DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

Office of Audit Services, Region III
Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106-3499

SEP 22 2009

Report Number: A-03-08-00011

Jennifer Velez, Esquire
Commissioner
New Jersey Department of Human Services
222 South Warren Street
Trenton, New Jersey 06825-0700

Dear Ms. Velez:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Review of Medicare Part D Drug Payments to Baron Drug Company for Service Dates January 1 – March 31, 2006." We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at http://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to call me at (215) 861-4470 or through email at Stephen.Virbitsky@oig.hhs.gov, or contact Nicole Freda, Audit Manager, at (215) 861-4497 or through email at Nicole.Freda@oig.hhs.gov. Please refer to report number A-03-08-00011 in all correspondence.

Sincerely,

Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Jonathan Blum, Acting Director
Centers for Drug and Health Plan Choice
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
314-G, HHH Building
Washington, DC 20201

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICARE PART D DRUG PAYMENTS TO BARON DRUG COMPANY FOR SERVICE DATES JANUARY 1 – MARCH 31, 2006

Daniel R. Levinson
Inspector General

September 2009
A-03-08-00011

Office of Inspector General

http://oig.hhs.gov

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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 (MMA) of 2003 amended Title XVIII of the Social Security Act (the Act) by establishing the Medicare Part D prescription drug benefit. The Part D benefit provides optional prescription drug coverage for individuals who are entitled to Medicare Part A or enrolled in Medicare Part B. The Centers for Medicare & Medicaid Services (CMS), which administers Medicare, contracts with private entities known as Part D sponsors (sponsors) to provide prescription drug coverage for beneficiaries enrolled in the Part D program.

Sponsors submit a summary record called a prescription drug event (PDE) record every time a pharmacy dispenses a prescription for a beneficiary covered under Medicare Part D. The PDE record contains prescription drug cost and payment data that enables CMS to make payment and otherwise administer the Part D benefit.

Full-benefit dually eligible beneficiaries are eligible for benefits under both Medicare and Medicaid. Pursuant to Title I, section 103(c) of the MMA, and upon implementation of Medicare Part D on January 1, 2006, prescription drug coverage for these beneficiaries was transferred from Medicaid to Medicare Part D. Despite CMS's efforts to ensure that these beneficiaries continued to receive needed medications as they made the transition, some States found it necessary to provide assistance to these beneficiaries by paying for their Medicare Part D drugs.

To reimburse States for costs incurred during the transition period, CMS implemented the "Reimbursement of State Costs for Provision of Part D Drugs" Medicare demonstration project, pursuant to section 402(a)(l)(A) of the Social Security Amendments of 1967, as amended (codified at 42 U.S.C. section 1395b-1(a)(1)(A) and expressly made applicable to Part D in section 1860D-42(b)). On February 14, 2006, New Jersey submitted its "Section 402 Demonstration Application" to CMS. By submitting its application, New Jersey agreed to pay for full-benefit dually eligible beneficiaries' Part D drug claims. New Jersey's participation in the demonstration project covered drugs dispensed between January 1 and March 31, 2006.

Baron Drug Company (Baron), located in Hoboken, New Jersey, is a retail pharmacy and surgical supplier. Baron participated in the Part D program and claimed costs for drugs dispensed to full-benefit dually eligible beneficiaries during the transition period.

OBJECTIVE

Our objective was to determine whether Baron received payment for Medicare Part D drug costs from sponsors and from New Jersey under the Medicare demonstration project.

SUMMARY OF FINDING

For all 110 sampled claims, Baron received payment both from sponsors and from New Jersey. Baron billed the sponsors and New Jersey for the same dispensing events. As a result, Baron received payments from the sponsors who were contractually obligated to pay for full-benefit dually eligible beneficiaries' Part D drugs and from New Jersey. Based on our sample results, we estimated that Baron received improper payments of at least $79,489 from New Jersey, which CMS reimbursed under the demonstration project.

RECOMMENDATION

We recommend that New Jersey refund to CMS $79,489 in improper demonstration project payments and recover the payments from Baron.

NEW JERSEY COMMENTS

In written comments on our draft report, New Jersey concurred with our finding, but did not concur with our recommendation. New Jersey stated that all payments made by New Jersey under the demonstration project were approved by CMS. New Jersey also stated that the audit report should be issued to either Baron or to the applicable Medicare Part D drug plan sponsors. New Jersey added that it does not have the means to adequately identify or correct this type of duplicate payment. New Jersey's comments are presented in their entirety as Appendix C.

OFFICE OF INSPECTOR GENERAL RESPONSE

Our audit report identified improper demonstration project payments that New Jersey received. Although CMS reimbursed New Jersey for the payments made to Baron, CMS did not determine whether the plan sponsors also paid for the same dispensing events. We recommend New Jersey refund the payments to CMS because the State of New Jersey, not Baron, received Federal funds under the demonstration project. We will provide detailed claim information related to our finding. Nothing in New Jersey's comments has given us cause to change our recommendation.

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INTRODUCTION

BACKGROUND

Medicare Part D Prescription Drug Benefit

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 amended Title XVIII of the Social Security Act (the Act) by establishing the Medicare Part D prescription drug benefit. Medicare Part D provides optional prescription drug coverage for individuals who are entitled to Medicare Part A or enrolled in Medicare Part B. The Centers for Medicare & Medicaid Services (CMS), which administers Medicare, contracts with private entities known as Part D sponsors (sponsors) to provide prescription drug coverage for beneficiaries enrolled in the Part D program. Sponsors may offer drug coverage through more than one drug plan.

CMS pays sponsors monthly prospective payments to provide Part D prescription drug coverage. These payments are based on estimates that sponsors provide in their approved bids before the beginning of the plan year. After the close of the plan year, CMS must reconcile these payments to the sponsors' actual costs to determine whether sponsors owe money to Medicare or Medicare owes money to sponsors. Sections 1860D-15(c)(1)(C) and (d)(2) of the Act and 42 CFR § 423.322 require sponsors to submit to CMS certain information necessary to conduct these reconciliations. This information includes summary records called prescription drug event (PDE) records that sponsors submit every time a pharmacy dispenses a prescription for a beneficiary covered under Medicare Part D. PDE records contain prescription drug cost and payment data that enable CMS to pay sponsors and otherwise administer the Part D benefit.

Full-Benefit Dually Eligible Beneficiaries

Full-benefit dually eligible beneficiaries are eligible for benefits under both Medicare and Medicaid. Pursuant to Title I, section 103(c) of the MMA and upon implementation of Medicare Part D on January 1, 2006, prescription drug coverage for these beneficiaries was transferred from Medicaid to Medicare Part D. CMS took numerous actions to ensure that full-benefit dually eligible beneficiaries continued to receive medications during the transition to Medicare Part D. Despite CMS's efforts to ensure a smooth transition to Medicare Part D, some full-benefit dually eligible beneficiaries did not enroll in or were not assigned to a Part D plan. As a result, some States paid for these beneficiaries' Medicare Part D drugs during the transition period.

Medicare Part D Demonstration Project

To reimburse States for costs incurred during the transition period, CMS implemented the "Reimbursement of State Costs for Provision of Part D Drugs" Medicare demonstration project pursuant to section 402(a)(l)(A) of the Social Security Amendments of 1967, as amended.[1] The

[1]Demonstration provisions are codified at 42 U.S.C. § 1395b-1(a)(1)(A) and expressly made applicable to Medicare Part D in section 1860D-42(b) of the Act.

demonstration project permitted Medicare to reimburse States for full-benefit dually eligible beneficiaries' Part D drugs to the extent that those costs were not recoverable from a sponsor and were not required Medicare cost sharing on the part of the beneficiary. To participate in the demonstration project and receive reimbursement for their incurred costs, States were required to submit a signed "Section 402 Demonstration Application" to CMS.

New Jersey's Participation in the Medicare Part D Demonstration Project

On February 14, 2006, New Jersey, through two of its agencies, the Department of Human Services (DHS) and the Department of Health and Senior Services (DHSS), submitted its Medicare demonstration application to CMS. By submitting its application, New Jersey agreed to pay for full-benefit dually eligible beneficiaries' Part D drug claims.[2] New Jersey's participation in the demonstration project covered drugs dispensed between January 1 and March 31, 2006.

Baron Drug Company

Baron Drug Company (Baron), located in Hoboken, New Jersey, is a retail pharmacy and surgical supplier. Baron participated in the Part D program and claimed costs for drugs dispensed to full-benefit dually eligible beneficiaries during the transition period.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Baron received payment for Medicare Part D drug costs from sponsors and from New Jersey under the Medicare demonstration project.

Scope

We judgmentally selected Baron from pharmacies that we identified as having both a PDE record and a demonstration claim for the same dispensing event. For the period January 1 through March 31, 2006, CMS reimbursed New Jersey $108,540 for 1,600 Baron demonstration claims that also had a sponsor-submitted PDE record.

Our audit objective did not require an understanding or assessment of the complete internal control structure of New Jersey or Baron. We limited our internal control review to obtaining an understanding of the guidance that New Jersey issued to the pharmacies for the demonstration project and procedures that Baron used to bill sponsors and New Jersey.

We conducted our fieldwork at Baron in Hoboken, New Jersey, in February 2009.

[2]New Jersey also agreed to pay for partial-benefit dually eligible beneficiaries' Part D drugs; however, payments for these beneficiaries' drug claims are not included in this review.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal and State requirements;
- interviewed Baron pharmacy staff regarding its billing procedures;
- obtained from CMS PDE records and demonstration project claims for the period January 1 through March 31, 2006;
- identified a sampling frame of 1,600 PDE records that matched claims paid to Baron under the demonstration project and:
    - from the sampling frame, selected a stratified random sample of 110 matched claims and
    - for each sampled claim, requested and reviewed payment documentation from applicable sponsors and New Jersey; and
- estimated the total dollar value of improper demonstration project payments.

Appendix A provides a description of the sampling methodology and Appendix B details the sample results and estimates the value of improper demonstration project payments.

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 finding and conclusions based on our audit objective.

FINDING AND RECOMMENDATION

For all 110 sampled claims, Baron received payment both from sponsors and from New Jersey. Baron billed the sponsors and New Jersey for the same dispensing events. As a result, Baron received payments from the sponsors who were contractually obligated to pay for full-benefit dually eligible beneficiaries' Part D drugs and from New Jersey. Based on our sample results, we estimated that Baron received improper payments of at least $79,489 from New Jersey, which CMS reimbursed under the demonstration project.

DEMONSTRATION PROJECT REQUIREMENTS

To participate in the demonstration project and receive reimbursement for their incurred costs, States were required to submit a signed "Section 402 Demonstration Application" (Medicare demonstration application) to CMS. By submitting Medicare demonstration applications, States

agreed to (1) require pharmacies to bill the Part D plan before relying on State payment (i.e., the State was the payer of last resort); (2) provide specific information to CMS on Part D drug claims and administrative costs; (3) ensure that claims submitted were for covered Part D drugs; (4) separate demonstration project claims from those payable under other programs; (5) submit claims only for drug costs (not including beneficiary cost sharing) and administrative costs incurred during the demonstration project's effective dates; (6) report to CMS the number of claims, beneficiaries, and expenditures on a timely basis; and (7) ensure that Medicare funding was not used as State Medicaid matching funds (State Medicaid Director Letter No. 06-001 (Feb. 2, 2006); CMS, Section 402 Demonstration Action Template: Reimbursement of State Costs for Provision of Part D Drugs).

IMPROPER PAYMENTS

For all 110 sampled claims, Baron billed and received payments both from the sponsors and from New Jersey. Because sponsors were contractually obligated to pay for full-benefit dually eligible beneficiaries' Part D drugs, the application required pharmacists to primarily bill the sponsor and rely on the State only as the payer of last resort. Baron's owner stated that billing system errors caused the sample items to be billed to both sponsors and New Jersey.

As shown in Appendix B, Baron received improper payments from New Jersey under the demonstration project totaling $17,587 for the 110 sampled claims. At the time of our audit, Baron had not refunded any of the sampled improper payments to New Jersey. Based on our sample results, we estimated that Baron received at least $79,489 in improper payments from New Jersey for Medicare Part D drugs dispensed between January 1 and March 31, 2006. Through the demonstration project, CMS reimbursed New Jersey for these improper payments.

RECOMMENDATION

We recommend that New Jersey refund to CMS $79,489 in improper demonstration project payments and recover the payments from Baron.

NEW JERSEY COMMENTS

In written comments on our draft report, New Jersey concurred with our finding, but did not concur with our recommendation. New Jersey stated that the audit report did not indicate that any payments were not in compliance with the Medicare demonstration project, and that all payments made by New Jersey under the demonstration project were approved by CMS. New Jersey also stated that the audit report should be issued to Baron because it acknowledged receipt of some duplicate payments, or to the applicable Medicare Part D drug plan sponsors because New Jersey believes plan sponsors made the subsequent, and thus duplicate, payment. Additionally, New Jersey stated they do not have the means to adequately identify or correct this type of duplicate payment. New Jersey's comments are presented in their entirety as Appendix C.

OFFICE OF INSPECTOR GENERAL RESPONSE

Our audit report identified improper demonstration project payments that New Jersey received. Although CMS reimbursed New Jersey for the payments made to Baron, CMS did not determine whether the plan sponsors also paid for the same dispensing events. We are recommending that New Jersey refund the payments to CMS because the State of New Jersey, not Baron, was the entity that received Federal funds under the demonstration project. In addition, the State of New Jersey agreed in its Section 402 Demonstration Application to require pharmacies to bill the Part D plan before relying on State payment, which made the Medicaid payment the secondary payment. CMS's payments to the prescription drug plan sponsors were the proper payments because prescription drug plan sponsors were contractually obligated to pay for full-benefit dually eligible beneficiaries' Part D drugs.

As discussed with New Jersey officials, we will provide detailed claim information related to our finding.

Based on New Jersey's comments, we made a minor revision to clarify our report; however, nothing in New Jersey's comments has given us cause to change our recommendation.

APPENDIXES

SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population represented prescription drug event (PDE) records that matched claims paid to Baron Drug Company (Baron) under the Medicare demonstration project.

SAMPLING FRAME

The sampling frame was an Excel spreadsheet of 1,600 PDE records, each of which matched a corresponding claim paid under the demonstration project. The matched claims totaled $108,540 in demonstration project reimbursement.

SAMPLE UNIT

The sampling unit was one individual line item identifying a PDE record matched to a demonstration project claim.

SAMPLE DESIGN

We used a stratified random sample, defining each stratum by demonstration project reimbursement amount, as shown below.

Sample Design

	Reimbursement Range	Number of Matched Claims	Demonstration Project Reimbursement Amount
Stratum 1	$499 or less	1,590	$96,060
Stratum 2	$500 or more	10	12,480
Total		**1,600**	**$108,540**

SAMPLE SIZE

We selected 100 matched claims from the first stratum and all 10 matched claims from the second stratum for a total sample size of 110 matched claims.

SOURCE OF RANDOM NUMBERS

The source of random numbers was the Office of the Inspector General, Office of Audit Services Statistical software. We used the random number generator for our stratified random sample.

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the matched claims in Stratum 1 from 1 to 1,590. After generating 100 random numbers, we selected the corresponding matched claims in the sampling frame. We selected all of the 10 payments in stratum 2.

ESTIMATION METHODOLOGY

We estimated the dollar value of improper demonstration project payments.

APPENDIX B

SAMPLE RESULTS AND ESTIMATES

Sample Results

Stratum Number	Sample Size	Value of Sample	Number of Improper Payments	Value of Improper Payments
1	100	$5,107	100	$5,107
2	10	12,480	10	12,480
Total	**110**	**$17,587**	**110**	**$17,587**

Estimates

(Limits Calculated for a 90-Percent Confidence Interval)

	Value of Improper Payments
Point Estimate	$93,680
Lower Limit	$79,489
Upper Limit	$107,872

State of New Jersey
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July 17, 2009

Stephen Virbitsky
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Philadelphia, PA 19106-3499

Report Number: A-03-08-00011

Dear Mr. Virbitsky:

This is in response to your letter of June 1, 2009 to Commissioner Velez concerning the Office of the Inspector General (OIG) draft audit report titled "Review of Medicare Part D Payments to Baron Drug Company for Service Dates January 1 – March 31, 2006". Your correspondence provides an opportunity to comment on the draft audit report.

The draft audit report contains one finding and one recommendation. The finding, recommendation and response of the Division of Medical Assistance and Health Services (DMAHS) are provided below:

FINDING
The audit report concludes that Baron Drug Company received payments from Medicare Part D plan sponsors and DMAHS for the same prescription drug events. This finding is based on a judgmental sample of claims paid by both Medicare Part D plan sponsors and DMAHS.

DMAHS RESPONSE
Based on the information provided by the auditor, this finding appears irrefutable. The payments analyzed by the auditor were drawn from a population comprised entirely of claims paid by both programs. Consequently, the likelihood of finding the pharmacy was paid by both programs is nearly certain.

RECOMMENDATION
The auditor recommends that New Jersey refund to CMS $79,489 in improper demonstration project payments and recover the payments from Baron.

DMAHS RESPONSE

DMAHS does not concur with this recommendation. While this audit clearly identifies duplicate payments to Baron Drug Company, there is no indication in the audit report that the DMAHS payments were not in compliance with the applicable Medicare Demonstration Project. Additionally, all DMAHS payments under the Medicare Demonstration Project were reconciled and approved by the Centers for Medicare and Medicaid Services (CMS). Finally, DMAHS does not possess the information needed to adequately identify or correct this type of duplicate payment.

The audit indicates that Baron Drug Company acknowledged receipt of some duplicate payments (100% of the sampled claims) from DMAHS and Medicare despite specific contrary instructions. Unfortunately, the auditor did not confirm the cause of the duplicate claims submitted by Baron Drug Company or their lack of corrective action since March 31, 2006. Consequently, it appears this audit report should be issued to the Baron Drug Company with the recommendation they return the overpayments to Medicare and correct the procedures that caused the duplicate payments.

The auditor's recommendation is based upon a small sample of the total claims cited. While this extrapolation is useful to statistically estimate the amount of duplicate payments, it is insufficient support for provider overpayment recoveries. In the absence of the provider's acceptance of the results of the auditor's extrapolation, it is unlikely DMAHS could prevail in the recovery of this amount. DMAHS would probably be required to identify the duplicate payments on a claim specific basis or litigate the specifics of the auditor's statistical extrapolation. Neither approach is likely to succeed since DMAHS does not possess the supporting information.

DMAHS payments to providers under the Medicare Demonstration Project were conditioned on the inability of the provider to access the appropriate Medicare Part D reimbursement. The audit report does not indicate whether Medicare Part D payments were readily available to the provider at the time of the DMAHS payment or if the Medicare payments were remitted later. Since the Medicare Demonstration Project includes the Department of Health and Human Services assurance that CMS will reconcile all DMAHS payments with the prescription drug plans, it appears these Medicare payments to Baron Drug Company were made subsequent to the DMAHS payment and the CMS Demonstration Project reconciliation. It seems reasonable to assume CMS shared the DMAHS payment information with the Medicare drug plans to recover their payments made to the States and to preclude subsequent duplicate payments. This indicates that duplicate payments were made by the Medicare Part D drug plans. In this case, it appears the audit report should be issued to the applicable drug

plans with the recommendation they recover the overpayment from this provider and review their records to recover any similar overpayments.

The methodology used in this audit shows that detailed payment information from DMAHS and the Medicare Part D drug plans are readily available at CMS. The auditor selected a sample of claims paid by both DMAHS and Medicare based upon the Medicare prescription drug event records maintained by CMS. As a result, it seems appropriate to issue the audit report to CMS with the recommendation they recover this and any other overpayments from the Medicare drug plans.

In summary, the contents of this draft audit report denote a significant financial control weakness within the Medicare Program. Inappropriate provider conduct is also suggested. These items represent significant concerns that warrant additional investigation. Unfortunately, the audit report recommends corrective action by the only entity that can not readily address these concerns. As a result, DMAHS does not concur that corrective actions should be initiated by the State. Instead, it seems more appropriate to suggest corrective action by the provider, CMS, or the Medicare drug plans. Due to the serious concerns presented in this report, DMAHS intends to forward a copy of the final audit report to the New Jersey Office of the Medicaid Inspector General for review and evaluation.

If you have any questions or require additional information, please contact me or David Lowenthal at 609-588-7933.

Sincerely,

John R. Guhl
Director

JRG:L
c: Jennifer Velez
David Lowenthal