

**FROM THE OFFICE OF THE  
INSPECTOR GENERAL:  
SAFE HARBOR REGULATIONS UNDER  
THE ANTI-KICKBACK STATUTE**

**GILL  
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ATTORNEYS

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On January 31, 2019, the United States Department of Health and Human Services shared a proposed rule that, if finalized, would amend the Office of Inspector General's safe harbor regulations under the Anti-Kickback Statute. The Anti-Kickback Statute is a criminal law that prohibits the knowing and willful offer, solicitation, payment, or receipt of anything of value in exchange for Federal health care program business. Safe harbor regulations describe payment practices that are not subject to liability under the Anti-Kickback Statute when all safe harbor conditions are satisfied.

In this proposed rule, the Department of Health and Human Services proposes to amend the safe harbor regulation concerning discounts, which are defined as certain conduct that is protected from liability under the Federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act). The amendment would revise the discount safe harbor to explicitly exclude from the definition of a discount eligible for safe harbor protection certain reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to plan sponsors under Medicare Part D, Medicaid managed care organizations as defined under section 1903(m) of the Act (Medicaid MCOs), or pharmacy benefit managers under contract with them. In addition, the Department is proposing two new safe harbors:

- 1) protect certain point-of-sale reductions in price on prescription pharmaceutical products, and**
- 2) protect certain pharmacy benefit managers service fees.**

This document is scheduled to be published in the Federal Register on 02/06/2019 and available online at <https://federalregister.gov/d/2019-01026>, and <https://www.govinfo.gov/>.

**OUR HEALTH LAW GROUP  
WILL BE GLAD TO ANSWER  
ANY QUESTIONS YOU MAY HAVE  
REGARDING SAFE HARBOR  
REGULATIONS UNDER THE ANTI-  
KICKBACK STATUTE.**



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