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GAPS IN OVERSIGHT OF CONFLICTS OF INTEREST IN MEDICARE PRESCRIPTION DRUG DECISIONS

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EXECUTIVE SUMMARY: GAPS IN OVERSIGHT OF CONFLICTS OF INTEREST IN MEDICARE PRESCRIPTION DRUG DECISIONS
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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 the Centers for Medicare & Medicaid Services (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. Most 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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OBJECTIVES

1. To assess sponsors' Pharmacy and Therapeutics (P&T) committees' conflict-of interest-definitions.
2. To determine whether sponsors' P&T committees established objective processes to determine and manage committee members' conflicts of interest.
3. To determine whether the Centers for Medicare & Medicaid Services (CMS) oversee sponsors' P&T committee compliance with conflict-of-interest requirements.

BACKGROUND

Federal law and regulations require Medicare Part D P&T committees to make prescription drug coverage decisions based on scientific evidence and standards of practice. Coverage decisions affect beneficiaries' access to specific prescription drugs and the cost of drugs to beneficiaries and the Federal Government. To ensure that coverage decisions are appropriate, sponsors' P&T committees must prevent members from giving preference to certain drugs based on their personal financial interests. 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.

Research has shown that financial interests between the pharmaceutical industry and health care professionals are common. There is evidence of pervasive conflicts of interest among pharmaceutical manufacturers and health care practitioners, researchers, and educators.[1, 2] For example, a national survey in 2009 found that 84 percent of practicing physicians reported some type of financial interest in the pharmaceutical industry.[3]

Evidence suggests that financial relationships may improperly influence medical decisionmaking. For example, physicians who accepted money

[1] Bernard Lo and Marilyn J. Fields (eds.), *Conflict of Interest in Medical Research, Education, and Practice*, Institute of Medicine of the National Academies, 2009.

[2] "Medical Research and Education: Higher Learning or Higher Earning?": Hearing Before the U.S. Senate Special Committee on Aging, 111th Congress 2009, Statement of Eric G. Campbell, Associate Professor and Director of Research, Institute for Health Policy, Massachusetts General Hospital and Harvard Medical School.

[3] Eric G. Campbell et al., "Physician Professionalism and Changes in Physician-Industry Relationships From 2004–2009," *Archives of Internal Medicine*, vol. 170, no. 20, November 8, 2010, pp. 1820–1826.

from pharmaceutical manufacturers were much more likely than others to have requested that drugs manufactured by those companies be added to hospital formularies.[4]

Medicare Part D

Medicare's prescription drug program, known as Part D, provides optional drug benefits to Medicare beneficiaries.[5] CMS contracts with private insurance companies, called sponsors, to provide Part D prescription drug coverage to beneficiaries who choose to enroll. Sponsors offer drug coverage to beneficiaries through Part D prescription drug plans. As of March 2012, approximately 31 million beneficiaries were enrolled in Part D plans.[6]

Part D Formularies

Sponsors can use a variety of methods to control the cost of providing prescription drug coverage through the Part D program. Sponsors can establish formularies, or lists of covered drugs, to give preference to certain drugs over others that treat the same condition. Formularies are generally organized into tiers, which have different copayments to drive utilization toward less-expensive drugs. Drugs in lower tiers are typically the least expensive and have the lowest beneficiary copayment. Drugs in ascending tiers are, in general, more expensive and have increasing beneficiary copayments. For example, a low-cost generic drug on Tier 1 may require a $5 copayment, a preferred brand-name drug on Tier 2 may require a $40 copayment, a nonpreferred brand-name drug on Tier 3 may require a $90 copayment, and specialty drugs on Tier 4 may require coinsurance for 30 percent of the drugs' cost.

Sponsors can employ utilization management practices, such as prior authorization, quantity limits, and generic substitution, to restrict the use of certain drugs on their formularies. For example, sponsors may require a beneficiary to try a less-expensive alternative drug before progressing to a costlier drug. Sponsors also can negotiate price concessions with pharmaceutical manufacturers to reduce the cost of prescription drugs for sponsors and beneficiaries.

Sponsors may contract with one or more pharmacy benefit managers (PBM) to help them manage their formularies and other aspects of their

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[4] Mary-Margaret Chren and C. Seth Landefeld, "Physicians' Behavior and Their Interactions With Drug Companies," *Journal of the American Medical Association (JAMA)*, vol. 271, no. 9, March 1994, pp. 684–689.

[5] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173 § 101; Social Security Act, § 1860D-1; U.S.C. § 1395w-101.

[6] CMS, *Medicare Advantage, Cost, PACE, Demo, and Prescription Drug Plan Contract Report - Monthly Summary Report (Data as of March 2012)*. Accessed at http://www.cms.gov on April 10, 2012.

prescription drug benefit. PBMs offer a wide variety of services including managing formularies, processing prescription drug claims, contracting with pharmacies, and negotiating price concessions with pharmaceutical manufacturers for particular drugs.[7] PBMs can be compensated for these services in a number of ways, one of which is retaining a percentage of price concessions that they negotiate on behalf of sponsors.[8]

Sponsors are responsible for complying with Federal requirements and all terms and conditions of their Part D contracts with CMS, even if the sponsor has delegated responsibilities for managing the formulary to a PBM.[9, 10] Sponsors must have contracts with their Part D contractors, including PBMs, to ensure that the contractors comply with all applicable Federal laws and regulations and with CMS instructions.[11]

P&T Committees

Sponsors that use formularies for their Part D plans are required by Federal law to maintain P&T committees.[12] Sponsors either manage their own formularies and, therefore, maintain the P&T committee; or contract out these functions to a PBM. Maintaining P&T committees could involve, among other functions, selecting members, appointing an individual to chair the committee, and creating the policies and administrative procedures that govern the committee.

P&T committees' role is to make clinical decisions about which drugs are on Part D plan formularies; many of these decisions are binding on the Part D plan. Per Federal regulations, sponsors are required to follow the decisions that P&T committees make regarding which drugs to include on the formulary.[13, 14] However, sponsors can decide which formulary tier to place these drugs on, based on the recommendation of their P&T committees.[15] Sponsors also must adhere to the P&T committees' decisions regarding prescription drug utilization management practices.[16]

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[7] CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 9, § 10.1.

[8] Office of Inspector General (OIG), *Concerns With Rebates in the Medicare Part D Program*, OEI-02-08-00050, March 2011.

[9] 42 CFR § 423.505(i).

[10] CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 6, § 30.1.3.

[11] 42 CFR § 423.505(i)(4)(iv).

[12] Section 1860D-4(b)(3)(A) of the Act; some plan types, such as the Program of All-Inclusive Care for the Elderly (PACE) plans, do not routinely use formularies to manage prescription drug utilization and therefore do not have P&T committees.

[13] 42 CFR 423.120(b)(1).

[14] CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 6, § 30.1.5.

[15] 42 CFR § 423.120(b)(1).

[16] 42 CFR § 423.120(b)(1)(ix).

When determining whether to include a drug on a formulary, Federal law requires P&T committees to base clinical decisions on the strength of scientific evidence and standards of practice.[17] For example, when voting to include a drug, P&T committees must consider whether the addition of that drug has therapeutic advantages in terms of safety and efficacy.[18] Cost considerations should be secondary to the determination of clinical efficacy and appropriateness of drugs.[19]

P&T committees typically make formulary decisions for multiple Part D plans. In general, we found that one P&T committee makes decisions for all the Part D plans managed by a sponsor or a PBM. See Appendix A for an illustration of how one P&T committee can provide services to multiple Part D sponsors and plans.

P&T committees vary in size. Our analysis showed that in 2010, P&T committees ranged from 3 to 62 members, with an average of 16.

Sponsors and PBMs may compensate their P&T committee members for serving on the committee and for standard expenses incurred while attending committee meetings. P&T committee members who were not employees of the sponsor or the PBM managing the P&T committee were paid, on average, $2,404 in 2010 for serving on the committee.

P&T Committee Conflicts of Interest

Federal law, regulations, and CMS guidance provide limited direction on how P&T committees should handle conflicts of interest. Federal law and regulations restrict some P&T committee members from having conflicts of interest with certain entities. They do not explicitly stipulate what constitutes a conflict. Beyond that, CMS guidance provides some general expectations for the disclosure of conflicts and recusal of P&T committee members with conflicts.

As the entities that contract with CMS to provide prescription drug coverage to Medicare beneficiaries, sponsors are responsible for ensuring that all Federal laws and regulations pertaining to P&T committee members' conflicts are followed. Although sponsors are ultimately responsible, entities that maintain the P&T committees establish the policies and procedures governing the definition, disclosure, determination, and management of P&T committee conflicts. These policies and procedures are unique to each P&T committee, not to each sponsor.

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[17] 42 U.S.C. 1395w-104(b)(3)(B).

[18] Ibid.

[19] CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 9, § 50.2.1.2.

Definition. Federal law and regulations address conflicts of interest with respect to P&T committees by defining members of the committees who must be free of conflict and the entities with which they must be free of conflict. The law stipulates that at least one physician and at least one pharmacist on each P&T committee be free of conflict relative to the sponsor and Part D plan.[20] Therefore, a minimum of two members on each P&T committee must be independent from the sponsor and Part D plan. However, CMS explained in the preamble to the 2005 Final Rule that this requirement should be viewed "as a floor which we encourage them to exceed."[21] Regulations expand the law by including pharmaceutical manufacturers as entities from which at least two members must be independent.[22, 23]

Federal law and regulations and CMS guidance do not explicitly define what constitutes a conflict with sponsors, Part D plans, and pharmaceutical manufacturers. However, CMS provides limited direction on what may be considered a conflict with pharmaceutical manufacturers. In the *Medicare Prescription Drug Benefit Manual*, CMS states that certain relationships with pharmaceutical manufacturers may still be considered independent and free of conflict. Specifically, P&T committee members who have nonemployee relationships with pharmaceutical manufacturers that do not constitute "significant sources of income" may still be considered independent. Such nonemployee relationships with pharmaceutical manufacturers could be advisory or involve consulting or research.[24]

The law, regulations, and guidance do not address P&T committee members' financial interests with any other entities involved in implementing the Part D program, such as PBMs. While CMS suggests in the preamble to the Final Rule that a conflict of interest is "any direct or indirect financial interest in any entity … that would benefit from decisions regarding plan formularies," the regulations specify only sponsors and pharmaceutical manufacturers; they do not specifically list PBMs.[25, 26]

Disclosure and Determination. CMS recommends that P&T committee members disclose financial interests by signing and continually updating

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[20] 42 U.S.C. 1395w-104(b)(3)(A)(ii).

[21] 70 Fed. Reg. 4255, 4256 (Jan. 28, 2005).

[22] 42 CFR § 423.120(b)(1)(ii).

[23] In the subsequent *Health Plan Management System Basic Contract Management Technical User's Manual*, CMS defines sponsor to include both the sponsor and the Part D plan.

[24] CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 6, § 30.1.1.

[25] 70 Fed. Reg. 4255, 4256 (Jan. 28, 2005).

[26] 42 CFR § 423.120(b)(1)(ii).

conflict-of-interest statements to reveal financial or other relationships with entities affected by drug coverage decisions.[27, 28] CMS explains in the preamble to the Final Rule that it expects P&T committee members to sign conflict-of-interest statements that are consistent with industry standards for conflict-of-interest disclosures.[29] However, CMS does not specify which industry standards to follow.

CMS does not provide any guidance on how disclosed financial interests are to be reviewed to determine whether they constitute conflicts of interest.

Recusal. While at least two members on each P&T committee must be free of conflict with sponsors and pharmaceutical manufacturers, the remaining members can have conflicts of interest. In the preamble to the Final Rule, CMS explains that it expects procedures to be established that are consistent with standard industry practice for recusing P&T committee members from discussions or votes if a particular drug presents a conflict of interest.[30] However, CMS does not specify which industry standards to follow. CMS does explain that implementing recusal procedures is necessary to ensure that formulary decisions are based on scientific evidence and standards of practice.[31]

CMS Oversight of P&T Committee Conflicts of Interest

CMS requires sponsors to attest on their initial Part D applications that the membership of their P&T committees will include at least one practicing physician and at least one practicing pharmacist, both of whom are free of conflict with the sponsor and pharmaceutical manufacturers.[32]

Additionally, sponsors must report membership information for their P&T committees on their initial Part D applications or ensure that their PBM reports this information on their behalf.[33, 34] This information includes the names of all P&T committee members and the start and end dates of their service on the committee. It also includes whether each committee member is free of any conflict of interest with the organization

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[27] CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 6, § 30.1.2.
[28] CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 9, § 50.2.1.2.
[29] 70 Fed. Reg. 4255, 4257 (Jan. 28, 2005).
[30] 70 Fed. Reg. 4255, 4256 (Jan. 28, 2005).
[31] Ibid.
[32] CMS, *Medicare Prescription Drug Benefit: Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*, 2011 Contract Year.
[33] Ibid.
[34] CMS, *Health Plan Management System Basic Contract Management Technical User's Manual*, Plan Version 1.0, January 5, 2010.

or pharmaceutical manufacturer.[35, 36] (See Appendix B for an example of the membership information reported.)

To report conflict-of-interest information to CMS, sponsors or their contracted PBMs obtain information about P&T committee members' financial interests using conflict-of-interest statements. These statements are not required to be submitted to CMS.

CMS also requires sponsors to report whether they maintain the P&T committee or contract with a PBM to do so. If sponsors contract with a PBM, they also must report the name of the contracted PBM and whether the P&T committee operates under a confidentiality agreement.[37, 38]

When sponsors and PBMs enter into confidentiality agreements, PBMs report their P&T committee members' names, service dates, and conflict-of-interest information directly to CMS.[39] They do not disclose this information to the sponsors.[40]

CMS requires sponsors or their contracted PBMs to report updates relating to their P&T committees at least annually.[41] Updates can include changes to P&T committee membership, confidentiality agreement status, or the entity that maintains the P&T committee. If a new P&T committee member is added, all of the member's information that would have been initially reported is included in this update.

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[35] Federal regulation states that at least one practicing physician and at least one practicing pharmacist must be independent and free of conflict relative to the sponsor and pharmaceutical manufacturers. However, the Member Disclosure Form in the Part D application requests sponsors to provide information on whether these P&T committee members are free of conflict relative to the "organization" and pharmaceutical manufacturers. The CMS *Health Plan Management System Basic Contract Management Technical User's Manual* indicates that "organization" refers to the sponsor.

[36] CMS, *Medicare Prescription Drug Benefit: Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*, 2011 Contract Year.

[37] CMS, *Medicare Part D Reporting Requirements*, January 1, 2010. Accessed at http://www.cms.gov on August 16, 2010.

[38] CMS, *Medicare Part D Reporting Requirements: Technical Specifications Document Contract Year 2010*, January 1, 2010. Accessed at http://www.cms.gov on September 10, 2010.

[39] CMS, *Medicare Prescription Drug Benefit: Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*, 2011 Contract Year.

[40] CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 6, § 30.1.3.

[41] CMS, *Medicare Part D Reporting Requirements*, January 1, 2010. Accessed at http://www.cms.gov on August 16, 2010.

CMS states that it may apply new or adjust existing quality assurance checks on the P&T committee information reported by sponsors.[42] These checks are used by CMS to identify outliers or data that are potentially erroneous.[43]

CMS Oversight of Formularies

CMS reviews and approves the formularies designed by P&T committees. CMS's review focuses on ensuring that formularies provide access to a range of Part D drug choices.[44] CMS checks the formularies to make sure they meet accepted pharmaceutical standards and include drugs from different therapeutic categories.[45] CMS generally does not review formularies for individual drugs. However, it does review individual drugs identified to treat some specific diseases and drugs in classes of clinical concern.[46]

CMS's formulary review also is designed to ensure that it does not substantially discourage any group of beneficiaries from enrolling in the Part D plan.[47] For example, if formularies place certain types of drugs only on tiers that require expensive beneficiary copayments, some beneficiaries might be discouraged from enrolling in the Part D plan. CMS generally reviews the formulary to make sure that low-cost drugs are available on low formulary tiers, which typically have the lowest copayments. CMS also checks that only high-cost drugs (over $600) are placed on the specialty tier, which typically has the highest copayments.

CMS also conducts targeted audits of sponsors to verify that approved formularies are being administered appropriately and that drug coverage decisions are based on scientific evidence.[48] During targeted audits, CMS reviews the development of a Part D plan's formulary by reviewing documents that would show the P&T committee's decisions regarding which drugs to cover and the scientific evidence used to support those

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[42] CMS, *Medicare Part D Reporting Requirements: Technical Specifications Document Contract Year 2010*, January 1, 2010. Accessed at http://www.cms.gov on September 10, 2010.

[43] Ibid.

[44] CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 6, § 30.2.

[45] Ibid.

[46] CMS is required by the Patient Protection and Affordable Care Act to identify categories and classes of drugs that are of clinical concern. Until CMS determines these categories and classes, all, or substantially all, drugs from the following six protected classes as specified by the Medicare Improvements for Patients and Providers Act must be included on Part D formularies: immunosuppressant for the treatment of transplant rejection, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic.

[47] CMS, *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, ch. 6, § 30.2.

[48] CMS, *Medicare Part C & Part D Universal Audit Guide*, Version 1, Appendix H.3: Audit Methodology Formulary Administration, October 28, 2009.

decisions.[49] CMS also may conduct an interview with the sponsor, asking questions related to whether the P&T committee appropriately developed the formulary.[50] CMS also may review P&T committee meeting minutes to determine whether the P&T committee reviewed utilization management practices for clinical appropriateness.[51] In 2010, CMS did not review P&T committee conflicts of interest as part of its targeted audits. However, for 2012, CMS added an optional conflict-of-interest review to its audit protocols. If CMS's targeted audit findings relate to the role of the P&T committee, then CMS reviews a list of P&T committee members to determine whether at least one practicing physician and at least one practicing pharmacist are independent and free of conflict with the sponsor and pharmaceutical manufacturers.

Related Work

OIG has issued numerous reports examining the oversight of conflicts of interest in the Department of Health and Human Services (HHS)[52] and several HHS agencies, including the National Institutes of Health,[53, 54] the Centers for Disease Control and Prevention (CDC),[55] and the Food and Drug Administration.[56] We made recommendations to all of these agencies to strengthen their oversight of conflicts of interest.

[49] CMS, *Medicare Part C & Part D Universal Audit Guide*, Version 1, Appendix H.3: Audit Methodology Formulary Administration, October 28, 2009.

[50] CMS, *Medicare Part C & Part D Universal Audit Guide*, Version 1, Appendix L.3: Interview Guide, Part D Formulary Administration, October 28, 2009.

[51] CMS, *Medicare Part C & Part D Universal Audit Guide*, Version 1, Appendix H.3: Audit Methodology Formulary Administration, October 28, 2009.

[52] OIG, *Conflict-of-Interest Waivers Granted to HHS Employees in 2009*, OEI-04-10-0010, August 2011.

[53] OIG, *National Institutes of Health: Conflicts of Interest in Extramural Research*, OEI-03-06-00460, January 2008.

[54] OIG, *How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health*, OEI-03-07-00700, November 2009.

[55] OIG, *CDC's Ethics Program for Special Government Employees on Federal Advisory Committees*, OEI-04-07-00260, December 2009.

[56] OIG, *The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information*, OEI-05-07-00730, January 2009.

METHODOLOGY

Scope

This study focuses on sponsor and CMS oversight in 2010 intended to ensure that formulary decisions are not biased by conflicts of interest. With respect to sponsor oversight, this evaluation reviewed P&T committee procedures for defining and determining conflicts of interest, and for managing members' conflicts of interest through recusal. With respect to CMS oversight, this evaluation examined how CMS oversees sponsors' compliance with the Federal requirement that at least two members on each P&T committee be free of conflict.

In addition to reviewing oversight, we originally planned to verify that at least two members on each P&T committee were free of conflict. We collected the P&T committee data from CMS to determine whether sponsors complied with Federal regulations. Had these data been accurate, we could have used them to determine compliance. However, our review of the P&T committee data revealed numerous discrepancies and made us question their accuracy. Ultimately, we decided the information was unreliable.

This study focused on Part D plans to which Federal P&T committee conflict-of-interest requirements uniformly applied. As such, we did not review PACE plans because they do not routinely use formularies and therefore do not routinely have P&T committees.

Data Sources and Collection

We collected information on sponsor oversight through a survey of P&T committees and a review of their policies. We collected information on CMS oversight through structured interviews.

We collected information by P&T committee, rather than by sponsor, because the policies and procedures governing P&T committee conflicts of interest are generally unique to each P&T committee and not necessarily unique to the sponsor. In fact, one sponsor may deal with several different P&T committees, each governed by its own set of policies and procedures related to conflicts of interest. This may occur when a sponsor contracts with a PBM to maintain the P&T committee for some, but not all, of its Part D plans. See Appendix A for an illustration of how sponsors may have multiple P&T committees. A single P&T committee maintained by a PBM also may serve multiple Part D plans, either for one sponsor or multiple sponsors.

CMS Data. We obtained Part D information from CMS's Health Plan Management System (HPMS) for all 682 contracts with sponsors in 2010. We removed two contracts because CMS terminated them midway

through 2010. This resulted in a population of 680 contracts with sponsors that were associated with 117 P&T committees.

Survey and Document Request. In January 2011, we conducted an online survey of the 117 P&T committees to determine their procedures for defining, determining, and managing conflicts by recusing members with conflicts.

To direct our survey to the correct entity, we first identified which entity—sponsor or PBM—maintained the plan's P&T committee. Because CMS's data were unreliable, we contacted each entity listed in HPMS as maintaining a P&T committee to verify that it did so. If the entity indicated that the information was incorrect, we asked it to identify the correct entity that maintained the P&T committee. We contacted the second entity to confirm that it was correctly identified. We also confirmed this information by sending a letter to all entities listed as maintaining a P&T committee.

As part of the survey, we asked P&T committees to report the size of their membership and whether members included employees of sponsors and PBMs. We made one followup attempt by telephone. We received 113 complete surveys—a 97-percent response rate.

We requested supporting documents for key survey questions to confirm how sponsors determine and manage P&T committee conflicts of interest. This documentation included conflict-of-interest statements, conflict-of-interest policies, and recusal policies. Two P&T committees did not submit documentation; therefore, we removed them from our analysis of survey questions that required survey documentation.

Structured Interviews. We conducted structured interviews with CMS staff regarding its oversight of sponsor compliance with P&T committee conflict-of-interest requirements and its oversight of sponsors' formularies. We conducted these interviews between September 2010 and September 2011.

Analysis

We analyzed the information we collected to determine the extent to which conflicts of interest were defined, determined, and managed. We analyzed the survey responses and extensively reviewed the submitted documents to develop our findings. When making our determinations, we relied primarily on the documentation, even when it conflicted with the survey responses.

When analyzing conflict-of-interest definitions, we compared them to the broader restriction in the Federal regulations. As previously stated, the

regulations refer to conflicts of interest with sponsors and pharmaceutical manufacturers. Federal law references only sponsors and plans.

We analyzed the P&T committee information reported to CMS and ascertained that this information was unreliable. We determined the data were unreliable by identifying internal inconsistencies in the data as well as discrepancies with other data sources. We then analyzed the data to determine the extent of the inaccuracies. We analyzed the number of P&T committee members reported to CMS for each Part D plan to determine the extent of discrepancies. We analyzed the information that lists which entity maintained the P&T committee to determine the extent of its accuracy.

We analyzed CMS interview responses to determine the extent to which CMS: (1) reviewed reported P&T committee conflict-of-interest information and (2) used any other means to oversee P&T committee members' conflicts.

Data Limitations

The document review we conducted accounted only for written policies. It did not account for unwritten practices. For survey questions that did not require supporting documentation, this report relies on self-reported data.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Most sponsors' P&T committees had limited definitions of conflicts of interest, which could prevent them from identifying conflicts

To comply with Federal law and regulations, P&T committees must make prescription drug formulary decisions based on scientific evidence and standards of practice. One way that the regulations attempt to ensure that this happens is to require that at least two P&T committee members be free of conflict with sponsors and pharmaceutical manufacturers. In addition, CMS suggests that financial interests in any entity that would benefit from formulary decisions could constitute a conflict. Therefore, to capture all possible conflicts, P&T committees' understanding of what constitutes a conflict of interest should include financial interests in sponsors and pharmaceutical manufacturers and with other entities that could benefit from formulary decisions. If P&T committee definitions do not include these factors, committees may not be able to identify potential conflicts that could compromise the independence of a P&T committee's formulary decisions.

Half of P&T committees' definitions did not address conflicts prohibited by Federal regulations

Fifty-three percent of P&T committees reported their definitions did not include any financial interests with either sponsors or pharmaceutical manufacturers as conflicts of interest. These committees' conflict-of-interest definitions failed to include at least one of the entities specified by Federal regulation. Six percent of P&T committees reported their definitions did not include any financial interests with both sponsors and pharmaceutical manufacturers as conflicts, as specified by Federal regulations.

Most P&T committees (52 percent) reported that their definitions did not consider any members' financial interests in sponsors to be conflicts of interest. Sponsors are defined in both Federal law and regulations as potential sources of conflict.

A much smaller percentage (7 percent) of P&T committees' definitions failed to consider any financial interests in pharmaceutical manufacturers to be conflicts of interest.

P&T committees' definitions did not always address relationships with other entities that could benefit from formulary decisions

P&T committees did not always include relationships with PBMs—which could benefit from formulary decisions—in their definitions of conflicts of interest. Thirty-three percent of P&T committees reported that they did not define any financial interests in PBMs as conflicts. P&T committees did not always include relationships with PBMs, even when PBMs were performing Part D functions. Of the 22 P&T committees maintained by PBMs, more than two-thirds reported that they did not define any financial interests in PBMs as conflicts.

Although regulations do not reference financial interests in PBMs as possible conflicts of interest, in the preamble to the Final Rule, CMS states that a conflict is any direct or indirect financial interest in any entity that would benefit from formulary decisions. Because PBMs perform Part D functions on behalf of sponsors, they can benefit from formulary decisions in the same way that sponsors can benefit from formulary decisions. For example, financial interests in the PBM that maintains the P&T committee and negotiates price concessions on behalf of the sponsors could influence a committee member to favor drugs made by pharmaceutical manufacturers with which the PBM has negotiated an arrangement advantageous to the PBM.

More than two-thirds of P&T committees' definitions did not address employment

Sixty-eight percent of P&T committees did not view employment by the entity that maintains the committee as a potential source of conflict or bias. Overall, 88 percent of P&T committees had such employees serving as members. The percentage of employees serving on P&T committees ranged from 4 to 97 percent, with a median of 38 percent.

Although regulations do not specify employment as a conflict, P&T committees that do not address employment could be overlooking potential conflicts among their P&T committee members. These committees could be at risk of not having at least two members who are independent and free of conflict, as required by law. They also could be at risk of not appropriately managing conflicts of interest among employees. For example, depending on their positions, certain employees serving on P&T committees could be privy to information about drug selections that are in the best interest of their employer. This could bias their committee discussions and influence the way they vote on formulary decisions. While employees may not introduce this bias intentionally to promote

their own financial interests, they might do so to serve the best interests of their employers.

Many sponsors' P&T committees allowed members to determine and manage their own conflicts of interest

Fifty-nine percent of sponsors' P&T committees allowed committee members to determine their own conflicts and manage them through recusal. By relying on members to determine and manage their own conflicts, sponsors' P&T committees may not be able to ensure that formulary decisions are based on scientific evidence and are not biased by financial interests. Regulations do not require sponsors' P&T committees to have policies and procedures to ensure that committee member conflicts are determined and managed objectively. However, relying on P&T committee members to determine and manage their own conflicts makes intentional misreporting easier and allows for unintentional misreporting because of a misunderstanding or misapplication of sponsors' P&T committee policies.

Nearly two-thirds of P&T committees relied on members to determine whether financial interests constituted conflicts

Overall, 65 percent of P&T committees relied on committee members to determine whether their financial interests constituted conflicts of interest. Eight percent of P&T committees had a conflict determination process that designated members as the parties responsible for determining whether their own financial interests should be considered conflicts. Another 57 percent, or 63 committees, did not have a process for reviewing financial interests disclosed on conflict-of-interest statements and determining whether they constitute conflicts of interest. Without an explicit determination process, P&T committees effectively defaulted to their members to determine whether they have conflicts.

Some P&T committees may not have established processes to determine whether financial interests were conflicts because they did not require members to disclose financial interests. Twenty-four percent of the 63 P&T committees that did not have a process for determining conflicts did not collect any financial interest information from members. These P&T committees' disclosure forms did not require members to disclose any financial interest information. The members were required only to sign a form stating whether they had financial interests or conflicts of interest. Members on these P&T committees were not asked to describe the nature or value of their financial interests or to submit any supporting information. P&T committees would need this information to make an objective determination of whether financial interests constituted conflicts.

More than three-quarters of P&T committees relied on members to recuse themselves from discussions and votes

Seventy-nine percent of P&T committees relied on members to recuse themselves from discussions or votes when they had a conflict of interest related to a particular drug. CMS advises recusal from discussions and votes if P&T committee members have a conflict. Specifically, 56 percent of P&T committees had recusal policies that designated members as responsible for recusing themselves from discussions or votes. Additionally, 23 percent of P&T committees did not have recusal policies. These P&T committees did not have a process to ensure that members with conflicts did not discuss or vote on a particular drug that presented a conflict. Essentially, these P&T committees defaulted to the conflicted members to recuse themselves.

CMS does not adequately oversee sponsors' P&T committee compliance with Federal conflict-of-interest requirements

CMS does not monitor conflicts of interest on P&T committees or review the P&T committee conflict-of-interest information that is required to be reported. Had CMS tried to review the information, it would have found the data unusable because of discrepancies. Also, during 2010, CMS did not perform onsite audits to assess compliance with Federal P&T committee conflict-of-interest requirements.

CMS does not review P&T committee conflict-of-interest information

CMS staff reported that they do not look at the information that sponsors and PBMs report about whether each P&T committee member is free of conflict. Without reviewing this information, CMS cannot know whether a minimum of two members on each P&T committee are free of conflict with sponsors and pharmaceutical manufacturers, as required.

Additionally, during 2010, CMS did not have audit protocols to specifically audit P&T committee member conflicts of interest. Similarly, CMS did not have audit protocols to assess compliance with P&T committee conflict-of-interest requirements as part of its sponsor audits. In 2012, CMS added an optional review of P&T committee documentation to determine compliance with Federal conflict-of-interest requirements. As of August 2012, CMS reported that less than 10 percent of its audits included these elements.

CMS does have audit protocols to review formulary management activities to confirm they are being administered consistent with the formulary as CMS approved it. During these audits, CMS reviews

P&T committee meeting minutes and interviews sponsors, focusing on formulary management activities, such as decisions about clinical appropriateness and drug utilization. However, CMS does not make use of these audit opportunities to review P&T committee member conflict-of-interest statements. In addition, CMS staff reported that they do not review meeting minutes to determine whether members are recused from discussions or votes. CMS also reported that it does not ask questions related to conflicts or recusal during interviews with sponsors.

Data discrepancies would prevent CMS from identifying with certainty the members of each P&T committee

Had CMS attempted to review the reported P&T committee information, it would have had problems using the information to assess whether conflicts existed because of data discrepancies. Using these data, CMS could not have identified members of P&T committees. Without identifying the members on each P&T committee, CMS cannot tell whether a minimum of two members are free of conflict.

Our review of the data uncovered discrepancies that would prevent CMS from identifying with certainty the members of each P&T committee. We found discrepancies such as duplicate names, similar names, different suffixes or prefixes, and names listed in different order (e.g., first name/last name and last name/first name). These discrepancies may have been data entry errors, but it is impossible to know definitively. We also found multiple data submissions for the same P&T committee. When comparing these submissions, we found these same problems existed across the committee membership information. In fact, 58 percent of P&T committees with multiple submissions had discrepancies that would make it difficult to ascertain committee membership.

Further, it would be difficult for CMS to determine whether it received all of the conflict-of-interest information for all P&T committee members. Using the reported data, CMS cannot always identify which entity should be reporting P&T committee conflict-of-interest information. According to our discussions with sponsors and PBMs to verify the data reported to CMS, 9 percent of the 680 contracts with sponsors had incorrect entities listed as maintaining the P&T committee. In addition, we found other problems with the data. For example, even when the PBM listed as maintaining the P&T committee was correct, the name of the PBM and contact information were often outdated because of mergers and other changes in the marketplace.

CONCLUSION AND RECOMMENDATIONS

Federal law and regulations require Medicare Part D P&T committees to make prescription drug formulary decisions based on scientific evidence and standards of practice. Our findings reveal that both sponsors and CMS conduct limited oversight of P&T committee conflicts of interest, compromising their ability to ensure that financial interests do not influence formulary decisions. Specifically, we found that without direction and oversight from CMS, many sponsors' P&T committees have limited oversight of members' conflicts of interest. Additionally, we found that CMS does not adequately oversee compliance with the Federal requirement that at least one physician and at least one pharmacist on each committee be free of conflict.

Limited sponsor oversight does not necessarily indicate that financial interests are influencing formulary decisions. However, it does expose sponsors to that possibility. In health care, financial interests in the pharmaceutical industry are common. In fact, there is widespread evidence that financial interests and conflicts of interest exist between pharmaceutical manufacturers and health care providers, and that these relationships influence behavior.

Conflicts of interest jeopardize the integrity of professional judgment, compromise the quality of patient care, and erode the public's trust in Federal health care. If conflicts of interest in the Part D program are undetected or not managed, beneficiaries may receive inferior therapies when safer or more effective therapies are available, limited Medicare dollars may be wasted to pay for inappropriate treatment, and public confidence in the Federal Government may be compromised.

To minimize the possibility that conflicts of interest influence formulary decisions, we recommend that CMS improve its oversight of P&T committee conflicts and set minimum standards for sponsor oversight of committee conflicts of interest.

To address limitations in how P&T committee members' conflicts are defined, determined, and managed, we recommend that CMS:

Define PBMs as Entities That Could Benefit From Formulary Decisions

P&T committee members may have conflicts of interest relative to PBMs, but current regulation does not address this vulnerability. CMS suggests in the preamble to the Final Rule that P&T committee members are not free of conflict if they have any direct or indirect financial interest in any entity that would benefit from decisions regarding plan formularies. However, in regulation, CMS specifies only sponsors and pharmaceutical

manufacturers and does not mention PBMs. Sponsors can delegate formulary management responsibilities to PBMs; therefore, PBMs also can benefit financially from plan formulary decisions because they can retain a percentage of price concessions negotiated with pharmaceutical manufacturers on behalf of sponsors.

CMS should define PBMs as entities that could be affected by drug coverage decisions. CMS should require the P&T committee members, who must be free of conflict with sponsors and pharmaceutical manufacturers, to also be free of conflict with any PBM that manages a sponsor's prescription drug benefit. To implement this, CMS could seek regulatory change or use existing regulatory provisions that address contractual arrangements between sponsors and their contracted entities.

Establish Minimum Standards Requiring Sponsors To Ensure That Safeguards Are Established To Prevent Improprieties Related to Employment by the Entity That Maintains the P&T Committee

Current CMS guidance does not address employment. CMS should amend current guidance to stipulate that sponsors establish safeguards to prevent any improprieties associated with being employed by the entity that maintains the P&T committee from influencing committee decisions. CMS could set minimum standards by publishing guidance or amending the *Medicare Prescription Drug Benefit Manual*.

While CMS may not want to specify exactly what safeguards sponsors should establish, it should require sponsors to ensure that these safeguards specify how employee relationships will be managed. This would allow sponsors the independence and flexibility granted to them by law. Entities that maintain a P&T committee could address these safeguards in their codes of conduct or ethics policies. When a sponsor contracts with a PBM to maintain its P&T committees, the sponsor should expect the PBM to have similar safeguards in place and should monitor the PBM to ensure that it meets the minimum standards.

Establish Minimum Standards Requiring Sponsors To Ensure That an Objective Process Is Used To Determine Whether Disclosed Financial Interests Are Conflicts

In practice, many sponsors rely on members to determine their own conflicts. CMS should require sponsors to use an objective process to determine whether a disclosed financial interest constitutes a conflict of interest. Current guidance only generally addresses disclosure of financial interests and does not address conflict-of-interest determination. CMS

could set minimum standards by publishing guidance or amending the *Medicare Prescription Drug Benefit Manual*.

Sponsors could determine what type of objective process best suits their business models. For example, a sponsor could direct a compliance officer to identify whether financial interests are conflicts and then alert the P&T committee chair that recusal is necessary. Establishing an objective determination process would help ensure that P&T committee members' financial interests do not bias committee discussions or votes. When a sponsor contracts with a PBM to maintain its P&T committees, it should expect the PBM to have similar objective processes in place and should monitor the PBM to ensure that it meets the requirement.

Regardless of the objective process established by sponsors, CMS should direct them to require P&T committee members to disclose financial interests on their conflict-of-interest statements. To facilitate an objective determination of conflicts of interest, sponsors need financial interest information from P&T committee members. Disclosed financial interests should include all direct and indirect financial interests with any entity that would benefit from decisions regarding plan formularies. P&T committee members could disclose specific information about their financial interests, such as the nature of the relationship and the value of the financial interest.

Establish Minimum Standards Requiring Sponsors To Ensure That an Objective Process Is Used To Manage Recusals Because of Conflicts of Interest

CMS should require sponsors to use an objective process to manage P&T committee members' allowable conflicts. Current guidance only generally addresses recusals. CMS could set minimum standards by publishing guidance or amending the *Medicare Prescription Drug Benefit Manual*.

As with establishing an objective process to determine conflicts, sponsors could determine the type of objective process that best suits their business model. However, CMS could tell sponsors that, at a minimum, they need to designate an objective party, such as a compliance officer, to flag and enforce the necessary recusals. By doing so, sponsors would ensure that members with conflicts are recused from discussions or votes associated with a particular drug and that they are not managing their own recusals. When a sponsor contracts with a PBM to maintain its P&T committees, it should expect the PBM to have similar objective processes in place and should monitor the PBM to ensure that it meets the requirement.

In addition, to address the lack of oversight of sponsors' compliance with Federal law and regulations regarding P&T committee conflicts of interest, we recommend that CMS:

Oversee Compliance With Federal P&T Committee Conflict-of-Interest Requirements and Guidance

CMS should oversee sponsors' P&T committee conflict-of-interest procedures to ensure that formulary decisions are based only on scientific evidence and standards of practice. First, CMS should review reported P&T committee conflict-of-interest information to ensure that all committees have at least one practicing physician and at least one practicing pharmacist who are free of conflicts with entities that would benefit from formulary decisions. By reviewing the reported P&T committee information, CMS also would be able to identify any discrepancies in the data and ensure that they are usable and reliable. CMS also should consider obtaining additional information to help it oversee compliance. For example, CMS could collect conflict-of-interest statements for each P&T committee member. This information could enable CMS to ensure that sponsors are requesting this information from their P&T committee members. Additionally, collecting basic details about the nature of financial interests could enable CMS to question whether certain financial interests could affect drug formulary decisions.

Second, CMS should broaden its audit protocols to include a review of sponsors' P&T committee conflict-of-interest determination and management policies. CMS also could review meeting minutes or ask questions related to recusal during audit interviews to determine whether members are being recused. In 2012, CMS added to its audit protocol an optional review of P&T committee membership lists to determine whether a sponsor's committee has met the Federal conflict-of-interest requirements. This change helps to ensure that minimum standards are met and that at least two members on each committee are free of conflict. However, by reviewing other documents, CMS could assess whether sponsors have policies and procedures in place to ensure that members with conflicts are being recused.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

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.

CMS maintained that it is not necessary to conduct additional P&T committee conflict-of-interest oversight because current formulary reviews and P&T committee audits appropriately protect beneficiaries from any adverse effects of potential conflicts of interest. Specifically, CMS noted that its formulary review process protects beneficiaries' access to prescription drugs and its audits review P&T committee documentation related to identified formulary administration problems.

We assert that CMS should improve its P&T committee oversight and set broad, minimum standards for sponsor oversight in guidance for several reasons. We continue to note that CMS does not adequately oversee compliance with P&T committee conflict-of-interest requirements. CMS states that it can conduct P&T audits. However, as of August 2012, CMS reviewed P&T committee information for less than 10 percent of audits. Further, given the information collected in these audits, it seems unlikely that CMS would detect situations in which a conflict of interest led a committee to prefer one drug over another that treated the same condition. In addition, based on current data, CMS cannot tell whether sponsors' P&T committees have two members on each committee who are free of conflict, as required by law. CMS oversight is especially important given that we found that sponsor oversight of committee member conflicts is limited.

If conflicts of interest among P&T committee members are not addressed, beneficiaries may receive inferior therapies when safer or more effective therapies are available, limited Medicare dollars may be wasted to pay for inappropriate treatment, and public confidence in the Federal Government may be undermined. In contrast, CMS asserts that conflicts of interest would not disadvantage beneficiaries or the Federal Government because it believes that formulary decisions influenced by conflicts would result in higher premiums and the plan would be priced out of the marketplace. This position assumes that beneficiaries select health insurance based only on cost. This does not consider beneficiaries' concerns about remaining with their current health care team, access issues, or the opportunity cost of having to select a new health insurance plan.

CMS noted that OIG did not identify any conflicts through our study. Our study was not designed to identify conflicts and, as such, we did not find

any. However, that does not mean conflicts do not exist. There is widespread evidence that conflicts of interest are pervasive among the pharmaceutical industry and health care practitioners and that financial relationships may influence practitioners' behavior.

In its comments, CMS indicated that the Physician Payment Sunshine Act will result in information that may help sponsors determine conflicts of interest. However, reported data will not contain information about pharmaceutical manufacturer payments to pharmacists and, therefore, will not help sponsors meet the requirement that at least one pharmacist on each P&T committee be free of conflict.

CMS did not concur with our first recommendation, that it define PBMs as entities that could benefit from formulary decisions. CMS asserted that its formulary review process provides the appropriate protections from any adverse effects of conflicts of interest. CMS noted that PBMs do have an interest in formulary decisions because they negotiate price concessions on behalf of sponsors as their subcontractors. However, CMS suggested that, by virtue of this contractual relationship, PBMs will be constrained by the same desire to be competitive as sponsors, forcing them to balance both quality and costs in developing formularies.

It is precisely because PBMs have an interest in formulary decisions that we continue to recommend that CMS include PBMs in the definition of entities that could benefit from formulary decisions. The delegated responsibility to negotiate price concessions means that PBMs have financial interests in formulary development, yet those financial interests may not be aligned with those of the sponsors that contracted with them. Because their financial interests may not be aligned, PBMs may not be constrained by the same competitive market forces as sponsors.

CMS did not concur with our second recommendation, that it establish minimum standards requiring sponsors to prevent improprieties associated with employment from influencing P&T committee decisions. CMS stated that it is not directed in statute to address employment standards. CMS further noted that as corporations, private drug plans maintain a competitive edge by managing their employees, who should act in their employers' best interest.

We agree that employees of private health plans would likely act in the best interest of their employers—interests that may not align with the interests of the Part D program—which is why we continue to recommend that CMS establish minimum standards requiring sponsors to address employment. Minimum standards established by CMS allow sponsors independence and flexibility to develop safeguards that best suit their business models. As we noted, CMS could stipulate these minimum

standards in guidance or in the *Medicare Prescription Drug Benefit Manual*.

For our third and fourth recommendations, CMS concurred that sponsors should ensure that an objective process is used to determine whether disclosed financial interests are conflicts and manage recusals. However, CMS did not concur that it should be responsible for establishing minimum standards. CMS noted that it will carefully consider this recommendation and evaluate the sufficiency of current evidence when considering future rulemaking.

We believe that, to ensure prescription drug coverage decisions are not based on financial interests, CMS should establish minimum standards requiring sponsors to have objective processes to determine conflicts of interest and manage recusals. Minimum standards from CMS allow sponsors flexibility to determine what type of process best suits their business models. CMS already has established minimum requirements for sponsors regarding Part D formularies and P&T committee membership. This recommendation continues this precedent. We also note that these additional minimum standards can be established in guidance or in the *Medicare Prescription Drug Benefit Manual*.

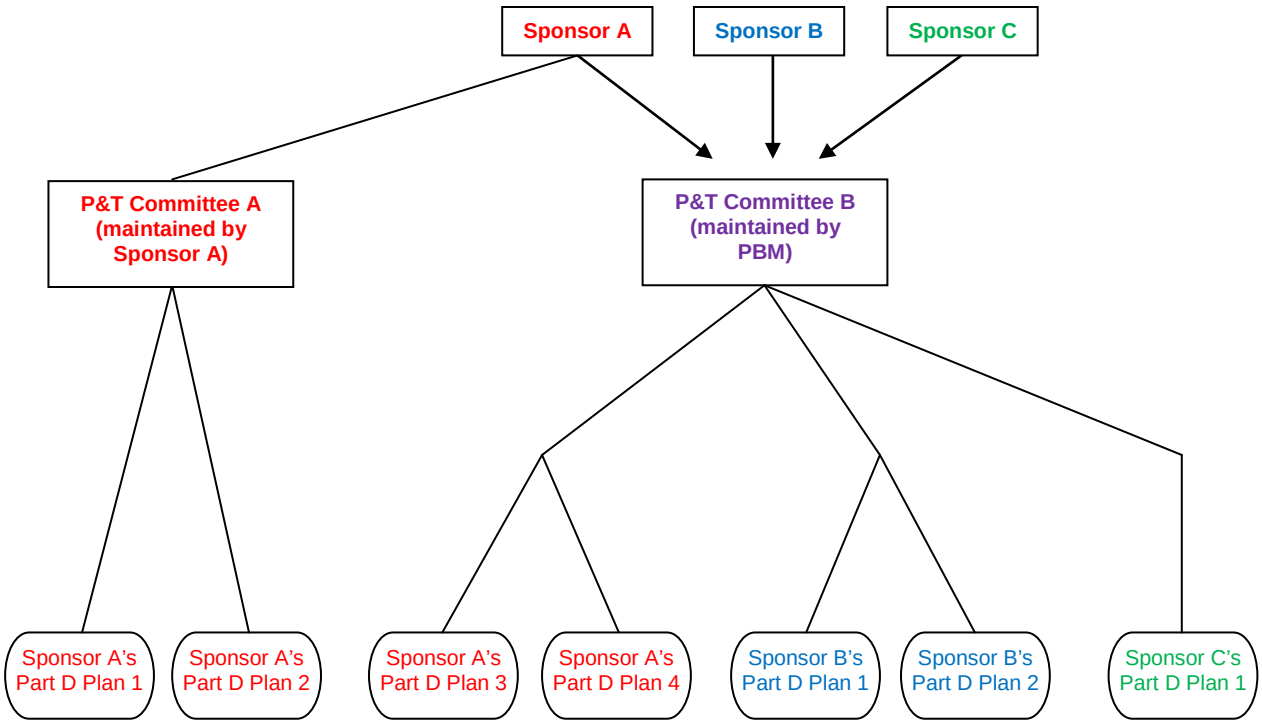
CMS concurred with our fifth recommendation, that it oversee compliance with Federal P&T committee conflict-of-interest requirements. CMS indicated that its P&T committee audit will be conducted when issues identified during the formulary administration audit warrant additional P&T committee audits. CMS also noted that it will consider updating its annual "readiness checklist" to ensure that sponsors or their contracted PBMs update P&T committee membership data in the Health Plan Management System. Finally, CMS indicated that it will explore other approaches for assessing compliance with P&T committee conflict-of-interest requirements.

We made minor changes to the report based on CMS's comments. For the full text of CMS's comments, see Appendix C.

APPENDIX A

Potential Sponsor and Pharmacy and Therapeutics Committee Relationships

Sponsors A, B, and C contract with a pharmacy benefit manager (PBM) for Pharmacy & Therapeutics (P&T) committee functions for some or all of their Part D plans.



APPENDIX B

Pharmacy and Therapeutics Committee Member Disclosure Form[57]

Sponsors or pharmacy benefit managers must

> Provide the names of the members of your organization's Pharmacy & Therapeutics committee. Indicate which members are practicing physicians or practicing pharmacists. Further, indicate which members are experts in the care of the elderly or disabled, and free of any conflict of interest with your organization and pharmaceutical manufacturers.

	Practice/Expertise *Mark an 'X' in Appropriate Column*			Free of Any Conflict of Interest *Type Yes or No*	
Full Name of Member Start Date and End Date	Practicing Physician	Practicing Pharmacist	Elderly/Disabled Expert	With Your Organization?	With Pharmaceutical Manufacturers?

[57] CMS, *Medicare Prescriptions Drug Benefit: Solicitation for Applications for New Prescription Drug Plans (PDP) Sponsors*, 2011 Contract Year.

APPENDIX C

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator
Washington, DC 20201

DATE: FEB 0 7 2013

TO: Daniel R. Levinson
Inspector General

/S/

FROM: Marilyn Tavenner
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions" (OEI-05-10-00450)

Thank you for the opportunity to review and comment on the OIG draft report "Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions." As part of this review, OIG conducted an evaluation of Part D Plan Sponsors' Pharmacy and Therapeutic (P&T) committee's conflicts of interest processes and the Centers for Medicare & Medicaid Services's (CMS's) oversight of P&T committees. OIG did not identify any actual conflicts of interest during the course of this review.

The CMS believes the agency's current Part D formulary review provides appropriate protections to beneficiaries from any adverse effects resulting from potential conflicts of interest. The agency thoroughly reviews Part D formularies to prevent discrimination against Medicare beneficiaries based on age, disease, or setting in which they receive care. The review process ensures inclusion of a broad distribution of therapeutic categories and classes by using reasonable benchmarks to ensure drug lists are robust. Further, CMS ensures that cost-sharing levels and utilization management strategies are appropriate and non-discriminatory. CMS identifies potential outliers at each review step for further investigation and requires reasonable clinical justification when outliers appear to create beneficiary access problems.

The CMS devotes extensive resources to plan formulary oversight—and reserves the right to reject them—to ensure compliance with industry best practices for development and management and to ensure beneficiaries' access to clinically appropriate therapies. Therefore, if a P&T committee were to create a formulary while operating under a potential conflict of interest, because a discriminatory formulary would not be approved, the only potential impact would be that the bid could be more expensive and, therefore, less competitive. Beneficiaries could easily evaluate these higher premiums in the marketplace and choose a more efficient plan to meet their needs. As a result, we could expect that any authentic conflicts of interest, given our level of formulary review, would disadvantage the sponsor and not the beneficiary or Medicare program.

Additionally, while no conflicts of interest have been identified to date, the OIG report noted that CMS implemented additional audit review elements for 2012. The P&T committee audit will be conducted when issues identified during the formulary administration or transition portions of the audit warrant additional P&T committee scrutiny. During the P&T audit, the sponsor (or their contracted pharmacy benefit managers (PBMs) if under confidentiality agreement) must submit P&T committee meeting minutes, as well as all supporting documents related to the calendar year (CY) formulary which were provided to the P&T members prior to or during the meeting. The sponsor (or PBM, if applicable) must submit the criteria used to establish that P&T committee members are practicing, independent and free of conflict relative to the Part D sponsor, Part D plan, and pharmaceutical manufacturers. In addition to the names of the P&T committee members, documentation supporting how those members meet the aforementioned criteria must also be provided. Consequently, CMS disagrees with OIG's finding that CMS does not conduct adequate oversight of sponsors' compliance with the conflict of interest requirement.

The CMS appreciates OIG's concerns that sponsors' P&T committees have limited definitions, determinations, and management of committee members' conflicts of interest; however, we think it is important to point out the statute does not direct CMS to establish consistent standards for these determinations, and we do not believe it is necessary for us to do so as our current review standards ensure that formularies are not discriminatory. Moreover, statute (42 U.S.C. 1395w-104(b) (3)) and regulation (42 9C.F.R. 423.120(b)) indicate that it is the plan sponsor's responsibility to meet the formulary requirements, which includes development of these definitions and processes. The statute and regulation require that a P&T committee must include at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict. The committee must also base its clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

Relative to conflict of interest disclosures, OIG reports that CMS does not specify which industry standards to follow, nor does OIG identify any industry standards. CMS does not prescribe an industry standard, as several standards already exist. These include conflict of interest disclosure statements currently in use by ethics offices within the federal government at the Food and Drug Administration, CMS, and others; the various state and district ethics commissions for members and commissioners for state oversight boards of physicians and pharmacists; as well as Medicare Part A hospitals, most of which have central or local P&T committees.

Additionally, although it specifically addresses Medicare physicians' financial interests related to pharmaceutical and device manufacturers, Title VI of the Affordable Care Act (PL 111-148) will result in information that may assist Part D sponsors to make these determinations. CMS published its proposed rule for this section (Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests) in December 2011, and is in the process of drafting its final rule pending review of stakeholder comments.

The CMS responses to the OIG recommendations are discussed below.

OIG Recommendation

The OIG recommends CMS define PBMs as entities that could benefit from formulary decisions.

CMS Response

The CMS does not concur with OIG's recommendation that PBMs be defined as entities that could benefit from formulary decisions. We believe that our current formulary review process confers appropriate protections to beneficiaries from any potential adverse effects of conflicts of interest. As discussed above, CMS has devoted extensive resources to the oversight of plan formularies and audit of P&T committee proceedings to ensure that they comply with industry best practices for development and management, and ensure beneficiaries' access to clinically appropriate therapies.

P&T committees must first base their clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate, consistent with the program goal of maintaining a competitive market. Therefore, given that sponsors must balance both quality and costs in developing formularies, and that PBMs are the entities that negotiate for price concessions on behalf of sponsors, we believe the PBM should have an interest in formulary decisions.

OIG Recommendation

The OIG recommends CMS establish minimum standards requiring sponsors to ensure that safeguards are established to prevent improprieties related to employment by the entity that maintains the P&T committee.

CMS Response

The CMS does not concur with OIG's recommendation that minimum standards be established requiring sponsors to ensure that safeguards are established to prevent improprieties related to employment by the entity that maintains the P&T committee. As noted above, the statute did not direct CMS to establish such standards. Moreover, corporations—including private drug plans—are able to obtain a competitive edge in the marketplace by managing their most valuable asset, their employees. For instance, we understand that in P&T committees operated by hospitals, it is an accepted industry standard that employees should act with their employers' best interests in mind. CMS believes that a minimum standard requirement would detract from the competitive nature of the Part D program.

OIG Recommendation

The OIG recommends CMS establish minimum standards requiring sponsors to ensure that an objective process is used to determine whether disclosed financial interests are conflicts.

CMS Response

The CMS concurs with OIG that P&T committees should have clearly articulated and objective processes to determine whether disclosed financial interests are conflicts. We do not concur that CMS is responsible for establishing such standards. Statutory (42 U.S.C. 1395w-104(b) (3)) and regulatory (42 C.F.R. 423.120(b)) provisions indicate that it is the plan sponsor's responsibility to meet the formulary requirements, which include development of these processes. When issues are identified during the formulary administration or transition portions of an audit, the auditor will invoke the P&T committee audit steps. At that time, the sponsor (or PBM, if applicable) must submit the criteria used to establish that P&T committee members are practicing, independent and free of conflict relative to the Part D sponsor, Part D plan, and pharmaceutical manufacturers. In addition to the names of the P&T committee members, documentation supporting how those members meet the aforementioned criteria must also be provided. The auditors would review the documentation to determine if the sponsor satisfies the criteria for membership. We will carefully consider this recommendation and evaluate the sufficiency of our current evidence when considering future rulemaking.

OIG Recommendation

The OIG recommends CMS establish minimum standards requiring sponsors to ensure that an objective process is used to manage recusals due to conflicts of interest.

CMS Response

The CMS concurs with OIG that P&T committees should have clearly articulated and objective processes to manage recusals due to conflicts of interest. We do not concur that CMS is responsible for establishing such standards. Statutory (42 U.S.C. 1395w-104(b) (3)) and regulatory (42 C.F.R. 423.120(b)) provisions indicate that it is the plan sponsor's responsibility to meet the formulary requirements, which includes development of these processes. The OIG report suggests that CMS could tell sponsors that they need to designate an objective party, such as a compliance officer, to flag and enforce the necessary recusals. CMS will carefully consider this recommendation and evaluate the sufficiency of our current requirements on plan sponsors when considering future rulemaking.

OIG Recommendation

The OIG recommends CMS oversee compliance with federal P&T conflicts of interest requirements and guidance.

CMS Response

The CMS concurs with OIG's recommendation to oversee compliance with existing Part D P&T committee conflicts of interest requirements and guidance. As discussed above, we believe that the potential effects of conflicts of interest would result in discriminatory or inefficiently priced

plans. Our formulary review process prevents discrimination, and higher priced plans will be subject to competition on premiums in the marketplace. As OIG noted, CMS added additional audit review elements for 2012, consistent with the intent of this recommendation prior to the report. In addition to the initial formulary review process, we conduct compliance audits that review sponsor P&T committee practices whenever significant problems with formulary administration have been detected, as detailed below.

The P&T committee audit will be conducted when issues identified during the formulary administration or transition portions of the audit warrant additional P&T audit steps. During the P&T audit, the sponsor (or their contracted PBM, if under confidentiality agreement) must submit P&T committee meeting minutes as well as all supporting documents related to the CY formulary that were provided to the P&T members prior to, or during the meeting. The sponsor (or PBM, if applicable) must submit the criteria used to establish that a minimum number of P&T committee members are practicing, independent and free of conflict relative to the Part D sponsor, Part D plan, and pharmaceutical manufacturers. In addition to the names of the P&T committee members, documentation supporting how those members meet the aforementioned criteria must also be provided.

The OIG report indicates that the P&T committee data appeared to be unreliable. Functioning as contact directory tools and not oversight mechanisms, all Health Plan Management System plan contact data are entered by the plan sponsor and are not independently validated by CMS. In the interim, CMS will consider updating its annual "readiness checklist" to ensure that sponsors (or their contracted PBMs, if under confidentiality agreement) have updated this information consistent with the current audit process. However, this report leads us to reconsider the value of collecting this P&T committee information in this manner, and we will explore other approaches for assessing compliance with our requirements.

Thank you for the opportunity to review and comment on the draft OIG report.

ACKNOWLEDGMENTS

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office; Thomas F. Komaniecki, Deputy Regional Inspector General; and Laura Kordish, Deputy Regional Inspector General.

Meghan Kearns served as the team leader for this study, and Melissa Baker served as lead analyst. Other principal Office of Evaluation and Inspections staff from the Chicago regional office who contributed to the report include Hilary Slover; central office staff who contributed include Debra Roush and Rita Wurm.

Office of Inspector General

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The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.