February 27, 2012

Report Number:  A-09-11-02074

Mr. Shawn D. Smith  
Director, Client & Benefit Audits  
CVS Caremark Corporation  
9501 East Shea Boulevard, MC 143  
Scottsdale, AZ  85260

Dear Mr. Smith:

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 Prescription Drug Event Data for Schedule II Drugs at CVS Caremark Corporation*. 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.


If you have any questions or comments about this report, please do not hesitate to call me, or contact Shon Dormoy, Audit Manager, at (415) 437-8360 or through email at Shon.Dormoy@oig.hhs.gov. Please refer to report number A-09-11-02074 in all correspondence.

Sincerely,

/Lori A. Ahlstrand/
Regional Inspector General  
for Audit Services

Enclosure
Direct Reply to HHS Action Official:

Mr. Timothy B. Hill
Deputy Director
Center for Drug and Health Plan Choice
Centers for Medicare & Medicaid Services
Mail Stop C5-19-16
7500 Security Boulevard
Baltimore, MD  21244-1850
Department of Health and Human Services
OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICARE PART D PRESCRIPTION DRUG EVENT DATA FOR SCHEDULE II DRUGS AT CVS CAREMARK CORPORATION

Daniel R. Levinson
Inspector General

February 2012
A-09-11-02074
The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

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

Office of Counsel to the Inspector General

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

BACKGROUND

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII 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.

The Centers for Medicare & Medicaid Services (CMS), which administers the Part D program, contracts with private entities called Part D sponsors that act as payers and insurers for prescription drug benefits. A Part D sponsor may contract with a pharmacy benefits manager (PBM) to manage or administer the prescription drug benefit on the sponsor’s behalf. Pursuant to 42 CFR § 423.505(i), the sponsor maintains ultimate responsibility for complying with its contract with CMS, which includes compliance with all Federal laws, regulations, and guidance.

Pursuant to sections 1860D-15(c)(1)(C) and (d)(2) of the Act and 42 CFR § 423.322, sponsors must submit the information necessary for CMS to carry out Part D payment provisions and program integrity activities. For every prescription filled, the Part D sponsor or its PBM prepares a Prescription Drug Event (PDE) record and submits it to CMS. Certain fields in the PDE record are completed using information provided by the pharmacy responsible for filling the prescriptions. The PDE record, which is a summary record of individual drug claim transactions at the pharmacy, enables CMS to make payment to the sponsor and otherwise administer the Part D benefit. Pursuant to 42 CFR § 423.505(k), the sponsor must provide certification as to the accuracy, completion, and truthfulness of the claims data submitted for payment purposes.

The Controlled Substances Act established five schedules based on the medical use acceptance and the potential for abuse of the substance or drug. Schedule II drugs have a high potential for abuse, have an accepted medical use (with severe restrictions), and may cause severe psychological or physical dependence if abused. Pursuant to 21 CFR § 1306.12(a), Schedule II prescription drugs may not be refilled. However, 21 CFR § 1306.13(b) provides that Schedule II drugs for patients residing in a long-term-care facility and for the terminally ill may be partially filled as long as the total quantity dispensed does not exceed the total quantity prescribed. Under this provision, Schedule II prescriptions for these patients are valid for a period not to exceed 60 days from the issue date. In addition, pursuant to 21 CFR § 1306.11, Schedule II drugs may not be dispensed without a practitioner’s written prescription.

CVS Caremark Corporation (Caremark) provided prescription drug benefits to eligible Part D beneficiaries through its two wholly owned subsidiaries, SilverScript Insurance Company and Accendo Insurance Company, which contracted with CMS as Part D sponsors. Caremark provided prescription drug coverage to over 389,000 beneficiaries and submitted to CMS over 4.2 million PDE records for Schedule II drugs for dates of service from January 1, 2008, through June 30, 2010.
OBJECTIVE

Our objective was to determine whether Caremark had adequate controls to (1) prevent refills and unallowable partial fills of Schedule II drugs and (2) ensure the accuracy of certain fields in the PDE records submitted for Schedule II drugs.

SUMMARY OF FINDINGS

Caremark did not have adequate controls to (1) prevent refills and unallowable partial fills of Schedule II drugs and (2) ensure the accuracy of certain fields in the PDE records submitted for Schedule II drugs as required by Federal regulations. Of 42 judgmentally selected PDE records, 7 records represented unallowable partial fills. (There were no refills.) In addition, of 62 judgmentally selected PDE records (which included the 42 records reviewed for refills and partial fills), 24 records contained inaccurate data when compared with the supporting documentation at the pharmacies. An additional two PDE records were missing pharmacy documentation, which prevented us from determining the accuracy of the data in the records.

The claims processing systems had no edits to identify refills and unallowable partial fills by pharmacies to prevent submission of PDE records related to those prescriptions nor did the systems have edits to ensure the accuracy of certain fields in the PDE records. In addition, Caremark has not provided to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or adequate guidance on submitting accurate claim information for Schedule II drugs.

RECOMMENDATIONS

We recommend that Caremark:

- strengthen its controls to (1) prevent refills and unallowable partial fills of Schedule II drugs and (2) ensure the accuracy of submitted PDE records and

- issue guidance to its pharmacies clarifying Federal requirements related to (1) refills and partial fills of Schedule II drugs and (2) submission of accurate claim information for Schedule II drugs.

AUDITEE COMMENTS

In written comments on our draft report, Caremark did not explicitly concur with our recommendations but provided information on communication, training, and compliance actions taken to address the recommendations. Caremark’s comments are included in their entirety as the Appendix.
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INTRODUCTION

BACKGROUND

Medicare Part D

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII 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.

The Centers for Medicare & Medicaid Services (CMS), which administers the Part D program, contracts with private entities called Part D sponsors that act as payers and insurers for prescription drug benefits. Sponsors may offer prescription drug benefits through a standalone prescription drug plan or as part of a managed care plan, known as a Medicare Advantage Prescription Drug Plan.

A Part D sponsor may contract with a pharmacy benefits manager (PBM) to manage or administer the prescription drug benefit on the sponsor’s behalf. PBM responsibilities vary, but include services such as processing and paying prescription drug claims, contracting with pharmacies, and negotiating rebates with drug manufacturers. Pursuant to 42 CFR § 423.505(i), the sponsor maintains ultimate responsibility for complying with its contracts with CMS, which includes compliance with all Federal laws, regulations, and guidance.

Prescription Drug Event Data

Pursuant to sections 1860D-15(c)(1)(C) and (d)(2) of the Act and 42 CFR § 423.322, sponsors must submit the information necessary for CMS to carry out Part D payment provisions and program integrity activities. For every prescription filled, the Part D sponsor or its PBM prepares a Prescription Drug Event (PDE) record and submits it to CMS. The PDE record, which is a summary record of individual drug claim transactions at the pharmacy, enables CMS to make payment to the sponsor and otherwise administer the Part D benefit. Pursuant to 42 CFR § 423.505(k), the sponsor must provide certification as to the accuracy, completion, and truthfulness of the claims data submitted for payment purposes.

A Part D sponsor, or its PBM, completes certain fields in the PDE record using information provided by the pharmacy responsible for filling the prescription. A PDE record contains fields that identify (1) the sponsor, beneficiary, physician, pharmacy, drug, prescription reference number, and fill number; (2) the dates that the prescription was filled and the PDE record was processed; (3) the prescription drug cost and other payment information; and (4) physician’s instructions on whether generic drugs may be dispensed.

Controlled Substances

The Controlled Substances Act (CSA), 21 U.S.C. §§ 801–971, established five schedules based on the medical use acceptance and the potential for abuse of the substance or drug. Schedule I,
which includes drugs or substances that have no currently accepted medical use and a high potential for abuse, is the most restrictive, and Schedule V is the least restrictive.

Schedule II drugs have a high potential for abuse, have an accepted medical use in treatment in the United States or an accepted medical use with severe restrictions, and may cause severe psychological or physical dependence if abused (21 U.S.C. § 812(b)(2)). Except in emergency situations or when dispensed directly by a practitioner other than a pharmacist to the ultimate user, Schedule II drugs may not be dispensed without a practitioner’s written prescription (21 CFR § 1306.11). Schedule II drugs include drugs such as oxycodone and morphine.

Pursuant to 21 CFR § 1306.12(a), Schedule II prescription drugs may not be refilled. However, 21 CFR § 1306.13(b) provides that Schedule II drugs for patients residing in a long-term-care facility and for the terminally ill may be partially filled as long as the total quantity dispensed does not exceed the total quantity prescribed. Under this provision, Schedule II prescriptions for these patients are valid for a period not to exceed 60 days from the issue date.

**CVS Caremark Corporation, SilverScript Insurance Company, and Accendo Insurance Company**

CVS Caremark Corporation (Caremark) provided prescription drug benefits to eligible Part D beneficiaries through its two wholly owned subsidiaries, SilverScript Insurance Company (SilverScript) and Accendo Insurance Company (Accendo), which contracted with CMS as Part D sponsors. Accendo was acquired by Caremark in October 2008. Caremark provided prescription drug coverage to over 389,000 beneficiaries and submitted to CMS over 4.2 million PDE records for Schedule II drugs for dates of service from January 1, 2008, through June 30, 2010. For these PDE records, pharmacies were paid approximately $516 million.

SilverScript and Accendo contracted with CVS Caremark Part D Services, LLC (Caremark Part D Services) and RxAmerica, LLC (RxAmerica), respectively, to provide PBM services, including claims processing and adjudication, as well as preparation and submission of PDE records. Caremark Part D Services and RxAmerica are also wholly owned subsidiaries of Caremark. Caremark Part D Services maintains SilverScript’s pharmacy network and beginning in April 2009 assumed responsibility for maintaining Accendo’s pharmacy network. Before April 2009, RxAmerica maintained Accendo’s pharmacy network.

As PBMs, Caremark Part D Services and RxAmerica processed prescription claims for SilverScript and Accendo from pharmacies for each drug dispensing event. The PBMs used their respective claim software to process prescription claims at the point of sale, which included implementing a series of edits and calculating certain data elements. The PBMs used these data elements, as well as other Part D data, to create the PDE records and submitted the PDE records.

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1 The CSA has an exception to the written prescription requirement for Schedule II drug prescriptions written for residents of long-term-care facilities. A prescription received by fax may serve as the original prescription.

2 The amount paid to the pharmacies is on behalf of the sponsor, beneficiaries, and third parties. The $516 million includes the amounts paid for original submissions of PDE records as well as any subsequent adjustments.
to CMS. The PBMs also performed audits of the data received from pharmacies. SilverScript and Accendo maintained an oversight role in the PBMs’ processes.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Caremark had adequate controls to (1) prevent refills and unallowable partial fills of Schedule II drugs and (2) ensure the accuracy of certain fields in the PDE records submitted for Schedule II drugs.

Scope

We limited our review to 3,511,180 PDE records for dates of service from January 1, 2008, through June 30, 2010, representing $425,159,489 paid for Schedule II drugs under Caremark’s two standalone prescription drug plans provided by SilverScript and Accendo. We excluded from our review PDE records that were (1) for noncovered Part D drugs under the prescription drug plan, (2) deleted, (3) plan-to-plan reconciliations, (4) subsequently adjusted, or (5) submitted in a nonstandard format.

We limited our review of internal controls to gaining an understanding of how Caremark maintained and monitored PDE records for Schedule II drugs and oversaw pharmacies’ claiming of these drugs. We did not review the completeness of the PDE records; we limited our review to the fields in the PDE records that contained data provided by the pharmacies responsible for filling the prescriptions.

We conducted our audit from May to December 2011 and performed fieldwork at Caremark’s office in Scottsdale, Arizona, and at selected pharmacies.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CMS officials about the Federal requirements related to Schedule II drugs;
- reviewed SilverScript’s and Accendo’s contracts with CMS regarding their roles and responsibilities as Part D sponsors;
- reviewed SilverScript’s contract with Caremark Part D Services and Accendo’s contract with RxAmerica regarding pharmacy contracting and processing of pharmacy claims;
- interviewed Caremark officials regarding their monitoring and oversight of PDE data;
• obtained SilverScript’s and Accendo’s PDE records for Schedule II drugs for dates of service from January 1, 2008, through June 30, 2010 (processed by CMS through November 2010);

• analyzed the PDE records by beneficiary, prescription reference number, and fill number to determine that 187,989 PDE records represented potential refills and/or potential unallowable partial fills;

• selected a judgmental sample of 42 PDE records and reviewed the supporting documentation at the pharmacies that submitted those claims to identify refills and unallowable partial fills;

• selected a judgmental sample of 62 PDE records (which included the 42 PDE records reviewed for refills and partial fills) and reviewed the supporting documentation at the pharmacies that submitted those claims to determine the accuracy of certain fields in the PDE records; and

• shared the results of our audit with Caremark officials.

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 objective.

FINDINGS AND RECOMMENDATIONS

Caremark did not have adequate controls to (1) prevent refills and unallowable partial fills of Schedule II drugs and (2) ensure the accuracy of certain fields in the PDE records submitted for Schedule II drugs as required by Federal regulations. Of 42 judgmentally selected PDE records, 7 records represented unallowable partial fills. (There were no refills.) In addition, of 62 judgmentally selected PDE records (which included the 42 records reviewed for refills and partial fills), 24 records contained inaccurate data when compared with the supporting documentation at the pharmacies. An additional two PDE records were missing pharmacy documentation, which prevented us from determining the accuracy of the data in the records.

The claims processing systems had no edits to identify refills and unallowable partial fills by pharmacies to prevent submission of PDE records related to those prescriptions nor did the systems have edits to ensure the accuracy of certain fields in the PDE records. In addition, Caremark has not provided to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or adequate guidance on submitting accurate claim information for Schedule II drugs.
FEDERAL REQUIREMENTS

Federal Regulations for Schedule II Drugs

Pursuant to Federal regulations (21 CFR § 1306.12(a)), Schedule II prescription drugs may not be refilled. A separate prescription is required if a physician wishes to authorize continuation of a patient’s use of a Schedule II drug beyond the amount specified on the first prescription. However, Federal regulations (21 CFR § 1306.13(b)) allow for a prescription for a Schedule II drug written for a patient in a long-term-care facility or for a patient with a medical diagnosis documenting a terminal illness to be filled in partial quantities to include individual dosage units. Under this provision, a Schedule II drug may be partially filled as long as the total quantity dispensed does not exceed the total quantity prescribed. The prescription is valid for a period not to exceed 60 days from the issue date.3

Pursuant to 21 CFR § 1306.11, except in emergency situations or when dispensed directly by a practitioner other than a pharmacist to the ultimate user, Schedule II drugs may not be dispensed without a practitioner’s written prescription.

Federal Regulations and Guidance for Sponsors

Pursuant to 42 CFR § 423.505(d), the sponsor agrees to maintain, for 10 years, records and documents that are sufficient to accommodate periodic auditing of data and to enable inspection of the quality, appropriateness, and timeliness of services performed under the contract with CMS. In addition, pursuant to 42 CFR § 423.505(k), the sponsor must provide certification as to the accuracy, completion, and truthfulness of the claims data submitted. For every individual drug claim transaction at the pharmacy, the Part D sponsor or its PBM prepares a PDE record.

Notwithstanding any relationship that the sponsor may have with related entities, contractors, or subcontractors, the sponsor maintains ultimate responsibility for complying with its contracts with CMS, which includes compliance with all Federal laws, regulations, and CMS instructions (42 CFR § 423.505(i)). In addition, CMS’s Prescription Drug Benefit Manual, chapter 9, section 50.2.6.3.1, recommends that the sponsor have systems capability to establish edits and use edits to automatically deny claims or suspend payments on claims when appropriate.

REFILLS AND UNALLOWABLE PARTIAL FILLS

Of 42 judgmentally selected PDE records, 7 records represented unallowable partial fills of Schedule II drugs. (There were no refills.)

- For three PDE records, the drug was dispensed more than 60 days after the issue date of the prescription.

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3 Federal regulations (21 CFR § 1306.13(a)) also permit the partial filling of a prescription for a Schedule II drug if the pharmacist is unable to supply the full quantity prescribed. The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist may not dispense any further quantity without a new prescription.
• For four PDE records, the drug was dispensed without a practitioner’s written prescription.

INACCURATE PRESCRIPTION DRUG EVENT DATA

Of 62 judgmentally selected PDE records (which included the 42 records reviewed for refills and partial fills), 24 records contained inaccurate data. An additional two PDE records were missing pharmacy documentation, which prevented us from determining the accuracy of the data in the records.

Inaccurate Data

We considered data to be inaccurate when certain fields in the PDE records did not match the supporting documentation that we reviewed at the pharmacies. The 24 PDE records contained the following inaccurate data:4

• The prescription date of service did not match the date that the prescribed drug was actually dispensed to the beneficiary.

• The National Drug Code did not match the drug that was actually dispensed by the pharmacy.

• The fill number did not match the number of refills or partial fills associated with the prescription as shown in the documentation maintained at the pharmacy.

• The days supply of the drug did not match the days supply of the drug actually dispensed by the pharmacy based on the prescriber’s directions for use written on the prescription.

• The prescriber identifier did not match the prescriber information on the prescription maintained at the pharmacy.

• The prescription origin code did not match the type of prescription that was presented at the pharmacy (i.e., written, telephone, electronic, or fax).

Missing Documentation

Of 62 judgmentally selected PDE records, 2 records were not supported by physician-signed prescriptions. The pharmacy was not able to provide us with any supporting documentation, such as physician-signed prescriptions, refill requests, or drug delivery receipts. Therefore, we were not able to determine the accuracy of the data in the PDE records.

4 All 24 PDE records had at least one of the types of inaccurate data shown.
INADEQUATE CONTROLS

The policies and procedures of the PBMs—Caremark Part D Services and RxAmerica—included the use of edits in their claims processing systems to identify discrepancies and errors in pharmacy claims. However, there were no edits to identify pharmacies’ refills and unallowable partial fills. In addition, the PBMs’ edits did not ensure the accuracy of certain fields in the PDE records based on information provided by the pharmacies.

Caremark Part D Services and RxAmerica send correspondence to their network pharmacies on operational and procedural issues related to claims processing. However, neither PBM has provided to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or adequate guidance on submitting accurate claim information for Schedule II drugs.

CONCLUSION

Schedule II drugs have a high potential for abuse. Therefore, having adequate controls to prevent refills and unallowable partial fills, while ensuring that an adequate and uninterrupted supply is available for legitimate medical needs, is a valuable program integrity safeguard. In addition, having adequate controls to ensure the accuracy of data in submitted PDE records is essential to program integrity. Without adequate controls, Part D sponsors cannot properly oversee the dispensing and monitoring of Schedule II drugs.

RECOMMENDATIONS

We recommend that Caremark:

- strengthen its controls to (1) prevent refills and unallowable partial fills of Schedule II drugs and (2) ensure the accuracy of submitted PDE records and

- issue guidance to its pharmacies clarifying Federal requirements related to (1) refills and partial fills of Schedule II drugs and (2) submission of accurate claim information for Schedule II drugs.

AUDITEE COMMENTS

In written comments on our draft report, Caremark did not explicitly concur with our recommendations but provided information on communication, training, and compliance actions taken to address the recommendations. Caremark’s comments are included in their entirety as the Appendix.
APPENDIX
APPENDIX: AUDITEE COMMENTS

February 2, 2012

Lori A. Ahlstrand
Regional Inspector General for Audit Services
Office of the Inspector General
Office of Audit Services, Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

Re: HHS/OIG DRAFT AUDIT REPORT: Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at CVS Caremark Corporation A-09-11-02074

Dear Ms. Ahlstrand:

This letter is in response to the above-referenced U.S. Department of Health and Human Services, Office of the Inspector General (OIG), draft report entitled Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at CVS Caremark Corporation. We understand your review was of SilverScript Insurance Company (SilverScript) and Accendo Insurance Company (Accendo), which contract with CMS as a Part D sponsor. Prescription Drug Event Data (PDE) records were analyzed for Schedule II drugs for the dates of service from January 1, 2008, through June 30, 2010. SilverScript and Accendo contracted with CVS Caremark Part D Services, LLC and RxAmerica, LLC, respectively, to provide PBM services, including claims processing and adjudication, as well as preparation and submission of PDE records.

The OIG’s draft report states that Caremark did not have adequate controls to (1) prevent refills and unallowable partial fills of Schedule II drugs and (2) ensure the accuracy of certain fields in the PDE records submitted for Schedule II drugs as required by Federal regulations. In addition, Caremark has not provided pharmacies with any guidance clarifying the Federal requirements related to refills and partial fills of Schedule II drugs or given adequate guidance on submitting accurate claim information for Schedule II drugs.

While CVS Caremark believes they have strong monitoring programs in place over the network providers, it is also recognized that additional communication, training and compliance actions can be applied to address the OIG’s concerns regarding refills and unallowable partial fills of Schedule II drugs. To that end, CVS Caremark has evaluated the recommendations and has taken the following communication, training and compliance actions to address the recommendations:
1. Two national communications were sent to all CVS Caremark pharmacy network providers. The pharmacy communication provided information on the importance of pharmacy practices in submitting accurate claims information for payment of Schedule II drugs. The pharmacy communication also details proper practices to be utilized by pharmacies to document the circumstances justifying the partial refill of a Schedule II drug. The first communication to all CVS Caremark pharmacy network providers was sent on October 5, 2011 and the second was sent December 5, 2011. In addition, SilverScript has also instructed CVS Caremark to send a reminder communication of this matter to all CVS Caremark pharmacy network providers. This will be completed within the next 90 days.

2. CVS Caremark provided additional focused training to their pharmacy audit staff reinforcing that they will need to include a sample of Schedule II claims—and specifically those which were refilled within their claims sample—and audit to validate compliance with state and/or federal Schedule II refill limitations. This additional focused training was provided on October 28, 2011.

3. Internal Policies and Procedures within the CVS Caremark Pharmacy Audit Department were updated to include verbiage related to the specific audit of Schedule II drugs refill limitations. This update was completed on November 3, 2011.

4. New audit software was developed that will include a flag on all controlled substances refilled: C2 codes for all refills and C3-5 codes if refilled more than 5 times. This new audit functionality was placed into service on January 1, 2012.

It is also noteworthy to add that CVS Caremark’s contracted network pharmacies have a regulatory compliance responsibility for refilling controlled substances within regulatory requirements and also a contractual obligation pursuant to CVS Caremark’s provider agreements with these pharmacies.

After your review of this response we would welcome any questions or lingering concerns. We appreciate your time and consideration. In addition, we would like this response to be included as a part of the Final Report.

Sincerely,

Shawn Smith, CPA, MBA
Director of Client Audit
THIS REPORT IS AVAILABLE TO THE PUBLIC
at http://oig.hhs.gov

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.

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.