



Region VII
601 East 12th Street
Room 0429
Kansas City, Missouri 64106

January 18, 2012

Report Number: A-07-11-06029

Mr. Lloyd D. McDonald
President
SilverScript Insurance Company, Inc.
9501 East Shea Boulevard, MC125
Scottsdale, AZ 85260

Dear Mr. McDonald:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Controls at SilverScript Insurance Company to Ensure Adherence to Formularies*. We will forward a copy of this report to the HHS action official noted below.

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 direct them to the HHS action official. Please refer to report number A-07-11-06029 in all correspondence.

Sincerely,

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

Enclosure

HHS Action Official:

Mr. Timothy B. Hill
Deputy Director
Centers for Drug and Health Plan Choice
Centers for Medicare & Medicaid Services
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7500 Security Boulevard
Baltimore, MD 21244-1850

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF CONTROLS AT
SILVERSCRIPT INSURANCE COMPANY
TO ENSURE ADHERENCE
TO FORMULARIES**



Daniel R. Levinson
Inspector General

January 2012
A-07-11-06029

Office of Inspector General

<http://oig.hhs.gov>

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THIS REPORT IS AVAILABLE TO THE PUBLIC
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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.

EXECUTIVE SUMMARY

BACKGROUND

Medicare Part D Prescription Drug Coverage

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

The Centers for Medicare & Medicaid Services (CMS), which administers Medicare, contracts with private prescription drug plans and Medicare Advantage plans (collectively known as sponsors) to offer prescription drug benefits to eligible individuals under Medicare Part D.

Every time a beneficiary fills a prescription covered under Part D, the sponsor must submit prescription drug event (PDE) data, including drug cost and payment information, to CMS. Sponsors are required to submit final PDE data within 6 months after the end of the coverage year.

Medicare Part D Formulary Drugs

The MMA requires that a drug meet the definition of a Part D drug to be covered by the Part D program. Federal regulations define a covered Part D drug as "... a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal..." For this report, we refer to a formulary as the entire list of Part D drugs covered by a Part D plan. CMS guidance provides both interpretive rules and guidelines for sponsors to implement Federal formulary regulatory requirements.

The Part D program allows sponsors to choose whether or not they will use a formulary to administer their Part D plans. Sponsors that use a formulary must comply with certain statutory and regulatory requirements governing formulary operation. In certain circumstances, sponsors that use a formulary can submit claims for drugs that are provided to beneficiaries but that are not included in a sponsor's Part D plan formulary (non-formulary drugs) for Part D coverage. If these circumstances are not met, the Part D program does not permit reimbursement for these non-formulary drugs.

SilverScript Insurance Company

SilverScript Insurance Company (SSIC) is a subsidiary of CVS Caremark Corporation. SSIC is a 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

Our objective was to determine whether the PDE data claimed by SSIC included non-formulary drugs.

RESULTS OF REVIEW

SSIC's claims for PDE data generally complied with Federal requirements regarding non-formulary drugs. Based on our review of 100 claims, 1 claim for \$47 was unallowable because the prescription was filled outside the allowable transition fill period. Because this is below the threshold of six errors needed for a statistical projection, we have no findings and are making no recommendations.

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INTRODUCTION

BACKGROUND

Medicare Part D Prescription Drug Coverage

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended Title XVIII of the Social Security Act (the Act) by establishing the Medicare Part D prescription drug benefit.¹ Under the Part D program, which began on January 1, 2006, individuals entitled to benefits under Medicare Part A or enrolled in Medicare Part B may obtain drug coverage. The Centers for Medicare & Medicaid Services (CMS), which administers Medicare, contracts with private prescription drug plans and Medicare Advantage plans (collectively known as sponsors) to offer prescription drug benefits to eligible individuals under Medicare Part D.

Every time a beneficiary fills a prescription covered under Part D, the sponsor must submit prescription drug event (PDE) data to CMS. PDE data include drug cost and payment information to enable CMS to administer the Part D benefit. Pursuant to 42 CFR § 423.343(c)(1), sponsors must submit final PDE data to CMS within 6 months after the end of the coverage year.

For calendar years (CY) 2007 through 2009, sponsors submitted final PDE data totaling approximately \$196 billion in gross drug costs. CMS's *PDE Instructions: Requirements for Submitting Prescription Drug Event Data*, section 7.2.3, defines gross drug costs as the sum of the following PDE payment fields: covered plan-paid amount, noncovered plan-paid amount, patient-pay amount, low-income cost-sharing payment, other true out-of-pocket costs, and patient liability reduction as a result of another pay amount.

Medicare Part D Formulary Drugs

The MMA requires that a drug meet the definition of a Part D drug to be covered by the Part D program. Federal regulations at 42 CFR § 423.100 define a covered Part D drug as "... a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal..." For this report, we refer to a formulary as the entire list of Part D drugs covered by a Part D plan. CMS has issued additional guidance to sponsors in the *Medicare Prescription Drug Benefit Manual*, Pub. No. 100-18, chapter 6, section 30. This guidance provides both interpretative rules and guidelines for sponsors to implement the formulary regulatory requirements specified in 42 CFR § 423.120(b).

The Part D program allows sponsors to choose whether or not they will use a formulary to administer their Part D plans. Sponsors that use a formulary must comply with certain statutory and regulatory requirements governing formulary operation. In certain circumstances, sponsors that use a formulary can submit claims for drugs that are provided to beneficiaries but that are not included in a sponsor's Part D plan formulary (non-formulary drugs) for Part D coverage. If

¹ P.L. No. 108-173 § 101, § 1860D-1(a) of the Act, 42 U.S.C. § 1395w-101(a).

these circumstances are not met, the Part D program does not permit reimbursement for these non-formulary drugs.

SilverScript Insurance Company

SilverScript Insurance Company (SSIC) is a subsidiary of CVS Caremark Corporation. SSIC is a 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, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the PDE data claimed by SSIC included non-formulary drugs.

Scope

Our audit covered approximately \$104 million in gross drug costs reflected in SSIC's final PDE data submitted to CMS for the period January 1, 2007, through December 31, 2009.

We limited our internal control review to SSIC's policies and procedures related to Part D drugs that were submitted for reimbursement and that were included in their plan's formulary or were treated as being included as a result of a coverage determination or appeal. We did not review the accuracy or completeness of the PDE data.

We conducted our audit from October 2010 to October 2011.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and program guidance;
- interviewed CMS officials responsible for administering the Part D program;
- interviewed SSIC officials responsible for administering their Part D plans;
- obtained a listing of formulary drugs by National Drug Codes (NDC) for CYs 2007 through 2009;
- obtained a listing of PDE data for NDCs that were not included on SSIC's formulary for any of the respective years under review;
- obtained enrollment data from SSIC for CYs 2007 through 2009;

- identified and removed all PDE data related to:
 - non-covered drugs offered as a supplemental benefit² and
 - records associated with possible transition fills;³
- identified 973,823 PDE claims (totaling \$60,768,342) associated with NDCs that were not included on SSICs formulary listing;
- selected a random sample of 100 claims from the 973,823 PDE claims;
- obtained and reviewed the supporting documentation for each sampled claim to determine the allowability of the claim; and
- shared the results of our review with SSIC officials on December 20, 2011.

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.

RESULTS OF REVIEW

SSIC's claims for PDE data generally complied with Federal requirements regarding non-formulary drugs. Based on our review of 100 claims, 1 claim was unallowable because the prescription was filled outside the allowable transition fill period.⁴ Because this is below the threshold of six errors needed for a statistical projection, we have no findings and are making no recommendations.

² CMS's *PDE Instructions: Requirements for Submitting Prescription Drug Event Data*, section 5, "Drug Coverage Status," defines a non-covered drug as "any prescription or over-the-counter drug that is not a Part D drug or that is already covered under Medicare Parts A or B as prescribed, dispensed, or administered."

³ A transition fill is a one-time fill allowed by CMS within 90 days of Part D enrollment.

⁴ CMS guidance in the *Medicare Prescription Drug Benefit Manual*, chapter 6, section 30.4.4, requires plans to "... provide a temporary supply fill anytime during the first 90 days of a beneficiary's enrollment in a plan." Our review identified that the prescription was filled on November 7, 2007, which was more than 90 days after the beneficiary's enrollment date of January 1, 2007. Therefore, this claim was considered unallowable. However, we determined the claim amount of \$47 to be immaterial and therefore we will not recommend that SSIC adjust for this claim.