



CMS and OIG release most expansive changes to the fraud and abuse laws in over a decade

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Healthcare Alert

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On October 9, CMS and OIG issued proposed rule changes to the Physician-Self Referral Law (commonly known as the Stark Law)¹ and the Anti-Kickback Statute (AKS)², creating new exceptions and safe harbors for value-based care arrangements and substantially easing burdensome technical requirements of the Stark Law, amongst other things.

The proposed rule changes represent the most significant changes to the fraud and abuse laws in over a decade and reflect a coordinated effort by CMS and OIG to address regulatory challenges impeding the expansion of value-based care models. The proposed changes are part of HHS' Regulatory Sprint, which seeks to remove regulatory barriers to care coordination and value-based care and have been highly anticipated by the healthcare industry since the agencies' Requests for Information were issued in the summer of 2018.

The proposals take into account stakeholders' concerns with respect to the substantial consequences for noncompliance with these laws as well as increasing administrative costs incurred through continued compliance and monitoring efforts. The proposals take a practical approach, particularly with respect to the Stark Law, in balancing needed flexibility and protecting beneficiaries and the federal healthcare programs.

Notably, however, certain provider types (pharmaceutical companies, durable medical equipment and prosthetics/orthotics and suppliers (DMEPOS), device manufacturers and distributors, and laboratories) are excluded from the new value-based care exceptions and safe harbors, potentially chilling these providers' participation in risk-sharing models.

Proposed changes to the AKS include five new safe harbors (Care Coordination Arrangements, Value-Based Arrangements with Substantial Downside Financial Risk, Value-Based Arrangements at Full Financial Risk, ACO Beneficiary Incentives Program, and Donations of Cybersecurity Technology and Related Services) as well as revisions to four existing safe harbors (Personal Services and Management Contracts, Warranties, Local Transportation, and Electronic Health Record Donations).

Proposed changes to the Stark Law include four new exceptions (Full Financial Risk, Meaningful Downside Financial Risk, Value-Based Arrangements, and Limited Remuneration to a Physician) as well as revisions and clarifications to the following existing exceptions and definitions: Payments by a Physician, Compensation Unrelated to DHS, Value-Based Indirect Compensation Arrangements, Fair Market Value, Commercial Reasonableness, Volume or Value, Isolated Transactions, Periods of Disallowance, Temporary Noncompliance, Group Practice Profit Sharing and Productivity Bonuses related to Value-Based Care Arrangements, Exclusive Use of Office Space and Equipment, and Physician and Non-Physician Practitioner Recruitment.

The Proposed Rules were published in the *Federal Register* on October 17, 2019, and comments are due December 31, 2019.

Our comprehensive, complimentary summary

The rules do not lessen the overall complexity of the governing regulatory regimes, and accordingly, we have taken a comprehensive and extensive approach to explaining the key proposals. We have prepared a detailed summary of the proposals, which is complimentary upon request. Please reach out to one of our healthcare partners identified below to receive your free copy.

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¹ CMS Proposed Rule is available at: <https://www.federalregister.gov/documents/2019/10/17/2019-22028/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>.

² OIG Proposed Rule is available at: <https://www.govinfo.gov/content/pkg/FR-2019-10-17/pdf/2019-22027.pdf>.

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