

Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions

Summary

WHY WE DID THIS STUDY

Federal law and regulations require Medicare Part D Pharmacy and Therapeutics (P&T) committees to make prescription drug coverage decisions based on scientific evidence and standards of practice. Formulary decisions affect beneficiaries' access to specific prescription drugs and the cost of drugs to beneficiaries and the Federal Government. To comply with the law, sponsors' P&T committees must prevent conflicts of interest from influencing members to give preference to certain drugs. In addition, sponsors' P&T committees must comply with Federal law and regulations that specifically address conflicts on P&T committees by requiring that at least one physician and at least one pharmacist on each committee be independent and free of conflict relative to the sponsor and pharmaceutical manufacturers.

HOW WE DID THIS STUDY

We conducted a document review and analyzed survey responses from P&T committees to determine the extent to which they defined, determined, and managed conflicts of interest. We also conducted structured interviews with staff at CMS to determine the extent to which CMS oversees Medicare Part D P&T committees' compliance with the requirement that at least two members be independent and free of conflict and whether CMS oversees members' recusals.

WHAT WE FOUND

Sponsors' P&T committees have limited oversight of committee members' conflicts of interest, compromising sponsors' ability to prevent financial interests from influencing coverage decisions. The majority of sponsors' P&T committees have limited definitions of

conflicts of interest, which could prevent them from identifying conflicts. Also, many sponsors' P&T committees allow their members to determine and manage their own conflicts. Additionally, CMS does not adequately oversee sponsors' compliance with the requirement that at least two members on each P&T committee be independent and free of conflict relative to the sponsor and pharmaceutical manufacturers.

WHAT WE RECOMMEND

We recommend that CMS: (1) define pharmacy benefit managers as entities that could benefit from coverage decisions, (2) direct sponsors to ensure that safeguards are in place to mitigate improprieties related to employment by the entity managing the P&T committee, (3) direct sponsors to ensure that an objective process is used to determine conflicts, (4) direct sponsors to ensure that an objective process is used to manage conflicts, and (5) oversee sponsors' compliance with the requirement that at least two committee members be independent and free of conflict. CMS did not concur with our first and second recommendations, concurred with part of our third and fourth recommendations, and concurred with our fifth recommendation.

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