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HHS OIG Issues Proposed Rule to Remove Regulatory Barriers to Care Coordination, Value-based Care

The HHS Office of Inspector General (OIG) on Oct. 17 issued a proposed rule that aims to reduce regulatory barriers to care coordination and value-based care by creating safe harbors in the Federal Anti-Kickback Statute (AKS).

The proposed rule, titled "[Medicare and State Healthcare Programs; Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducement](#)," is part of a broader regulatory sprint to remove potential regulatory barriers in health care. This proposal includes three new safe harbors for remuneration exchanged between or among participants in a value-based arrangement, a move that aims to foster better coordinated and managed patient care, among others.

Among other things, OIG proposes to use the term "value-based enterprise" (VBE) to describe individuals and entities participating in value-based arrangements eligible for safe harbor protection. Pharmaceutical manufacturers are expressly excluded as a VBE participant in the proposal.

Comments on the proposal may be submitted to OIG through Dec. 31.

AMCP has advocated for regulatory changes to address barriers to value-based contracts and will urge OIG to create a safe harbor protection for value-based contracting in future rulemaking.

Provide feedback by Dec. 13 to Afton Wagner, AMCP director of regulatory affairs, at awagner@amcp.org.

NEXUS2019
— The Intersection of Value and Care

- TUESDAY, OCT 29 – FRIDAY, NOV 1
- GAYLORD NATIONAL HARBOR
- NATIONAL HARBOR, MD



Legislative Update

Advocacy Tip

Congress Continues Work on Drug Pricing Bills in House and Senate

The House and Senate recently introduced legislation to address high pharmaceutical costs, an issue that continues to dominate policy discussions on Capitol Hill.

Speaker Nancy Pelosi (D-Calif.) last month introduced [The Lower Drug Costs Now Act of 2019](#) (H.R.3). Included in the bill are provisions that give HHS broad authority to negotiate drug prices under Medicare and extend those negotiated prices to the private market. The Speaker's bill also caps drug costs by forcing drug companies to give rebates to Medicare if they increase prices above inflation. In addition, H.R.3 would redesign the Medicare Part D drug benefit, including capping patients' out-of-pocket costs to \$2,000 annually. Two House committees held H.R.3 markups on Oct. 17: the Energy and Commerce Committee, and the Education and Labor Committee. The House Ways and Means Committee also held a hearing on the bill that day.

Meanwhile, the Senate Finance Committee finalized language last month on the [Prescription Drug Pricing Reduction Act of 2019](#) (S.2543). The bill, released Sept. 25, also includes language to cap drug costs by forcing drug companies to give rebates to Medicare if they increase their prices above inflation. In addition, S.2543 would create a \$3,100 out-of-pocket cap on prescription drugs for Medicare beneficiaries by 2022 and implement pharmacy quality measure starting in 2023.

Stay up-to-date: Read AMCP's [Letters, Statements and Analysis](#) on all legislation and regulation impacting managed care pharmacy.

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