



January 20, 2010

Report Number: A-07-09-03124

Mr. Todd Meek  
Vice President of Compliance Medicare Part D  
CVS Caremark Corporation  
9501 East Shea Boulevard  
Scottsdale, Arizona 85260

Dear Mr. Meek:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Review of SilverScript Insurance Company's Internal Controls to Guard Against Fraud, Waste and Abuse for The Medicare Part D Program." 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.

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If you have any questions or comments about this report, please do not hesitate to call me at (816) 426-3591, or contact Greg Tambke, Audit Manager, at (573) 893-8338, extension 30, or through email at [Greg.Tambke@oig.hhs.gov](mailto:Greg.Tambke@oig.hhs.gov). Please refer to report number A-07-09-03124 in all correspondence.

Sincerely,

/Patrick J. Cogley/  
Regional Inspector General  
for Audit Services

Enclosure

**Direct Reply to HHS Action Official:**

Mr. Timothy B. Hill  
Deputy Director  
Centers for Drug and Health Plan Choice  
Centers for Medicare and Medicaid Services  
Mail Stop C5-19-16  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**REVIEW OF SILVERSCRIPT  
INSURANCE COMPANY'S  
INTERNAL CONTROLS TO GUARD  
AGAINST FRAUD, WASTE AND  
ABUSE FOR THE MEDICARE  
PART D PROGRAM**



Daniel R. Levinson  
Inspector General

January 2010  
A-07-09-03124

# *Office of Inspector General*

<http://oig.hhs.gov>

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Section 8L of the Inspector General Act, 5 U.S.C. App., requires that  
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## **OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS**

The designation of financial or management practices as questionable, a  
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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**

#### **The Medicare Part D Program**

Title I of the Medicare Prescription Drug, Improvement, and the Modernization Act of 2003 (MMA) amended Title XVIII of the Social Security Act by establishing the Medicare Part D prescription drug benefit. Under the Part D program, which began January 1, 2006, individuals entitled to benefits under Part A or enrolled in Part B may obtain drug coverage. Although the Part D program is overseen by the Centers for Medicare & Medicaid Services (CMS), Part D drug benefit plans are administered by private companies that apply to CMS to participate in the Part D program. When approved, these private companies contract with the Federal Government to be Part D sponsors and market Part D drug plans directly to Medicare beneficiaries.

#### **Centers for Medicare & Medicaid Services Oversight Responsibilities**

CMS is responsible for safeguarding the Part D program from fraud, waste and abuse (FWA), including ensuring Part D sponsors' compliance with applicable requirements. CMS contracts with Medicare Drug Integrity Contractors (MEDIC) to perform many Part D oversight activities. The MEDICs' responsibilities include analyzing claims and other data, investigating complaints, and reviewing the FWA components of Part D sponsors' compliance plans.

#### **Part D Sponsors' Responsibilities**

The MMA includes a requirement that all Part D sponsors have a program to control FWA in the Part D program; accordingly, CMS regulations establish the requirements for comprehensive compliance plans for Part D sponsors. Chapter 9 of CMS's "Prescription Drug Benefit Manual" contains further interpretation and guidelines on the steps Part D sponsors should take to detect, correct and prevent FWA. In that guidance, CMS recommends that Part D sponsors promptly refer all potential incidents of FWA to the MEDICs.

#### **SilverScript Insurance Company**

SilverScript Insurance Company (SSIC) is a subsidiary of CVS Caremark Corporation. SSIC is a Part D sponsor and has been approved as such by CMS since the beginning of the Part D program. SSIC offers Part D drug plans that are available in all 50 states, the District of Columbia and Puerto Rico.

### **OBJECTIVE**

The objective of our review was to determine whether SSIC had adequate internal controls in place to detect, correct and prevent FWA in the Part D program during the period of January 1, 2007, through December 31, 2008.

## **SUMMARY OF FINDINGS**

Although most of SSIC's internal controls were adequate, SSIC had several internal control weaknesses that compromised its ability to detect, correct and prevent FWA in the Part D program during the period of January 1, 2007, through December 31, 2008. Specifically:

- SSIC generally did not self-report potential FWA to the MEDICs as recommended by CMS guidance.
- Contrary to Federal regulations, SSIC paid claims for prescriptions written by physicians or other health care professionals who are excluded from Federal health care programs (excluded providers).
- SSIC did not have a procedure in place to track complaints made against providers as recommended by CMS guidance.

SSIC had written procedures requiring the self-reporting of potential FWA to the MEDICs, but SSIC did not follow its own procedures. In addition, SSIC's policies and procedures for the denial of claims for prescriptions written by excluded providers did not conform to Federal regulations. Furthermore, SSIC did not have policies and procedures to track complaints made against providers.

As a result of these weaknesses, SSIC paid claims totaling at least \$46,223 to excluded providers. In addition, the internal control weaknesses increased the risk that additional improper payments may have occurred.

## **RECOMMENDATIONS**

We recommend that SSIC strengthen internal controls by:

- adhering to its policies and procedures to self-report potential FWA to the MEDICs pursuant to CMS guidance,
- revising its policies and procedures to deny claims for prescriptions written by excluded providers, as of the effective date of the exclusion, as required by Federal regulations,
- working with CMS to determine the proper resolution of the \$46,223 in payments to excluded providers, and
- establishing policies and procedures to track complaints made against providers pursuant to CMS guidance.

## **SILVERSCRIPT INSURANCE COMPANY COMMENTS**

In written comments on our draft report, SSIC concurred with our recommendations and described corrective actions that it has implemented.

SSIC's comments are included in their entirety as the Appendix.

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# **INTRODUCTION**

## **BACKGROUND**

### **Medicare Part D Program**

Title I of the Medicare Prescription Drug, Improvement, and the Modernization Act of 2003 (MMA) amended Title XVIII of the Social Security Act by establishing the Medicare Part D prescription drug benefit. Under the Part D program, which began January 1, 2006, individuals entitled to benefits under Part A or enrolled in Part B may obtain drug coverage. Although the Part D program is overseen by the Centers for Medicare & Medicaid Services (CMS), Part D drug benefit plans are administered by private companies that apply to CMS to participate in the Part D program. When approved, these private companies contract with the Federal Government to be Part D sponsors and market Part D drug plans directly to Medicare beneficiaries.

### **Centers for Medicare & Medicaid Services Oversight Responsibilities**

CMS is responsible for safeguarding the Part D program from fraud, waste and abuse (FWA), including ensuring Part D sponsors' compliance with applicable requirements. CMS developed chapter 9 of the "Prescription Drug Benefit Manual," which provides guidance to Part D sponsors for developing a program to control FWA.

CMS contracts with Medicare Drug Integrity Contractors (MEDIC) to perform many Part D oversight activities. The MEDICs' responsibilities include analyzing claims and other data, investigating complaints, and reviewing the FWA components of Part D sponsors' compliance plans.

### **Part D Sponsors' Responsibilities**

The MMA includes a requirement that all Part D sponsors have a program to control FWA in the Part D program; accordingly, CMS regulations establish the requirements for comprehensive compliance plans for Part D sponsors. Chapter 9 of CMS's "Prescription Drug Benefit Manual" contains further interpretation and guidelines on the steps Part D sponsors should take to detect, correct and prevent FWA.

In the chapter 9 guidance, CMS (a) recommends that Part D sponsors design their FWA programs to safeguard against identified risk areas and (b) identifies examples of potential FWA, to include potential incidents of FWA performed by Medicare beneficiaries. One such example involves beneficiaries misrepresenting their identity to illegally obtain benefits from the Part D program. Another example appears when beneficiaries engage in the practice known as doctor shopping, whereby a patient who intends to abuse or sell drugs seeks prescriptions from a number of physicians. When a Part D sponsor identifies potential FWA, CMS recommends that the Part D sponsor promptly refer the incident to the MEDICs.

## **SilverScript Insurance Company**

SilverScript Insurance Company (SSIC) is a subsidiary of CVS Caremark Corporation. SSIC is a Part D sponsor and has been approved as such by CMS since the beginning of the Part D program. SSIC offers Part D drug plans that are available in all 50 states, the District of Columbia and Puerto Rico.

## **Excluded Providers in Medicare Part D**

Federal regulations at 42 CFR § 1001.1901(b)(1) prohibit payment under Medicare, Medicaid, and other Federal health care programs for prescriptions written by physicians or other health care professionals who are excluded from Federal health care programs (excluded providers) on or after the effective date of the exclusion, until such time as the provider is reinstated. The Office of Inspector General (OIG) and the General Services Administration (GSA) maintain lists of excluded providers.

The OIG exclusion list is a listing of all individuals and entities that are prohibited from receiving payment under Medicare, Medicaid, and other Federal health care programs. The GSA exclusion list is a comprehensive listing of all parties excluded, throughout the U.S. Government, from receiving Federal contracts or certain subcontracts and from certain types of Federal financial and nonfinancial assistance and benefits.

CMS guidance in the “Prescription Drug Benefit Manual,” chapter 9, § 50.2.6.3.3, recommends that Part D sponsors (a) review the OIG and GSA exclusion lists to identify excluded providers and (b) have a process in place to deny claims for prescriptions written by excluded providers.

## **Previous Office of Inspector General Work**

The OIG, Office of Evaluation and Inspections (OEI), issued two reports regarding Part D sponsors’ compliance plans. In the first report, entitled “Prescription Drug Plan Sponsors’ Compliance Plans” (OEI-03-06-00100) and issued in December 2006, OEI found that most Part D sponsors’ compliance plans did not address all of the CMS requirements or recommendations. The second report, issued in October 2008 and entitled “Oversight of Prescription Drug Plan Sponsors’ Compliance Plans” (OEI-03-08-00230), found that CMS had conducted only one audit of a Part D sponsor’s compliance plan in 2007.

In addition, OEI issued a report in October 2008 entitled “Medicare Drug Plan Sponsors’ Identification of Potential Fraud and Abuse” (OEI-03-07-00380). OEI found that 24 of the 86 Part D sponsors reviewed did not identify any potential FWA, and that inappropriate billing was the most prevalent type of potential FWA that was identified.

## **OBJECTIVE, SCOPE, AND METHODOLOGY**

### **Objective**

The objective of our review was to determine whether SSIC had adequate internal controls in place to detect, correct and prevent FWA in the Part D program during the period of January 1, 2007, through December 31, 2008.

### **Scope**

We reviewed SSIC's internal controls that pertained to the detection, correction and prevention of FWA in the Part D program for the period of January 1, 2007, through December 31, 2008. We did not test the claims processing edits that were in place to ensure unallowable claims are properly rejected.

We conducted fieldwork at the CVS Caremark Corporation offices in Phoenix, Arizona, and in our field office in Des Moines, Iowa, from January through June 2009.

### **Methodology**

To accomplish our objective, we:

- reviewed applicable Federal regulations and CMS guidance;
- held discussions with CMS officials and MEDIC staff members to gain an understanding of the oversight activities pertaining to Part D sponsors' FWA programs;
- interviewed SSIC officials to gain an understanding of both SSIC's FWA program and its internal controls to detect, correct and prevent FWA in the Part D program;
- reviewed the SSIC Compliance Plan as well as policies and procedures related to the internal controls to detect, correct and prevent FWA in the Part D program;
- reviewed SSIC's potential FWA cases for the period of January 1, 2007, through December 31, 2008; and
- reviewed prescription drug event (PDE)<sup>1</sup> data pertaining to claims that were paid for prescriptions written by excluded providers.

We conducted this 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

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<sup>1</sup>Part D sponsors must submit a summary record to CMS called the PDE record every time a beneficiary fills a prescription covered under Part D. The PDE record contains prescription drug cost and payment data that will enable CMS to meet payment provisions of the Part D program.

objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

## **FINDINGS AND RECOMMENDATIONS**

Although most of SSIC's internal controls were adequate, SSIC had several internal control weaknesses that compromised its ability to detect, correct and prevent FWA in the Part D program during the period of January 1, 2007, through December 31, 2008. Specifically:

- SSIC generally did not self-report potential FWA to the MEDICs as recommended by CMS guidance.
- Contrary to Federal regulations, SSIC paid claims for prescriptions written by excluded providers.
- SSIC did not have a procedure in place to track complaints made against providers as recommended by CMS guidance.

SSIC had written procedures requiring the self-reporting of potential FWA to the MEDICs, but SSIC did not follow its own procedures. In addition, SSIC's policies and procedures for the denial of claims for prescriptions written by excluded providers did not conform to Federal regulations. Furthermore, SSIC did not have policies and procedures to track complaints made against providers.

As a result of these weaknesses, SSIC paid claims totaling at least \$46,223 to excluded providers. In addition, the internal control weaknesses increased the risk that additional improper payments may have occurred.

## **REPORTING POTENTIAL FRAUD, WASTE AND ABUSE**

CMS guidance in the "Prescription Drug Benefit Manual," chapter 9, § 50.2.8.2, recommends that Part D sponsors self-report potential FWA: "CMS believes that self-reporting of fraud, waste and abuse is a critical element to an effective program to control fraud, waste and abuse." Furthermore, after the Part D sponsor has conducted an inquiry of an incident and determines it to be potential FWA, the Part D sponsor should promptly refer the incident to the MEDICs, but no later than 60 days after the determination that a violation may have occurred.

In keeping with this CMS guidance, the SSIC policy that addresses communication with the MEDICs specifies that cases of potential FWA be referred to the appropriate MEDIC and/or CMS within a reasonable time period, but no later than 60 days after the potential FWA has been identified.

SSIC did not follow its own policy and written procedures for referring potential FWA to the MEDICs. SSIC generally did not self-report potential FWA to the MEDICs as recommended by CMS guidance. Instead, SSIC internally managed the majority of potential incidents of FWA. During the period of January 1, 2007, through December 31, 2008, the SSIC FWA program

investigated 275 cases to identify potential incidents of FWA. Of the 275 potential FWA cases, SSIC referred only 7 cases to the MEDICs.

For those cases that SSIC investigated for potential doctor shopping, SSIC routinely referred these cases to its Plan Participant Safety and Quality Management (PSQM) program rather than to the MEDICs.

As described in SSIC's written documentation of its procedures, the PSQM program evaluated the appropriateness of beneficiaries' utilization of controlled substances and other targeted drugs. On a quarterly basis, SSIC staff evaluated controlled substance claims to identify potential medication abuse and fraudulent claims, thereby to determine appropriate intervention by SSIC as a Part D sponsor. When this evaluation identified patterns of potentially excessive or abusive utilization on the part of particular beneficiaries, the PSQM program used written notifications to correct and deter excessive or abusive utilization. Specifically, SSIC sent letters to the appropriate beneficiaries and their physicians, to inform them that the beneficiaries' claim histories exhibited a pattern of excessive or abusive utilization of controlled substances. The program then gave the beneficiaries an opportunity to change their utilization patterns and the physicians the chance to discuss the utilization with their patients. If a subsequent decrease in the beneficiaries' drug utilization patterns did not occur, the cases were continually monitored by the PSQM program.

The cases that SSIC deemed appropriate for continued monitoring involved beneficiaries who had used a number of physicians and pharmacies to obtain prescriptions for controlled substances. For example, one beneficiary had used 28 different physicians and 12 different pharmacies during an eight-month period to obtain controlled substances. Rather than referring this case to the MEDICs, as recommended in the CMS "Prescription Drug Benefit Manual," SSIC handled the case internally.

Of the 275 cases of potential FWA that SSIC investigated during the period of January 1, 2007, through December 31, 2008, SSIC referred only 7 cases to the MEDICs for further investigation. None of the 7 referred cases involved potential doctor shopping, although SSIC investigated 22 cases on this basis. In an effort to deter excessive or abusive utilization of controlled substances, SSIC managed these cases internally by referring them to the PSQM program. SSIC did not refer any of the 22 cases to the MEDICs for further investigation.

SSIC did not have adequate internal controls relating to the reporting of potential FWA. Specifically, SSIC did not follow its own policy and written procedures for referring cases of potential FWA to the MEDICs. As stated earlier, the SSIC policy specifies that cases of potential FWA be referred to the appropriate MEDIC and/or CMS within a reasonable time period, but no later than 60 days after the potential FWA has been identified.

## **PAYMENTS TO EXCLUDED PROVIDERS**

Federal regulations at 42 CFR § 1001.1901(b)(1) prohibit payment under Medicare, Medicaid, and other Federal health care programs for prescriptions written by excluded providers on or after the effective date of the exclusion, until such time as the provider is reinstated.

Contrary to these Federal regulations, SSIC paid claims for prescriptions written by excluded providers on or after the effective date of the exclusion. Specifically, SSIC paid 610 claims totaling \$46,223<sup>2</sup> during the period of July 1, 2007, through December 31, 2008, for prescriptions written by excluded providers. Although Federal regulations prohibit payments to excluded providers on or after the effective date of their exclusion, SSIC paid the 610 claims over the course of a period of 60 days after SSIC had notified beneficiaries that their providers were excluded from the Part D program. In addition, SSIC paid all claims for excluded providers prior to July 1, 2007,<sup>3</sup> because during that period SSIC did not have a process in place to identify excluded providers or to deny claims for prescriptions written by excluded providers.

On April 1, 2007, SSIC completed and launched a program that identified excluded providers and gave beneficiaries notification that specific providers were not eligible to participate in the Part D program. On July 1, 2007, SSIC began denying claims for prescriptions written by excluded providers. Prior to this date, though, SSIC did not have a process in place to identify excluded providers or to deny claims for prescriptions written by excluded providers.

According to SSIC's policy, SSIC updates its provider exclusion list monthly based on updates from the OIG and GSA exclusion lists. When an excluded provider is identified, SSIC notifies, in writing, all of the beneficiaries who have used that provider during the previous six months. Pursuant to SSIC's policy, this notification informs beneficiaries that the provider is no longer ". . . able to take part in federally funded programs like the Medicare Part D prescription benefit." SSIC gives the beneficiaries 60 days from the date of the notification to find an alternative provider. During this 60-day period, beneficiaries can continue to use their providers without denial of their claims.

SSIC's policies and procedures for denying claims for prescriptions written by excluded providers did not conform to Federal regulations. The SSIC policy states that "SSIC rejects all claims written by an excluded provider **in accordance with CMS regulations sixty days after identifying a prescriber** on either the HHS OIG or GSA lists of excluded parties." (Emphasis added.) Contrary to SSIC's policy, Federal regulations prohibit payment for prescriptions written by excluded providers on or after the effective date of the exclusion.

## **TRACKING PROVIDER COMPLAINTS**

CMS guidance in the "Prescription Drug Benefit Manual," chapter 9, § 50.2.6.3.2, recommends that Part D sponsors maintain files on providers who have been the subject of complaints, investigations, violations, and prosecutions. This guidance adds that Part D sponsors are expected to comply with law enforcement, CMS, and MEDIC requests to monitor providers within their network that CMS has viewed as potentially abusive or fraudulent.

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<sup>2</sup>SSIC provided us with the amount that it paid for prescriptions written by excluded providers; we did not independently verify the accuracy of this amount.

<sup>3</sup>SSIC could not provide the amount paid to excluded providers for the time period prior to July 1, 2007, because it did not have a process in place to identify excluded providers.

SSIC did not have a procedure in place to track complaints made against providers as recommended by CMS guidance. SSIC officials said that there was not a procedure because there was not a definitive source that SSIC could use for complaints made against providers. The absence of a procedure may inhibit SSIC's ability to (a) identify potential incidents of FWA and (b) respond to requests to monitor providers that are viewed as potentially abusive or fraudulent.

SSIC did not have sufficient internal controls to detect, correct and prevent FWA pertaining to the tracking of complaints made against providers. Specifically, SSIC did not have a procedure in place to track complaints made against providers.

## **EFFECT OF INTERNAL CONTROL WEAKNESSES**

SSIC had several internal control weaknesses that compromised its ability to detect, correct and prevent FWA in the Part D program. These internal control weaknesses increased the risk that additional improper payments may have occurred.

SSIC did not refer any of the 22 cases that were investigated for potential doctor shopping to the MEDICs for further investigation. As a result, the MEDICs would not be aware of the potential FWA issues. Consequently, the MEDICs could not coordinate with other Part D sponsors to prevent the same inappropriate utilization from occurring under other prescription drug plans in the event that the beneficiaries in question switched to other Part D plans. For example, two of the beneficiaries who were part of the PSQM program ended their enrollment with the SSIC plan. One of these two beneficiaries switched twice to prescription drug plans managed by other Part D sponsors and, during a subsequent 15-month period, used 36 different physicians and 25 different pharmacies to obtain controlled substances. The other beneficiary also switched twice to prescription drug plans managed by other Part D sponsors after leaving SSIC and, during a subsequent 21-month period, used 30 different physicians and 14 different pharmacies to obtain controlled substances. Because it did not refer the cases to the MEDICs, SSIC increased the risk that improper payments may have occurred for prescriptions for controlled substances that were obtained by beneficiaries for the purpose of excessive or abusive utilization.

SSIC also paid claims totaling at least \$46,223 for prescriptions written by providers who were excluded from the Part D program. Furthermore, the absence of a procedure to track provider complaints may inhibit SSIC's ability to (a) identify potential incidents of FWA and (b) respond to requests to monitor providers that are viewed as potentially abusive or fraudulent.

## **RECOMMENDATIONS**

We recommend that SSIC strengthen internal controls by:

- adhering to its policies and procedures to self-report potential FWA to the MEDICs pursuant to CMS guidance,
- revising its policies and procedures to deny claims for prescriptions written by excluded providers, as of the effective date of the exclusion, as required by Federal regulations,

- working with CMS to determine the proper resolution of the \$46,223 in payments to excluded providers, and
- establishing policies and procedures to track complaints made against providers pursuant to CMS guidance.

## **SILVERSCRIPT INSURANCE COMPANY COMMENTS**

In written comments on our draft report, SSIC concurred with our recommendations and described corrective actions that it has implemented. Specifically, SSIC stated that it has revised the way it manages and reports cases of potential doctor shopping by increasing the number of cases it reports to the MEDICs. In addition, SSIC said that it revised its policies and procedures regarding the excluded provider process by (a) requiring that claims that are written for prescriptions by excluded providers are denied as of the effective date of the provider's exclusion, and (b) implementing a procedure to report to the MEDICs any paid claims that SSIC identifies as having been written by excluded providers. SSIC also stated that it will consult CMS to determine the proper resolution of the \$46,233 in payments to excluded providers. Furthermore, SSIC said that it has established policies and procedures on how files will be maintained on providers who have been the subject of complaints, investigations, violations and prosecutions.

SSIC's comments are included in their entirety as the Appendix.

# **APPENDIX**

APPENDIX: AUDITEE COMMENTS



9501 E. Shea Blvd | Scottsdale, AZ 85260 | T: 480-391-4600

December 21, 2009

Patrick J. Cogley  
Regional Inspector General for Audit Services  
Region VII  
601 East 12th Street  
Room 0429  
Kansas City, Missouri 64106

Subject: Audit Report Number: A-07-09-03124

Dear Mr. Cogley:

Enclosed please find SilverScript Insurance Company's (SSIC) response to the U.S. Department of Health and Human Services, Office of Inspector General's (OIG) draft report entitled "Review of SilverScript Insurance Company's Internal Controls to Guard Against Fraud, Waste and Abuse for the Medicare Part D Program" (Report Number: A-07-09-03124).

In addition to the enclosed paper copy of our responses we are including a CD with an electronic copy of this response, per your request.

If you have any questions or comments please do not hesitate to call me at 480-614-7202, or contact Patrick Jeswald, Director Compliance Medicare Part D, at 480-661-2030, or through email at [patrick.jeswald@caremark.com](mailto:patrick.jeswald@caremark.com).

Sincerely,

/Todd Meek/  
VP Compliance Medicare Part D

Enclosures

**SilverScript Insurance Company's Response to OIG draft report entitled "Review of SilverScript Insurance Company's Internal Controls to Guard Against Fraud, Waste and Abuse for the Medicare Part D Program" (Report Number: A-07-09-03124) (OIG Report)**

**Finding #1:**

SilverScript Insurance Company (SSIC) generally did not self-report potential Fraud, Waste and Abuse (FWA) to the Medicare Drug Integrity Contractors (MEDICs) as recommended by the Centers for Medicare & Medicaid Services (CMS) Guidance.

**Recommendation:**

We recommend SSIC strengthen internal controls by adhering to its policies and procedures to self-report potential FWA to the MEDICs pursuant to CMS Guidance.

**Response:**

SSIC concurs with the recommendation. Although the Part D regulations and CMS guidance make it clear that self-reporting of potential fraud is voluntary and not required, SSIC's policy is (and has been) to report potential FWA cases, once SSIC determines that potential fraud or misconduct occurred. SSIC performs reasonable inquiries and investigations of cases of suspected potential fraud identified in order to determine if potential fraud or misconduct occurred.

In light of the preliminary audit findings, SSIC has revised how potential "doctor shopping" cases are managed and reported, and this has increased its volume of reporting of these types of cases to the MEDICs. During 2009, SSIC made 98 case referrals to the MEDICs, with 58 of those 98 referrals being related to potential "doctor shopping" cases.

In the past, SSIC chose to manage and evaluate a beneficiaries' suspected over-utilization of controlled substances (including "doctor shopping") through its clinical Patient Safety Quality Management Program (PSQM). There was nothing in the CMS regulation or guidance that required that these cases be reported to the MEDIC and SSIC deemed it reasonable to handle these cases internally.

The PSQM program was a program designed to identify and address patterns of potentially excessive or abusive utilization of controlled substances on the part of beneficiaries. It involved a multi-prong approach, including (1) beneficiary communications meant to correct questionable utilization patterns, (2) prescriber communications designed to inform prescribers of the beneficiary's unusual prescription claims history, (3) review and monitoring by clinical pharmacists, and (4) a "pharmacy lock-in" program that, when applicable, restricted beneficiaries to receiving controlled substances from one pharmacy. The goal of these tools was to provide the beneficiary with an opportunity to change his or her pattern of excessive or abusive utilization of controlled substances. If the utilization pattern did not change, the beneficiary was locked into a particular pharmacy to obtain controlled substances. SSIC no longer uses the

“lock-in” option as part of this PSQM program. Individuals who would previously have been subject to lock in are now referred to the MEDIC.

**Finding #2:**

SSIC paid claims for prescriptions written by excluded providers.

**Recommendation:**

We recommend SSIC strengthen internal controls by:

- revising its policies and procedures to deny claims for prescriptions written by excluded providers, as of the effective date of the exclusion, as required by Federal regulations;
- working with CMS to determine the proper resolution of the \$46,223 in payments to excluded providers.

**Response:**

SSIC concurs with the recommendation to revise its policies and procedures to deny claims for prescriptions written by excluded providers, particularly in light of CMS’ clarifying guidance in the 2010 Part D call letter. SSIC implemented procedures effective April 2007 to identify and prevent payment of Part D claims at point-of-sale (POS) when such claims have been prescribed by providers who have been excluded by either the United States Department of Health and Human Services Office of Inspector General (OIG) or General Services Administration (GSA).

When the procedures were first established, SSIC provided beneficiaries with a 60 day window (from notification date) to find a new prescriber before denying claims. This step was primarily intended to avoid substantial inconvenience for beneficiaries who were patients of (in particular) newly excluded prescribers. A beneficiary will present at POS with the prescription for a needed medication being unaware of the prescriber’s excluded status. If the prescription is denied at POS with no grace period available, the beneficiary is faced with having to obtain an appointment with another provider, seeing the new provider, and getting a new prescription. In these situations, substantial delays can occur in the beneficiary’s obtaining needed medications. As a result, it was SSIC’s policy to provide the beneficiary with the specified grace period while also providing the beneficiary with written notice of the provider’s exclusion and advising that future prescriptions written by such provider would not be filled after a certain date. CMS was aware of SSIC’s policy to provide a 60 day grace period, and approved the written communication to the beneficiary. Providing this kind of notice and grace period was consistent in spirit with the procedures that apply in the Medicare Part B context under relevant regulation (42 C.F.R. § 1001.1901).

Consistent with current government policy, SSIC revised its policies and procedures regarding the Excluded Provider process in June 2009, and no longer provides beneficiaries with a 60 grace period to find a new prescriber. SSIC’s current procedures are to deny claims for prescriptions written by excluded providers, as of the effective date of the exclusion. SSIC updates its provider exclusion list monthly based on updates from the OIG and GSA lists and notifies

beneficiaries in writing that their providers are excluded from the Part D program and that claims prescribed by these providers will no longer be covered as of the effective date of the exclusion. Beginning in 2010, and consistent with the CMS 2010 Call Letter, SSIC will also provide pharmacies with notice of the provider exclusion and future denial of claims, in addition to the claim denial messaging that is currently in place at POS when a claim for an excluded provider is submitted for payment (and rejected).

In addition, SSIC has implemented a procedure to report to the MEDIC any paid claims that it identifies that were written by excluded providers, that are discovered to have been submitted and paid and report these claims to the MEDICs, per the guidance in section 50.2.6.3.3 of Fraud, Waste and Abuse Chapter 9 of the Prescription Drug Manual.

Per CMS guidance and clarification provided in the CMS 2010 Call Letter, if SSIC discovers, due to timing issues associated with identifying excluded prescribers (such as those related to the timing of updates to the OIG and GSA exclusion lists or to SSIC's systems) any such claims have been submitted and paid, SSIC:

"...should not reverse the claims, and no adjustment to the prescription drug event (PDE) data is required."

SSIC will continue to report to the MEDIC any identified claims where the prescription was written by an excluded provider that are discovered to have been submitted and paid.

We will consult CMS to determine proper resolution of the \$46,223 in payments to excluded providers identified during the period in question, as set forth in the OIG Report.

**Finding #3:**

SSIC did not have a procedure in place to track complaints made against providers.

**Recommendation:**

We recommend SSIC strengthen internal controls by establishing policies and procedures to track complaints made against providers pursuant to CMS guidance.

**Response:**

SSIC concurs with the recommendation. Although CMS guidance recommends that Plans have a process for tracking complaints, investigations, violations, and prosecutions against providers, SSIC has established policies and procedures on how files will be maintained on providers who have been the subject of complaints, investigations, violations and prosecutions. The policies and procedures describe the processes established by SSIC to track information on providers (e.g., pharmacies and prescribing physicians) and maintain files for future reference in the investigation and analysis of potential fraud, waste and abuse. SSIC will provide training to appropriate personnel on these policies and procedures and will review and revise such policies and procedures, as necessary, on an annual basis.