regulations to codify the changes made by MSIAA in the regulations. At the same time, OIG proposes to amend other sections of the exclusion regulations to ensure consistency with statutory authority, decrease administrative burdens, enhance transparency, and improve the efficiency and effectiveness of government. The proposed amendments include factors that will be considered in determining the lengths of exclusions, the processes governing notices of exclusions, and certain provisions related to reinstatement into the programs, as well as clarifying changes and updates to the regulations.

B. Legal Authority

The legal authority for this regulatory action is found in: 42 U.S.C. 1302; 1320a–7; 1395u(j); 1395u(k); 1395y(e); and 1395hh.

II. Summary of Major Provisions

We propose changes to the exclusion regulations at 42 CFR parts 1000 and 1001 to codify an authority under MSIAA, update processes, and make clarifying and technical changes to existing regulations. Specifically, section 6(d) of MSIAA amended section 1128(b) of the Social Security Act (the Act) to add an exclusion authority for certain conduct related to the misclassification of outpatient drugs, and knowingly providing false information related to drug pricing, drug product information, or data related to drug pricing or drug product information.

We propose clarifying changes to aggravating and mitigating factors that are used to determine periods of exclusion under section 1128 of the Act. We propose to simplify the mitigating factor relating to cooperation and to consolidate certain aggravating factors relating to other criminal, civil, and administrative sanctions into a single factor. We propose to modify the exclusion authority under section 1128(b)(12) of the Act, for failure to grant immediate access, to eliminate a requirement for OIG or a State Medicaid Fraud Control Unit (MFCU) to demonstrate that the requested material is about to be altered or destroyed in order to obtain access to the material at the time the request is made. We propose to modify OIG's obligations with respect to beneficiaries' access to physician services in imposing exclusions under section 1128(b)(14) of the Act in accordance with the Act. We propose to modify the regulatory language to align the regulations with certain, current OIG practices for exclusions imposed under sections 1128(a) and (b) of the Act and for waivers. We propose certain changes to the definitions to remove duplication. We propose to modify the circumstances under which early reinstatement is available for individuals and entities excluded under section 1128(b)(4) of the Act to permit individuals who lost their health care licenses for reasons related to patient abuse and neglect to apply for early reinstatement in limited circumstances.

III. Costs and Benefits

There are no significant costs associated with the proposed regulatory revisions that would impose any mandates on State, local, or Tribal governments or the private sector.

IV. Background

A. Exclusion Authority

The exclusion authorities found in section 1128 of the Act are intended to protect the Federal health care programs and their beneficiaries from untrustworthy individuals and entities whose behavior has demonstrated that those individuals and entities pose a risk to program beneficiaries or to the integrity of these programs. These authorities encompass both mandatory exclusions (section 1128(a) of the Act) and permissive exclusions (section 1128(b) of the Act). The Secretary's authority under section 1128 of the Act has been delegated to OIG. *See* 53 FR 12993 (Apr. 20, 1988).

The mandatory exclusion authorities require OIG to exclude from program participation any individual or entity convicted of an offense that is: related to items or services delivered under Medicare and Medicaid; related to patient abuse or neglect; or a felony related to health care delivery, governmental health care programs, or controlled substances. Mandatory exclusions must be imposed for a minimum 5-year period. The permissive authorities do not require the imposition of an exclusion and may either be: (1) ''derivative'' exclusions that are based on actions previously taken by a court, other law enforcement, or regulatory agencies; or (2) ''non-derivative'' exclusions that are based on OIG-initiated determinations of misconduct, *e.g.,* poor quality care or submission of false claims for Medicare or Medicaid payment. With certain exceptions, there are no specified minimum periods of exclusion under these permissive authorities.

Over the years, several statutory and regulatory provisions have amended or

further clarified OIG's exclusion authorities. For example, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) expanded OIG's authorities to add several exclusion authorities (sections 1128(a)(3), (a)(4), and (b)(15)) and increase minimum or benchmark periods of exclusion for certain permissive exclusions. The Balanced Budget Act (BBA) of 1997 further amended OIG's exclusion authorities by: (1) extending the scope of an OIG exclusion beyond Medicare and State health care programs to all Federal health care programs; (2) establishing permanent exclusions for persons convicted of three or more health care-related crimes and 10-year exclusions for persons convicted of two health care-related crimes; and (3) expanding the scope of exclusions under section 1128(b)(8) of the Act.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended OIG's authority to waive mandatory exclusions. In 2010, the Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, 124 Stat. 1029 (2010) (ACA), broadened OIG's waiver authority to permit the administrator of a Federal health care program to request a waiver if the administrator determines that exclusion would impose a hardship on beneficiaries of that program. In addition, the ACA expanded OIG's exclusion authority in several ways, including by establishing a new permissive exclusion authority under section 1128(b)(16) of the Act. On January 17, 2017, OIG published a final rule addressing new and revised exclusion authorities in accordance with the ACA and the MMA, as well as technical, policy, and clarifying changes to 42 CFR parts 1000, 1001, 1002, and 1006.

B. Changes Made by MSIAA

MSIAA expanded OIG's authority to exclude certain individuals and entities from participation in the Federal health care programs under section 1128 of the Act. Section 6(d) of MSIAA established a new permissive exclusion authority applicable to any manufacturer, or officer, director, agent, or managing employee of such manufacturer, that knowingly misclassifies a covered outpatient drug, knowingly fails to correct such misclassification, or knowingly provides false information related to drug pricing, drug product information, or data related to drug pricing or drug product information. The proposed rule would codify this statutory authority within the existing regulatory framework and address how OIG will set the length of exclusions imposed under that authority.

C. Proposed Policy Changes and Clarifying Changes

The proposed rule would revise the section governing exclusions under section 1128(b)(14) of the Act based on an individual's default on a health education loan or scholarship obligation. The section currently requires OIG to take into account access of beneficiaries to physician services for which payment may be made under Medicare, Medicaid, or other Federal health care programs in determining whether to impose an exclusion. We propose to align the regulation with section 1128(b)(14) of the Act by limiting OIG's obligations under this section to take into account access of beneficiaries to only Medicare and Medicaid physician services. By aligning the regulation with the statutory authority and removing the requirement for OIG to take into account beneficiary access to physician services under Federal health care programs other than Medicare and Medicaid, we hope to allow for more efficient imposition of exclusions under this section.

We propose clarifying changes to aggravating and mitigating factors that are used to determine periods of exclusion under section 1128 of the Act. We propose to simplify the mitigating factor relating to cooperation and to combine certain overlapping factors relating to prior civil, criminal, and administrative sanctions into a single factor. We propose to revise the regulation that permits OIG to exclude individuals and entities who fail to grant OIG or a State MFCU immediate access to certain records, to eliminate the requirement that OIG or a MFCU demonstrate that the requested materials are about to be altered or destroyed in order to obtain access to the materials at the time the request is made, instead of within 24 hours of the request. We propose to make technical changes to the regulations governing exclusions under section 1128 of the Act and for waivers. We propose to modify the circumstances under which early reinstatement is available for individuals and entities excluded under section 1128(b)(4) of the Act.

The proposed rule would also modify the sections governing notice to the public and other agencies regarding exclusions, notice regarding approval of reinstatement requests, and notice regarding denial of reinstatement requests. These proposed changes would modernize notice to the public and other agencies and more clearly outline OIG's process for appeals of denials of reinstatement requests.

Finally, the proposed rule would also include clarifying changes and updates to the exclusion regulations, including plain language changes to definitions, phrasing, and verbiage ensuring higher readability and comprehension for the public. Additionally, the proposed rule proposes to modernize pronoun references.

V. Provisions of the Proposed Rule

A. Changes to Part 1000 (Definitions)

We propose to move the definitions of ''agent,'' ''indirect ownership interest,'' ''ownership interest,'' and ''patient'' from § 1001.2 to § 1000.10 (General definitions), because these terms are used not only in part 1001 but also in other parts of subchapter B. We propose to modify ''indirect ownership interest'' to correct certain language. The current language states that '''Indirect ownership interest' includes an ownership interest through any other entities that ultimately have an ownership interest in the entity in issue.'' We propose to modify this language to clarify that the indirect ownership interest could be in one entity or through multiple entities. We also propose a technical edit changing ''in issue'' to ''at issue.'' We propose to modify the definition of ''ownership interest'' to correct certain language. The current language states that an ownership interest includes any interest in any mortgage, deed, trust or note, or other obligation secured in whole or in part by the assets of the entity. We propose to replace the phrase ''deed, trust or note, or other obligation'' with ''deed of trust, note, or other obligation.'' The reference to ''deed of trust'' appears in the definition of ''ownership or control interest'' at § 1001.2 and in section 1124 of the Act, and we believe that ''deed, trust or note'' was a typographical error in the regulatory definition because a ''deed of trust'' is an obligation similar to a mortgage or note.

We also propose to modify the definition of ''patient'' to change the reference to ''Medicare, Medicaid and any other Federal health care program'' to ''any Federal health care program'' because ''Federal health care program'' is a statutorily defined term that includes (and is broader than) Medicare and State health care programs. *See* 42 U.S.C. 1320a–7b(f). Section 1320a–7b(f) of U.S. Code title 42 and § 1000.10 define ''Federal health care program'' as

''(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5); or (2) any State health care program, as defined as defined in section 1128(h).''

Lastly, we propose to add a regulatory definition of ''knowingly'' to § 1000.10 because the term is used in the new exclusion authority added by MSIAA. We propose the same definition of ''knowingly'' that appears in § 1003.110, applicable to OIG's civil monetary penalty authorities in section 1128A of the Social Security Act (Act). By adding the definition to § 1000.10, the definition will apply to the regulations interpreting both the exclusion statute (section 1128 of the Act) and the OIG's civil monetary penalty authorities (section 1128A of the Act). The proposed language is as follows: ''*Knowingly* means that a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and no proof of specific intent to defraud is required.'' The definition mirrors the definition used in the False Claims Act, and is the most widely used knowledge standard for civil health care fraud.

B. Changes to Part 1001

References to Medicare, Medicaid, and State Health Care Programs. Title, Sections 1001.1, 1001.2, 1001.101, 1001.102, 1001.201, 1001.301, 1001.401, 1001.701, 1001.1301, 1001.1401, 1001.1901, 1001.3002, 1001.3005

We propose to change the title of part 1001 from ''Medicare and State health care programs'' to ''The Federal health care programs'' because the statutory basis for many of the OIG authorities in part 1001 derives from section 1128 of the Act, which references ''Federal health care program,'' a defined term that includes (and is broader than) Medicare and State health care programs, as described above. Similarly, we propose removing references to Medicare and Medicaid in variations of the phrase ''Medicare, Medicaid and all other Federal health care programs'' throughout part 1001, because the statutorily defined term ''Federal health care program'' encompasses Medicare and Medicaid. We are proposing to remove the references to Medicare and Medicaid in the following sections: 1001.1(a), 1001.101(b), 1001.401(c)(2)(ii), 1001.701(d)(2)(iv), 1001.1301(b)(2)(iii), 1001.1401(b)(1), 1001.1401(b)(4); 1001.1901(a), 1001.1901(b)(1), 1001.1901(c)(3), and 1001.1901(c)(5)(i), 1001.3002(b)(3), and 1001.3005(a). We also propose corresponding technical changes to the phrases in those sections to account for the removal of the references to Medicare and Medicaid. Neither the removal of the references to Medicare and Medicaid, nor the technical conforming changes, are meant to change the meaning of the phrases to which the changes are made. Finally, we propose to modernize the pronouns throughout part 1001 and make corresponding grammatical edits.

Section 1001.2 Definitions

We propose deleting the definition of ''Controlled substance'' from 1001.2 because the relevant regulations at §§ 1001.101(d) and 1001.401 already indicate that the term ''controlled substance'' is being used as defined in Federal or State law, so the definition of ''Controlled substance'' in § 1001.2 is unnecessary. We also propose to move certain definitions from § 1001.2 to § 1000.10 and modify them as described above.

Section 1001.101 Basis for Liability

In § 1001.101(c) and (d), we propose to remove the date limitation of August 21, 1996. The date limitation was included because when HIPAA amended section 1128 of the Act to add new exclusion authorities in sections 1128(a)(3) and (a)(4) of the Act, it specified that only convictions after August 21, 1996 (the date of HIPAA's enactment) would be subject to the exclusion authorities in those subsections. We are proposing to delete the date limitation in the corresponding regulatory authorities in § 1001.101(c) and (d) because it is now obsolete. We believe that this change will not impact any future exclusions because virtually all criminal offenses before August 21, 1996, are now time-barred from prosecution.

Section 1001.101(c)(2) states ''with respect to any act or omission in a health care program (other than Medicare and a State health care program). . . .'' We propose to make a technical change from the word ''and'' to the word ''or'' in the parenthetical for grammatical accuracy. Similar language appears in § 1001.201(a)(1)(ii). We propose the same technical change for that section for grammatical accuracy.

Aggravating Factors

When OIG imposes an exclusion under section 1128(a), the minimum period of the exclusion is required by statute to be at least 5 years. However, under the regulations the length of an exclusion may be extended beyond the 5-year minimum period if certain aggravating factors, as defined in the regulations, are present. OIG exclusions under certain permissive authorities in section 1128(b) are for a period of 3 years but may be lengthened if certain aggravating factors (again, as defined in the regulations) are present. This section discusses proposed changes to these aggravating factors.

Financial Loss

The financial loss aggravating factor at § 1001.102(b)(1) currently reads as follows: ''The acts resulting in the conviction, or similar acts, caused, or were intended to cause, a financial loss to a government agency or program or to one or more other entities of $50,000 or more. (The entire amount of financial loss to such government agencies or programs or to other entities, including any amounts resulting from similar acts not adjudicated, will be considered regardless of whether full or partial restitution has been made).'' A similar aggravating factor appears in §§ 1001.201 and 1001.301. We believe that the language of this factor should be consistent in each place it appears to avoid any question about whether court decisions interpreting it under one section should apply to its application under other sections. Therefore, we propose two technical changes to § 1001.102(b)(1) to match the language of this factor as it appears in §§ 1001.201(b)(2)(i) and 1001.301(b)(2)(viii): to move the phrase ''of $50,000 or more'' to after ''a financial loss,'' and to delete the phrase in the parenthetical ''to such government agencies or programs or to other agencies'' because it is duplicative of language outside the parenthetical. In §§ 1001.201(b)(2)(i) and 1001.301(b)(2)(viii), we propose to delete the phrase ''or had a significant financial impact on program beneficiaries or other individuals'' because we propose adding this concept to a separate aggravating factor at §§ 1001.201(b)(2)(iii) and 1001.301(b)(2)(ii) as described in the next paragraph.

Impact on Beneficiaries and Other Individuals

Section 1001.102(b)(3), applicable to mandatory exclusions, includes as an aggravating factor whether the acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental, or financial impact on one or more program beneficiaries or other individuals. A similar aggravating factor applies to certain permissive exclusions under §§ 1001.201 and 1001.301, but

those sections do not reference ''financial'' impact. In §§ 1001.201(b)(2)(iii) and 1001.301(b)(2)(ii), we propose to add ''or financial'' to the aggravating factor relating to impact on program beneficiaries and other individuals. We believe it is appropriate to consider all impacts on beneficiaries under the same aggravating factor. This change would make this aggravating factor consistent with a similar factor applicable to mandatory exclusions under § 1001.102(b)(3) and would move the analysis of financial impact on beneficiaries from the aggravating factor relating to financial loss (discussed above) to the aggravating factor relating to impact on beneficiaries.

In § 1001.301(b)(2)(ii), the aggravating factor is applied to convictions related to obstruction of an investigation or audit under section 1128(b)(2) of the Act. We are proposing language changes to this factor because we believe it is important to apply similar factors consistently in all applicable exclusions. Consistent language ensures that judicial interpretations of certain language will be applicable wherever the language appears, and that the public can reasonably expect OIG to apply the factors consistently. Therefore, we propose to replace the words ''interference or obstruction'' with ''acts that resulted in the conviction.'' When referring to the conduct leading to a conviction, other sections of the regulation use the word ''acts,'' and interference or obstruction are the ''acts'' at issue in the exclusion authority related to convictions for obstruction.

For the same reason, in § 1001.401(c)(2)(ii), which applies this aggravating factor to misdemeanor convictions relating to controlled substances, we propose to reorder the words ''mental, physical or financial impact'' to ''physical, mental, or financial impact'' for consistency with the language as it appears in this factor in other sections of the regulation. Neither of these modifications are intended to change the substance of this aggravating factor in either § 1001.301 or § 1001.401; instead, these changes are intended to simplify the regulations by using consistent language across various sections where the same meaning is intended.

Convictions Involving Patient Abuse and Neglect

Section 1001.102(b) includes the following as an aggravating factor: ''In convictions involving patient abuse or neglect, the action that resulted in the conviction was premeditated, was part of a continuing pattern of behavior, or consisted of non-consensual sexual acts.'' *See* § 1001.102(b)(4). We propose a technical change to change ''action'' to ''acts'' for consistency with § 1001.102(b)(1) through (3). We propose additional conforming and technical changes to § 1001.102(b)(4) to account for the grammatical change from ''action'' to ''acts'' so that the new language would read as follows: ''In convictions involving patient abuse or neglect, the acts that resulted in the conviction were premeditated, were part of a continuing pattern of behavior, or consisted of non-consensual sexual acts.'' These changes to § 1001.102(b)(4) are not meant to change the meaning of the phrases to which the changes are made.

Criminal, Civil, and Administrative Sanctions

We propose to modify the aggravating factors relating to criminal, civil, and administrative sanctions. For mandatory exclusions, the regulations contain four separate factors that can be overlapping: ''The convicted individual or entity has a prior criminal, civil or administrative sanction record'' (§ 1001.102(b)(6)); ''The individual or entity has previously been convicted of a criminal offense involving the same or similar circumstances'' (§ 1001.102(b)(7)); ''The individual or entity has been convicted of other offenses besides those that formed the basis for the exclusion'' (§ 1001.102(b)(8)); and ''The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion'' (§ 1001.102(b)(9)). We propose to modify these factors to clarify how OIG would consider other civil, criminal, or administrative actions involving the excluded person for purposes of setting the period of exclusion.

First, we propose to modify § 1001.102(b)(6) to replace the phrase ''a prior'' with ''other documented instances'' and replace ''sanction record'' with ''wrongdoing.'' The proposed revised language would read as follows: ''The individual or entity has other documented instances of criminal, civil, or administrative wrongdoing.'' This proposed language is intended to encompass any documented instances of other criminal, civil, or administrative wrongdoing, including convictions that occurred before, at the same time as, or after the conviction forming the basis for exclusion. OIG may place greater emphasis on this aggravating factor in determining the appropriate period of exclusion if multiple documented instances exist (*e.g.,* an individual or entity has a prior conviction, the individual or entity was found liable under the False Claims Act, or a licensing authority imposed a sanction on the individual's or entity's license to provide health care).

Second, we propose to remove § 1001.102(b)(7) and (8) because they are duplicative of proposed § 1001.102(b)(6). Both a previous conviction of a criminal offense involving the same or similar circumstances (§ 1001.102(b)(7)) and a conviction for other offenses besides those that formed the basis for the exclusion (§ 1001.102(b)(8)) would be included in the proposed aggravating factor for other documented instances of criminal, civil, or administrative wrongdoing in § 1001.102(b)(6).

Third, we propose to remove the aggravating factor relating to ''any other adverse action'' in § 1001.102(b)(9) because it would be unnecessary with the new proposed language in § 1001.102(b)(6). Adverse actions by Federal, State, or local government agencies and boards would be included in other documented instances of administrative wrongdoing under proposed § 1001.102(b)(6).

For permissive exclusions, the regulations contain three separate aggravating factors relating to civil, criminal, and administrative sanctions that can be overlapping: (1) ''Whether the individual or entity has a documented history of criminal, civil, or administrative wrongdoing;'' (2) ''Whether the individual or entity has been convicted of other offenses besides those that formed the basis for the exclusion;'' and (3) ''Whether the individual or entity has been the subject of any other adverse action by any Federal, State, or local government agency or board if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.'' *See, e.g.,* § 1001.201(b)(2)(v) through (vii). One or more of these three aggravating factors, with some language variations (as addressed below) also appear in §§ 1001.301, 1001.401, 1001.701, 1001.801, 1001.901, 1001.951, 1001.1101, 1001.1201, 1001.1301, 1001.1552, 1001.1601, and 1001.1701. We intend the proposed changes described below to clarify how OIG would consider other civil, criminal, and administrative sanctions involving an excluded person for purposes of setting the length of exclusion.

First, we propose to modify §§ 1001.201(b)(2)(v), 1001.301(b)(2)(v),

1001.401(c)(2)(iv), 1001.701(d)(2)(iii), 1001.801(c)(2)(iv), 1001.901(b)(3), 1001.951(b)(1)(iii), 1001.1101(b)(3), 1001.1201(b)(4), 1001.1301(b)(2)(iv), 1001.1401(b)(5), 1001.1552(d)(3), 1001.1601(b)(1)(iv), and 1001.1701(c)(1)(v) to make the first of the three aggravating factors referenced above consistent in each section, as ''The individual or entity has other documented instances of criminal, civil, or administrative wrongdoing.'' The proposed language is intended to encompass any documented instances of other criminal, civil, or administrative wrongdoing, including convictions that occurred before, at the same time as, or after the conviction forming the basis for exclusion. OIG may place greater emphasis on this aggravating factor in determining the appropriate period of exclusion if multiple documented instances exist (*e.g.,* an individual or entity has a prior conviction, the individual or entity was previously found liable under the False Claims Act, or a licensing authority imposed a sanction on the individual's or the entity's license to provide health care).

Several of the permissive exclusion authority sections (§§ 1001.901, 1001.951, 1001.1101, 1001.1201, 1001.1301, 1001.1401, 1001.1601, and 1001.1701) include a parenthetical stating that ''the lack of any prior record is to be considered neutral.'' In these sections, we propose to replace ''lack'' with ''absence'' to increase readability and ''prior record'' with ''such instances'' for consistency within the factor. In § 1001.1401(b)(5), the proposed language would use ''hospital'' instead of ''individual or entity,'' as that section applies to hospitals only. In §§ 1001.1601(b)(1)(iv) and 1001.1701(c)(1)(v), the proposed language would use ''physician'' instead of ''individual or entity,'' as those sections apply to physicians only. The change from ''lack'' to ''absence'' is not meant to change the meaning of the phrase to which the change is made. Lastly, in §§ 1001.201(b)(2)(v), 1001.301(b)(2)(v), 1001.401(c)(2)(iv), 1001.701(d)(2)(iii), and 1001.801(c)(2)(iv), the proposed language would remove the word ''whether'' at the beginning of this factor, as the word is extraneous. This technical change is not meant to change the meaning of the phrases to which the changes are made. In § 1001.801(c)(2)(iv), which currently reads, ''Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing,'' we propose to remove the words ''Whether the individual or'' because this authority only applies to entities.

Second, we propose to remove the second aggravating factor discussed above (whether the individual or entity has been convicted of other offenses besides those that formed the basis for the exclusion) found in §§ 1001.201(b)(2)(vi), 1001.301(b)(2)(vi), and 1001.401(c)(2)(v) as duplicative of the proposed aggravating factor in §§ 1001.201(b)(2)(v), 1001.301(b)(2)(v), and 1001.401(c)(2)(iv), described in the preceding paragraph. A conviction for other offenses besides those that formed the basis for the exclusion would be included in the proposed aggravating factor for other documented instances of criminal, civil, or administrative wrongdoing.

We also propose to remove the aggravating factor relating to ''any other adverse action'' in §§ 1001.201(b)(2)(vii), 1001.301(b)(2)(vii), 1001.401(c)(2)(vi), 1001.701(d)(2)(v), 1001.801(c)(2)(v), 1001.901(b)(4), and 1001.951(b)(iv) because it would be unnecessary. Adverse actions by Federal, State, or local government agencies and boards would be included in other documented instances of administrative wrongdoing under the proposed changes to §§ 1001.201(b)(2)(v), 1001.301(b)(2)(v), 1001.401(c)(2)(iv), 1001.701(d)(2)(iii), 1001.801(c)(2)(iv), 1001.901(b)(3), 1001.951(b)(1)(iii), 1001.1101(b)(3), 1001.1201(b)(4), 1001.1301(b)(2)(iv), 1001.1552(d)(3), 1001.1601(b)(1)(iv), and 1001.1701(c)(1)(v). We propose technical changes renumbering § 1001.901(b)(5) to § 1001.901(b)(4) and technical changes to the other sections to account for the deletions described above.

Effect on Civil and Administrative Investigations

The exclusion authority in section 1128(b)(2) of the Act and in § 1001.301, in part, allows OIG to exclude for convictions for obstruction of or interference with investigations related to the use of funds received from the Federal health care programs. We propose to remove the aggravating factors at § 1001.301(b)(2)(i) (the interference or obstruction caused the expenditure of significant additional time and resources) and § 1001.301(b)(2)(iii) (the interference or obstruction also affected a civil or administrative investigation). We propose removing § 1001.301(b)(2)(i) because in our experience the subjectivity of the language makes it challenging to apply consistently. We propose removing § 1001.301(b)(2)(iii) because it is OIG's position that this exclusion authority already includes administrative and civil investigations in the scope of the term ''investigations.'' We are concerned that including a separate aggravating factor at § 1001.301(b)(2)(iii) where the interference or obstruction affected a civil or administrative investigation could be misconstrued as suggesting that the exclusion authority does not include civil and administrative investigations. Also, the application of this factor in matters where the obstruction or interference occurred in a civil or administrative investigation would be duplicative of the statutory basis for exclusions under section 1128(b)(2) of the Act. To avoid confusion, we propose to remove this aggravating factor. Lastly, we propose to renumber the aggravating factors consistent with the proposed changes described above.

Nature of Violations, Length of Scheme, and Impact on Beneficiaries

We propose to modify the aggravating factor at § 1001.701(d)(2)(i) for exclusions related to excessive claims or furnishing of unnecessary or substandard care. The aggravating factor currently reads ''the violations were serious in nature, and occurred over a period of one year or more.'' We propose to replace the phrase ''violations were serious in nature, and'' with ''conduct.'' The severity of the conduct is considered under the impact on beneficiaries aggravating factor at § 1001.701(d)(2)(ii) (''the violations had a significant adverse physical, mental or financial impact on program beneficiaries or other individuals'') and does not also need to be separately considered under the length of scheme factor at § 1001.701(d)(2)(i). We also propose to modify the aggravating factor at § 1001.701(d)(2)(ii), by replacing the word ''violations'' with ''conduct.''

Finally, we propose to modify the aggravating factor at § 1001.701(d)(2)(iv), which currently reads, ''The violation resulted in financial loss to Medicare, Medicaid, or any other Federal health care program of $15,000 or more'' to change ''violation'' to ''conduct,'' to increase the amount of financial loss from $15,000 to $50,000, and to change ''Medicare, Medicaid, or any other Federal health care program'' to ''any Federal health care program'' as described above.

The use of the word ''conduct'' in this section reflects that § 1001.701 contemplates behavior that may not be easily characterized as a set of identifiable violations or acts, such as the provision of health care that, over time or in one instance, may be of a

quality that fails to meet professionally recognized standards of health care. Also, the change in the financial loss amount makes this section consistent with §§ 1001.102(b)(1), 1001.201(b)(2)(i), and 1001.301(b)(2)(viii) (proposed to become § 1001.301(b)(2)(i)) and reflects that the passage of time and inflation have increased the average amount of financial loss to the Federal health care programs in fraud schemes.

Serious Adverse Effect

We propose technical changes to § 1001.801(c)(2)(iii), for exclusions relating to the failure of health maintenance organizations to furnish medically necessary care. For § 1001.801(c)(2)(iii), which currently reads, ''The entity's failure to provide a necessary item or service that had or could have had a serious adverse effect,'' we propose to remove ''that'' after ''service'' as an unnecessary word that causes the language to be confusing and grammatically incorrect (and therefore difficult to apply). The revised language would read: ''The entity's failure to provide a necessary item or service had or could have had a serious adverse effect.''

Mitigating Factors

When OIG is determining the length of exclusion for a mandatory exclusion with a minimum exclusion period of 5 years, if any of the aggravating factors described in the regulations are present and result in a period of exclusion longer than 5 years, OIG may consider the mitigating factors specified in the regulations as a basis for reducing the period of exclusion to no less than 5 years. For exclusions imposed under the permissive authorities with a baseline period of 3 years (§§ 1001.201, 1001.301, and 1001.401) the presence of any of the mitigating factors specified in the regulations may provide a basis for shortening the period of exclusion. Proposed changes to some of these mitigating factors are described below.

We propose to remove §§ 1001.102(c)(1) and 1001.201(b)(3)(i), which are mitigating factors for situations in which a person was convicted of three or fewer misdemeanors and caused less than $5,000 of loss. First, in our experience, this factor is very rarely present in mandatory exclusion cases that present aggravating factors warranting an exclusion period longer than the minimum period of 5 years. Second, we question whether it is appropriate to shorten an exclusion for conduct involving patient harm, a criminal scheme that extended beyond 1 year, an individual or entity with a record of additional sanctions, or conduct that warranted incarceration, simply because the person was convicted of three or fewer misdemeanors. Third, in the case of permissive exclusions under § 1001.201 we believe this factor should be considered by OIG in determining whether a permissive exclusion should be imposed, but not whether to reduce the length of exclusion.

Reduced Culpability

Sections 1001.102(c)(2), 1001.201(b)(3)(ii), and 1001.301(b)(3)(i) describe a mitigating factor that considers whether the record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional, or physical condition before or during the commission of the offense that reduced the individual's culpability.

We propose to revise §§ 1001.102(c)(2), 1001.201(b)(3)(ii), and 1001.301(b)(3)(i) to remove the phrase ''including sentencing documents'' because those documents are clearly part of the record in the criminal proceedings. We also propose to delete the phrase ''mental, emotional or physical'' prior to ''condition'' to allow OIG to consider any condition that a court determines to have reduced an individual's culpability. We also propose to renumber the remaining paragraphs accordingly.

Addition of Mitigating Factor to § 1001.401

In § 1001.401(c)(3), we propose to add a mitigating factor relating to whether a court determined that the excluded individual had a condition that reduced their culpability for the underlying criminal offense. Section 1001.401 permits OIG to exclude individuals or entities convicted of misdemeanors related to controlled substances, while § 1001.101(d) mandates OIG exclude individuals and entities for felonies related to controlled substances. The mandatory authority permits consideration of a mitigating factor relating to whether a court determined that the excluded individual had a condition that reduced their culpability for the underlying criminal offense (currently § 1001.102(c)(2)). We propose adding the same factor to § 1001.401 because we believe it is appropriate to consider the same mitigating circumstances under the permissive authority and the mandatory authority.

Cooperation

Sections 1001.102(c)(3), 1001.201(b)(3)(iii), 1001.301(b)(3)(ii), and 1001.401(c)(3) include a mitigating factor that reads as follows: ''The individual's or entity's cooperation with Federal or State officials resulted in—(A) Others being convicted or excluded from Medicare, Medicaid, and all other Federal health care programs, (B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or (C) The imposition of a civil money penalty against others.'' We propose to revise §§ 1001.102(c)(3), 1001.201(b)(3)(iii), 1001.301(b)(3)(ii), and 1001.401(c)(3) to allow the mitigating factor of cooperation to be demonstrated based on the record in the criminal proceedings or a written statement by a government official that demonstrates that the individual's or entity's cooperation resulted in other individuals or entities being excluded, indicted, or otherwise charged, convicted, or investigated. Under the proposed language, the application of the cooperation mitigating factor would be based on documentation provided by an official involved in the underlying criminal proceedings rather than OIG's later independent assessment of the criminal proceedings. In OIG's experience, it is not always possible to obtain court records relating to cooperation because they may be sealed or otherwise unavailable at the time the exclusion is processed. In addition, the proposed language would broaden the first criteria for cooperation (*i.e.,* the cooperation resulted in others being convicted or excluded) to include circumstances in which others have been indicted or otherwise charged or investigated. In OIG's experience, subjects have not relied on reports being issued by law enforcement agencies identifying program vulnerabilities or weaknesses, or civil monetary penalties being imposed against other individuals or entities as a basis to demonstrate cooperation, so we are proposing to remove those criteria.

Alternative Sources of Health Care Items and Services Mitigating Factor

We propose to delete §§ 1001.201(b)(3)(iv) and 1001.301(b)(3)(iii), a mitigating factor applicable to exclusions related to misdemeanor convictions for health care fraud and convictions for obstruction. The factor allows OIG to consider whether alternative sources of the type of health care items or services furnished by the individual or entity are not available. We propose to remove this factor from these two sections because we believe this factor should be considered by OIG in determining

whether a permissive exclusion should be imposed and whether a waiver is appropriate but does not relate to the length of exclusion. Therefore, we propose removing this mitigating factor.

Few Violations Over a Short Period of Time Mitigating Factor

We propose to modify § 1001.701(d)(3), which currently reads: ''Only the following factor may be considered mitigating and a basis for reducing the period of exclusion: Whether there were few violations and they occurred over a short period of time,'' to read as follows: ''Only the following factor may be considered mitigating and a basis for reducing the period of exclusion: Whether there were few occurrences of the conduct, and the conduct occurred over a short period of time.'' This change makes this section consistent with the changes from ''violations'' to ''conduct'' in § 1001.701(d)(2) discussed above.

Other Changes to § 1001.102 (Length of Exclusion)

Section 1001.102(d) describes the requirement, added by HIPAA, that OIG impose exclusions for at least 10 years or permanently in certain situations involving multiple criminal convictions. We propose to modify § 1001.102(d) to remove the reference to August 5, 1997, in the flush language, as unnecessary because virtually all criminal offenses before August 5, 1997, are now time-barred from prosecution.

We propose a technical modification to § 1001.102(d)(1) and (2) to replace ''effected'' with ''imposed'' for consistency with § 1001.102(a), which references exclusions being imposed. The revision is not intended to change the meaning of § 1001.102(d)(1) and (2). In § 1001.102(d)(1), we propose to revise the parenthetical language (which allows OIG to lengthen exclusions beyond 10 years if aggravating and mitigating factors are present) to remove the reference to mitigating factors because only aggravating factors can be used to impose a period of more than 10 years.

Section 1001.401 Conviction Relating to Controlled Substances

We propose removing § 1001.401(b), which states ''the definition of controlled substance will be the definition that applies to the law forming the basis for the conviction,'' because it is unnecessary. This definition is already incorporated into § 1001.401(a) by the phrase ''as defined under Federal or State law.'' In other words, the definition of controlled substance will be based on the Federal or State law under which the individual or entity is convicted. We also propose corresponding technical changes renumbering § 1001.401(c) to § 1001.401(b).

Section 1001.501 Exclusions Based on the Loss or Suspension of a Health Care License

We propose removing the aggravating factors outlined in § 1001.501(b)(2), which permit OIG to lengthen periods of exclusion based on the loss of the individual's or entity's health care license, and the mitigating factors outlined in § 1001.501(b)(3), which could be considered by OIG if aggravating factors are applied. Because exclusions under section 1128(b)(4) of the Act are derivative of a licensing board action, OIG generally imposes exclusions under this section for the same period of time as that of the licensing board's action. As a result, an individual is generally eligible for reinstatement once they regain the health care license on which the exclusion is based. Our proposed removal of these aggravating and mitigating factors would make the regulations consistent with OIG's general practice of imposing exclusions under this section that are the same length as the licensing board actions. We propose corresponding technical changes by renumbering § 1001.501(b)(4) to § 1001.501(b)(2) and modifying the flush language at § 1001.501(b)(1) to remove language referring to § 1001.501(b)(2).

We are also proposing adding the word ''surrendered'' to § 1001.501(b)(1) so that this section addresses all the bases upon which an exclusion may be imposed under this section, which includes when an individual's or entity's license is revoked, suspended, surrendered, or otherwise lost. *See* section 1128(b)(4)(B) of the Act.

We also propose changes to § 1001.501(c). In 2017, OIG published a Final Rule implementing a process that allows individuals and entities excluded under section 1128(b)(4) of the Act to request reinstatement before regaining the license that was lost and on which the exclusion is based (referred to as ''early reinstatement'') under two sets of circumstances. 82 FR 4100, 4105 (Jan. 12, 2017). We propose modifications to both sets of circumstances.

First, under § 1001.501(c)(1), an individual or entity excluded under § 1001.501 can apply for reinstatement if, after fully and accurately disclosing the circumstances surrounding the original license action that formed the basis for the exclusion, the individual or entity obtained a health care license in another State or a different health care license in the same State, or was allowed to retain a health care license in another State or a different health care license in the same State. We discuss proposed changes to this section below.

Second, under § 1001.501(c)(2), a person excluded under this section could request early reinstatement if they did not have a valid license to provide health care of any kind, based on OIG's consideration of several factors outlined in the regulation. One of these factors is the length of time the person has been excluded. The regulation states that OIG will apply a presumption against early reinstatement if the individual or entity has been excluded for less than 3 years and, if the revocation or suspension on which the exclusion was based was for a set period of longer than 3 years, the presumption against reinstatement would be coterminous with the period set by the licensing board.

We propose modifying § 1001.501(c)(2)(i) to state that, rather than applying a presumption against early reinstatement for persons who are excluded less than 3 years, OIG will not consider a request for early reinstatement submitted by an individual or entity if such individual or entity has been excluded for less than 3 years. We think this change is appropriate because the statute provides a 3-year baseline period in certain other permissive exclusion authorities (§§ 1001.201, 1001.301, and 1001.401). The proposal would further modify the language in the second clause of the second sentence of § 1001.501(c)(2)(i). This clause of § 1001.501(c)(2)(i) states that if the action on which the exclusion is based is for a set period longer than 3 years, OIG will apply a presumption against early reinstatement ''coterminous with the period set by the licensing board.'' We propose to modify this language to state that when the action underlying the exclusion is for a set period longer than 3 years, OIG will not consider a request for early reinstatement at any time before the expiration of the period set by the licensing board. We believe this change is appropriate because the period of exclusion should be at least as long as the period of the underlying action.

At § 1001.501(c)(3), the early reinstatement regulation includes a bar to early reinstatement for individuals excluded under this section whose license revocation or suspension was for reasons related to patient abuse or neglect. We propose to modify this prohibition. In OIG's experience, the bar has the unintended consequence of

creating a permanent period of exclusion for certain individuals and entities who have been excluded under § 1001.501 due to a license revocation or suspension related to patient abuse or neglect, unless that individual or entity has regained the original license. This *de facto* permanent bar to reinstatement creates an imbalance between mandatory and permissive exclusion because individuals and entities that have been convicted of an offense related to the neglect or abuse of a patient and excluded under section 1128(a)(2) of the Act are eligible to apply for reinstatement at the end of their period of exclusion, which may be the statutory minimum period of 5 years. OIG recognizes that the loss of a professional license for issues related to patient abuse or neglect is significant and the circumstances of the loss of such license in those instances should be taken into consideration in determining whether early reinstatement should be granted. Therefore, we propose to modify § 1001.501(c)(1)(i) and (ii) such that, in reviewing requests for early reinstatement, OIG will consider the circumstances that formed the basis for the exclusion, including whether such circumstances were related to patient abuse or neglect. In addition, we propose to modify this section to require that, in the case of a license revocation or suspension for reasons related to patient abuse or neglect, OIG will not consider a request for early reinstatement until the individual or entity has been excluded for at least 5 years for parity with those excluded for the statutory minimum period of 5 years for a conviction related to the neglect or abuse of a patient.

We also propose several clarifying changes throughout § 1001.501(c). These changes are not intended to change the meaning of § 1001.501 but are intended to make the language clearer based upon our experience implementing this section since 2017. We propose to add references to ''entity'' every time the word ''individual'' is used in § 1001.501 to clarify that, consistent with section 1128(b)(4) of the Act, entities as well as individuals are subject to exclusion under this section. In § 1001.501(c)(1)(iii), we propose replacing ''Evidence that'' with ''Documentation from'' to clarify that OIG expects documentation from the second licensing authority and not evidence from a proceeding with that authority. We also propose adding ''indicating that it'' after ''second licensing authority'' to clarify that the documentation must indicate that the licensing authority knew of the circumstances surrounding the action that formed the basis for the exclusion. In § 1001.501(c)(1)(iv), we propose removing ''satisfactorily'' and adding ''to OIG's satisfaction'' after ''has demonstrated'' to clarify that whether the individual or entity has resolved any underlying problem is in the opinion of OIG and not the excluded party. We propose a nearly identical change in § 1001.501(c)(2)(iii) for the same reason.

Section 1001.601 Exclusion or Suspension Under a Federal or State Health Care Program

We propose a technical change to § 1001.601(a)(1)(ii) to offset the phrase ''for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity,'' as it applies to both circumstances under § 1001.601(a)(1). As currently written, the phrase could be read to modify only § 1001.601(a)(1)(ii), referring to actions by State health care programs, but the statute clearly requires that this clause apply to all exclusions under section 1128(b)(5) of the Act.

We propose revising § 1001.601(a)(2) by replacing the phrase ''is intended to cover'' with ''means'' to clarify that ''otherwise sanctioned'' is limited to the definition provided (and does not include anything else). We also propose adding the phrase ''or otherwise sanctioned'' to § 1001.601(b)(1) for consistency with § 1001.601(a)(1) and section 1128(b)(5) of the Act, and changing the word ''from'' to ''by'' for grammatical accuracy.

We propose removing the aggravating and mitigating factors outlined in § 1001.601(b)(2) and (3), which permit OIG to lengthen periods of exclusion based on an individual's or entity's exclusion, suspension, or other sanction by a Federal or State health care program, so that all exclusions under this section would be coterminous with the period of time that the individual or entity is excluded, suspended, or otherwise sanctioned by the applicable Federal or State health care program. Because exclusions under section 1128(b)(5) of the Act are derivative of a Federal or State health care program action, OIG generally imposes exclusions under this section for the same period of time as the agency's action. As a result, individuals and entities are generally eligible to apply for reinstatement once the individual or entity is allowed to resume participation in the Federal or State health care program under which the individual or entity was previously suspended, excluded, or sanctioned. Our proposed removal of these aggravating and mitigating factors would make the regulations consistent with OIG's general practice under this section and clarifies our intention. Due to the removal of § 1001.601(b)(2) and (3), we propose a technical change renumbering § 1001.601(b)(4) to § 1001.601(b)(2).

Section 1001.901 False or Improper Claims

In § 1001.901(b), we propose to change ''will'' to ''may'' to reflect OIG's discretion to consider only the factors that are appropriate according to the facts and circumstances of each case and to reflect that not every factor will be present in every case.

Section 1001.951 Fraud and Kickbacks and Other Prohibited Activities

We propose several changes to § 1001.951 to align the factors with those found in the proposed revisions to § 1001.901. These two sections should align because both authorities are based on section 1128(b)(7) of the Act and require OIG to affirmatively prove fraud, kickbacks, or other prohibited activities. Because neither authority is derivative of other actions taken by adjudicative bodies, aligning the factors for determining length of exclusions under § 1001.951 with the factors under § 1001.901 would create parity and provide OIG discretion to consider relevant facts and circumstances under both authorities that are not derivative of the actions of other courts or adjudicative bodies, as is appropriate for derivative exclusions.

Specifically, to align §§ 1001.951 and 1001.901, we are proposing a series of revisions and technical changes, which collectively will result in both authorities having the same factors for determining length of exclusion, as follows. We propose to remove the numbering for § 1001.951(b)(1) to make it flush language and to revise the language to mirror the proposed language in proposed § 1001.901(b) by changing ''will'' to ''may.'' We propose to modify the numbering of the factors to change the factor at § 1001.951(b)(1)(i) to § 1001.951(b)(1) and to modify the language to mirror § 1001.901(b)(1). The proposed language would read: ''The nature and circumstances surrounding the actions that are the basis for liability, including the period of time over which the acts occurred, the number of acts, whether there is evidence of a pattern and the amount claimed.''

We propose to delete the factor at § 1001.951(b)(1)(ii), which is not a factor in § 1001.901(b). We propose to add a factor at new § 1001.951(b)(2), ''the

degree of culpability,'' which appears at § 1001.901(b)(2). We propose to change the numbering of § 1001.951(b)(1)(iii) (related to other documented instances of wrongdoing) to § 1001.951(b)(3) and modify its language consistent with proposed § 1001.901(b)(3) and the other places this language appears in part 1001 as described above. We propose to add new § 1001.951(b)(4), ''Other matters as justice may require,'' consistent with the proposed § 1001.901(b)(4). We further propose to remove the factors at § 1001.951(b)(1)(iv) and (v) and remove the mitigating factors at § 1001.951(b)(2) to align § 1001.951 with § 1001.901. Removal of mitigating factors under this section is appropriate because the factors proposed for § 1001.951 allow OIG to consider all the relevant facts and circumstances, aggravating and mitigating, in setting lengths of exclusion under this section.

Section 1001.1301 Failure To Grant Immediate Access

This section provides OIG with the authority to exclude individuals and entities that fail to grant immediate access to, among others, OIG or a State MFCU. Section 1001.1301(a)(2) currently defines a ''failure to grant immediate access'' for purposes of paragraphs (a)(1)(i) and (ii) of this section (applying to requests for immediate access by the Secretary or a State survey agency) as ''the failure to grant access at the time of a reasonable request or to provide a compelling reason why access may not be granted.'' The regulation does not explain what circumstance would constitute ''a compelling reason.''

We propose to revise the definition of ''failure to grant immediate access'' in § 1001.1301(a)(2) to specify what would constitute ''a compelling reason,'' namely, that the requested material does not exist or is not at the location where the request is presented. The proposed language is consistent with OIG's general practice in evaluating immediate access requests.

Section 1001.1301(a)(3) provides a separate definition of ''failure to grant immediate access'' for purposes of paragraphs (a)(1)(iii) and (iv) of the section (applying to requests for immediate access by OIG and State MFCUs) as ''(i) The failure to produce or make available for inspection and copying the requested material upon reasonable request, or to provide a compelling reason why they cannot be produced, within 24 hours of such request, except when the OIG or State Medicaid Fraud Control Unit (MFCU) reasonably believes that the requested material is about to be altered or destroyed, or (ii) When the OIG or MFCU has reason to believe that the requested material is about to be altered or destroyed, the failure to provide access to the requested material at the time the request is made.'' We propose to revise this section so that the definition of ''failure to grant immediate access'' for purposes of § 1001.1301(a)(1)(iii) and (iv) is consistent with the proposed definition of ''failure to grant immediate access'' for purposes of § 1001.1301(a)(1)(i) and (ii). The impact of this change would be that all immediate access requests will require production of materials at the time the request is made unless the records do not exist or are in a different location and would eliminate the analysis of whether records are about to be altered or destroyed. We believe this change is appropriate because it is consistent with the common meaning of ''immediate'' as requiring something instantly or without delay, and it removes the burden from the requesting agency to determine whether records may be altered or destroyed in the intervening 24 hours, which may be impossible to know.

Section 1001.1501 Default of Health Education Loan or Scholarship Obligations

Section 1128(b)(14) of the Act, which authorizes OIG to exclude individuals who default on repayments of health education loan or scholarship obligations, or the obligations of any loan repayment program, requires OIG to take into account ''access of beneficiaries to physician services for which payment may be made under title XVIII or XIX.'' [1] Section 1001.1501(a)(3) of the regulations expands this requirement to access to physicians' services for which payment may be made under Medicare, Medicaid, or other Federal health care programs, expanding OIG's obligations beyond Medicare and Medicaid. As a result, we propose modifying § 1001.1501(a)(3) to limit the requirement in this section to the Medicare and Medicaid programs, consistent with section 1128(b)(14) of the Act. We propose a technical modification to § 1001.1501(a)(3) to replace ''physicians' services'' with ''physician services'' for consistency with section 1128(b)(14) of the Act. The revision is not intended to change the meaning of § 1001.1501(a)(3).

Next, § 1001.1501(b) indicates that an individual excluded under this section will remain excluded until OIG receives notice that the individual has cured the payment default that provided the basis for the exclusion, at which time OIG notifies the individual that the individual is eligible to apply for reinstatement. However, it has been OIG's longstanding practice to allow individuals excluded under this section to participate in the Federal health care programs prior to their health education loan or scholarship obligation being completely repaid if such individual has entered into a repayment agreement with the administrator of the health education loan, scholarship, or loan repayment program following an initial payment default. We propose modifying § 1001.1501(b) so that an individual who has entered into such repayment agreements would be eligible to obtain a ''stay'' of their exclusion for as long as the individual remains in compliance with the terms of the agreement. While this ''stay'' is in place, the individual would be eligible to participate in the Federal health care programs. However, if OIG receives notice from the administrator of the health education loan, scholarship, or loan repayment program that the individual is no longer in compliance with the repayment agreement, the ''stay'' would be lifted and the exclusion would be given full effect. This proposed change would make the regulations consistent with OIG's current practice.

Section 1001.1551 Exclusion of Individuals With Ownership or Control Interest in Sanctioned Entities

We propose modifying § 1001.1551(b)(2) to change ''Medicare, Medicaid and all other Federal health care programs'' to ''Medicare or a State health care program'' and to remove the phrase ''terminated or'' for consistency with the language of section 1128(b)(15), which does not reference all Federal health care programs or use the word ''terminated.''

We also propose modifying § 1001.1551(c)(1) to clarify that the length of the individual's term of exclusion will be the same as that of the sanctioned entity, regardless of whether the individual terminates their relationship with the sanctioned entity after they have been excluded. For example, if Entity A is excluded by OIG

[1] Section 1128(b)(14) has been used by OIG to exclude borrowers that have defaulted on loans from the Health Education Assistance Loan (HEAL) Program. The HEAL program is a program of Federal insurance of educational loans that were made to graduate students in the fields of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, chiropractic, health administration, and clinical psychology. *See* 34 CFR 681.1. Authorization to fund new HEAL loans expired September 30, 1998. 82 FR 53374 (Nov. 15, 2017). A list of borrowers currently in default can be found at 86 FR 54950 (Oct. 5, 2021).

for a period of 5 years and Person A (who has an ownership interest in Entity A) is excluded by OIG under section 1128(b)(15) of the Act 6 months later, the term of Person A's exclusion will be for 5 years, starting from the effective date of Person A's exclusion. Also, Person A will remain excluded for the entire 5-year term even if Person A divests their ownership interest in Entity A at any point during the 5-year term of Person A's exclusion. It would be inequitable for an individual with knowledge of the conduct that resulted in an entity being excluded by OIG and who had an ownership interest in the entity at the time the conduct occurred to be able to avoid exclusion by divesting their interest after the entity's term of exclusion is imposed.

Section 1001.1553 Establishment of a New Permissive Exclusion Authority

Section 6(d) of MSIAA granted a new permissive exclusion authority to the Secretary under Section 1128(b) of the Act. Under the newly enacted section 1128(b)(17) of the Act, the Secretary may exclude any manufacturer or an officer, director, agent, or managing employee of such manufacturer that knowingly misclassifies a covered outpatient drug under an agreement under section 1927 of the Act, knowingly fails to correct such misclassification, or knowingly provides false information related to drug pricing, drug product information, or data related to drug pricing or drug product information. Accordingly, we propose adding a new § 1001.1553 entitled ''Knowingly misclassifying covered outpatient drugs.'' Under this proposal, OIG would have the authority to exclude any manufacturer (as defined in section 1927 of the Act) or an officer, director, agent, or managing employee of such manufacturer that knowingly misclassifies a covered outpatient drug, knowingly fails to correct such misclassification, or knowingly provides false information to HHS related to drug pricing, drug product information, or data related to drug pricing or drug product information. This exclusion authority applies to covered outpatient drugs supplied by manufacturers under agreements under section 1927 of the Act in effect on or after April 18, 2019. The definitions proposed for § 1000.10 would apply to the terms ''agent,'' ''managing employee,'' and ''knowingly.''

Under this proposal, we would determine the length of exclusion based on five factors consistent with OIG's other non-derivative exclusion authorities in §§ 1001.901 and 1001.951: the nature and circumstances surrounding the actions that are the basis for liability, including the period of time over which the acts occurred, the number of acts, whether there is evidence of a pattern, and the amount claimed; the degree of culpability; whether the entity has other documented instances of criminal, civil, or administrative wrongdoing; or other matters as justice may require. Because this authority requires OIG to prove that the manufacturer knowingly misclassified a drug or made false statements and is not derivative of actions taken by other adjudicative bodies, we believe it is appropriate to apply the same factors to this authority that apply to §§ 1001.901 and 1001.951, which are also non-derivative authorities.

Section 1001.1801 Waivers of Exclusions

We propose deleting the cross-reference to the statutory definition of Federal health care program in § 1001.1801(a) as unnecessary because the term ''Federal health care program'' is defined in § 1000.10. We also propose revising § 1001.1801(d), which currently states that ''if the basis for the waiver ceases to exist, the waiver will be rescinded, and the individual or entity will be excluded for the period remaining on the exclusion, measured from the time the exclusion would have been imposed if the waiver had not been granted,'' to state: ''If the basis for the waiver ceases to exist, the waiver will be rescinded.'' The existing reference to ''the time the exclusion would have been imposed if the waiver had not been granted'' implies that the waiver stops the exclusion from being imposed; however, exclusions typically are imposed prior to a waiver being put in place. We do not intend for the proposal to change the current meaning of the original provision, which is: If the basis for a waiver ceases to exist, the waiver will be rescinded, and the existing exclusion will then be in effect.

Section 1001.1901 Scope and Effect of Exclusion

At the end of § 1001.1901(a), we propose to correct a cross-reference to the definition of ''Federal health care programs'' from § 1001.2 to § 1000.10 because the definition does not appear in § 1001.2. We also propose inserting the phrase ''Federal health care'' prior to the word ''program'' and ''programs'' in § 1001.1901(b)(2) and (4), respectively, for clarity. Finally, we propose deleting the parenthetical in § 1001.1901(c)(3)(iii) because it refers to an exemption that was limited to the period between October 2, 1998, and October 4, 1999, and therefore is no longer applicable. None of the proposed changes to § 1001.1901 are intended to change the meaning of the provisions of that section.

Section 1001.2001 Notice of Intent To Exclude

Under the current regulatory text in this section, OIG is only required to issue a notice of intent to exclude with respect to mandatory exclusions under section 1128(a) of the Act if the proposed period of exclusion is for longer than 5 years. We propose modifying § 1001.2001(a) to provide that OIG will issue a notice of intent to exclude for all mandatory and permissive exclusions, of any length, that are proposed under subpart B or C of part 1001. The notice of intent to exclude affords individuals and entities the opportunity to provide OIG with information related to the proposed exclusion before it goes into effect and, in our experience, the process allows OIG to impose exclusions after considering as much relevant information as possible. We therefore believe it should apply to all exclusions under subparts B and C of part 1001.

We also propose modifying this section to indicate that a notice of intent to exclude will be deemed to have been received 7 days after the date of the notice (instead of 5 days, as currently specified), based on changes in service standards and expected delivery times for First-Class Mail.

Sections 1001.2004 Through 1001.2006 Notice to State Agencies, State Licensing Agencies, and Others Regarding Exclusion

We propose to clarify that the notice to State Medicaid program agencies, State licensing authorities, and others required by §§ 1001.2004, 1001.2005, and 1001.2006 is made by OIG, not by HHS. In § 1001.2005(a), we propose to remove the words ''from participation'' and the parenthetical ''(or directed to be excluded),'' and to reword the sentence so that this section now reads as follows: ''OIG will promptly notify the appropriate State(s) or local agencies or authorities having responsibility for the licensing or certification of an excluded individual or entity of the facts and circumstances of the exclusion.'' These changes are not intended to change the meaning of this section.

Section 1001.2006 currently provides that OIG will give notice of an exclusion and the effective date to the public, beneficiaries, and as appropriate to various agencies and entities specified in the regulation including: (1) any entity in which the excluded individual

is known to be serving as an employee, administrator, or operator, or in which the individual is serving in any other capacity and is receiving payment for providing services; (2) medical societies and other professional organizations; and (3) other Federal agencies or organizations, as appropriate. However, many of these notifications are not required by the statute and it is impractical for OIG to provide individual notice of each exclusion imposed by OIG to all the entities listed in § 1001.2006. Furthermore, OIG has made exclusion information available online since at least 1999. As a result, we propose to modify § 1001.2006(a) by stating that OIG will give notice of exclusions to the public, beneficiaries, and others via monthly online updates to the List of Excluded Individuals/Entities (commonly referred to as ''the LEIE''), which reflects OIG's longstanding practice.

Section 1001.2007 Appeal of Exclusions

We propose a few technical changes in § 1001.2007. First, in § 1001.2007(a)(1)(i) we propose to change the word ''sanction'' to ''exclusion'' for consistency with other parts of this section and because the only relevant actions under this section are exclusions. Second, we propose to replace the word ''should'' with ''shall'' in § 1001.2007(a)(3) to reflect that certain information must be included in the request for a hearing. For example, § 1005.2(d) requires a request for a hearing to contain certain information, and § 1005.2(e)(4) requires dismissal of a hearing request that fails to raise any issues which may be properly addressed in a hearing. Third, in § 1001.2007(b), we propose to add ''the'' before ''notice of exclusion'' and delete ''such'' before ''a hearing.'' Finally, in § 1001.2007(d) we propose to change ''Government'' to ''government.'' These changes are not intended to change the meaning of this section.

Sections 1001.3001 Through 1001.3002 Timing and Method of Request and Basis for Reinstatement

We propose making changes to §§ 1001.3001(a)(1) and 1001.3002(b)(5) to replace references to ''program provider number'' with ''Federal health care program provider number'' for clarity.

Section 1001.3003 Approval of Request for Reinstatement

We propose changes to § 1001.3003 to track the statutory language in section 1128(g) of the Act, which requires that notice of reinstatement be provided to each appropriate State agency administering or supervising the administration of each State health care program and requires notice to the Attorney General in the case of exclusions under section 1128(a) of the Act to which section 304(a)(95) of the Controlled Substances Act may apply. We also are proposing to revise this section to state that OIG will notify the public and others through posting of reinstatement information on OIG's website. We are proposing to limit the direct notice requirements for reinstatements to reduce the burden on OIG and to reflect OIG's longstanding practice of providing general notice of all reinstatements through the posting of a monthly reinstatement file on OIG's public website. Lastly, we are proposing to modify § 1001.3003(b) to clarify that a reinstatement by OIG does not require any other Federal health care program to reinstate such individual or entity into that program if the program has taken an action against the individual or entity under its own authority. This proposal is intended to clarify the language of this section and is not intended to change the substance of the provision. The current language, which states that a reinstatement by OIG has no effect if a Federal health care program has imposed a longer period of exclusion under its own authorities, is imprecise and confusing because a reinstatement by OIG has effect independent of the actions of individual Federal health care programs.

Section 1001.3004 Denial of Request for Reinstatement

We propose several changes to § 1001.3004 to better reflect OIG's current processes regarding denial of reinstatement appeal requests and to clarify for the public the process by which an individual or entity may appeal the denial of their request for reinstatement. We propose to modify § 1001.3004(a) to reflect a three-step process when a request for reinstatement is denied. First, OIG would send a written notice to the individual or entity notifying them that their request for reinstatement has been denied and the basis for the denial. Second, the individual or entity would then have 30 days from the date of the notice of the reinstatement denial to submit a written request to appeal the denial. Third, once the individual or entity has submitted a written appeal request, the individual would have 30 days from the date of the written request for appeal to submit: (1) any written argument or additional evidence the individual or entity has regarding the basis for the denial of reinstatement identified in the denial notice, or (2) a written request to present oral argument or any additional evidence to an OIG official. The proposed language would provide requesters with an additional 30 days to submit the documentary evidence or the request for oral argument allowed under § 1001.3004(a).

We also propose to clarify § 1001.3004(b) to indicate that OIG will only issue a decision regarding a reinstatement denial if a written argument or additional evidence are submitted to OIG or any oral argument or additional evidence are presented to an OIG official. The current language may incorrectly suggest that a decision might be issued at the end of the 30-day appeal period even if no written or oral argument and additional evidence are submitted or presented regarding the denial of the request for reinstatement.

Section 1001.3005 Withdrawal of Exclusion for Reversed or Vacated Decisions

We propose a technical change to clarify § 1001.3005(b) by deleting the words ''CMS and other'' before Federal health care programs (because the Centers for Medicare & Medicaid Services (CMS) is not itself a Federal health care program but the agency that administers Medicare and Medicaid). Finally, we propose to change the word ''exclusion'' to ''action'' in § 1001.3004(d) to reflect the fact that all other Federal health care programs do not use the term ''exclusion.''

VI. Regulatory Impact Statement

We have examined the impacts of this rulemaking as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Order Nos. 12866 13563, and 14094

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and

equity). The Executive Order 14094 entitled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). A Regulatory Impact Analysis (RIA) must be prepared for significant rules with significant effects ($200 million or more in any 1 year).

Based on our estimates, OMB's Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is not significant per section 3(f)(1) as measured by the $200 million or more in any given year. This is not a major rule as defined at 5 U.S.C. 804(2); it is not economically significant because it does not reach that economic threshold 1 year.

This proposed rule is designed to propose implementation of one, new statutory provision consisting of a new exclusion authority. It is also designed to clarify existing regulatory requirements. The vast majority of providers and the Federal health care programs would be minimally, if at all, impacted by these proposed revisions.

The proposed changes to the exclusion regulations would have little economic impact. On average per year, OIG excludes approximately 3,000 individuals and entities, defends 100 appeals of exclusions, and hears 2 reinstatement denial appeals. Historically, one waiver of exclusion has been requested and granted in any given year. Thus, we believe that any aggregate economic effect of the proposed modifications would be minimal and the likely aggregate economic effect of these proposed modifications to the regulations would be significantly less than the monetary thresholds under Executive Order 12866, as amended by Executive Order 14094, and 5 U.S.C. 804(2).

Regulatory Flexibility Act

The RFA and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Providers are considered small entities by having revenues of less than $8.0 million to $41.5 million in any 1 year. For purposes of the RFA, most physicians and suppliers are considered small entities.

The aggregate economic impact of the exclusion provisions on small entities would be minimal. The rulemaking directly impacts small entities that may be excluded by clarifying how OIG determines exclusion lengths, waivers, reinstatement, and affirmative exclusion. It also codifies exclusion authorities added to section 1128 of the Act by MSIAA, adding clarity for members of the health care community regarding the scope of OIG's actions. Because the rulemaking adds transparency to OIG's process and implements exclusion authorities designed to protect the Federal health care programs and their beneficiaries from untrustworthy individuals and entities, we believe any resulting impact will be positive for the health care community. In summary, this notice of proposed rulemaking will not have a significant impact on the operations of a substantial number of small providers and a regulatory flexibility analysis is not required for this rulemaking.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (UMRA) generally requires that each agency conduct a cost-benefit analysis, identify and consider a reasonable number of regulatory alternatives, and select the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule before promulgating any proposed or final rule that includes a Federal mandate that may result in expenditures of more than $100 million (adjusted for inflation) in at least one year by State, local, and Tribal governments, or by the private sector. Each agency must also seek input from State, local, and Tribal governments. The current threshold after adjustment for inflation using the Implicit Price Deflator for the Gross Domestic Product is $183 million, reported in 2023 dollars. This proposed rule, if finalized, would not result in an unfunded mandate in any year that meets or exceeds this amount.

Executive Order 13132

Executive Order 13132, Federalism, establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has federalism implications. In reviewing this rulemaking under the threshold criteria of Executive Order 13132, we have determined that this proposed rule would not significantly affect the rights, roles, or responsibilities of State or local governments.

VII. Paperwork Reduction Act

These proposed changes impose no new information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

List of Subjects in 42 CFR Parts 1000 and 1001

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare.

For the reasons stated in the preamble, OIG proposes to amend 42 CFR parts 1000 and 1001 as set forth below:

PART 1000—INTRODUCTION; GENERAL DEFINITIONS

■ 1. The authority citation to part 1000 continues to read as follows:

Authority: 42 U.S.C. 1320 and 1395hh.

■ 2. Revise and republish § 1000.10 to read as follows:

§ 1000.10 General definitions.

In this chapter, unless the context indicates otherwise—

Act means the Social Security Act, and titles referred to are titles of that Act.

Administrator means the Administrator, Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA).

Agent means any person who has express or implied authority to obligate or act on behalf of an entity.

ALJ means an Administrative Law Judge.

Beneficiary means any individual eligible to have benefits paid to the beneficiary, or on the beneficiary's behalf, under Medicare or any State health care program.

CFR stands for Code of Federal Regulations.

CMS stands for Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration (HCFA).

Department means the Department of Health and Human Services (HHS), formerly the Department of Health, Education, and Welfare.

Directly, as used in the definition of ''furnished'' in this section, means the provision or supply of items and services by individuals or entities (including items and services provided or supplied by them but manufactured, ordered, or prescribed by another individual or entity) who request or receive payment from Medicare, Medicaid, or other Federal health care programs.

ESRD stands for end-stage renal disease.

Exclusion means that items and services furnished, ordered, or prescribed by a specified individual or entity will not be reimbursed under Medicare, Medicaid, or any other Federal health care programs until the individual or entity is reinstated by OIG.

Federal health care program means any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the Federal Employees Health Benefits Program), or any State health care program as defined in this section.

FR stands for **Federal Register**.

Furnished refers to items or services provided or supplied, directly or indirectly, by any individual or entity.

HHS stands for the Department of Health and Human Services.

HHA stands for home health agency.

HMO stands for health maintenance organization.

ICF stands for intermediate care facility.

Indirect ownership interest includes an ownership interest through any other entity or entities that ultimately have an ownership interest in the entity at issue. (For example, an individual has a 10-percent ownership interest in the entity at issue if they have a 20-percent ownership interest in a corporation that wholly owns a subsidiary that is a 50-percent owner of the entity at issue.)

Indirectly, as used in the definition of ''furnished'' in this section, means the provision or supply of items and services manufactured, distributed, supplied, or otherwise provided by individuals or entities that do not directly request or receive payment from Medicare, Medicaid, or other Federal health care programs, but that provide items and services to providers, practitioners, or suppliers who request or receive payment from these programs for such items or services.

Inspector General means the Inspector General for the Department of Health and Human Services.

Knowingly means that a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and no proof of specific intent to defraud is required.

Managing employee means an individual (including a general manager, business manager, administrator, or director) who exercises operational or managerial control over the entity or part thereof or directly or indirectly conducts the day-to-day operations of the entity or part thereof.

Medicaid means medical assistance provided under a State plan approved under Title XIX of the Act.

Medicare means the health insurance program for the aged and disabled under Title XVIII of the Act.

OIG means the Office of Inspector General within HHS.

Ownership interest means an interest in:

(1) The capital, the stock, or the profits of the entity; or

(2) Any mortgage, deed of trust, note, or other obligation secured in whole or in part by the property or assets of the entity.

Patient means any individual who is receiving health care items or services, including any item or service provided to meet their physical, mental, or emotional needs or well-being (including a resident receiving care in a facility as described in part 483 of this chapter), whether or not reimbursed under any Federal health care program and regardless of the location in which such item or service is provided.

QIO means a quality improvement organization as that term is used in section 1152 of the Act (42 U.S.C. 1320c–1) and its implementing regulations.

Secretary means the Secretary of the Department or the Secretary's designees.

SNF stands for skilled nursing facility.

Social Security benefits means monthly cash benefits payable under section 202 or 223 of the Act.

SSA stands for Social Security Administration.

State includes the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

State health care program means:

(1) A State plan approved under title XIX of the Act (Medicaid);

(2) Any program receiving funds under title V of the Act or from an allotment to a State under such title (Maternal and Child Health Services Block Grant program);

(3) Any program receiving funds under subtitle A of title XX of the Act or from any allotment to a State under such subtitle (Block Grants to States for Social Services); or

(4) A State child health plan approved under title XXI (Children's Health Insurance Program).

United States means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

U.S.C. stands for United States Code.

PART 1001—PROGRAM INTEGRITY—THE FEDERAL HEALTH CARE PROGRAMS

■ 3. The authority citation to part 1001 continues to read as follows:

Authority: 42 U.S.C. 1302; 1320a–7; 1320a–7b; 1395u(j); 1395u(k); 1395w–104(e)(6), 1395y(d); 1395y(e); 1395cc(b)(2)(D), (E), and (F); 1395hh; 1842(j)(1)(D)(iv), 1842(k)(1), and sec. 2455, Pub. L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

■ 4. Revise the heading to part 1001 as set forth above.

■ 5. Revise and republish subpart A, consisting of §§ 1001.1 and 1001.2 to read as follows:

Subpart A—General Provisions

§ 1001.1 Scope and purpose.

(a) The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in all Federal health care programs. They also state the effect of exclusion, the factors that will be considered in determining the length of any exclusion, the provisions governing notices of exclusions, and the process by which an excluded individual or entity may seek reinstatement into the programs.

(b) The regulations in this part are applicable to and binding on the Office of Inspector General (OIG) in imposing and proposing exclusions, as well as to Administrative Law Judges (ALJs), the Departmental Appeals Board, and Federal courts in reviewing the imposition of exclusions by OIG (and, where applicable, in imposing exclusions proposed by OIG).

§ 1001.2 Definitions.

For purposes of this part:

Convicted means that—

(1) A judgment of conviction has been entered against an individual or entity by a Federal, State, or local court, regardless of whether:

(i) There is a post-trial motion or an appeal pending; or

(ii) The judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed;

(2) A Federal, State, or local court has made a finding of guilt against an individual or entity;

(3) A Federal, State, or local court has accepted a plea of guilty or nolo contendere by an individual or entity; or

(4) An individual or entity has entered into participation in a first offender, deferred adjudication, or other program or arrangement where judgment of conviction has been withheld.

HHS means Department of Health and Human Services.

Immediate family member means a person's husband or wife; natural or adoptive parent; child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-, mother-, daughter-, son-, brother-, or sister-in-law; grandparent or grandchild; or spouse of a grandparent or grandchild.

Incarceration means imprisonment or any type of confinement with or without supervised release, including, but not limited to, community confinement, house arrest, and home detention.

Member of household means, with respect to a person, any individual with whom the person is sharing a common abode as part of a single-family unit, including domestic employees and others who live together as a family unit. A roomer or boarder is not considered a member of a household.

Ownership or control interest means, with respect to an entity, a person who:

(1) Has a direct or an indirect ownership interest (or any combination thereof) of 5 percent or more in the entity;

(2) Is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the entity or any of the property assets thereof, if such interest is equal to or exceeds 5 percent of the total property and assets of the entity;

(3) Is an officer or a director of the entity;

(4) Is a partner in the entity if the entity is organized as a partnership;

(5) Is an agent of the entity; or

(6) Is a managing employee of the entity.

Professionally recognized standards of health care are statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a State. When the Department has declared a treatment modality not to be safe and effective, practitioners who employ such a treatment modality will be deemed not to meet professionally recognized standards of health care. This definition will not be construed to mean that all other treatments meet professionally recognized standards.

Sole community physician means a physician who is the only physician who provides primary care services to Federal or State health care program beneficiaries within a defined service area.

Sole source of essential specialized services in the community means that an individual or entity—

(1) Is the only practitioner, supplier, or provider furnishing specialized services in an area designated by the Health Resources Services Administration as a health professional shortage area for that medical specialty, as listed in 42 CFR part 5, appendices B through F;

(2) Is a sole community hospital, as defined in § 412.92 of this title; or

(3) Is the only source of specialized services in a reasonably defined service area where services by a non-specialist could not be substituted for the source without jeopardizing the health or safety of beneficiaries.

State Medicaid Fraud Control Unit means a unit certified by the Secretary as meeting the criteria of 42 U.S.C. 1396b(q) and § 1002.305 of this chapter.

■ 6. Revise and republish subpart B, consisting of §§ 1001.101 and 1001.102, to read as follows:

Subpart B—Mandatory Exclusions

§ 1001.101 Basis for liability.

OIG will exclude any individual or entity that—

(a) Has been convicted of a criminal offense related to the delivery of an item or service under Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services under any such program;

(b) Has been convicted, under Federal or State law, of a criminal offense related to the neglect or abuse of a patient, in connection with the delivery of a health care item or service, including any offense that OIG concludes entailed, or resulted in, neglect or abuse of patients (the delivery of a health care item or service includes the provision of any item or service to an individual to meet the individual's physical, mental, or emotional needs or well-being, whether or not reimbursed under a Federal health care program);

(c) Has been convicted, under Federal or State law, of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(1) In connection with the delivery of a health care item or service, including the performance of management or administrative services relating to the delivery of such items or services; or

(2) With respect to any act or omission in a health care program (other than Medicare or a State health care program) operated or financed in whole or in part by any Federal, State, or local government agency; or

(d) Has been convicted, under Federal or State law, of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance, as defined under Federal or State law. This applies to any individual or entity that—

(1) Is, or has ever been, a health care practitioner, provider, or supplier, or furnished or furnishes items or services;

(2) Holds, or has held, a direct or an indirect ownership or control interest in an entity that furnished or furnishes items or services or is, or has ever been, an officer, director, agent, or managing employee of such an entity; or

(3) Is, or has ever been, employed in any capacity in the health care industry.

§ 1001.102 Length of exclusion.

(a) No exclusion imposed in accordance with § 1001.101 will be for less than 5 years.

(b) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(1) The acts resulting in the conviction, or similar acts, caused, or were intended to cause, a financial loss of $50,000 or more to a government agency or program or to one or more other entities. (The entire amount of financial loss, including any amounts resulting from similar acts not adjudicated, will be considered regardless of whether full or partial restitution has been made.);

(2) The acts that resulted in the conviction, or similar acts, were committed over a period of 1 year or more;

(3) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental, or financial impact on one or more program beneficiaries or other individuals;

(4) In convictions involving patient abuse or neglect, the acts that resulted in the conviction were premeditated, part of a continuing pattern of behavior, or consisted of non-consensual sexual acts;

(5) The sentence imposed by the court included incarceration; or

(6) The convicted individual or entity has other documented instances of criminal, civil, or administrative wrongdoing.

(c) Only if any of the aggravating factors set forth in paragraph (b) of this section justifies an exclusion longer than 5 years, may mitigating factors be considered as a basis for reducing the period of exclusion to no less than 5 years. Only the following factors may be considered mitigating—

(1) The record in the criminal proceedings demonstrates that the court

determined that the individual had a condition before or during the commission of the offense that reduced the individual's culpability; or

(2) The record in the criminal proceedings or a written statement by a government official demonstrates that the individual's or entity's cooperation with Federal or State officials resulted in other individuals or entities being excluded, indicted, or otherwise charged, convicted, or investigated.

(d) In the case of an exclusion under this subpart, an exclusion will be—

(1) For not less than 10 years if the individual has been convicted on one previous occasion of one or more offenses for which an exclusion may be imposed under section 1128(a) of the Act. (The aggravating factors in paragraph (b) of this section can be used to impose a period of time in excess of the 10-year minimum.); or

(2) Permanent if the individual has been convicted on two or more previous occasions of one or more offenses for which an exclusion may be imposed under section 1128(a) of the Act.

Subpart C—Permissive Exclusions

■ 7. Revise and republish §§ 1001.201 through 1001.951 to read as follows:

Sec.

* * * * *

§ 1001.201 Conviction relating to program or health care fraud.

(a) *Circumstance for exclusion.* OIG may exclude an individual or entity convicted under Federal or State law of—

(1) A misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(i) In connection with the delivery of any health care item or service, including the performance of management or administrative services relating to the delivery of such items or services; or

(ii) With respect to any act or omission in a health care program, other than Medicare or a State health care program, operated or financed in whole or in part by any Federal, State, or local government agency; or

(2) Fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct with respect to any act or omission in a program, other than a health care program, operated or financed in whole or in part by any Federal, State, or local government agency.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years unless aggravating or mitigating factors listed in paragraphs (b)(2) and (3) of this section form a basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The acts resulting in the conviction, or similar acts, caused or reasonably could have been expected to cause a financial loss of $50,000 or more to a government agency or program or to one or more other entities. (The entire amount of financial loss will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made.);

(ii) The acts that resulted in the conviction, or similar acts, were committed over a period of 1 year or more;

(iii) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental, or financial impact on one or more program beneficiaries or other individuals;

(iv) The sentence imposed by the court included incarceration; or

(v) The individual or entity has other documented instances of criminal, civil, or administrative wrongdoing.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The record in the criminal proceedings demonstrates that the court determined that the individual had a condition, before or during the commission of the offense, that reduced the individual's culpability; or

(ii) The record in the criminal proceedings or a written statement by a government official demonstrates that the individual's or entity's cooperation with Federal or State officials resulted in other individuals or entities being excluded, indicted, or otherwise charged, convicted, or investigated.

§ 1001.301 Conviction relating to obstruction of an investigation or audit.

(a) *Circumstance for exclusion.* OIG may exclude an individual or entity that has been convicted, under Federal or State law, in connection with the interference with or obstruction of any investigation or audit related to—

(1) Any offense described in § 1001.101 or § 1001.201; or

(2) The use of funds received, directly or indirectly, from any Federal health care program.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (3) of this section form the basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The acts resulting in the conviction, or similar acts, caused, or reasonably could have been expected to cause a financial loss of $50,000 or more to a government agency or program or to one or more other entities. (The entire amount of financial loss will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made.);

(ii) The acts that resulted in the conviction had a significant adverse physical, mental, or financial impact on one or more program beneficiaries or other individuals;

(iii) The sentence imposed by the court included incarceration;

(iv) The individual or entity has other documented instances of criminal, civil, or administrative wrongdoing.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The record of the criminal proceedings demonstrates that the court determined that the individual had a condition, before or during the commission of the offense, that reduced the individual's culpability; or

(ii) The record in the criminal proceedings or a written statement by a government official demonstrates that the individual's or entity's cooperation with Federal or State officials resulted in other individuals or entities being excluded, indicted, or otherwise charged, convicted, or investigated.

§ 1001.401 Conviction relating to controlled substances.

(a) *Circumstance for exclusion.* OIG may exclude an individual or entity convicted under Federal or State law of a misdemeanor relating to the unlawful

manufacture, distribution, prescription, or dispensing of a controlled substance, as defined under Federal or State law. This section applies to any individual or entity that—

(1) Is, or has ever been, a health care practitioner, provider, or supplier, or furnished or furnishes items or services;

(2) Holds, or held, a direct or indirect ownership or control interest in an entity that furnished or furnishes items or services or is or has ever been an officer, director, agent, or managing employee of such an entity; or

(3) Is, or has ever been, employed in any capacity in the health care industry.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (c)(2) and (3) of this section form a basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and to be a basis for lengthening the period of exclusion—

(i) The acts that resulted in the conviction or similar acts were committed over a period of 1 year or more;

(ii) The acts that resulted in the conviction or similar acts had a significant adverse physical, mental, or financial impact on program beneficiaries or other individuals or a Federal health care program;

(iii) The sentence imposed by the court included incarceration; or

(iv) The individual or entity has other documented instances of criminal, civil, or administrative wrongdoing.

(3) Only the following factors may be considered to be mitigating and to be a basis for shortening the period of exclusion—

(i) The record of the criminal proceedings demonstrates that the court determined that the individual had a condition, before or during the commission of the offense, that reduced the individual's culpability; or

(ii) The record in the criminal proceedings or a written statement by a government official demonstrates that the individual's or entity's cooperation with Federal or State officials resulted in other individuals or entities being excluded, indicted, or otherwise charged, convicted, or investigated.

§ 1001.501 License revocation or suspension.

(a) *Circumstance for exclusion.* OIG may exclude an individual or entity that has—

(1) Had a license to provide health care revoked or suspended by any State licensing authority, or has otherwise lost such a license (including the right to apply for or renew such a license), for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity; or

(2) Has surrendered such a license while a formal disciplinary proceeding concerning the individual's or entity's professional competence, professional performance, or financial integrity was pending before a State licensing authority.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will not be for a period of time less than the period during which an individual's or entity's license is revoked, suspended, or otherwise not in effect as a result of, or in connection with, a State licensing agency action.

(2) When an individual or entity has been excluded under this section, OIG will consider a request for reinstatement in accordance with § 1001.3001 if:

(i) The individual or entity obtains the license in the State where the license was originally revoked, suspended, surrendered, or otherwise lost; or

(ii) The individual meets the conditions for early reinstatement set forth in paragraph (c) of this section.

(c) *Consideration of early reinstatement.* (1) If an individual or entity that is excluded in accordance with this section fully and accurately discloses the circumstances surrounding the action that formed the basis for the exclusion to a licensing authority of a different State or to a different licensing authority in the same State and that licensing authority grants the individual or entity a new health care license or has decided to take no adverse action as to a currently held health care license, OIG will consider a request for early reinstatement. OIG will consider the following factors in determining whether a request for early reinstatement under this paragraph (c)(1) will be granted:

(i) The circumstances that formed the basis for the exclusion, including whether the circumstances were related to patient abuse or neglect;

(ii) Whether the second licensing authority is in a State that is not the individual's or entity's primary place of practice;

(iii) Documentation from the second licensing authority indicating that it was aware of the circumstances surrounding the action that formed the basis for the exclusion;

(iv) Whether the individual or entity has demonstrated that the individual or entity has satisfactorily resolved any underlying problem that caused or contributed to the basis for the initial licensing action;

(v) The benefits to the Federal health care programs and program beneficiaries of early reinstatement;

(vi) The risks to the Federal health care programs and program beneficiaries of early reinstatement;

(vii) Any additional or pending license actions in any State;

(viii) Any ongoing investigations involving the individual or entity; and

(ix) All the factors set forth in § 1001.3002(b).

(2) If an exclusion has been imposed under this section and the individual or entity does not have a valid health care license of any kind in any State, that individual or entity may request OIG to consider whether the individual or entity may be eligible for early reinstatement. OIG will consider the following factors in determining whether a request for early reinstatement under this paragraph (c)(2) will be granted:

(i) The length of time the individual or entity has been excluded. OIG will not consider a request for early reinstatement under paragraph (c)(2) of this section if the individual or entity has been excluded for less than 3 years; however, if the action on which the exclusion is based was for a set period longer than 3 years, OIG will not consider a request for early reinstatement at any time prior to the expiration of the period set by the licensing board;

(ii) The circumstances that formed the basis for the exclusion, including whether the circumstances were related to patient abuse or neglect;

(iii) Whether the individual or entity has demonstrated that the individual or entity has satisfactorily resolved any underlying problem that caused or contributed to the basis for the initial licensing action;

(iv) The benefits to the Federal health care programs and program beneficiaries of early reinstatement;

(v) The risks to the Federal health care programs and program beneficiaries of early reinstatement;

(vi) Any additional or pending license actions in any State;

(vii) Any ongoing investigations involving the individual or entity; and

(viii) All the factors set forth in § 1001.3002(b).

(3) Notwithstanding paragraphs (c)(1) and (2) of this section, if an individual's or entity's license revocation or suspension was for reasons related to patient abuse or neglect, OIG will not consider an application for early reinstatement if the individual or entity has been excluded for less than 5 years.

(4) Except for § 1001.3002(a)(1)(i), all provisions of subpart F (§§ 1001.3001 through 1001.3005) apply to early reinstatements under this section.

§ 1001.601 Exclusion or suspension under a Federal or State health care program.

(a) *Circumstance for exclusion.* (1) OIG may exclude an individual or entity suspended or excluded from participation, or otherwise sanctioned, under—

(i) Any Federal program involving the provision of health care; or

(ii) A State health care program, for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity.

(2) The term ''or otherwise sanctioned'' in paragraph (a)(1) of this section means all actions that limit the ability of a person to participate in the program at issue regardless of what such an action is called, and includes situations where an individual or entity voluntarily withdraws from a program to avoid a formal sanction.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will not be for a period of time less than the period during which the individual or entity is excluded or suspended, or otherwise sanctioned, from a Federal or State health care program.

(2) If the individual or entity is eligible to apply for reinstatement in accordance with § 1001.3001, and the sole reason why the State or Federal health care program denied reinstatement to that program is the existing exclusion imposed by OIG as a result of the original State or Federal health care program action, OIG will consider a request for reinstatement.

§ 1001.701 Excessive claims or furnishing of unnecessary or substandard items and services.

(a) *Circumstance for exclusion.* OIG may exclude an individual or entity that has—

(1) Submitted, or caused to be submitted, bills or requests for payments under Medicare or any of the State health care programs containing charges or costs for items or services furnished that are substantially in excess of such individual's or entity's usual charges or costs for such items or services; or

(2) Furnished, or caused to be furnished, to patients (whether or not covered by Medicare or any of the State health care programs) any items or services substantially in excess of the patient's needs, or of a quality that fails to meet professionally recognized standards of health care.

(b) *Sources.* OIG's determination under paragraph (a)(2) of this section—that the items or services furnished were excessive or of unacceptable quality—will be made on the basis of information, including sanction reports, from the following sources:

(1) The QIO for the area served by the individual or entity;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies; or

(5) Any other sources deemed appropriate by OIG.

(c) *Exceptions.* An individual or entity will not be excluded for—

(1) Submitting, or causing to be submitted, bills or requests for payment that contain charges or costs substantially in excess of usual charges or costs when such charges or costs are due to unusual circumstances or medical complications requiring additional time, effort, expense or other good cause; or

(2) Furnishing, or causing to be furnished, items or services in excess of the needs of patients, when the items or services were ordered by a physician or other authorized individual, and the individual or entity furnishing the items or services was not in a position to determine medical necessity or to refuse to comply with the order of the physician or other authorized individual.

(d) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors set forth in paragraphs (d)(2) and (3) of this section form a basis for lengthening or shortening the period. In no case may the period be shorter than 1 year for any exclusion taken in accordance with paragraph (a)(2) of this section.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The conduct occurred over a period of 1 year or more;

(ii) The conduct had a significant adverse physical, mental, or financial impact on program beneficiaries or other individuals;

(iii) The individual or entity has other documented instances of criminal, civil, or administrative wrongdoing; or

(iv) The conduct resulted in financial loss to any Federal health care program of $50,000 or more.

(3) Only the following factor may be considered mitigating and a basis for reducing the period of exclusion: Whether there were few occurrences of the conduct, and the conduct occurred over a short period of time.

§ 1001.801 Failure of HMOs and CMPs to furnish medically necessary items and services.

(a) *Circumstances for exclusion.* OIG may exclude an entity—

(1) That is a—

(i) Health maintenance organization (HMO), as defined in section 1903(m) of the Act, providing items or services under a State Medicaid Plan;

(ii) Primary care case management system providing services, in accordance with a waiver approved under section 1915(b)(1) of the Act; or

(iii) HMO or competitive medical plan (CMP) providing items or services in accordance with a risk-sharing contract under section 1876 of the Act;

(2) That has failed substantially to provide medically necessary items and services that are required under a plan, waiver or contract described in paragraph (a)(1) of this section to be provided to individuals covered by such plan, waiver or contract; and

(3) Where such failure has adversely affected or has a substantial likelihood of adversely affecting covered individuals.

(b) *Sources.* OIG's determination under paragraph (a)(2) of this section—that the medically necessary items and services required under law or contract were not provided—will be made on the basis of information, including sanction reports, from the following sources:

(1) The QIO or other quality assurance organization under contract with a State Medicaid plan for the area served by the HMO or competitive medical plan;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies;

(5) CMS's HMO compliance office; or

(6) Any other sources deemed appropriate by OIG.

(c) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors set forth in paragraphs (c)(2) and (3) of this section form a basis for lengthening or shortening the period.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The entity failed to provide a large number or a variety of items or services;

(ii) The failures occurred over a lengthy period of time;

(iii) The entity's failure to provide a necessary item or service had or could have had a serious adverse effect; or

(iv) The entity has other documented instances of criminal, civil, or administrative wrongdoing.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) There were few violations and they occurred over a short period of time; or

(ii) The entity took corrective action upon learning of impermissible activities by an employee or contractor.

§ 1001.901 False or improper claims.

(a) *Circumstance for exclusion.* OIG may exclude any individual or entity that it determines has committed an act described in section 1128A of the Act. The imposition of a civil money penalty or assessment is not a prerequisite for an exclusion under this section.

(b) *Length of exclusion.* In determining the length of an exclusion imposed in accordance with this section, OIG will consider the following factors—

(1) The nature and circumstances surrounding the actions that are the basis for liability, including the period of time over which the acts occurred, the number of acts, whether there is evidence of a pattern, and the amount claimed;

(2) The degree of culpability;

(3) Whether the individual or entity has other documented instances of criminal, civil, or administrative wrongdoing (the absence of any such instances is to be considered neutral); or

(4) Other matters as justice may require.

(c) *Limitations.* OIG may not impose an exclusion under this section more than 10 years after the date when an act which is described in section 1128A of the Act occurred.

§ 1001.951 Fraud and kickbacks and other prohibited activities.

(a) *Circumstance for exclusion.* (1) Except as provided for in paragraph (a)(2)(ii) of this section, OIG may exclude any individual or entity that it determines has committed an act described in section 1128B(b) of the Act.

(2) With respect to acts described in section 1128B of the Act, OIG—

(i) May exclude any individual or entity that it determines has knowingly and willfully solicited, received, offered or paid any remuneration in the manner and for the purposes described therein, irrespective of whether the individual or entity may be able to prove that the remuneration was also intended for some other purpose; and

(ii) Will not exclude any individual or entity if that individual or entity can prove that the remuneration that is the subject of the exclusion is exempted from serving as the basis for an exclusion.

(b) *Length of exclusion.* In determining the length of an exclusion imposed in accordance with this section, OIG may consider the following factors—

(1) The nature and circumstances surrounding the actions that are the basis for liability, including the period of time over which the acts occurred, the number of acts, whether there is evidence of a pattern and the amount claimed;

(2) The degree of culpability;

(3) Whether the individual or entity has other documented instances of criminal, civil, or administrative wrongdoing (the absence of any such instances is to be considered neutral); or

(4) Other matters as justice may require.

(c) *Limitations.* OIG may not impose an exclusion under this section more than 10 years after the date when an act which is described in section 1128B(b) of the Act occurred.

■ 8. Revise and republish §§ 1001.1101 through 1001.1552 to read as follows:

Sec.

* * * * *

§ 1001.1101 Failure to disclose certain information.

(a) *Circumstance for exclusion.* OIG may exclude any entity that did not fully and accurately, or completely, make disclosures as required by section 1124, 1124A or 1126 of the Act, and by part 455, subpart B and part 420, subpart C of this title.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where full and accurate, or complete, disclosure was not made;

(2) The significance of the undisclosed information;

(3) Whether the individual or entity has other documented instances of criminal, civil, or administrative wrongdoing (the absence of such instances is to be considered neutral);

(4) Any other facts that bear on the nature or seriousness of the conduct; and

(5) The extent to which the entity knew that the disclosures made were not full or accurate.

§ 1001.1201 Failure to provide payment information.

(a) *Circumstance for exclusion.* OIG may exclude any individual or entity that furnishes, orders, refers for furnishing, or certifies the need for items or services for which payment may be made under Medicare or any of the State health care programs and that—

(1) Fails to provide such information as is necessary to determine whether such payments are or were due and the amounts thereof; or

(2) Has refused to permit such examination and duplication of its records as may be necessary to verify such information.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where information was not provided;

(2) The circumstances under which such information was not provided;

(3) The amount of the payments at issue; and

(4) Whether the individual or entity has other documented instances of criminal, civil, or administrative wrongdoing (the absence of such instances is to be considered neutral).

§ 1001.1301 Failure to grant immediate access.

(a) *Circumstance for exclusion.* (1) OIG may exclude any individual or entity that fails to grant immediate access upon reasonable request to—

(i) The Secretary, a State survey agency or other authorized entity for the purpose of determining, in accordance with section 1864(a) of the Act, whether—

(A) An institution is a hospital or skilled nursing facility;

(B) An agency is a home health agency;

(C) An agency is a hospice program;

(D) A facility is a rural health clinic as defined in section 1861(aa)(2) of the Act, or a comprehensive outpatient rehabilitation facility as defined in section 1861(cc)(2) of the Act;

(E) A laboratory is meeting the requirements of section 1861(s) (15) and (16) of the Act, and section 353(f) of the Public Health Service Act;

(F) A clinic, rehabilitation agency or public health agency is meeting the

requirements of section 1861(p)(4) (A) or (B) of the Act;

(G) An ambulatory surgical center is meeting the standards specified under section 1832(a)(2)(F)(i) of the Act;

(H) A portable x ray unit is meeting the requirements of section 1861(s)(3) of the Act;

(I) A screening mammography service is meeting the requirements of section 1834(c)(3) of the Act;

(J) An end-stage renal disease facility is meeting the requirements of section 1881(b) of the Act;

(K) A physical therapist in independent practice is meeting the requirements of section 1861(p) of the Act;

(L) An occupational therapist in independent practice is meeting the requirements of section 1861(g) of the Act;

(M) An organ procurement organization meets the requirements of section 1138(b) of the Act; or

(N) A rural primary care hospital meets the requirements of section 1820(i)(2) of the Act;

(ii) The Secretary, a State survey agency or other authorized entity to perform the reviews and surveys required under State plans in accordance with sections 1902(a)(26) (relating to inpatient mental hospital services), 1902(a)(31) (relating to intermediate care facilities for individuals with intellectual disabilities), 1919(g) (relating to nursing facilities), 1929(i) (relating to providers of home and community care and community care settings), 1902(a)(33), and 1903(g) of the Act;

(iii) OIG for reviewing records, documents, and other material or data in any medium (including electronically stored information and any tangible thing) necessary to OIG's statutory functions; or

(iv) A State Medicaid fraud control unit (MFCU) for the purpose of conducting its activities.

(2) For purposes of paragraphs (a)(1)(i) and (ii) of this section—

(i) *Failure to grant immediate access* means the failure to grant access at the time of a reasonable request unless the requested material does not exist or is not at the location where the request is presented.

(ii) *Reasonable request* means a written request made by a properly identified agent of the Secretary, of a State survey agency, or of another authorized entity, during hours that the facility, agency or institution is open for business.

(iii) The request will include a statement of the authority for the request, the rights of the entity in responding to the request, the definitions of *reasonable request* and *failure to grant immediate access,* and the penalties for failure to comply, including when the exclusion will take effect.

(3) For purposes of paragraphs (a)(1)(iii) and (iv) of this section—

(i) *Failure to grant immediate access* means the failure to produce or make available for inspection and copying the requested material at the time of a reasonable request unless the requested material does not exist or is not at the location where the request is presented.

(ii) *Reasonable request* means a written request, signed by a designated representative of OIG or a MFCU and made by a properly identified agent of OIG or a MFCU during reasonable business hours, where there is information to suggest that the person has violated statutory or regulatory requirements under titles V, XI, XVIII, XIX, or XX of the Act.

(iii) The request will include a statement of the authority for the request, the person's rights in responding to the request, the definitions of *reasonable request* and *failure to grant immediate access,* and the effective date, length, and scope and effect of the exclusion that would be imposed for failure to comply with the request, and the earliest date that a request for reinstatement would be considered.

(4) Nothing in this section shall in any way limit access otherwise authorized under State or Federal law.

(b) *Length of exclusion.* (1) An exclusion of an individual under this section may be for a period equal to the sum of:

(i) The length of the period during which the immediate access was not granted; and

(ii) An additional period of up to 90 days.

(2) The exclusion of an entity may be for a longer period than the period in which immediate access was not granted based on consideration of the following factors—

(i) The impact of the failure to grant the requested immediate access on Medicare or any of the State health care programs, beneficiaries, or the public;

(ii) The circumstances under which such access was refused;

(iii) The impact of the exclusion on any Federal health care program, beneficiaries, or the public; and

(iv) Whether the entity has other documented instances of criminal, civil, or administrative wrongdoing (the absence of any such instances is to be considered neutral).

(3) For purposes of paragraphs (b)(1) and (2) of this section, the length of the period in which immediate access was not granted will be measured from the time the request is made, or from the time by which access was required to be granted, whichever is later.

(c) The exclusion will be effective as of the date immediate access was not granted.

§ 1001.1401 Violations of Prospective Payment System corrective action.

(a) *Circumstance for exclusion.* OIG may exclude any hospital that CMS determines has failed substantially to comply with a corrective action plan required by CMS under section 1886(f)(2)(B) of the Act.

(b) *Length of exclusion.* The following factors will be considered in determining the length of exclusion under this section—

(1) The impact of the hospital's failure to comply on any Federal health care program, program beneficiaries, or other individuals;

(2) The circumstances under which the failure occurred;

(3) The nature of the failure to comply;

(4) The impact of the exclusion on any Federal health care program, beneficiaries, or the public; and

(5) Whether the hospital has other documented instances of criminal, civil, or administrative wrongdoing (the absence of any such instances is to be considered neutral).

§ 1001.1501 Default of health education loan or scholarship obligations.

(a) *Circumstance for exclusion.* (1) Except as provided in paragraph (a)(4) of this section, OIG may exclude any individual that the administrator of the health education loan, scholarship, or loan repayment program determines is in default on repayments of scholarship obligations or loans, or the obligations of any loan repayment program, in connection with health professions education made or secured in whole or in part by the Secretary.

(2) Before imposing an exclusion in accordance with paragraph (a)(1) of this section, OIG must determine that the administrator of the health education loan, scholarship, or loan repayment program has taken all reasonable administrative steps to secure repayment of the loans or obligations. When an individual has been offered a Medicare offset arrangement as required by section 1892 of the Act, OIG will find that all reasonable steps have been taken.

(3) OIG will take into account access of beneficiaries to physician services for

which payment may be made under the Medicare and Medicaid programs in determining whether to impose an exclusion.

(4) OIG will not exclude a physician who is the sole community physician or the sole source of essential specialized services in a community if a State requests that the physician not be excluded.

(b) *Length of exclusion.* The individual will be excluded until the administrator of the health education loan, scholarship, or loan repayment program notifies OIG that the individual has entered into an agreement with the administrator of the health education loan, scholarship, or loan repayment program to cure the default or that there is no longer an outstanding debt. If the administrator of the health education loan, scholarship, or loan repayment program notifies OIG that the individual has entered into an agreement to cure the default, the individual may be eligible for a stay of the effect of exclusion by OIG for as long as the individual remains in compliance with the terms of the agreement. If the administrator of the health education loan, scholarship, or loan repayment program notifies OIG that there is no longer an outstanding debt, OIG will inform the individual of the individual's right to apply for reinstatement.

§ 1001.1551 Exclusion of individuals with ownership or control interest in sanctioned entities.

(a) *Circumstance for exclusion.* OIG may exclude any individual who—

(1) Has a direct or indirect ownership or control interest in a sanctioned entity, and who knows or should know (as defined in section 1128A(i)(6) of the Act) of the action constituting the basis for the conviction or exclusion set forth in paragraph (b) of this section; or

(2) Is an officer or managing employee (as defined in section 1126(b) of the Act) of such an entity.

(b) For purposes of paragraph (a) of this section, the term ''sanctioned entity'' means an entity that—

(1) Has been convicted of any offense described in §§ 1001.101 through 1001.401; or

(2) Has been excluded from participation in Medicare or a State health care program.

(c) *Length of exclusion.* (1) If the entity has been excluded, the length of the individual's exclusion will be for the same length as that of the sanctioned entity, regardless of whether the individual terminates the relationship with the sanctioned entity.

(2) If the entity was not excluded, the length of the individual's exclusion will be determined by considering the factors that would have been considered if the entity had been excluded.

(3) An individual excluded under this section may apply for reinstatement in accordance with the procedures set forth in § 1001.3001.

§ 1001.1552 Making false statements or misrepresentation of material facts.

(a) *Circumstance for exclusion.* OIG may exclude any individual or entity that it determines has knowingly made or caused to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a Federal health care program, including Medicare Advantage organizations under Part C of Medicare, prescription drug plan sponsors under Part D of Medicare, Medicaid managed care organizations, and entities that apply to participate as providers of services or suppliers in such managed care organizations and such plans.

(b) *Definition of ''material.''* For purposes of this section, the term ''material'' means having a natural tendency to influence or be capable of influencing the decision to approve or deny the request to participate or enroll as a provider of services or supplier under a Federal health care program.

(c) *Sources.* OIG's determination under paragraph (a) of this section will be made on the basis of information from the following sources:

(1) CMS;

(2) Medicaid State agencies;

(3) Fiscal agents or contractors or private insurance companies;

(4) Law enforcement agencies;

(5) State or local licensing or certification authorities;

(6) State or local professional societies; or

(7) Any other sources deemed appropriate by OIG.

(d) *Length of exclusion.* In determining the length of an exclusion imposed in accordance with this section, OIG will consider the following factors:

(1) The nature and circumstances surrounding the false statement;

(2) Whether and to what extent payments were requested or received from the Federal health care program under the application, agreement, bid, or contract on which the false statement, omission, or misrepresentation was made; and

(3) Whether the individual or entity has other documented instances of criminal, civil, or administrative wrongdoing (the absence of any such instances is to be considered neutral).

■ 9. Add § 1001.1553 to read as follows:

§ 1001.1553 Knowingly misclassifying covered outpatient drugs.

(a) *Circumstance for exclusion.* OIG may exclude any manufacturer (as defined in section 1927 of the Act), or officer, director, agent, or managing employee of such manufacturer that:

(1) Knowingly misclassifies a covered outpatient drug;

(2) Knowingly fails to correct such misclassification; or

(3) Knowingly provides false information related to drug pricing, drug product information, or data related to drug pricing or drug product information.

(b) This section applies to covered outpatient drugs supplied by manufacturers under agreements under section 1927 of the Act in effect on or after April 18, 2019.

(c) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section:

(1) The nature and circumstances surrounding the actions that are the basis for liability, including the period of time over which the acts occurred, the number of acts, and whether there is evidence of a pattern;

(2) The degree of culpability;

(3) Whether the entity has other documented instances of criminal, civil, or administrative wrongdoing (the absence of any such instances is to be considered neutral); or

(4) Other matters as justice may require.

■ 10. Revise and republish §§ 1001.1601 and 1001.1701 to read as follows:

§ 1001.1601 Violations of the limitations on physician charges.

(a) *Circumstance for exclusion.* (1) OIG may exclude a physician whom it determines—

(i) Is a non-participating physician under section 1842(j) of the Act;

(ii) Furnished services to a beneficiary;

(iii) Knowingly and willfully billed—

(A) On a repeated basis for such services actual charges in excess of the maximum allowable actual charge determined in accordance with section 1842(j)(1)(C) of the Act for the period January 1, 1987 through December 31, 1990; or

(B) Individuals enrolled under part B of title XVIII of the Act during the statutory freeze for actual charges in excess of such physician's actual charges determined in accordance with section 1842(j)(1)(A) of the Act for the period July 1, 1984, to December 31, 1986; and

(iv) Is not the sole community physician or sole source of essential specialized services in the community.

(2) OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(b) *Length of exclusion.* (1) In determining the length of an exclusion in accordance with this section, OIG will consider the following factors—

(i) The number of services for which the physician billed in excess of the maximum allowable charges;

(ii) The number of beneficiaries for whom services were billed in excess of the maximum allowable charges;

(iii) The amount of the charges that were in excess of the maximum allowable charges; and

(iv) Whether the physician has other documented instances of criminal, civil, or administrative wrongdoing (the absence of any such instances is to be considered neutral).

(2) The period of exclusion may not exceed 5 years.

§ 1001.1701 Billing for services of assistant at surgery during cataract operations.

(a) *Circumstance for exclusion.* OIG may exclude a physician whom it determines—

(1) Has knowingly and willfully presented or caused to be presented a claim, or billed an individual enrolled under Part B of the Medicare program (or the individual's representative) for:

(i) Services of an assistant at surgery during a cataract operation; or

(ii) Charges that include a charge for an assistant at surgery during a cataract operation;

(2) Has not obtained prior approval for the use of such assistant from the appropriate Utilization and Quality Control Quality Improvement Organization (QIO) or Medicare carrier; and

(3) Is not the sole community physician or sole source of essential specialized services in the community.

(b) *Access to services.* OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(c) *Length of exclusion.* (1) In determining the length of an exclusion in accordance with this section, OIG will consider the following factors—

(i) The number of instances for which claims were submitted or beneficiaries were billed for unapproved use of assistants during cataract operations;

(ii) The amount of the claims or bills presented;

(iii) The circumstances under which the claims or bills were made, including whether the services were medically necessary;

(iv) Whether approval for the use of an assistant was requested from the QIO or carrier; and

(v) Whether the physician has other documented instances of criminal, civil, or administrative wrongdoing (the absence of any such instances is to be considered neutral).

(2) The period of exclusion may not exceed 5 years.

Subpart D—Waivers and Effect of Exclusion

■ 11. Revise and republish §§ 1001.1801 and 1001.1901 to read as follows:

§ 1001.1801 Waivers of exclusions.

(a) OIG has the authority to grant or deny a request from the administrator of a Federal health care program that an exclusion from that program be waived with respect to an individual or entity, except that no waiver may be granted with respect to an exclusion under § 1001.101(b). The request must be in writing and from an individual directly responsible for administering the Federal health care program.

(b) With respect to exclusions under § 1001.101(a), (c), or (d), a request from a Federal health care program for a waiver of the exclusion will be considered only if the Federal health care program administrator determines that—

(1) The individual or entity is the sole community physician or the sole source of essential specialized services in a community; and

(2) The exclusion would impose a hardship on beneficiaries (as defined in section 1128A(i)(5) of the Act) of that program.

(c) With respect to exclusions imposed under subpart C of this part, a request for waiver will only be granted if OIG determines that imposition of the exclusion would not be in the public interest.

(d) If the basis for the waiver ceases to exist, the waiver will be rescinded.

(e) In the event a waiver is granted, it is applicable only to the program(s) for which waiver is requested.

(f) The decision to grant, deny, or rescind a request for a waiver is not subject to administrative or judicial review.

§ 1001.1901 Scope and effect of exclusion.

(a) *Scope of exclusion.* Exclusions of individuals and entities under this title will be from all Federal health care programs, as defined in § 1000.10 of this chapter.

(b) *Effect of exclusion on excluded individuals and entities.* (1) Unless and until an individual or entity is reinstated into the Federal health care programs in accordance with subpart F of this part, no payment will be made by any Federal health care program for any item or service furnished, on or after the effective date specified in the notice—

(i) By an excluded individual or entity; or

(ii) At the medical direction or on the prescription of a physician or an authorized individual who is excluded when the person furnishing such item or service knew, or had reason to know, of the exclusion.

(2) This section applies regardless of whether an individual or entity has obtained a Federal health care program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated.

(3) An excluded individual or entity may not take assignment of an enrollee's claim on or after the effective date of exclusion.

(4) An excluded individual or entity that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act and criminal liability under section 1128B(a)(3) of the Act and other provisions. In addition, submitting claims, or causing claims to be submitted or payments to be made, for items or services furnished, ordered, or prescribed, including administrative and management services or salary, may serve as the basis for denying reinstatement to the Federal health care programs.

(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.

(2) CMS will not pay an enrollee 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 more than 15 days after the date on the notice to the enrollee, or after the effective date of the exclusion, whichever is later.

(3) Unless the Secretary determines that the health and safety of

beneficiaries receiving services under any Federal health care program warrants the exclusion taking effect earlier, payment may be made under such program for up to 30 days after the effective date of the exclusion for—

(i) Inpatient institutional services furnished to an individual who was admitted to an excluded institution before the date of the exclusion;

(ii) Home health services and hospice care furnished to an individual under a plan of care established before the effective date of the exclusion; and

(iii) Any health care items that are ordered by a practitioner, provider, or supplier from an excluded manufacturer before the effective date of the exclusion and delivered within 30 days of the effective date of such exclusion.

(4) CMS will not pay any claims submitted by, or for items or services ordered or prescribed by, an excluded provider for dates of service 15 days or more after the notice of the provider's exclusion was mailed to the supplier.

(5)(i) Notwithstanding the other provisions of this section, payment may be made under any Federal health care program 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.

(ii) Notwithstanding paragraph (c)(5)(i) of this section, no claim for emergency items or services will be payable if such items or services were provided by an excluded individual who, through an employment, contractual or any other arrangement, routinely provides emergency health care items or services.

Subpart E—Notice and Appeals

■ 12. Revise and republish § 1001.2001 to read as follows:

§ 1001.2001 Notice of intent to exclude.

(a) Except as provided in paragraph (c) of this section, if OIG proposes to exclude an individual or entity in accordance with subpart B or C of this part, it will send written notice of its intent, the basis for the proposed exclusion, and the potential effect of an exclusion. Within 30 days of receipt of notice, which will be deemed to be 7 days after the date on the notice, the individual or entity may submit documentary evidence and written argument concerning whether the exclusion is warranted and any related issues.

(b) If OIG intends to exclude an individual or entity under the provisions of § 1001.701, § 1001.801, or § 1001.1552, in conjunction with the submission of documentary evidence and written argument, an individual or entity may request an opportunity to present oral argument to an OIG official.

(c) *Exception.* If OIG intends to exclude an individual or entity under the provisions of § 1001.901, § 1001.951, § 1001.1301, § 1001.1401, § 1001.1601, or § 1001.1701, paragraph (a) of this section will not apply.

(d) If an entity has a provider agreement under section 1866 of the Act, and OIG proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice provided for in paragraph (a) of this section will so state.

■ 13. Revise and republish § 1001.2004 through 1001.2007 to read as follows:

Sec.

* * * * *

§ 1001.2004 Notice to State agencies.

OIG will promptly notify each appropriate State agency administering or supervising the administration of each State health care program of:

(a) The facts and circumstances of each exclusion; and

(b) The period for which the State agency is being directed to exclude the individual or entity.

§ 1001.2005 Notice to State licensing agencies.

(a) OIG will promptly notify the appropriate State(s) or local agencies or authorities having responsibility for the licensing or certification of an excluded individual or entity of the facts and circumstances of the exclusion.

(b) OIG will request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and will request that the State or local agency or authority keep the Secretary and OIG fully and currently informed with respect to any actions taken in response to the request.

§ 1001.2006 Notice to others regarding exclusion.

(a) OIG will give notice of the exclusion and the effective date to the public and others via online publication of the List of Excluded Individuals/Entities (commonly referred to as ''the LEIE'').

(b) In the case of an exclusion under § 1001.101, if section 304(a)(5) of the Controlled Substances Act (21 U.S.C. 824(a)(5)) applies, OIG will give notice to the Attorney General of the United States of the facts and circumstances of the exclusion and the length of the exclusion.

§ 1001.2007 Appeal of exclusions.

(a)(1) Except as provided in § 1001.2003, an individual or entity excluded under this part may file a request for a hearing before an ALJ only on the issues of whether:

(i) The basis for the imposition of the exclusion exists; and

(ii) The length of exclusion is unreasonable.

(2) When OIG imposes an exclusion under subpart B of this part for a period of 5 years, paragraph (a)(1)(ii) of this section will not apply.

(3) The request for a hearing shall contain the information set forth in § 1005.2(d) of this chapter.

(b) The excluded individual or entity has 60 days from the receipt of notice of exclusion provided for in § 1001.2002 to file a request for a hearing.

(c) The standard of proof at a hearing is preponderance of the evidence.

(d) When the exclusion is based on the existence of a criminal conviction or a civil judgment imposing liability by a Federal, State, or local court, a determination by another government agency, or any other prior determination where the facts were adjudicated and a final decision was made, the basis for the underlying conviction, civil judgment, or determination is not reviewable and the individual or entity may not collaterally attack it either on substantive or procedural grounds in this appeal.

(e) The procedures in part 1005 of this chapter will apply to the appeal.

■ 14. Revise and republish subpart F to read as follows:

Subpart F—Reinstatement Into the Programs

Sec.

Subpart F—Reinstatement Into the Programs

§ 1001.3001 Timing and method of request for reinstatement.

(a)(1) Except as provided in paragraph (a)(2) of this section or in § 1001.501(b)(2), § 1001.501(c), or § 1001.601(b)(2), an excluded individual or entity (other than those excluded in accordance with §§ 1001.1001 and 1001.1501) may submit a written request for reinstatement to OIG only after the date specified in the notice of exclusion. Obtaining a Federal health care program provider number or equivalent does not reinstate eligibility.

(2) An entity excluded under § 1001.1001 may apply for reinstatement prior to the date specified in the notice of exclusion by submitting a written request for reinstatement that includes documentation demonstrating that the standards set forth in § 1001.3002(c) have been met.

(b) Upon receipt of a written request, OIG will require the requestor to furnish specific information and authorization to obtain information from private health insurers, peer review bodies, probation officers, professional associates, investigative agencies, and such others as may be necessary to determine whether reinstatement should be granted.

(c) Failure to furnish the required information or authorization will result in the continuation of the exclusion.

(d) If a period of exclusion is reduced on appeal (regardless of whether further appeal is pending), the individual or entity may request reinstatement once the reduced exclusion period expires.

§ 1001.3002 Basis for reinstatement.

(a) OIG will authorize reinstatement if it determines that—

(1) The period of exclusion has expired;

(2) There are reasonable assurances that the types of actions that formed the basis for the original exclusion have not recurred and will not recur; and

(3) There is no additional basis under sections 1128(a) or (b) or 1128A of the Act for continuation of the exclusion.

(b) In making the reinstatement determination described in paragraph (a) of this section, OIG will consider—

(1) Conduct of the individual or entity occurring prior to the date of the notice of exclusion, if not known to OIG at the time of the exclusion;

(2) Conduct of the individual or entity after the date of the notice of exclusion;

(3) Whether all fines and all debts due and owing (including overpayments) to any Federal, State, or local government that relate to any Federal health care program have been paid or satisfactory arrangements have been made to fulfill obligations;

(4) Whether CMS has determined that the individual or entity complies with, or has made satisfactory arrangements to fulfill, all the applicable conditions of participation or supplier conditions for coverage under the statutes and regulations;

(5) Whether the individual or entity has, during the period of exclusion, submitted claims, or caused claims to be submitted or payment to be made by any Federal health care program, for items or services the excluded party furnished, ordered, or prescribed, including health care administrative services. This section applies regardless of whether an individual or entity has obtained a Federal health care program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated; and

(c) If OIG determines that the criteria in paragraphs (a)(2) and (3) of this section have been met, an entity excluded in accordance with § 1001.1001 will be reinstated upon a determination by OIG that the individual whose conviction, exclusion, or civil money penalty was the basis for the entity's exclusion—

(1) Has properly reduced the individual's ownership or control interest in the entity below 5 percent;

(2) Is no longer an officer, director, agent, or managing employee of the entity; or

(3) Has been reinstated in accordance with paragraph (a) of this section or § 1001.3005.

(d) Reinstatement will not be effective until OIG grants the request and provides notice under § 1001.3003(a). Reinstatement will be effective as provided in the notice.

(e) A determination with respect to reinstatement is not appealable or reviewable except as provided in § 1001.3004.

(f) An ALJ may not require reinstatement of an individual or entity in accordance with this chapter.

§ 1001.3003 Approval of request for reinstatement.

(a) If OIG grants a request for reinstatement, OIG will—

(1) Give written notice to the excluded individual or entity specifying the date of reinstatement;

(2) Notify each appropriate State agency administering or supervising the administration of each State health care program (and, in the case of an exclusion effected pursuant to § 1001.101 and to which 21 U.S.C. 824(a)(5) may apply, the Attorney General) of the date of the individual's or entity's reinstatement; and

(3) Notify the public and others through posting of reinstatement information on OIG's website.

(b) An action taken by OIG under this section will not require a Federal health care program to reinstate the individual or entity if such program has imposed an action under its own authority.

§ 1001.3004 Denial of request for reinstatement.

(a) If a request for reinstatement is denied, OIG will give written notice to the requesting individual or entity that the request for reinstatement has been denied and the basis for the denial. Within 30 days of the date on the notice, the excluded individual or entity may submit a written request to appeal the denial of the individual's or entity's reinstatement. The individual or entity will have 30 days from the date of the written request to appeal to submit:

(1) Any written argument or additional evidence the individual or entity has regarding the basis for the denial of reinstatement; or

(2) A written request to present oral argument or any additional evidence to an OIG official regarding the basis for the denial of reinstatement.

(b) After evaluating any written argument or additional evidence submitted by the excluded individual or entity or any oral argument and additional evidence presented to an OIG official, OIG will send written notice either confirming the denial and indicating that a subsequent request for reinstatement will not be considered until at least 1 year after the date of denial, or approving the request consistent with the procedures set forth in § 1001.3003(a).

(c) The decision to deny reinstatement will not be subject to administrative or judicial review.

§ 1001.3005 Withdrawal of exclusion for reversed or vacated decisions.

(a) An exclusion will be withdrawn and an individual or entity will be reinstated into all Federal health care programs retroactive to the effective date of the exclusion when such exclusion is based on—

(1) A conviction that is reversed or vacated on appeal;

(2) An action by another agency, such as a State agency or licensing board, that is reversed or vacated on appeal; or

(3) An OIG exclusion action that is reversed or vacated at any stage of an individual's or entity's administrative appeal process.

(b) If an individual or entity is reinstated in accordance with paragraph (a) of this section, the Federal health care programs will make payment for services covered under such programs that were furnished or performed during the period of exclusion.

(c) OIG will give notice of a reinstatement under this section in accordance with § 1001.3003(a).

(d) An action taken by OIG under this section will not require a Federal health care program to reinstate the individual or entity if such program has imposed an exclusion under its own authority.

(e) If an action which results in the retroactive reinstatement of an individual or entity is subsequently overturned, OIG may reimpose the exclusion for the initial period of time, less the period of time that was served prior to the reinstatement of the individual or entity.

Xavier Becerra,

Secretary.

[FR Doc. 2024–26804 Filed 11–29–24; 8:45 am]

BILLING CODE P