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HEALTH LAW NEWS

AUGUST 09, 2023

OIG SIGNALS EXPANSION TO ITS EXCLUSION AUTHORITIES

The Office of Information and Regulatory Affairs recently released the Biden administration's Spring 2023 Unified Agenda of Regulatory and Deregulatory Actions (the "Unified Agenda"). Contained in the Unified Agenda is an Advanced Notice of Proposed Rulemaking from the Office of Inspector General ("OIG") of a proposed rule which would, among other changes, expand the scope of OIG's exclusion authorities.

The proposed rule is expected to be published in November 2023 in the Federal Register, but a brief summary is currently available in the Unified Agenda.

BACKGROUND

OIG has the authority to exclude individuals and entities convicted of certain offenses in connection with health care from participation in Medicare, Medicaid and all other federal health care programs. Such exclusions can be *mandatory* for certain types of convictions relating to health care, such as a felony conviction in connection with the delivery of a health care service, or *permissive* for other types of convictions, such as misdemeanors involving health care fraud. An exclusion results in the individual or entity being placed on the List of Excluded Individuals and Entities.

The proposed rule would modify various modalities of such exclusions.

KEY POTENTIAL CHANGES AND UPDATES

1. Drug misclassification

Under the proposed rule, OIG could exclude drug manufacturers that "misclassify outpatient drugs, fail to correct such misclassifications, or provide false information or data related to drug pricing or product information." This proposed expansion of the scope of OIG's exclusion authority falls within CMS's larger effort to increase drug price transparency.

2. Updates to several exclusion regulation sections

The proposed rule would also update several sections of 42 CFR 1001 to reflect the corresponding statutory authority, including § 1001.1501 relating to the default of health education loan or scholarship obligations. Given that the full text of the proposed rule will not be available until November, additional information regarding these updates will be forthcoming.

3. Modification of aggravating or mitigating factors in deciding exclusions

The proposed rule would additionally "modify or eliminate various aggravating and mitigating factors used to set the length of an exclusion."

4. Modification of rules governing the notice of exclusions and reinstatements to the public and state agencies

The proposed rule would affect sections of 42 CFR 1001 relating to the notice of exclusions to the public and state agencies, such as § 1001.2004 "Notice to state agencies" and § 1001.2006 "Notice to others regarding exclusion." The proposed rule could potentially modify the process by which OIG notifies State Medicaid agencies of exclusions. Timely notification of these agencies by OIG is critical in ensuring accurate database listings.

PRACTICAL TAKEAWAYS

- The rule's proposed expansion of OIG's exclusion authorities to drug manufacturers knowingly misclassifying covered outpatient drugs would act as a deterrent for those manufacturers seeking to avoid the rebates required by the Medicare Drug Rebate Program while still reaping the rewards of the program. This is part of a larger effort by CMS to increase drug transparency and cost-effectiveness by imposing more stringent regulations on both drug manufacturers and pharmacy benefit managers.
- The proposed rule would also: 1) update sections of OIG's exclusion authorities for Providers defaulting on their education loans; 2) modify factors aggravating and mitigating the length of an exclusion; and 3) revise the process by which OIG gives notice of Providers' exclusions to the public and state agencies.

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- OIG would use this rule as an opportunity to incorporate the practical insights it gained through recent enforcement actions into several sections of 42 CFR 1001.
- Because the proposed rule has not yet been published, additional detail will be forthcoming at the time of publication in the Federal Register (November 2023).
- Please note that it is currently not possible to formally submit comments via the Federal eRulemaking Portal or by mail. However, informal comments about the proposed rule (RIN: 0936-AA12) can be submitted at this time.

If you have any questions regarding OIG's exclusion authorities, would like to submit informal comments or would like assistance in a matter involving the exclusion of a Provider from participation in federally funded health care programs, please contact:

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Special thanks to Antoine Neumann, summer associate, for his assistance with the preparation of this article.

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