DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JUL 2 9 2008

TO: Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: Daniel R. Levinson Daniel R. Levinson
Inspector General

SUBJECT: Review of Medicare Part D Contracting for Contract Year 2006 (A-06-07-00082)

The attached final report provides the results of our review of Medicare Part D contracting for contract year 2006. We conducted this review at the request of 33 Senators.

Under Medicare Part D, the Centers for Medicare & Medicaid Services (CMS) contracts with prescription drug plan (PDP) sponsors to offer prescription drug benefits to eligible individuals. Pharmacies contract with these sponsors to obtain Part D reimbursement for prescription drugs dispensed to individuals enrolled in Part D plans. Pharmacies may use third-party contractors known as pharmacy services administrative organizations (PSAO) to negotiate contracts with PDP sponsors. This report is based on information provided by 40 PDP sponsors and 100 randomly selected pharmacies and their PSAOs.

Our objectives were to determine (1) the number of local, community pharmacies that relied on PSAOs for assistance in contracting with PDP sponsors and the pharmacies' satisfaction with PSAO services and (2) the contracting methods that PDP sponsors used to develop their Medicare networks and the pharmacies' and PSAOs' contracting experiences.

Of the 100 local, community pharmacies in our sample, 78 relied on PSAOs to contract with PDP sponsors. Overall, these pharmacies were satisfied with the services that their PSAOs provided.

Almost all of the 100 sampled pharmacies and all of their PSAOs reported concerns about contracting with PDP sponsors. These concerns related to PDP sponsors' network development methods, standard terms and conditions, extended-day supply terms, negotiations, and network requirements and contracting requirements. We also present other PDP sponsor process concerns raised by the pharmacies and PSAOs.

We recommend that Congress and CMS consider the results of our review, including the data provided, in any deliberations regarding Medicare Part D contracting. Our report provides specific recommendations related to the concerns voiced by the pharmacies and PSAOs.

In its written comments on our draft report, CMS concurred with five of our recommendations. CMS did not concur with the remaining five recommendations, stating that they were contrary to the competitive market principles that are fundamental to the Part D program. CMS said that it interprets section 1860D-11(i) of the Social Security Act (the Act) as prohibiting Government interference in the sort of price negotiations suggested in some of the recommendations.

We agree that the Act prohibits the Government from interfering with negotiations between PDP sponsors and pharmacies and from instituting a price structure for the reimbursement of covered Part D drugs. To more fully recognize that prohibition in our final report, we have revised three recommendations. Our recommendations, as revised, focus on increasing transparency and disclosure in contracting and do not interfere with negotiations between PDP sponsors and pharmacies or institute a price structure.

Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, Office of Inspector General reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5). Accordingly, this report will be posted on the Internet at http://oig.hhs.gov.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through e-mail at George.Reeb@oig.hhs.gov. Please refer to report number A-06-07-00082 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICARE PART D CONTRACTING FOR CONTRACT YEAR 2006

Daniel R. Levinson
Inspector General

July 2008
A-06-07-00082

Office of Inspector General

http://oig.hhs.gov

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Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, Office of Inspector General reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5).

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established the Medicare Part D prescription drug program. Under Part D, which began January 1, 2006, individuals entitled to benefits under Part A or enrolled in Part B may obtain drug coverage.

The Centers for Medicare & Medicaid Services (CMS), which administers Medicare, contracts with prescription drug plan (PDP) sponsors to offer prescription drug benefits to eligible individuals. Pharmacies contract with these sponsors to obtain Part D reimbursement for prescription drugs dispensed to individuals enrolled in Part D plans. PDP sponsors may subcontract with pharmacy benefit managers (PBM) for services such as pharmacy network administration and claim processing. If a PDP sponsor subcontracts pharmacy network administration to a PBM, the Part D contract is usually between the PBM and the pharmacy or between the PBM and a third party that contracts on the pharmacy's behalf. These third-party contractors are known as pharmacy services administrative organizations (PSAO).

In a letter dated June 6, 2006, 33 Senators requested that we analyze three issues related to local, community pharmacies' participation in the Medicare Part D program: network adequacy, reimbursement, and contracting. This report, which addresses the contracting aspect of the request, is based on information provided by 40 PDP sponsors and 100 randomly selected pharmacies and their PSAOs for contract year 2006.

OBJECTIVES

Our objectives were to determine (1) the number of local, community pharmacies that relied on PSAOs for assistance in contracting with PDP sponsors and the pharmacies' satisfaction with PSAO services and (2) the contracting methods that PDP sponsors used to develop their Medicare networks and the pharmacies' and PSAOs' contracting experiences.

SUMMARY OF RESULTS

Of the 100 local, community pharmacies in our sample, 78 relied on PSAOs to contract with PDP sponsors. Overall, these pharmacies were satisfied with the services that their PSAOs provided.

Almost all of the 100 sampled pharmacies and all of their PSAOs reported concerns about contracting with PDP sponsors. These concerns related to:

- *Network Development Methods*: Most PDP sponsors reported that they had solicited pharmacies from their existing commercial networks and/or had solicited other pharmacies. Pharmacies and PSAOs reported concerns about the short timeframes to review numerous contracts, uncertainty regarding which companies would eventually

become PDP sponsors, the sponsors' use of addendums to existing contracts, and PDP sponsors' refusal to contract with the pharmacies' PSAOs.

- *Standard Terms and Conditions*: Most PDP sponsors reported that they had offered standard terms and conditions based on how they categorized pharmacies and that they had updated brand-name drug payment rates regularly and developed their own generic drug payment methodologies. Additionally, most PDP sponsors stated that they had offered long-term-care contracts with enhanced rates to retail pharmacies that serviced long-term-care facilities.

  Some pharmacies and PSAOs reported that Part D reimbursement rates were lower than commercial and Medicaid rates. Further, some pharmacies and PSAOs reported that PDP sponsors did not provide information about their standard terms and conditions, including the source of their average wholesale prices and their maximum allowable cost methodologies and pricing. Additionally, some pharmacies and PSAOs reported that PDP sponsors had not offered long-term-care contracts.

- *Extended-Day Supply Terms*: Most PDP sponsors reported using a definition of extended-day supplies that ranged from 30 to 90 days. Additionally, PDP sponsors reported that they offered varied reimbursement rates to pharmacies for extended-day supplies. Most pharmacies reported that extended-day reimbursement rates were unacceptable.

- *Negotiations*: According to most PDP sponsors, pharmacies were responsible for initiating contract negotiations. Most PDP sponsors said that they would consider any counteroffers and that the acceptance of a counteroffer depended on multiple factors. Some pharmacy and PSAO officials reported that they were not able to contact PDP sponsors to initiate negotiations. Officials of those pharmacies that were able to contact PDP sponsors stated that the negotiation processes were often unproductive.

- *Network Requirements and Contracting Deadlines*: Most PDP sponsors stated that pharmacies were not required to contract with the sponsors' commercial networks to be included in the Part D networks. Some PDP sponsors said that they had imposed deadlines on pharmacies to meet CMS's network adequacy requirements but that pharmacies could have joined at any time and received the same rate. Some pharmacies reported that PDP sponsors required participation in both the Part D and commercial networks and that they felt pressured to enroll by the deadline or be excluded from the network or be reimbursed at a lower rate.

We also present other PDP sponsor process concerns raised by the pharmacies and PSAOs.

RECOMMENDATIONS

We recommend that Congress and CMS consider the results of our review, including the data provided, in any deliberations regarding Medicare Part D contracting. The body of this report provides specific recommendations related to the concerns voiced by pharmacies and PSAOs.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In its written comments on our draft report (Appendix M), CMS concurred with five of our recommendations. CMS did not concur with the remaining five recommendations, stating that they were contrary to the competitive market principles that are fundamental to the Part D program. CMS said that it interprets section 1860D-11(i) of the Social Security Act (the Act) as prohibiting Government interference in the sort of price negotiations suggested in some of the recommendations.

OFFICE OF INSPECTOR GENERAL RESPONSE

We agree that the Act prohibits the Government from interfering with negotiations between PDP sponsors and pharmacies and from instituting a price structure for the reimbursement of covered Part D drugs. To more fully recognize that prohibition in our final report, we have revised three recommendations. Our recommendations, as revised, focus on increasing transparency and disclosure in contracting and do not interfere with negotiations between PDP sponsors and pharmacies or institute a price structure.

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INTRODUCTION

BACKGROUND

Senate Request Letter

In a letter dated June 6, 2006, 33 Senators requested that we analyze three issues related to local, community pharmacies' participation in the Medicare Part D program: network adequacy, reimbursement, and contracting. With respect to contracting, the Senators requested that we analyze the methods that prescription drug plan (PDP) sponsors used to develop their Medicare networks and the extent to which local, community pharmacies relied on third parties for assistance in contracting with PDP sponsors. The Senators expressed concerns about PDP sponsors' contracting strategies, such as a requirement that pharmacies participate in a plan's Medicare network as a condition of participation in the plan's networks for other lines of business. In other correspondence between Senators and the Centers for Medicare & Medicaid Services (CMS), the Senators expressed a general concern about disclosure of certain contract terms and the need for CMS to be more proactive in improving several of the program areas discussed in this report.

This report addresses the contracting aspect of the request and identifies areas in which better communication and disclosure of information may improve the contracting process between PDP sponsors and pharmacies. We previously issued separate reports addressing network adequacy (OEI-05-06-00320) and reimbursement (A-06-07-00107).

Medicare Part D Reimbursement of Drugs

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) significantly expanded the Medicare program (Title 18 of the Social Security Act (the Act)) by establishing the Medicare Part D prescription drug program. Under Part D, which began January 1, 2006, individuals entitled to benefits under Part A or enrolled in Part B may obtain drug coverage.

Unlike Parts A and B of the Medicare program, under which Medicare acts as the payer and insurer and generally pays on a fee-for-service basis, the prescription drug benefit is based on a private market model. CMS contracts with PDP sponsors, which act as the payers and insurers for prescription drug benefits. Retail pharmacies contract with PDP sponsors to obtain reimbursement for prescription drugs dispensed to Part D beneficiaries. The sponsors pay pharmacies for ingredient costs (i.e., drug acquisition costs), usually the average wholesale price (AWP) minus some percentage, as well as a dispensing fee. In the case of some generic drugs, PDP sponsors reimburse pharmacies based on a maximum allowable cost (MAC). In general, the MAC is a ceiling price that applies to a group of therapeutically equivalent generic drugs.

Prescription Drug Plan Sponsors

In 2006, CMS had 79 contracts with PDP sponsors that offered 1,446 drug plans. PDP sponsors may subcontract with pharmacy benefit managers (PBM), which provide services such as pharmacy network administration and claim processing.

A PDP sponsor's network includes the retail, mail-order, and long-term-care (LTC) pharmacies with which it contracts. If a PDP sponsor subcontracts pharmacy network administration to a PBM, the Part D contract is usually between the PBM and the pharmacy or between the PBM and a third party that contracts on the pharmacy's behalf.

Third-Party Contractors

Pharmacies may contract with PDP sponsors through third-party contractors known as pharmacy services administrative organizations (PSAO). A PSAO may be a pharmacy franchise home office, a business component of a wholesaler or buying group, or any other entity that has the authority to negotiate contracts on behalf of a pharmacy. By negotiating contracts for multiple pharmacies, PSAOs may reduce the pharmacies' contracting workload and increase the negotiating power of individual pharmacies. Additionally, PSAOs may provide central payment and reconciliation services to pharmacies. (See Appendix A for an illustration of the various Part D contractual relationships.)

National Council for Prescription Drug Programs Pharmacy Database

The National Council for Prescription Drug Programs, Inc. (NCPDP), maintains a database of licensed pharmacies. As of October 2, 2006, the NCPDP Pharmacy Database contained 59,848 retail pharmacies in the United States and Puerto Rico classified as chain, independent, or franchise. As defined by NCPDP, a chain pharmacy is part of a group of four or more pharmacies under common ownership; an independent pharmacy is part of a group of three or fewer pharmacies under common ownership; and a franchise pharmacy is independently owned but has a franchise agreement with another company to receive marketing, training, and/or other support.[1] [2] For this review, we defined local, community pharmacies as independent retail or franchise retail pharmacies.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to determine (1) the number of local, community pharmacies that relied on PSAOs for assistance in contracting with PDP sponsors and the pharmacies' satisfaction with

[1]"Pharmacy Update." Available online at http://www.ncpdp.org/provider_update.asp. Accessed on July 24, 2007.

[2]According to the National Association of Chain Drug Stores, chain drugstores filled 70.9 percent of the 3.42 billion prescriptions filled in 2006, independent pharmacies filled 21.1 percent, and franchise pharmacies filled 1.2 percent. Mail-order pharmacies accounted for the remaining prescriptions.

PSAO services and (2) the contracting methods that PDP sponsors used to develop their Medicare networks and the pharmacies' and PSAOs' contracting experiences.

Scope

Our review covered contract year 2006, the first year of the Part D program.

We used the same pharmacy sample that was used in our review of Part D reimbursement (A-06-07-00107). The sampling population consisted of the 21,331 independent and franchise retail pharmacies in the United States and Puerto Rico with NCPDP provider numbers as of October 2, 2006. Because the sampling unit for the reimbursement review was a pharmacy week during September 2006, each pharmacy in the population was included in the population four times. We randomly selected 100 of these pharmacy weeks for review. Our sample for this review consisted of the 100 pharmacies associated with those pharmacy weeks. We derived nonstatistical estimates of the number of pharmacies by dividing the statistical estimates of pharmacy weeks by 4. (See Appendix B for the pharmacy sample description.)

We identified from CMS's Web site the PDP sponsors available to the 100 selected pharmacies. We selected 40 of these sponsors based on the PDP sponsors' locations and specific concerns raised by the pharmacies and PSAOs about certain sponsors. We collected information from the 40 sponsors regarding their contracting methods and visited 10 of the 40 sponsors to discuss those methods.

We determined whether the 100 selected pharmacies had used PSAOs to contract with PDP sponsors and obtained an understanding of their contracting experiences. We also attempted to confirm whether these pharmacies had contracted with all of the PDP sponsors available to them and whether the Medicare Prescription Drug Plan Finder data on CMS's Web site accurately reflected the pharmacies' status in the sponsors' networks.

For all 13 PSAOs that provided contracting services to the 100 selected pharmacies, we obtained an understanding of their contracting experiences with PDP sponsors.

Because our objectives did not require an understanding or assessment of the PDP sponsors' or the selected pharmacies' and PSAOs' internal control structures, we did not perform such a review. We also did not independently verify the validity of the responses to questionnaires that we sent to the PDP sponsors, pharmacies, and PSAOs selected for review.

We conducted fieldwork at 10 PDP sponsors from March through May 2007 and at the 100 selected pharmacies from December 2006 through May 2007.

Methodology

To accomplish our objectives, we:

- reviewed the MMA, CMS guidance, and letters from several Senators to CMS regarding Part D contracting (summarized in Appendix C);

- developed a standardized questionnaire and obtained information from the 40 selected PDP sponsors on their contracting methods;

- interviewed officials of 10 PDP sponsors about their responses to the questionnaire, issued restricted reports to these sponsors, provided them the opportunity to comment, and incorporated their comments in the final reports;

- reviewed selected contracts between PDP sponsors and PBMs;

- developed a standardized questionnaire and obtained information from the 100 selected pharmacies and their 13 PSAOs on their contracting experiences, issued restricted reports to these pharmacies and PSAOs, provided them the opportunity to comment, and incorporated their comments in the final reports;

- reviewed the CMS Medicare Prescription Drug Plan Finder data to determine the PDP sponsors with which the selected pharmacies had enrolled and asked the selected pharmacies to confirm their network status;

- reviewed selected contracts and other documentation related to contracting efforts between PDP sponsors and pharmacies and PSAOs; and

- reviewed proposed legislative actions relevant to our review.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

RESULTS OF REVIEW

Of the 100 local, community pharmacies in our sample, 78 relied on PSAOs to contract with PDP sponsors. Overall, these pharmacies were satisfied with the services that their PSAOs provided.

Almost all of the 100 sampled pharmacies and all of their PSAOs reported concerns about contracting with PDP sponsors. These concerns related to:

- *Network Development Methods*: Most PDP sponsors reported that they had solicited pharmacies from their existing commercial networks and/or had solicited other pharmacies. Pharmacies and PSAOs reported concerns about the short timeframes to review numerous contracts, uncertainty regarding which companies would eventually become PDP sponsors, the sponsors' use of addendums to existing contracts, and PDP sponsors' refusal to contract with the pharmacies' PSAOs.

- *Standard Terms and Conditions*: Most PDP sponsors reported that they had offered standard terms and conditions based on how they categorized pharmacies and that they had updated brand-name drug payment rates regularly and developed their own generic drug payment methodologies. Additionally, most PDP sponsors stated that they had offered LTC contracts with enhanced rates to retail pharmacies that serviced LTC facilities.

  Some pharmacies and PSAOs reported that Part D reimbursement rates were lower than commercial and Medicaid rates. Further, some pharmacies and PSAOs reported that PDP sponsors did not provide information about their standard terms and conditions, including the source of their AWPs and their MAC methodologies and pricing. Additionally, some pharmacies and PSAOs reported that PDP sponsors had not offered LTC contracts.

- *Extended-Day Supply Terms*: Most PDP sponsors reported using a definition of extended-day supplies that ranged from 30 to 90 days. Additionally, PDP sponsors reported that they offered varied reimbursement rates to pharmacies for extended-day supplies. Most pharmacies reported that extended-day reimbursement rates were unacceptable.

- *Negotiations*: According to most PDP sponsors, pharmacies were responsible for initiating contract negotiations. Most PDP sponsors said that they would consider any counteroffers and that the acceptance of a counteroffer depended on multiple factors. Some pharmacy and PSAO officials reported that they were not able to contact PDP sponsors to initiate negotiations. Officials of those pharmacies that were able to contact PDP sponsors stated that the negotiation processes were often unproductive.

- *Network Requirements and Contracting Deadlines*: Most PDP sponsors stated that pharmacies were not required to contract with the sponsors' commercial networks to be included in the Part D networks. Some PDP sponsors said that they had imposed deadlines on pharmacies to meet CMS's network adequacy requirements but that pharmacies could have joined at any time and received the same rate. Some pharmacies reported that PDP sponsors required participation in both the Part D and commercial networks and that they felt pressured to enroll by the deadline or be excluded from the network or be reimbursed at a lower rate.

Appendix D presents estimates of the percentage and number of pharmacies in the population that reported these concerns.

This report also presents concerns raised by the pharmacies and PSAOs related to other PDP sponsor processes.

PHARMACIES' RELIANCE ON AND SATISFACTION WITH PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS

Of the 100 sampled pharmacies, 78 relied on PSAOs to contract with PDP sponsors, and 64 of the 78 pharmacies were satisfied with the PSAOs' services. Many pharmacy officials indicated that

using PSAOs allowed them to join many networks in a short time with minimal effort. The officials said that as a result, they were able to spend more time with customers. (See Appendix E for the sampled pharmacies' reliance on and satisfaction with PSAOs.)

Officials of the 14 pharmacies that were not satisfied with their PSAOs provided several reasons for their dissatisfaction, including:

- Pharmacy officials stated that they were unaware of all contract terms because their PSAOs did not provide copies of the contracts or sufficient information concerning contract terms.

- Pharmacy officials said that they had difficulty communicating with their PSAOs.

- Pharmacy officials stated that they were obligated to honor all of the terms in contracts signed by their PSAOs.

- Pharmacy officials stated that their PSAOs should have negotiated more favorable terms when contracting with PDP sponsors.

SPONSORS' CONTRACTING METHODS AND PHARMACIES' AND PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS' EXPERIENCES

We have categorized PDP sponsors' contracting methods and pharmacies' and PSAOs' contracting experiences based on the concerns raised by the pharmacies and PSAOs. These concerns related to network development methods, standard terms and conditions, extended-day supply terms, negotiations, and network requirements and contracting deadlines. (See Appendixes F and G for the types of concerns reported by pharmacies and PSAOs, respectively.)

Network Development Methods

Regardless of whether a PDP sponsor contracted with pharmacies directly or through a PBM to develop its Part D network, the methods were generally the same. Most of the PDP sponsors that we surveyed reported that they had solicited pharmacies from their existing commercial networks and/or had solicited other pharmacies. All PDP sponsors reported that they had enrolled pharmacies using either a new contract or an addendum to an existing contract. Half of the pharmacies and all of the PSAOs in our survey expressed concerns about PDP sponsors' network development methods.

Background

Federal regulations (42 CFR § 423.120(a)(8)(i)) require that, in establishing a pharmacy network, a PDP sponsor "offering qualified prescription drug coverage must contract with any pharmacy that meets the Part D plan's standard terms and conditions."

Pursuant to 42 CFR § 423.505(b)(18), a PDP sponsor "must have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy

may access the standard contract and participate as a network pharmacy." CMS's "Medicare Prescription Drug Benefit Manual," Chapter 5, section 50.8.1, explains that the "any willing pharmacy" provision "extends to an agent authorized to negotiate and/or sign contracts on behalf of a pharmacy [if the agent] is in compliance with all Federal and State laws."

Pursuant to section 1860D-4(b)(1)(C)(ii) of the Act,[3] CMS was required to establish retail pharmacy network access standards no less favorable than the standards used by the Department of Defense TRICARE Retail Pharmacy program, the health care plan for military personnel and their families.

Prescription Drug Plan Sponsors' Responses

The 40 PDP sponsors in our survey described their network development methods as summarized below.[4] (See Appendix H for a breakdown of the methods by sponsor.)

- Thirty-nine PDP sponsors stated that they had solicited pharmacies from their existing commercial networks and/or had actively solicited other pharmacies for their Part D networks. Eleven of those that used their existing commercial networks added that they had solicited additional pharmacies only as needed to meet CMS network access requirements.

- Twenty-six PDP sponsors stated that they had contracted with pharmacies in their Part D networks through signed contracts, and 13 PDP sponsors stated that they had contracted through addendums to existing contracts.

- Thirty-six PDP sponsors stated that they had subcontracted with PBMs, which then contracted with the pharmacies. Of the 36 sponsors, 17 stated that the contracts between the PBMs and the pharmacies identified the PDP as the sponsor.

- Thirty-five PDP sponsors stated that they had contracted with pharmacies through PSAOs. One sponsor stated that it preferred to contract directly with pharmacies, and another sponsor stated that its PBM had contracted only with PSAOs that could "add value." Two PDP sponsors stated that they would not contract with PSAOs.

Pharmacies' and Pharmacy Services Administrative Organizations' Responses

Of the 100 sampled pharmacies, 50 reported that they had concerns about PDP sponsors' network development methods, and all 13 of the PSAOs in our survey stated that they had similar concerns. The 50 other pharmacies did not express concerns in this area; however, 41 of these pharmacies relied on PSAOs and may not have been able to provide any information concerning this area. The concerns expressed included the following:

[3]42 U.S.C. § 1395w-104(b)(1)(C)(ii).

[4]Although we received responses to our questionnaire from all 40 sampled PDP sponsors, not all sponsors answered all of the questions, and some answers were unclear. Thus, the information in the bulleted text does not always include responses from all 40 sponsors.

- Officials from 35 pharmacies and 10 PSAOs stated that they were overwhelmed by the amount of paperwork involved in the Part D process and by the volume of contracts, all with different terms, that needed to be reviewed and negotiated in short timeframes. Officials stated that they would have negotiated more contract terms had they been given more time.

- Officials from 10 pharmacies and 5 PSAOs stated that the contracting process was not logical because pharmacies were forced to sign contracts with companies before knowing whether they would become PDP sponsors. As a result, officials stated that they expended effort and expense to review and attempt to negotiate contracts with companies that ultimately did not become PDP sponsors.

- Officials from 17 pharmacies and 7 PSAOs expressed concern about participating in Part D networks through addendums to existing contracts. They explained that if a pharmacy was already in a PDP sponsor's commercial network, the sponsor sent an addendum to the existing commercial contract stating that the pharmacy would automatically be included in the Medicare network if it did not take certain actions to prevent its inclusion. Officials from five of these pharmacies and two of these PSAOs said that they had experienced difficulty contacting the PDP sponsors. One official stated: "I had to fight tooth and nail to get our name off a list . . . . I can tell you from experience that many of the faxed-back refusals get somehow lost in 'fax space.'"

- Officials from 3 pharmacies and 10 PSAOs stated that some PDP sponsors had declined to contract with pharmacies' PSAOs and that the practice had imposed an additional burden on PSAO member pharmacies.

Summary

Most PDP sponsors reported that they had solicited pharmacies from their existing commercial networks and/or had solicited other pharmacies. Pharmacies and PSAOs reported concerns about the short timeframes to review numerous contracts, uncertainty regarding which companies would eventually become PDP sponsors, the sponsors' use of addendums to existing contracts, and PDP sponsors' refusal to contract with the pharmacies' PSAOs.

Standard Terms and Conditions

Most of the PDP sponsors that we surveyed reported that the terms and conditions that they offered to pharmacies were based on how they categorized pharmacies, i.e., by pharmacy type, geographic location, and the services provided. Most also said that they updated their brand-name drug payment rates regularly and that they had developed their own methodologies to determine generic drug payments. Additionally, most PDP sponsors stated that they had offered LTC contracts with enhanced rates to retail pharmacies that serviced LTC facilities.

About half of the pharmacies and all of the PSAOs reported concerns related to the standard terms and conditions offered by PDP sponsors, including the level of reimbursement and lack of

disclosure of reimbursement rates. Some pharmacies and PSAOs were also concerned that PDP sponsors had not offered enhanced LTC reimbursement rates to qualified pharmacies.

Background

In 70 Federal Register 4193, 4254 (January 28, 2005), CMS stated:

> . . . it is unreasonable to assume—the any willing pharmacist requirement notwithstanding—that a Part D plan could establish a network using a uniform set of terms and conditions throughout a service area because it will likely need to modify contracting terms and conditions to ensure access to certain pharmacies (for example, rural and long-term care pharmacies). We clarify that standard terms and conditions particularly for payment terms may vary to accommodate geographic areas or types of pharmacies . . . and that this is acceptable, provided that all similarly situated pharmacies are offered the same standard terms and conditions. Thus, for example, provided Part D plans offer all mail-order pharmacies in a particular area with the same standard terms and conditions, they may offer separate standard terms and conditions to mail-order pharmacies. With standard terms and conditions as a "floor" of minimum requirements that all similarly situated pharmacies must abide by, Part D plans may modify some of their standard terms and conditions to encourage participation by particular pharmacies.

PDP sponsors generally reimburse pharmacies for ingredient costs (i.e., drug acquisition costs) based on the AWP minus some percentage, as well as a dispensing fee. In the case of some generic drugs, PDP sponsors reimburse pharmacies based on a MAC. In general, the MAC is a ceiling price that applies to a group of therapeutically equivalent generic drugs.

Legislation proposed in S. 1954, 110th Cong. (2007), states that if a contract references MAC lists or pricing, the PDP sponsor must disclose such lists or pricing to the pharmacy at the time of contract offering and must disclose updates at least every 7 days through a Web site and a toll-free telephone number (at a minimum).[5]

Pursuant to 42 CFR § 423.120(a)(5), a PDP sponsor "must offer to all LTC pharmacies in its area standard contracting terms and conditions, including performance and service criteria that CMS specifies. The [PDP sponsor] must provide convenient access to LTC pharmacies consistent with written policy guidelines and other CMS instructions."

CMS's "Long Term Care Guidance," issued March 16, 2005, outlines minimum performance and service elements for pharmacies that provide LTC services.[6] These elements include requirements that the pharmacy provide a comprehensive inventory; provide special packaging; and have a qualified pharmacist on call 24 hours a day, 7 days a week. CMS's "Long-Term Care

[5]The Senate bill was referred to the Senate Committee on Finance on August 2, 2007.

[6]The guidance has been incorporated into the "Medicare Prescription Drug Benefit Manual," Chapter 5, section 50.5.2.

(LTC) Convenient Access Standard Statement," issued November 8, 2005, emphasizes that "LTC pharmacies must have the capability to meet the performance and service criteria, either directly or through a subcontractor. It does not mean that prospective LTC network pharmacies must show that they currently provide such services or that they could provide all these service[s] directly."

Prescription Drug Plan Sponsors' Responses

The 40 PDP sponsors in our survey described their standard terms and conditions as summarized below. (See Appendix I for a breakdown by sponsor.)

- Thirty-nine PDP sponsors stated that they typically categorized pharmacies by type, geographic location, and the services provided to determine the standard terms and conditions for similarly situated pharmacies. Thirty-one PDP sponsors stated that they had offered certain types of pharmacies, such as LTC or home infusion pharmacies, different rates from those offered to retail pharmacies. Twenty-six PDP sponsors stated that they had offered the same Part D reimbursement terms to all retail pharmacies.

- Seventeen PDP sponsors stated that they had updated AWP values daily; 16 sponsors stated that they had updated these values weekly. All PDP sponsors stated that they had used MediSpan, First Databank, or both as their source for brand-name and generic drug AWPs.[7]

- Thirty-nine PDP sponsors stated that they had developed their own methodologies for determining reimbursement amounts for generic drugs, and most stated that their MAC prices could change frequently. Twenty-eight PDP sponsors stated that they would not share with pharmacies the methodologies they had used to develop their MAC prices, while eight stated that they would share their methodologies upon request. Twenty PDP sponsors stated that they would not disclose their MAC lists to pharmacies, while 18 stated that they had made their MAC lists available, typically upon request and receipt of a signed confidentiality agreement.

- Thirty-five PDP sponsors stated that they had offered enhanced LTC reimbursement rates to retail pharmacies that serviced LTC facilities. These PDP sponsors stated that they had determined whether a retail pharmacy should be offered LTC rates based on the services the pharmacy included in its network agreement. Of the 35 sponsors, 5 required pharmacies to certify that they were able to perform the CMS LTC performance and service elements, and 27 sponsors required pharmacies to certify that they were currently performing all of the CMS LTC elements. Four PDP sponsors stated that they would contract with a pharmacy as either retail or LTC but not both. Five PDP sponsors stated that they did not offer LTC contracts to retail pharmacies that serviced LTC facilities.

[7]MediSpan, First Databank, and other drug-pricing database companies survey wholesalers to determine AWPs. Insurance companies often use the AWPs to determine pharmacy reimbursement amounts.

Pharmacies' and Pharmacy Services Administrative Organizations' Responses

Of the 100 sampled pharmacies, 49 reported concerns related to the PDP sponsors' standard terms and conditions, and all 13 PSAOs reported similar concerns. Some concerns related to dissatisfaction with the reimbursement terms, and others related to a lack of transparency with respect to those terms. The 51 other pharmacies did not express concerns in this area; however, 38 of these pharmacies relied on PSAOs and may not have been able to provide any information concerning this area. The concerns expressed included the following:

- Officials from 37 pharmacies and 9 PSAOs stated that, compared with commercial and Medicaid reimbursement terms, Part D reimbursement was consistently lower among PDP sponsors.

- Officials from eight pharmacies and six PSAOs stated that some PDP sponsors had adopted the lower Medicare rates for their commercial businesses, or the officials were concerned that if they accepted the contracts with lower Part D reimbursement, PDP sponsors would expect the lower rate to be sufficient for all of their commercial networks.

- Officials from 13 pharmacies and 9 PSAOs stated that the pharmacies did not know what reimbursement rates they should have received because the PDP sponsors' contracts did not provide sufficient information regarding the reimbursement methodology for brand-name and generic drugs. Regarding brand-name drugs, officials explained that PDP sponsors had not disclosed in the contracts which AWP pricing source they used or how often they updated AWPs in their payment systems. Regarding generic drugs, the officials stated that most PDP sponsors' reimbursement was based on their MAC lists, which are not consistent among sponsors and may change at any time. Additionally, the officials said that some PDP sponsors had multiple MAC lists and that sponsors generally did not disclose those lists. The officials explained that, as a result, the pharmacies did not know what they were agreeing to when they accepted the contracts and could not determine whether the PDP sponsors had correctly reimbursed them. One official used this analogy: "You buy a new car but do not find out the price until three days after the fact."

- Officials from two pharmacies and five PSAOs stated that PDP sponsors had not offered LTC contracts to retail pharmacies that qualified as LTC pharmacies.

Summary

Most of the PDP sponsors that we surveyed reported that they had offered standard terms and conditions based on how they categorized pharmacies and that they had updated brand-name drug payment rates regularly and developed their own generic drug payment methodologies. Additionally, most PDP sponsors stated that they had offered LTC contracts with enhanced rates to retail pharmacies that serviced LTC facilities.

Some pharmacies and PSAOs reported that Part D reimbursement rates were lower than commercial and Medicaid rates. Further, some pharmacies and PSAOs reported that PDP

sponsors did not provide information about their standard terms and conditions, including the source of their AWPs and their MAC methodologies and pricing. Additionally, some pharmacies and PSAOs reported that PDP sponsors had not offered LTC contracts.

Extended-Day Supply Terms

Most of the PDP sponsors that we surveyed reported using varying definitions and reimbursement terms for extended-day supplies. Most of the pharmacies and all of the PSAOs reported that they found the extended-day supply terms offered by PDP sponsors to be unacceptable.

Background

Pursuant to 42 CFR § 423.120(a)(10), a PDP sponsor "must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network . . . retail pharmacies." A PDP sponsor may require an enrollee to pay the difference between the cost of a drug at a retail pharmacy and the cost at a mail-order pharmacy.

CMS's "Medicare Prescription Drug Benefit Manual," Chapter 5, section 50.10, states that, to the extent a PDP sponsor offers benefits through network mail-order pharmacies, the sponsor must ensure that enrollees have reasonable access to the same benefits at network retail pharmacies. Section 50.10 describes two contracting options. One option provides retail pharmacies with the same rate as that paid to the network mail-order pharmacy. The second option provides retail pharmacies with a higher reimbursement rate, but any difference between the mail-order rate and the higher retail rate would be paid by the beneficiary.

Prescription Drug Plan Sponsors' Responses

The 40 PDP sponsors in our survey described their extended-day supply contract terms as summarized below. (See Appendix J for a breakdown by sponsor.)

- Thirty-seven PDP sponsors reported that they had provided beneficiaries the option to purchase from retail pharmacies drug supplies that were for more than 30 days. The sponsors' definition of extended-day supplies ranged from more than 30 days to 90 days. Twenty-seven PDP sponsors reported that their definition was more than 30 to 34 days; 13 sponsors reported that their definition was more than 60 to 90 days.

- Nineteen PDP sponsors reported that they had offered to retail pharmacies one of the extended-day contract options described in the "Medicare Prescription Drug Benefit Manual." Seven sponsors said that they offered the same reimbursement rate as that paid to their mail-order pharmacies. Three sponsors said that they offered a rate that was lower than the non-extended-day supply rate but higher than the rate paid to mail-order pharmacies. Nine sponsors said that they offered the same rate for both extended-day and non-extended-day supplies.

- One PDP sponsor reported that it had offered pharmacies both of the CMS extended-day contract options. If a pharmacy chose the mail-order rate, it was listed as a preferred

pharmacy; if a pharmacy chose the higher reimbursement rate, it was listed as nonpreferred.[8]

- Twenty-seven PDP sponsors stated that they or their PBMs owned or managed their own mail-order pharmacies. Eleven others stated that they contracted with mail-order pharmacies.

Pharmacies' and Pharmacy Services Administrative Organizations' Responses

Of the 100 sampled pharmacies, 66 reported concerns related to extended-day supply terms, and all 13 PSAOs reported similar concerns. The 34 other pharmacies did not express concerns in this area; however, 25 of these pharmacies relied on PSAOs and may not have been able to provide any information concerning this area. The concerns expressed included the following:

- Officials from seven PSAOs described the number of fill days that qualified as extended-day supplies as various and wide ranging, which created confusion for the pharmacies.

- Officials from 65 pharmacies and 13 PSAOs stated that the reimbursement rates for extended-day supplies were unacceptable because the rates (1) had been reduced to levels much lower than those for non-extended-day supplies, typically at or below the pharmacy's product acquisition cost, and (2) did not include a dispensing fee.

- Officials from 11 pharmacies and 8 PSAOs reported concerns related to the PDP sponsors' affiliations with mail-order pharmacies. The officials explained that retail pharmacies could not compete with the PDP sponsors' mail-order businesses because mail-order pharmacies are considered a different class of trade and can purchase drugs at a lower price than retail pharmacies.

Summary

Most PDP sponsors reported using a definition of extended-day supplies that ranged from 30 to 90 days. Additionally, PDP sponsors reported that they offered varied reimbursement rates to pharmacies for extended-day supplies. Most pharmacies reported that extended-day reimbursement rates were unacceptable.

Negotiations

According to most of the PDP sponsors we surveyed, pharmacies were responsible for initiating contract negotiations if they did not agree to the standard terms and conditions. Most PDP sponsors also said that they would consider any counteroffers and that the acceptance of a counteroffer depended on multiple factors. Most of the pharmacies and all of the PSAOs reported concerns related to negotiating contracts with PDP sponsors.

[8]Beneficiaries are responsible for paying the difference between the mail-order rate and the higher reimbursement rate accepted by the pharmacy. Therefore, the beneficiary may pay more at a nonpreferred pharmacy.

Background

Proposed legislation in H.R. 971, 110th Cong. (2007), would create a 5-year exemption to antitrust laws to permit independent pharmacies to negotiate collectively with health plans and issuers of health insurance about payment rates and other contract terms. That exemption would apply to negotiations between independent pharmacies and PDP sponsors.[9]

Prescription Drug Plan Sponsors' Responses

The 40 PDP sponsors in our survey described their negotiation processes as summarized below. (See Appendix K for a breakdown by sponsor.)

- Thirty-eight PDP sponsors stated that they had considered counteroffers from pharmacies and had permitted contract negotiations provided that the pharmacies initiated the negotiations. One PDP sponsor said that State law prohibited it from negotiating with pharmacies. Some PDP sponsors stated that the pharmacies typically had to call the sponsors' main numbers to initiate negotiations. The sponsors stated that they had handled negotiations on a case-by-case basis. According to the PDP sponsors, acceptance of a counteroffer depended on its reasonableness, the pharmacy type, access issues in a particular geographic area, and competition.

- Twenty-six PDP sponsors stated that they would consider providing rural retail pharmacies an enhanced reimbursement rate if the pharmacies requested an enhanced rate and met the sponsors' qualifications for a rural pharmacy. PDP sponsors reported using a variety of criteria to determine whether a pharmacy qualified as rural, ranging from the distance between pharmacies (5 to 20 miles) to whether a pharmacy was located in a metropolitan statistical area.[10] Some PDP sponsors reported using no criteria.

- Nine PDP sponsors stated that pharmacies had complained about the negotiation process. The complaints included an inability to contact PDP sponsors, dissatisfaction with the terms of the agreements, and delays in contract negotiations.

Pharmacies' and Pharmacy Services Administrative Organizations' Responses

Of the 100 sampled pharmacies, 90 reported concerns related to negotiating contracts, and all 13 PSAOs reported similar concerns. The 10 other pharmacies did not express concerns in this area; however, 9 of these pharmacies relied on PSAOs and may not have been able to provide any information concerning this area. The concerns expressed included the following:

- Officials from 25 pharmacies and 6 PSAOs stated that negotiating contracts with PDP sponsors was difficult and frustrating because the sponsors did not return telephone calls or left pharmacies on hold for long periods. Officials stated that one PDP sponsor shut

[9]The proposed legislation was ordered to be reported (amended) by voice vote on November 7, 2007. The bill was recommended to be considered by the House as a whole.

[10]CMS uses the Office of Management and Budget metropolitan area designations in the Medicare program.

down its voice mail at the beginning of 2006 and would allow pharmacies to initiate contract negotiations only through facsimile or interactive voice response.

- Officials from 76 pharmacies and 13 PSAOs described the negotiation process as unproductive and contract offers as take-it-or-leave-it deals. Most officials said that PDP sponsors would not negotiate contract terms. For the few contracts that the officials reported that they had negotiated, the contract terms were not significantly different from the standard terms and conditions.

- Officials from six pharmacies and two PSAOs stated that pharmacies were not allowed to have a unified voice when negotiating or that antitrust laws limited the ability of independent retail pharmacies to collectively negotiate. One official stated that policymakers' assumption that "the market would sort things out" did not materialize and emphasized that such an assumption could be true only if equitable relationships existed between the contracting parties.

- Officials from 11 pharmacies and 10 PSAOs stated that they believed that the pharmacies qualified as rural pharmacies eligible for enhanced reimbursement rates. Officials from five pharmacies and five PSAOs reported that they had attempted to obtain rural designation but were not successful. The remaining officials reported that not all PDP sponsors offered a rural rate or that they did not know that a rural rate was available.

- Officials from 57 pharmacies and 4 PSAOs said that they felt pressured to sign contracts with PDP sponsors, regardless of the terms, to retain the business of longstanding customers. Some pharmacies indicated that they were willing to accept contracts regardless of the payment terms because they could not afford to lose a high percentage of their customer base. Some pharmacies stated that they were willing to participate in Part D because of the magnitude of the program and initially accepted lower reimbursement, or even losses, hoping that reimbursement rates would improve.

Summary

According to most PDP sponsors, pharmacies were responsible for initiating contract negotiations. Most PDP sponsors said that they would consider any counteroffers and that the acceptance of a counteroffer depended on multiple factors. Some pharmacy and PSAO officials reported that they were not able to contact PDP sponsors to initiate negotiations. Officials of those pharmacies that were able to contact PDP sponsors stated that the negotiation processes were often unproductive.

Network Requirements and Contracting Deadlines

Most PDP sponsors stated that pharmacies were not required to contract with the sponsors' commercial networks to be included in the Part D networks. Additionally, some PDP sponsors said that they had imposed deadlines on pharmacies to meet CMS's network adequacy requirements but that pharmacies could have joined at any time and received the same rate. Some pharmacies and PSAOs reported concerns related to the network requirements and contracting deadlines imposed by PDP sponsors.

Background

Potential PDP sponsors began soliciting pharmacies around April 2005 and were required to submit their networks to CMS for approval by August 1, 2005. To obtain CMS's approval as a PDP sponsor, the sponsor was required to meet retail pharmacy network access standards defined in 1860D-4(b)(1)(C)(ii) of the Act.

Prescription Drug Plan Sponsors' Responses

The 40 PDP sponsors in our survey described their network requirements and contracting deadlines as summarized below. (See Appendix L for a breakdown by sponsor.)

- Thirty-nine PDP sponsors stated that pharmacies were not required to contract with the sponsors' commercial networks to be included in their Part D networks.

- Thirty-two PDP sponsors stated that their initial contract solicitation specified a deadline for accepting the contract. These sponsors stated that pharmacies could have joined at a later date and received the same rates. Several PDP sponsors added that they had imposed a deadline to meet CMS's network adequacy requirements for approval as a PDP sponsor.

Pharmacies' and Pharmacy Services Administrative Organizations' Responses

Of the 100 sampled pharmacies, 23 reported concerns related to network requirements and contracting deadlines, and 9 PSAOs stated that they had similar concerns. The 77 other pharmacies did not express concerns in this area; however, 62 of these pharmacies relied on PSAOs and may not have been able to provide any information concerning this area. The concerns expressed included the following:

- Officials from 11 pharmacies and 5 PSAOs stated that some PDP sponsors required that pharmacies participate in the commercial network to participate in the Part D network and vice versa.

- Officials from 11 pharmacies and 3 PSAOs stated that if the pharmacies did not enroll by a deadline, PDP sponsors would not allow them to enroll or would offer a lower reimbursement rate.

Summary

Most PDP sponsors stated that pharmacies were not required to contract with the sponsors' commercial networks to be included in the Part D networks. Some PDP sponsors said that they had imposed deadlines on pharmacies to meet CMS's network adequacy requirements but that pharmacies could have joined at any time and received the same rate. Some pharmacies reported that PDP sponsors required participation in both the Part D and commercial networks and that they felt pressured to enroll by the deadline or be excluded from the network or be reimbursed at a lower rate.

Other Sponsor Processes

Most of the PDP sponsors that we surveyed stated that they did not offer electronic funds transfer (EFT) as a payment method or have plans to do so. Most PDP sponsors also said that they did not contract with pharmacies for the delivery of medication therapy management (MTM) services to Medicare beneficiaries. Almost half of the pharmacies and most PSAOs stated that they had concerns involving untimely payments, the lack of EFT as a payment option, and the lack of MTM provisions in contracts.

Background

Prior to Part D, many Medicare beneficiaries paid cash for their prescriptions, or, if they were also eligible for Medicaid, Medicaid usually paid pharmacies on a weekly or biweekly basis. Insurance companies typically pay pharmacies by EFT for their commercial business.

Pursuant to 42 CFR § 423.153(d), a Part D sponsor must have established an MTM program that, among other requirements, ensures optimum therapeutic outcomes for targeted beneficiaries through improved medication use and that reduces the risk of adverse events. Targeted beneficiaries are those who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur a minimum annual cost for covered Part D drugs as specified by the Secretary.

Legislation proposed in S. 1954, 110th Cong. (2007), and H.R. 1474, 110th Cong. (2007), includes the following provisions:[11]

- A provision requiring PDP sponsors to promptly pay clean claims (1) states that payment must be made within 14 days of receipt of an electronic claim and 30 days of receipt of all other claims and that an interest penalty will be assessed on claims paid after this time, (2) defines the payment date as the date that the provider receives the full payment, and (3) requires a PDP sponsor to pay all clean claims submitted electronically by EFT.

- A provision related to MTM services states that "face-to-face interaction" is the "preferred method of delivery."

Prescription Drug Plan Sponsors' Responses

The 40 PDP sponsors in our survey described their processes as follows:

- Thirty-eight PDP sponsors stated that they had paid pharmacies by mailing checks, typically via first-class mail. Ten PDP sponsors stated that they had offered pharmacies the choice of having payments sent by EFT. Of the 28 that did not offer EFT, 23 stated that they had no plans to implement EFT for Part D in the future.

- Thirty-six PDP sponsors stated that they had not offered MTM terms to retail pharmacies. These sponsors said that they either contracted with their PBMs to perform MTM

[11]The Senate bill was referred to the Senate Committee on Finance on August 2, 2007. The House bill was referred to the House Subcommittee on Health on March 20, 2007.

services or performed the services themselves. One PDP sponsor stated that it had included MTM terms in the contracts with pharmacies, and two sponsors stated that they had included MTM terms as contract amendments.

Pharmacies' and Pharmacy Services Administrative Organizations' Responses

Of the 100 sampled pharmacies, 48 expressed concerns about other PDP sponsor processes, and 11 PSAOs stated that they had similar concerns. The 52 other pharmacies did not express concerns in this area; however, 39 of these pharmacies relied on PSAOs and may not have been able to provide any information concerning this area. The concerns expressed included the following:

- Officials from 16 pharmacies and 7 PSAOs stated that the implementation of Medicare Part D had caused hardship, particularly in the timing of payments. The officials explained that pharmacies received payments later than they had before Part D; therefore, according to the officials, pharmacies were unable to make timely payments to their wholesalers, which caused the pharmacies to forego prompt payment discounts.

- Officials from four pharmacies expressed concern that PDP sponsor contracts did not include MTM services. Another official stated that MTM services provided a revenue stream for pharmacies.

Summary

Most PDP sponsors reported that they did not offer or have plans to offer EFT. Most also reported that they had not contracted with pharmacies for the delivery of MTM services to Medicare beneficiaries. Some pharmacies and PSAOs stated that they had concerns about the timing of payments, the lack of EFT as a payment option, and the lack of MTM provisions in contracts. If enacted, the proposed legislation would address the EFT and MTM issues.

RECOMMENDATIONS

We recommend that Congress and CMS consider the results of our review, including the data provided, in any deliberations regarding Medicare Part D contracting.

With respect to network development, we recommend that CMS:

- consider issuing guidance requiring PDP sponsors to make available to pharmacies the procedures for opting out of contract addendums and

- determine whether PDP sponsors are complying with the "any willing pharmacy" provision as it relates to contracting with PSAOs, as required by CMS's "Medicare Prescription Drug Benefit Manual," Chapter 5, section 50.8.1.

With respect to standard terms and conditions, we recommend that CMS:

- consider proposing legislation through departmental channels to increase the transparency of contracting by requiring PDP sponsors to disclose how they define similarly situated pharmacies and to disclose the data source, basis, and methodology they use to develop reimbursement rates, including the MAC, and

- determine whether PDP sponsors are offering, upon request, LTC contracts to pharmacies that meet the criteria for participating as LTC pharmacies, as required by 42 CFR § 423.120(a)(5).

With respect to extended-day supplies, we recommend that CMS:

- consider issuing guidance requiring PDP sponsors to make available to pharmacies the PDP sponsors' definition of an extended-day supply and

- study the extent to which retail pharmacies are participating in offering extended-day supplies and, if participation is low, consider eliminating the contracting option that allows PDP sponsors to pay retail pharmacies the same rate as that paid to network mail-order pharmacies.

With respect to negotiations, to the extent that PDP sponsors offer enhanced rates to certain categories of pharmacies (e.g., rural pharmacies), we recommend that CMS increase the transparency of contracting by encouraging PDP sponsors to communicate to pharmacies the criteria for qualifying for those enhanced rates.

With respect to contracting deadlines, we recommend that CMS determine whether PDP sponsors have complied with the "any willing pharmacy" provision as it relates to contracting deadlines.

With respect to issues related to other sponsor processes, we recommend that:

- Congress and CMS consider the results of our review, including information on the timing of payments, in deliberating the proposed legislation and any future legislation regarding Medicare Part D contracting and

- CMS study MTM service delivery options to determine which option(s) are most effective for achieving the goals of MTM and whether additional legislative or regulatory change is needed.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In its written comments on our draft report, CMS concurred with five of our recommendations related to the "any willing pharmacy" provision, LTC contracts, legislative deliberations, and MTM services. CMS did not concur with the remaining five recommendations, stating that they were contrary to the competitive market principles that are fundamental to the Part D program.

CMS said that it interprets section 1860D-11(i) of the Act as prohibiting Government interference in the sort of price negotiations suggested in some of the recommendations. CMS also provided technical comments.

We have included CMS's comments as Appendix M.

OFFICE OF INSPECTOR GENERAL RESPONSE

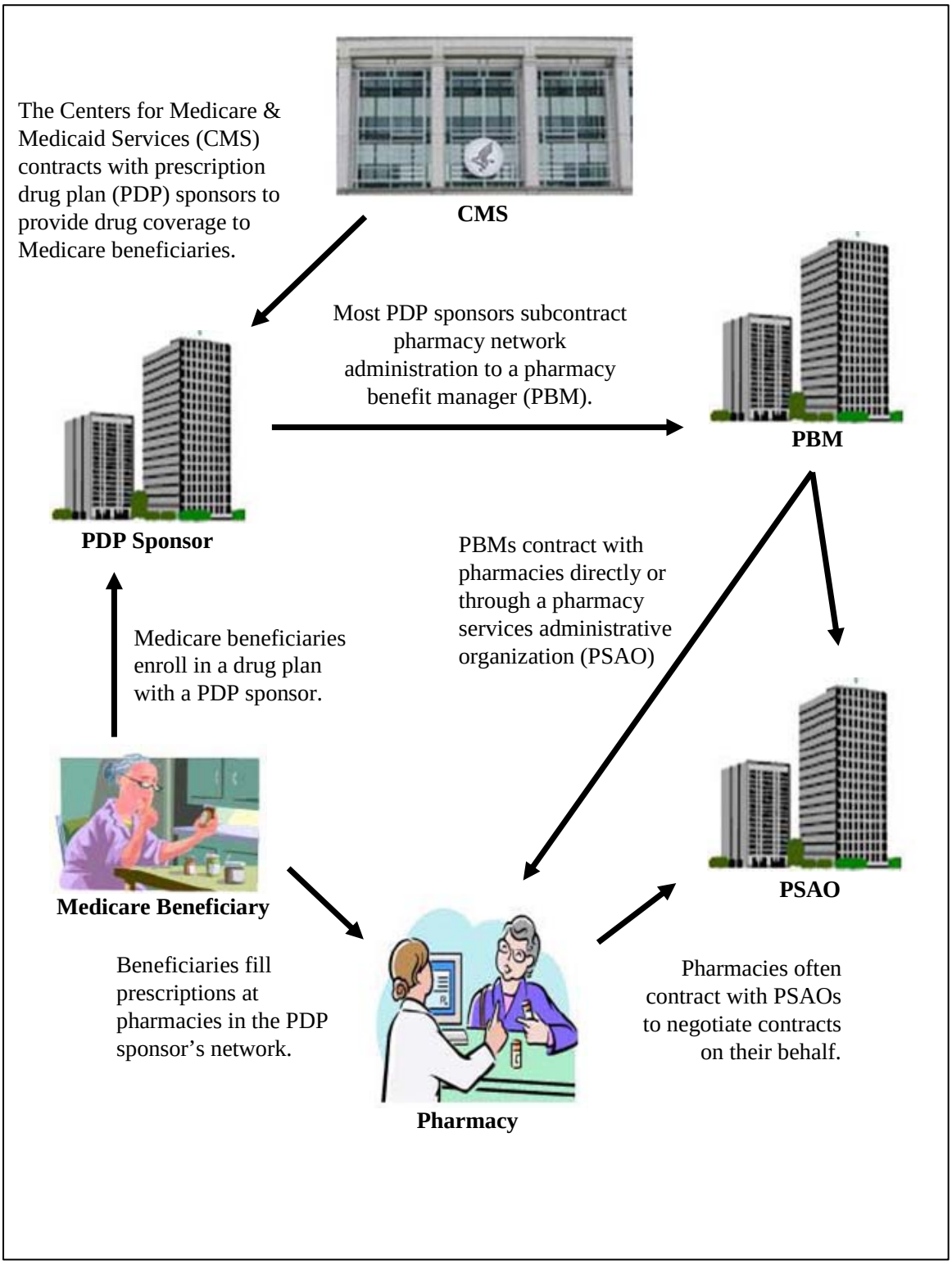
We agree that the Act prohibits the Government from interfering with negotiations between PDP sponsors and pharmacies and from instituting a price structure for the reimbursement of covered Part D drugs. To more fully recognize that prohibition in our final report, we have revised three recommendations pertaining to contract addendums and extended-day supplies. Our recommendations, as revised, focus on increasing transparency and disclosure in contracting and do not interfere with negotiations between PDP sponsors and pharmacies or institute a price structure.

We have also addressed CMS's technical comments as appropriate.

APPENDIXES

APPENDIX A

MEDICARE PART D CONTRACTUAL RELATIONSHIPS



PHARMACY SAMPLE DESCRIPTION[1]

AUDIT OBJECTIVES

Our objectives were to determine (1) the number of local, community pharmacies that relied on PSAOs for assistance in contracting with PDP sponsors and the pharmacies' satisfaction with PSAO services and (2) the contracting methods that PDP sponsors used to develop their Medicare networks and the pharmacies' and PSAOs' contracting experiences.

POPULATION

The sampling population consisted of the 21,331 independent and franchise retail pharmacies (local, community pharmacies) in the United States and Puerto Rico with National Council for Prescription Drug Programs, Inc. (NCPDP), provider numbers as of October 2, 2006. We included each pharmacy in our population four times to represent the 4 weeks in September 2006. As a result, the population size was 85,324 (21,331 x 4).[2]

SAMPLING FRAME

The NCPDP Pharmacy Database included pharmacies in the U.S. territories of Guam and the Virgin Islands, as well as the Commonwealth of the Northern Mariana Islands. We removed the 42 independent retail pharmacies in these locations from our population. (No franchise retail pharmacies were shown in these locations.)

Additionally, we used a CMS list of pharmacies that participated in Medicare Part D to identify pharmacies that did not participate. We removed the 1,260 nonparticipating pharmacies (1,257 independent retail pharmacies and 3 franchise retail pharmacies) from our population.

Each of the 21,331 local, community pharmacies appeared four times in the sampling frame, one time for each of the 4 pharmacy weeks in September 2006.

SAMPLE UNIT

The sample unit was a pharmacy week (a 5-day span of weekdays, excluding Federal holidays) of Medicare Part D payments.

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[1]We used the same pharmacy sample that was used in our prior review of Part D reimbursement (A-06-07-00107). Although the sample selection was the same for both reviews, the objectives and characteristics to be measured were different.

[2]Our original population included 21,346 local community pharmacies with 85,384 pharmacy weeks (21,346 x 4). However, we removed 15 pharmacies from the population for the reasons cited in the "Treatment of Missing Sample Items" section of this appendix.

SAMPLE DESIGN

We used a two-phase sample design. The first phase entailed selecting a random sample of 300 pharmacy weeks. Our survey work revealed that the payment cycles for third-party payers, including Part D sponsors, typically ranged from 15 to 45 days. As a result, some pharmacies might not have received a remittance advice with a Medicare Part D payment during a given week. We contacted the 300 pharmacies to determine whether they had received a remittance advice with a Medicare Part D payment during the selected pharmacy week. That helped ensure that we had 100 viable sample units by reducing the number of sample units that needed to be replaced because a pharmacy did not receive a Medicare Part D payment during the pharmacy week.

In the second phase, we selected a random subsample of 125 pharmacy weeks from the pharmacies that we confirmed to have received Medicare Part D payments during the selected pharmacy weeks. (The first 100 were our initial sample units, and the remaining 25 were used for replacements when needed).

SAMPLE SIZE

We selected 100 pharmacy weeks.

SOURCE OF RANDOM NUMBERS

We generated the random numbers using the Office of Inspector General, Office of Audit Services, RAT-STATS statistical sampling software.

METHOD OF SELECTING SAMPLE ITEMS

Each NCPDP provider number was replicated four times and assigned a numerical indicator from 1 to 4 signifying the 4 pharmacy weeks in September 2006. We numbered the resulting 85,324 sample items sequentially from 1 to 85,324 and generated 300 random numbers based on them.

We also generated 125 random numbers based on the sequential numbers of those pharmacies that we confirmed to have received Medicare Part D payments during the selected pharmacy weeks.

CHARACTERISTICS TO BE MEASURED

We determined whether the sampled pharmacies had used a PSAO to negotiate contracts with PDP sponsors and obtained an understanding of their contracting experiences.

TREATMENT OF MISSING SAMPLE ITEMS

If 1 of the initial 300 pharmacies that we contacted was out of business; did not participate in Medicare Part D; or was not a local, community pharmacy, we removed the pharmacy week

from the sample and all 4 pharmacy weeks for the pharmacy from the population. If one of these pharmacies did not receive a Medicare Part D payment during the selected pharmacy week but participated in Medicare Part D, we removed the pharmacy week from the sample but not from the population. We left all 4 pharmacy weeks in the population.

If 1 of the 100 pharmacies selected for a site visit had gone out of business between the date of initial contact (to determine whether it had received a Medicare Part D payment during the selected pharmacy week) and the date of our site visit, we replaced that pharmacy week with a spare from the subsample and removed all 4 pharmacy weeks for the pharmacy from our population. If 1 of the 100 pharmacies selected for a site visit could not produce all of the data necessary for our analysis, we replaced the pharmacy week with a spare from the subsample but left all 4 pharmacy weeks in the population.

ESTIMATION METHODOLOGY

We used RAT-STATS to estimate the number of pharmacies that relied on PSAOs for assistance in contracting with PDP sponsors and the number that reported concerns relating to contracting with the sponsors.

APPENDIX C

SUMMARY OF SENATE LETTERS RELATED TO PART D CONTRACTING

In 2006, a group of Senators corresponded with CMS about continued improvements needed in Medicare prescription drug benefit policies. The letters covered five issues, four of which are pertinent to our review.

- Disclosure of maximum allowable cost (MAC) lists: The Senators recommended that CMS encourage PDP sponsors to disclose MAC lists and any subsequent changes to ensure that pharmacists can fully assess the nature of Part D contracts.

- Updating average wholesale price (AWP): In the Senators' view, there should be no lag between a PDP's receipt of an AWP change and updates to its price list. PDP sponsors should update their price lists on the day they receive AWP changes.

- Option for electronic funds transfer (EFT): In the Senators' view, promoting EFT availability and utilization is a responsibility that lies with CMS.

- Access to extended-day supplies of Part D drugs at retail pharmacies: The Senators were concerned that CMS's current policies might undermine the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requirements to ensure (1) beneficiaries' access to their medicines through retail pharmacies and (2) a level playing field between mail-order and retail pharmacies.

With respect to the "level playing field" requirement, the Senators emphasized that the statutory language is not ambiguous and that congressional intent is obvious. The MMA states that PDP sponsors "shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail order pharmacy), with any differentials in charge paid by such enrollees." The Senators stated: "The provision is intentionally designed as a requirement on plan sponsors to ensure that beneficiaries with prescriptions for longer term supplies can fill those prescriptions at either their local retail pharmacies or through mail order."

Although the Senators said that they were pleased that CMS was monitoring complaints, they did not believe that the approach was sufficient to determine compliance and enforce contract requirements. The Senators said that CMS should be more proactive in ensuring PDP sponsors' compliance with the law and beneficiaries' access to extended-day supplies in retail settings.

PHARMACY ESTIMATES

Description	Point Estimate	90-Percent Confidence Interval	
		Lower Limit	Upper Limit
Number of pharmacies that relied on PSAOs			
Percent	78.0%	70.103%	84.607%
Number[1]	16,638	14,954	18,048
Number of pharmacies that did not rely on PSAOs			
Percent	22.0%	15.393%	29.897%
Number	4,693	3,284	6,377
Number of pharmacies that reported concerns in any contracting category			
Percent	98.0%	93.841%	99.643%
Number	20,905	20,017	21,255
Number of pharmacies that did not report concerns in any contracting category[2]			
Percent	2.0%	0.357%	6.159%
Number	427	76	1,314
Number of pharmacies that reported concerns with network development methods			
Percent	50.0%	41.367%	58.633%
Number	10,666	8,824	12,507
Number of pharmacies that did not report concerns with network development methods			
Percent	50.0%	41.367%	58.633%
Number	10,666	8,824	12,507
Number of pharmacies that reported concerns with standard terms and conditions			
Percent	49.0%	40.392%	57.653%
Number	10,452	8,616	12,298
Number of pharmacies that did not report concerns with standard terms and conditions			
Percent	51.0%	42.347%	59.608%
Number	10,879	9,033	12,715

[1]We derived these nonstatistical estimates by dividing each statistical estimate of pharmacy weeks by 4. As a result of rounding, the sum of the two numbers may not always equal 21,331.

[2]Two sampled pharmacies did not provide any experiences because they relied on a PSAO and did not review or try to negotiate any contracts.

Description	Point Estimate	90-Percent Confidence Interval	
		Lower Limit	Upper Limit
Number of pharmacies that reported concerns with extended-day supply terms			
Percent	66.0%	57.427%	73.844%
Number	14,079	12,250	15,752
Number of pharmacies that did not report concerns with extended-day supply terms			
Percent	34.0%	26.156%	42.573%
Number	7,253	5,579	9,081
Number of pharmacies that reported concerns with negotiations			
Percent	90.0%	83.633%	94.470%
Number	19,198	17,840	20,152
Number of pharmacies that did not report concerns with negotiations			
Percent	10.0%	5.530%	16.367%
Number	2,133	1,180	3,491
Number of pharmacies that reported concerns with network requirements and contracting deadlines			
Percent	23.0%	16.263%	30.978%
Number	4,906	3,469	6,608
Number of pharmacies that did not report concerns with network requirements and contracting deadlines			
Percent	77.0%	69.022%	83.737%
Number	16,425	14,723	17,862

PHARMACIES' RELIANCE ON AND SATISFACTION WITH PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS

Sample Item[1]	Relied on a PSAO	Satisfied With PSAO		Sample Item	Relied on a PSAO	Satisfied With PSAO
1	Yes	Yes		45	Yes	No
3	Yes	Yes		46	Yes	Yes
4	Yes	Yes		48	No	-
6	No	-		49	Yes	Yes
7	Yes	Yes		50	Yes	No
8	Yes	No		51	Yes	Yes
9	No	-		52	No	-
10	Yes	Yes		53	Yes	Yes
11	Yes	Yes		54	No	-
12	No	-		55	Yes	No
13	Yes	Qualified Yes		56	Yes	Yes
14	No	-		57	Yes	Yes
15	Yes	No		58	Yes	Yes
16	Yes	Yes		59	Yes	Yes
17	Yes	Yes		60	Yes	Yes
18	Yes	Yes		61	Yes	Yes
19	Yes	Qualified Yes		62	No	-
21	Yes	Yes		63	No	-
22	No	-		64	Yes	Yes
23	No	-		65	Yes	Yes
24	Yes	No		66	No	-
26	Yes	Yes		68	Yes	Yes
27	No	-		69	Yes	Yes
28	Yes	Qualified Yes		70	Yes	Qualified Yes
29	No	-		71	Yes	No
30	Yes	No		72	No	-
31	Yes	Qualified Yes		73	No	-
32	No	-		74	Yes	Yes
33	Yes	Yes		77	Yes	Yes
34	Yes	Yes		78	Yes	Qualified Yes
35	No	-		79	Yes	Yes
36	Yes	Yes		80	Yes	No
37	Yes	Yes		81	Yes	No
38	Yes	Yes		82	Yes	Yes
39	Yes	Yes		83	Yes	No
40	Yes	Yes		84	Yes	Yes
41	Yes	Yes		85	Yes	Yes
43	Yes	Yes		86	Yes	Yes
44	Yes	Yes		87	Yes	Yes

[1]The gaps in sample item number indicate that we replaced that pharmacy week with a spare from the subsample.

Sample Item[1]	Relied on a PSAO	Satisfied With PSAO		Sample Item	Relied on a PSAO	Satisfied With PSAO
88	No	-		99	No	-
89	Yes	Qualified Yes		100	Yes	Yes
90	Yes	Yes		101	Yes	Yes
91	Yes	No		102	Yes	Yes
92	Yes	Yes		103	Yes	Yes
93	Yes	Yes		104	Yes	Qualified Yes
94	Yes	No		105	Yes	Yes
95	No	-		106	Yes	No
96	Yes	Yes		108	Yes	Yes
97	Yes	Yes		109	Yes	Yes
98	No	-		110	Yes	Yes
				Total	**78 - Yes** **22 - No**	**56 - Yes** **8 - Qualified Yes** **14 - No**

TYPES OF CONCERNS PHARMACIES REPORTED

Sample Item[1]	Network Development Methods	Standard Terms and Conditions	Extended-Day Supply Terms	Negotiations	Network Requirements and Contracting Deadlines	Other Sponsor Processes
1			x	x		
3		x		x		x
4			x	x		
6			x	x		
7		x		x	x	
8	x	x	x	x		x
9	x			x		
10			x	x		
11	x			x		
12		x	x	x		x
13	x		x	x		x
14		x	x	x		
15			x	x	x	x
16			x	x		
17				x		x
18		x	x	x		
19		x	x	x		x
21		x	x	x		
22		x		x		x
23	x		x	x	x	x
24	x	x		x		x
26		x	x	x		x
27		x		x		
28						
29	x	x	x	x	x	x
30		x	x	x	x	
31	x		x	x		
32	x		x	x	x	
33	x		x	x	x	
34	x		x	x	x	
35	x		x	x	x	x
36	x	x	x	x		x
37				x		
38			x			
39	x		x	x	x	x
40			x	x		
41				x		
43	x	x	x	x	x	x
44			x	x		
45		x	x	x	x	

[1]The gaps in sample item number indicate that we replaced that pharmacy week with a spare from the subsample.

Sample Item[1]	Network Development Methods	Standard Terms and Conditions	Extended-Day Supply Terms	Negotiations	Network Requirements and Contracting Deadlines	Other Sponsor Processes
46		x		x		x
48	x	x	x	x	x	x
49	x	x				
50	x	x	x	x		x
51			x	x	x	x
52	x		x	x		x
53	x	x	x	x		x
54	x					x
55	x			x		x
56	x		x	x		
57	x	x		x		
58	x	x	x	x	x	
59	x		x	x		x
60	x	x	x	x		x
61		x		x		
62	x		x	x		
63				x		
64						x
65				x		
66		x		x		
68	x	x	x	x		
69			x	x		x
70			x	x	x	x
71			x	x		
72	x	x	x	x		
73	x		x	x		x
74		x		x		
77	x	x	x	x		
78	x	x	x	x		
79	x		x	x		x
80				x		
81	x		x			x
82	x			x		
83		x	x	x		x
84	x	x	x	x		x
85	x	x		x	x	
86	x		x	x		x
87						
88				x		
89	x		x	x		x
90	x	x				
91			x	x		
92		x	x	x	x	

Sample Item[1]	Network Development Methods	Standard Terms and Conditions	Extended-Day Supply Terms	Negotiations	Network Requirements and Contracting Deadlines	Other Sponsor Processes
93	x	x	x	x		x
94	x	x	x	x		x
95	x	x		x	x	
96		x		x	x	x
97			x	x		x
98				x	x	
99	x		x	x		
100	x	x	x	x	x	x
101		x				
102	x		x	x		x
103	x	x	x	x		x
104	x		x	x		x
105		x		x		x
106		x				x
108		x	x	x	x	
109	x	x	x	x		x
110		x	x	x		x
Total	**50**	**49**	**66**	**90**	**23**	**48**

APPENDIX G

TYPES OF CONCERNS PHARMACY SERVICES ADMINISTRATIVE ORGANIZATIONS REPORTED

Sample Item	Network Development Methods	Standard Terms and Conditions	Extended-Day Supply Terms	Negotiations	Network Requirements and Contracting Deadlines	Other Sponsor Processes
PSAO 1	x	x	x	x	x	x
PSAO 2	x	x	x	x		x
PSAO 3	x	x	x	x	x	x
PSAO 4	x	x	x	x	x	x
PSAO 5	x	x	x	x	x	
PSAO 6	x	x	x	x		x
PSAO 7	x	x	x	x	x	x
PSAO 8	x	x	x	x	x	
PSAO 9	x	x	x	x	x	x
PSAO 10	x	x	x	x	x	x
PSAO 11	x	x	x	x		x
PSAO 12	x	x	x	x		x
PSAO 13	x	x	x	x	x	x
Total	**13**	**13**	**13**	**13**	**9**	**11**

PRESCRIPTION DRUG PLAN SPONSORS' NETWORK DEVELOPMENT METHODS

PDP Sponsor	Used Existing Network and/or Actively Solicited Pharmacies	Pharmacies Contracted Directly With PBM	Contracted With a PSAO	Would Not Contract With a PSAO	Contracted Through Signed Contracts	Contracted Through Contract Addendums
1		x			x	
2	x	x[1]	x		x	
3	x	x				
4	x	x[1]	x		x	
5	x[2]	x[3]	x			x
6	x	x[1]	x		x	
7	x[2]	x[3]	x			x
8	x[2]	x[3]	x			x
9	x	x[1]	x		x	
10	x[2]	x	x			x
11	x	x		x		x
12	x	x	x		x	
13	x	x[1]	x		x	
14	x[2]	x	x			x
15	x[2]	x[3]	x			x
16	x[2]	[1]	x			x
17	x		x		x	
18	x	x[1]	x		x	
19	x	x[1]	x		x	
20	x	x	x		x	
21	x	x[1]	x		x	
22	x	x[1]	x		x	
23	x				x	
24	x	x[1]	x		x	
25	x[2]	x	x			x
26	x	x[1]	x		x	
27	x	x[1]		x		x
28	x	x[1]	x		x	
29	x	x[1]	x		x	
30	x[2]	x	x			x
31	x	x	x		x	
32	x	[1]	x		x	
33	x	x[4]	x		x	
34	x	x	x		x	
35	x[2]	x[3]	x			x
36	x	x[4]	x		x	
37	x	x	x		x	
38	x	x[1]	x		x	
39	x[2]	x[3]	x			x
40	x	x[4]	x		x	

[1]The PDP sponsor name was included in the contract.

[2]The PDP sponsor used its existing network to solicit pharmacies and solicited additional pharmacies only to meet CMS network access requirements.

[3]The PDP sponsor name was provided separately from the contract.

[4]The pharmacy could request the PDP sponsor name.

PRESCRIPTION DRUG PLAN SPONSORS' STANDARD TERMS AND CONDITIONS

PDP Sponsor	Pharmacies Categorized by Type, Geographic Location, and Services	All Retail Pharmacies Offered the Same Rates	AWP Updated	PDP Disclosure of MAC List	Enhanced Rural Rates Offered	Enhanced LTC Rates Offered[1]
1		x			N	N
2	x	x	x[2]	x[3 4]	Y	Y[5]
3	x	x		x[3]	N	Y[5]
4	x	x	x[6]	x[3 7]	Y	Y[5]
5	x			x[3 4]	Y	Y[5]
6	x	x	x[2]	x[3 4]	N	Y[5]
7	x			x[3 4]	Y	Y[5]
8	x			x[3 4]	Y	Y[5]
9	x	x	x[2]	x[3 4]	Y	Y[5]
10	x	x	x[6]	x[3 4]	Y	Y[5]
11	x		x[6]	x[7 8]		N[5]
12	x		x[2]	x[7 8]	Y	Y[5]
13	x	x	x[2]	x[3 4]	Y	Y[5]
14	x	x	x[6]	x[3 4]	Y	Y[5]
15	x			x[3 4]	Y	Y[5]
16	x		x[6]	x[7]	Y	Y[9]
17	x	x	x[6]	x[7]	N	Y[9]
18	x	x	x[6]	x[3 7]	Y	Y[5]
19	x	x	x[2]	x[3 4]	N	Y[9]
20	x		x[2]	x[7 8]	Y	Y[5]
21	x	x	x[2]	x[3 4]		Y[5]
22	x	x	x[2]	x[3 4]	Y	Y[5]
23	x	x	x[6]	x[3 4]	N	N
24	x	x	x[6]	x[3 7]	Y	Y[5]
25	x	x	x[6]	x[3 4]	Y	Y[5]
26	x	x	x[2]	x[3 7]	N	Y
27	x	x	x[6]	x[7 8]	Y	N
28	x	x	x[2]	x[3 7]	N	Y
29	x	x	x[2]	x[3 4]	Y	Y[5]
30	x	x	x[6]	x[3 4]	Y	Y[5]
31	x	x	x[6]	x[3 7]	N	N
32	x	x	x[2]	x[7 8]	Y	Y[5]
33	x	x	x[2]	x[7 8]	N	Y[9]
34	x		x[6]	x[7]	Y	Y[5]
35	x		x[6]	x[3 4]	Y	Y
36	x			x[7 8]	Y	Y[5]
37	x		x[6]	x[3 7]	Y	Y[5]
38	x	x	x[2]	x[3 4]	N	Y[9]
39	x			x[3 4]	Y	Y[5]
40	x		x[2]	x[7 8]	N	Y[5]

[1]LTC = long-term care.

[2]AWP updated daily.

[3]The PDP sponsor did not share with pharmacies the methodology used to develop its MAC list.

[4]The PDP sponsor did not disclose its MAC list.

[5]The PDP sponsor required pharmacies to certify that they were currently performing all of the CMS LTC services.

[6]AWP updated weekly.

[7]The PDP sponsor would have disclosed its MAC list if requested by the pharmacy.

[8]The PDP sponsor would have shared the methodology used to develop its MAC list if requested by the pharmacy.

[9]The PDP sponsor required pharmacies to certify that they were able to perform the CMS LTC services.

PRESCRIPTION DRUG PLAN SPONSORS' EXTENDED-DAY SUPPLY TERMS

PDP Sponsor	Contract Provided for More Than 30-Day Supply	Pharmacy Had Option To Accept Extended-Day Terms	Offered Rate Options	Owned or Managed Mail-Order Pharmacies	Contracted With Mail-Order Pharmacies
1	x[1]	x			
2	x[2]	x		x	
3	x[1]			x	
4					x
5	x[2]	x	x[3]		x
6	x[2]	x		x	
7	x[2]	x	x[3]		x
8	x[2]	x	x[3]	x	
9	x[2]	x		x	
10	x[1]	x	x[4]	x	
11	x[2]	x	x[5]		x
12	x[2]	x		x	
13	x[2]	x		x	
14	x[1]	x	x[4]	x	
15	x[2]	x	x[3]	x	
16	x[2]	x	x[4]	x	
17	x[1]	x	x[4]	x	
18					x
19	x[2]	x		x	
20	x[2]	x		x	
21	x[2]	x		x	
22	x[2]	x		x	
23	x[2]	x	x[3]		
24					x
25	x[1]	x	x[4]		x
26	x[1]	x	x[6]	x	
27	x[1]		x[3]	x	
28	x[1]	x	x[6]	x	
29	x[2]	x		x	
30	x[1]	x	x[4]	x	
31	x[2]	x	x[6]		x
32	x[2]	x	x[3]		x
33	x[2]	x	x[4]	x	
34	x[1]	x			x
35	x[1]	x	x[3]	x	
36	x[2]	x		x	
37	x[1]	x			x
38	x[2]	x		x	
39	x[2]	x	x[3]	x	
40	x[2]	x		x	

[1]The PDP sponsor considered any supply greater than 60 days as extended day.

[2]The PDP sponsor considered any supply greater than 30 days as extended day.

[3]The PDP sponsor offered the same rate regardless of the number of days for which the prescription was written.

[4]The PDP sponsor offered the same rate as that paid to its mail-order pharmacy.

[5]The PDP sponsor offered pharmacies two options: mail-order or higher reimbursement.

[6]The PDP sponsor offered pharmacies a reimbursement rate lower than that for a 30-day supply but higher than that paid to its mail-order pharmacies.

APPENDIX K

PRESCRIPTION DRUG PLAN SPONSORS' NEGOTIATIONS

PDP Sponsor	Considered Negotiations With Pharmacies	Received Complaint About Negotiating Process
1		
2	x	
3	x	
4	x	
5	x	
6	[1]	
7	x	
8	x	
9	x	
10	x	
11	x	
12	x	
13	x	x
14	x	
15	x	
16	x	
17	x	x
18	x	
19	x	
20	x	
21	x	x
22	x	
23	x	
24	x	
25	x	
26	x	x
27	x	x
28	x	x
29	x	
30	x	
31	x	
32	x	x
33	x	
34	x	x
35	x	
36	x	
37	x	x
38	x	
39	x	
40	x	

[1]The PDP sponsor said that State law prohibited it from negotiating with pharmacies.

APPENDIX L

PRESCRIPTION DRUG PLAN SPONSORS' NETWORK REQUIREMENTS AND CONTRACTING DEADLINES

PDP Sponsor	Pharmacy Required To Contract With Commercial Network	Initial Contract Specified a Date To Return Signed Contract
1		
2		x
3		
4		x
5		x
6		x
7		x
8		x
9		x
10		x
11		x
12		x
13		x
14		x
15		x
16		
17		
18		x
19		x
20		x
21		x
22		x
23	x	
24		x
25		x
26		x
27		
28		x
29		x
30		x
31		
32		
33		x
34		x
35		x
36		x
37		x
38		x
39		x
40		x

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator
Washington, DC 20201

DATE: MAY 0 9 2008

TO: Daniel R. Levinson
Inspector General

FROM: Kerry Weems
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Review of Medicare Part D Contracting for Contract Year 2006" (A-06-07-00082)

Thank you for the opportunity to review and comment on this OIG draft report to determine: 1) the number of local, community pharmacies that relied on pharmacy services administrative organizations (PSAOs) for assistance in contracting with prescription drug plan (PDP) sponsors and the pharmacies' satisfaction with PSAO services and 2) the contracting methods PDP sponsors used to develop their Medicare networks and the pharmacies' and PSAOs' contracting experiences.

The Centers for Medicare & Medicaid Services (CMS) concurs with a number of the report recommendations. We agree that CMS must continue to ensure compliance with various important protections for pharmacies established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), such as the "any willing pharmacy" provision and convenient access to long-term care pharmacy requirements, in order to ensure pharmacy participation in the Part D benefit in sufficient numbers to meet mandated beneficiary access standards. Moreover, CMS believes that some of the issues reported to OIG were limited to the unique circumstances associated with the initial year of the program.

However, we believe that several of the report's other recommendations intrude into the competitive market construct established in the MMA as a fundamental feature of the Part D program. This reliance on private market forces means that there are circumstances when contracting entities must be left alone to resolve issues without government direction or interference. The MMA contemplated competitive market negotiations between Part D plans and a wide range of pharmacies in order to satisfy the statute's beneficiary access standards. In order to meet these requirements, PDP sponsors must contract widely, and this would not be possible in the absence of mutually acceptable, reasonable, and relevant standard contracting terms and conditions. We interpret section 1860D-11(i) of the statute as prohibiting government interference in precisely the sort of price negotiations suggested in many of the report's recommendations.

OIG Recommendation

The OIG recommends that CMS consider issuing guidance on the procedures for opting out of contract addendums.

CMS Response

The CMS does not concur with this recommendation. CMS does not believe it should regulate such specific contract negotiation processes for contracting vehicles between PDP sponsors and prospective Part D network pharmacies, as these are terms best determined between the contracting parties and their legal counsel. However, we do exercise oversight of plan standard terms and conditions. We review sponsors' standard pharmacy agreements templates, including addendums, to ensure that all CMS required terms and conditions are included. In addition, if we receive pharmacy complaints about contracting with PDP sponsors, we will investigate to determine if CMS requirements are being violated and undertake corrective action as needed.

OIG Recommendation

The OIG recommends that CMS determine whether PDP sponsors are complying with the "any willing pharmacy" provision as it relates to contracting with PSAOs, as required by CMS' "Medicare Prescription Drug Benefit Manual," Chapter 5, Section 50.8.1.

CMS Response

The CMS concurs with this recommendation. We continue to monitor our complaint tracking module (CTM) for complaints relating to "any willing pharmacy" requirements. In addition, we will continue to educate pharmacy stakeholders, including retail, long-term care, and safety-net pharmacies, on the use of our complaint process. If we receive complaints, we will investigate to determine if CMS requirements are being violated – including through targeted audits – and undertake corrective action as needed.

OIG Recommendation

The OIG recommends that CMS consider proposing legislation through departmental channels to increase the transparency of contracting by requiring PDP sponsors to disclose how they define similarly situated pharmacies and to disclose the data source, basis, and methodology they use to develop reimbursement rates, including maximum allowable costs (MAC).

CMS Response

The CMS does not concur with this recommendation, because the current statutory and regulatory framework relies on the marketplace to determine Part D price negotiation and contracting terms and conditions. In addition, the MMA prohibits CMS from interfering with such negotiations between PDP sponsors and network pharmacies, including terms and conditions for reimbursement rates and MAC. While PDP sponsors must make available to pharmacies, upon request, a copy of their standard contracting terms and conditions for all

similarly situated pharmacies, CMS does not specify the manner in which sponsors should make this information available. We believe the benefit is effectively being administered under the current framework.

OIG Recommendation

The OIG recommends that CMS determine whether PDP sponsors are offering long-term care contracts to pharmacies that meet the criteria for participating as long-term care pharmacies, as required by 42 CFR 423.120(a)(5).

CMS Response

The CMS concurs with this recommendation. We will monitor our CTM to determine the extent to which pharmacies meeting the criteria for participating as long-term care pharmacies are not being offered long-term care contracts, when requested. We also will continue to educate pharmacy stakeholders, including retail, long-term care, and safety-net pharmacies, on the use of our complaint process. If we receive complaints, we will investigate to determine if CMS requirements are being violated – including through targeted audits – and undertake corrective action as needed.

In addition, CMS believes that OIG should clarify its recommendation by specifying that PDP sponsors should offer long-term care contracts upon request. A PDP sponsor will not necessarily be aware of a pharmacy's ability to provide both retail and long-term care services, so it is unreasonable to expect such a pharmacy would be provided with both contracts unless it specifically requests them. However, as provided in our "any willing pharmacy" requirements, to the extent that a pharmacy requests both contracts and can meet the terms and conditions of those contracts, it must be allowed to participate in a sponsor's network as both a retail and a long-term care pharmacy.

OIG Recommendation

The OIG recommends that CMS study whether it should define the length of an extended-day supply.

CMS Response

The CMS does not concur with this recommendation because this is really a payment-related term negotiated between PDP sponsors and pharmacies. Further, the MMA prohibits CMS from interfering with price negotiations between PDP sponsors and network pharmacies. In other words, the "definition" of an extended-day supply is only germane to the price negotiations between the sponsor and pharmacy as to whether the pharmacy wishes to offer additional discounts for dispensing greater amounts. We permit PDP sponsors some flexibility in defining extended-day supplies, provided they do so consistently across all their network pharmacies. However, any benefit that is available at a network mail-order pharmacy must be made available to plan enrollees at some network retail pharmacies.

OIG Recommendation

The OIG recommends that CMS study whether current retail pharmacy reimbursement rates for extended-day supplies are adequate to ensure that enrollees have reasonable access to retail pharmacies to fill prescriptions for extended-day supplies.

CMS Response

The CMS does not concur with this recommendation. Over and above the statutory prohibition on interference in price negotiations, we believe that the best way to ensure reasonable access to extended-day supplies at retail is to measure the network participation of retail pharmacies offering extended-day supplies. In 2008, CMS is requiring PDP sponsors that offer extended-day supplies at mail order to report the number of retail pharmacies that are offering extended-days supplies at retail. In 2009, PDP sponsors will also need to identify which retail pharmacies provide extended-day supplies in their network pharmacy directory, so beneficiaries will have clear information on comparative availability of extended-day supplies between plans.

OIG Recommendation

The OIG recommends that CMS increase the transparency of contracting by encouraging PDP sponsors to communicate to pharmacies the criteria for qualifying for enhanced rates if the PDP sponsors offer enhanced rates to certain categories of pharmacies (e.g., rural pharmacies).

CMS Response

The CMS does not concur with this recommendation, because the MMA prohibits CMS from interfering with price negotiations between PDP sponsors and network pharmacies. As provided under the "any willing pharmacy" requirement in our regulations (see 42 CFR 423.120(a)(8)), PDP sponsors must make available to any pharmacy, upon request, a copy of their standard contracting terms and conditions for similarly situated pharmacies, and they must include in their networks any pharmacy that can meet those standard contracting terms and conditions. Standard terms and conditions are a "floor" of minimum requirements, and offering a standard contract does not preclude sponsors and pharmacies from negotiating different contracting terms and conditions, including higher or lower reimbursement rates.

OIG Recommendation

The OIG recommends that CMS determine whether PDP sponsors have complied with the "any willing pharmacy" provision as it relates to contracting deadlines.

CMS Response

The CMS concurs with this recommendation, but believes this issue was limited to the unique circumstances associated with the initial year of the program. CMS imposed deadlines on prospective PDP sponsors to complete pharmacy contracting in order to satisfy network pharmacy access requirements prior to contracting with CMS. These deadlines made it

unavoidable that pharmacies and PSAOs received multiple offers to contract within a short period of time. Once again, however, this situation was limited to the 2005 contracting process.

With rare exceptions, CMS does not involve itself in determining whether standard contracting terms and conditions are "reasonable and relevant," since these are fact-specific questions that are best left between negotiating parties. Provided that standard contracting terms and conditions are consistent with explicit Part D statutory and regulatory requirements, are not so onerous as to significantly deter participation in the sponsor's pharmacy networks (as demonstrated by inadequate access complaints from beneficiaries or by pharmacists' complaints), and are clearly articulated and documented by PDP sponsors to pharmacies in advance of contracting negotiations, we generally do not intervene in contracting disputes. However, where warranted based on beneficiary or pharmacist complaints, we will investigate any reports that CMS requirements are being violated and undertake corrective action as needed.

OIG Recommendation

The OIG recommends that Congress and CMS consider the results of our review, including information on the timing of payments, in deliberating the proposed legislation and any future legislation regarding Medicare Part D contracting.

CMS Response

The CMS concurs with this recommendation in general. All relevant considerations should be taken into account when considering legislation.

OIG Recommendation

The OIG recommends that CMS study MTM service delivery options to determine which option(s) are most effective for achieving the goals of MTM and whether additional legislative or regulatory change is needed.

CMS Response

The CMS concurs with this recommendation. As stated in our 2009 call letter, Medication Therapy Management Programs (MTMPs) remain an important quality improvement initiative for CMS and Medicare beneficiaries. Since the outset of the Medicare Prescription Drug Benefit, the MTMPs requirements have provided a framework that gives PDP sponsors maximum flexibility to develop MTMPs. In exchange for this flexibility, CMS expects PDP sponsors to analyze and evaluate their MTMPs and make changes to continuously improve their programs.

The CMS is continuing to monitor and evaluate MTMPs offered by PDP sponsors in an effort to identify and understand attributes of MTMPs that may be most effective for the Medicare program. CMS requires PDP sponsors to submit plan-reported data, including the number of beneficiaries satisfying the MTMP qualifying criteria, participating in the program, and declining participation. CMS is analyzing these data to identify best practices for appropriately targeting

Medicare beneficiaries and maximizing participation. Beginning in 2008, CMS requires PDP sponsors to submit expanded beneficiary level data that will enable us to perform more robust analyses of MTMPs in 2009. We believe this additional information will help us identify those programs that demonstrate the most positive impact on medication use by Medicare beneficiaries.

The CMS will continue its collaboration with various stakeholders as MTMP best practices evolve into industry standards that could be adopted as Part D standards. CMS will also continue its collaboration with the pharmacy quality alliance (PQA). The measures being developed by the PQA for pharmacy quality and patient satisfaction will be considered for use by CMS in the Part D Plan Ratings and may help inform decisions for future Part D MTMP requirements.

Other Comments

1. **Page 8, paragraph 1**-- Pharmacy officials stated "that they expended effort and expense to review and attempt to negotiate contracts with companies that CMS ultimately did not approve." CMS did not disapprove any Part D applications. Only those applicants that chose to withdraw their application did not receive a contract to be a PDP sponsor.

2. **Page 9, last paragraph**-- references the March 2005 long-term care guidance. The reference should be amended to reflect that the guidance has been incorporated into Chapter 5, Section 50.5.2 of the Medicare Prescription Drug Benefit Manual.

3. **Page 14, paragraph 2**-- "...the pharmacies typically had to call the sponsor's main number to initiate negotiations." CMS posted on its Web page several PDP sponsor key contacts for network contracting, specifically for pharmacies interested in becoming a participating Part D pharmacy. The Web posting can be found at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/11_PartDContacts.asp#TopOfPage.

We appreciate the effort that went into this report. Again, we thank you for the opportunity to review and comment.