DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850


**PROGRAM COMPLIANCE AND OVERSIGHT GROUP**

January 15, 2013

**VIA:**
**EMAIL (Lloyd.Mcdonald@CVSCaremark.com)**
**AND FACSIMILE: (480) 314-6480**

Mr. Lloyd D. McDonald
Chief Executive Officer
Silverscript Insurance Company
9501 E. Shea Boulevard, MC125
Scottsdale, AZ 85260
Phone: 480-661-2395

Re: Notice of Imposition of Immediate Intermediate Sanctions (Suspension of Enrollment and Marketing) for Medicare Prescription Drug Plan Sponsor Contract S5601

Dear Mr. McDonald:

Pursuant to 42 C.F.R. § 423.756, the Centers for Medicare & Medicaid Services (CMS) hereby informs Silverscript Insurance Company (SSIC) of its determination to immediately impose intermediate sanctions on the following Medicare Prescription Drug Plan (PDP) Sponsor Contract: S5601.

These intermediate sanctions will consist of the suspension of the enrollment of Medicare beneficiaries (42 C.F.R. § 423.750(a)(1)) and the suspension of all marketing activities to Medicare beneficiaries (42 C.F.R. § 423.750(a)(3)). CMS is imposing these intermediate sanctions immediately, effective January 15, 2013 at 11:59 p.m. EST, pursuant to 42 C.F.R. § 423.756(c)(2), because it has determined that SSIC's conduct poses a serious threat to the health and safety of Medicare beneficiaries. Pursuant to 42 C.F.R. § 423.756(c)(3), the intermediate marketing and enrollment sanctions will remain in effect until CMS is satisfied that the deficiencies upon which the determination was based have been corrected and are not likely to recur. CMS will provide SSIC with detailed instructions regarding the marketing and enrollment suspension in a separate communication.

**Summary of SSIC's Non-Compliance**

SSIC currently holds a contract with CMS to administer stand-alone outpatient prescription drug benefits (i.e., Medicare Part D) to Medicare beneficiaries throughout the United States. As of January 1, 2013, SSIC is responsible for the delivery of Part D benefits to approximately four million beneficiaries. Since January 1, 2013, SSIC has experienced widespread data system failures that have directly led to extensive violations of the Part D program's requirements regarding enrollment processing, call center operation, and claims processing. These failures have created disruptions in tens of thousands of Medicare beneficiaries' access to prescription medications. CMS has determined that SSIC's operational deficiencies have resulted in the substantial failure to comply with SSIC's PDP contract and warrant the imposition of an intermediate sanction in the form of the suspension of its marketing and enrollment activities. CMS has further determined that SSIC's failures pose a serious risk to its current and prospective members' health and safety and therefore is making the sanction effective immediately.

**Relevant Part D Benefit Requirements**

To receive Part D benefits, Medicare beneficiaries must elect to enroll in a prescription drug benefit plan offered by an organization that contracts with CMS to operate as a Part D sponsor (sponsor). Sponsors are required to operate systems that adjudicate claims in real time at the point of sale (i.e., at a pharmacy). 42 C.F.R. § 423.505(b)(17). To operate such a system, sponsors must accurately process enrollment transactions. 42 C.F.R. Part 423, Subpart B. This includes assigning individuals to their elected plans, transmitting enrollment data to CMS and maintaining accurate information on beneficiaries' eligibility for a low-income subsidy (LIS) that would exempt them from liability for premiums and deductibles and afford them access to special low co-payment amounts. 42 C.F.R. Part 423, Subpart B and § 423.800.

Unlike health benefits offered under the Part C or Original Medicare programs, where beneficiary payments and claims are normally processed after the delivery of covered services, outpatient prescription drug claims must be adjudicated in light of the structure (e.g., deductibles and cost sharing amounts) of the beneficiary's plan benefit package in real time at the point of sale and result in an adjudicated paid response before a pharmacy will fill a beneficiary's prescription. 42 C.F.R. §§ 423.104(a) and 423.505(b)(17). Any failure of a sponsor's data systems can immediately cause interruptions in claims processing for its enrollees at pharmacies. In those instances, the beneficiary will have to leave the pharmacy without the drug unless he or she can pay the entire cost of the drug out of his or her own pocket.

Sponsors must pay particular attention to their enrollment operations each December in preparation for the start of a new plan benefit year the following January. They must make certain that prior to January 1, their enrollment records (upon which the operation of their claims adjudication system will depend) show that the sponsor's continuing enrollees are assigned to the correct benefit plan package for the upcoming year, that new enrollees who elected the sponsor's plan during the annual election period are assigned to the plan they chose, and that the correct LIS status is recorded for each beneficiaries. 42 C.F.R. Part 423, Subparts B and § 423.800.

**Deficiencies Related to the Part D Benefit**

On January 2, 2013, the 1-800-MEDICARE phone line began receiving numerous beneficiary complaints about SSIC's Part D operations. These complaints are recorded in CMS' complaints tracking module (CTM) which plan sponsors have access to and must review. At the same time, CMS received reports from at least 5 state health insurance program (SHIP) counseling organizations (state-operated programs that provide information and counseling to residents concerning their health insurance options) that SSIC enrollees in their states were experiencing customer service and claims processing problems.

CMS immediately contacted SSIC for more information. On January 3, 2013, SSIC told CMS that, among other problems, it had failed to load thousands of new enrollees into its claims adjudication system. SSIC management explained that an update of SSIC's Part D data systems performed during late 2012 had led to significant disruptions in its enrollment, LIS tracking, and claims processing operations. SSIC has confirmed that tens of thousands of SSIC enrollees were affected by these system errors.

From January 1 through January 14, 2013, CMS received 2,340 complaints about SSIC's Part D operations. CMS has received complaints about SSIC at a rate four times greater than the rate of complaints received about all other Part D sponsors combined during the same period. CMS' analysis of the complaints indicates failures fall into three broad categories: (1) beneficiaries not enrolled in an SSIC plan; (2) beneficiaries are enrolled in the wrong SSIC plan; and (3) incorrect LIS status for the beneficiaries. In addition, the SSIC customer service call center experienced a dramatic increase in call volume as its members sought resolution to claims issues they were experiencing at the pharmacy as a result of SSIC system errors.

A significant number of the SSIC enrollee complaints describe instances where the member had to pay more out of pocket than was required under the terms of the benefit plan because SSIC systems could not correctly adjudicate the member's claims in real time. For some beneficiaries, this meant paying a higher copay amount while others were charged the full cost of the drug. In many instances, beneficiaries could not afford the higher charge and left the pharmacy without their medication. SSIC has acknowledged to CMS that many of its enrollees have had difficulty obtaining their medications or are being charged incorrect co-pay or cost-sharing amounts. While SSIC tried to mitigate the impact of its systems failures by authorizing pharmacies to use a universal claim form for any customer claiming to be an SSIC member (which would allow the pharmacist to dispense the drug without any cost sharing and without adjudication by the sponsor), the complaints received via 1-800-MEDICARE indicate that in many instances, SSIC enrollees are continuing to leave the pharmacy counter without their prescription medications.

Therefore, CMS analysis of disclosures made by SSIC as well as complaints received by CMS demonstrate that SSIC is substantially out of compliance with 42 C.F.R.§ 423.505(b)(17), which obligates Part D sponsors to use point of service systems to adjudicate claims in a timely and efficient manner. This was a result of SSIC's substantial failure to meet its obligation, stated at 42 C.F.R. § 423.505(b)(2), to process enrollments in a manner consistent with the requirements stated at 42 C.F.R. Part 423, Subpart B. In addition, SSIC is substantially out of compliance

with the requirement, stated at 42 C.F.R. § 423.800(b), that it charge its LIS-qualified enrollees the reduced cost sharing amounts to which they are entitled.

Since January 4, 2013, CMS has held daily conference calls with SSIC management to discuss SSIC's efforts to resolve its data systems issues. At each of these meetings, SSIC management has reported that they continue to design and implement updates to their data systems to improve the accuracy of SSIC's enrollment, LIS, and claims processing systems. However, as of January 15, 2013, SSIC's deficiencies remain unresolved. This is evidenced by SSIC's own identification of new issues as well as the daily receipt of numerous urgent complaints from its beneficiaries. Therefore, CMS concludes that SSIC has not yet fully diagnosed the root causes or the extent of its current failures, information which is critical to the development and execution of an effective corrective action plan. CMS expects that SSIC will use the enrollment and marketing suspension period as an opportunity to maintain its focus on coming into compliance promptly and ensuring that its members are consistently receiving the Part D benefits to which they are entitled.

**Legal Basis for Immediate Imposition of Marketing and Enrollment Sanctions**

As described above, since January 1, 2013, there SSIC has experienced widespread systems failures impacting its ability to correctly adjudicate Part D claims for its enrollees at the point of sale.

Therefore, CMS has determined that SSICs deficiencies provide a sufficient basis for the immediate imposition of intermediate sanctions (42 C.F.R. §§ 422.752(b) and 423.752(b)). CMS has determined that:

- SSIC substantially failed to carry out the terms of its Prescription Drug Plan contract with CMS (42 C.F.R. §423.509(a)(1)); and
- SSIC is carrying out its contracts with CMS in a manner that is inconsistent with the effective and efficient implementation of the program (42 C.F.R. §423.509(a)(2)).

*SSIC Deficiencies Create a Serious Threat to Enrollee Health and Safety*

SSIC has reported that its own records indicate that large numbers of its enrollees have been denied access to covered drugs. For example, SSIC reported to CMS on January 9, 2013, that its records show reversals of prescription drug claims for over 15,000 of its LIS plan enrollees since January 1, 2013. Claim reversals are frequently done when a beneficiary declines to have a prescription filled after being told by the pharmacist that his or her claim is denied or incorrectly adjudicated to require a higher cost-share than the beneficiary can afford.

Beneficiary access to prescribed medications is the most fundamental aspect of the Part D program because it most directly affects clinical care. The nature of SSIC's deficiencies, combined with the multiple reported instances of denied access to critical medications resulting from those deficiencies, provide a sufficient basis for CMS to find the presence of a serious threat to beneficiaries' health and safety supporting the immediate suspension of SSIC's Part D

enrollment and marketing activities. Consequently, these sanctions are effective on January 15, 2013, pursuant to the authority provided by 42 C.F.R. §423.756(c)(2).

**Corrective Action Steps**

As stated above, pursuant to 42 C.F.R. § 423.756(c)(3), the sanctions will remain in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. Attached to this notice is a template Corrective Action Plan with instructions for SSIC to complete. SSIC should submit its Corrective Action Plan to CMS seven (7) calendar days from the date of receipt of this notice, or by January 23, 2013. If SSIC needs additional time beyond seven (7) days to submit a corrective action plan contact your enforcement lead.

The Corrective Action Plan will assist SSIC in correcting the deficiencies that are the basis for the sanction determination as quickly as possible. The completed document will also guide communications with CMS and serve as a tool for CMS to monitor SSIC's progress.

Once SSIC has fully implemented its Corrective Action Plan and submitted to CMS an attestation from the SSIC's Chief Executive Officer, or most senior official, stating that SSIC has corrected the deficiencies that are the basis for the sanction and they are not likely to recur, validation activities will be scheduled by CMS. CMS will provide further guidance on validation activities in a subsequent notice to SSIC. The results of validation are used in conjunction with information gathered from SSIC's Corrective Action Plan, issues discovered during routine account management monitoring, and the identification of any additional sanction related issues to determine whether the underlying deficiencies have been corrected and are not likely to recur.

**Opportunity to Respond to Notice**

Pursuant to 42 C.F.R. § 423.756(a)(2), SSIC has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by January 28, 2013. Please note that CMS considers receipt as the day after the notice is sent by fax, e-mail, or overnight mail, or in this case, January 16, 2013. If you choose to submit a rebuttal, please send it to the attention of Gerard J. Mulcahy at the address noted below. Note that the sanctions imposed pursuant to this letter are not stayed pending a rebuttal submission.

**Right to Request a Hearing**

SSIC may also request a hearing before a CMS hearing officer in accordance with the procedures outlined in 42 C.F.R. § 423.650-662. Pursuant to 42 C.F.R. § 423.756(b), a written request for a hearing must be received by CMS within fifteen (15) calendar days of receipt of this notice, or by January 31, 2013. [1] Please note, however, a request for a hearing will not delay the date

[1] If the 15th day falls on a weekend or federal holiday, you have until the next regular business day to submit your request.

specified by CMS when the sanction becomes effective. Your hearing request will be considered officially filed on the date that it is mailed; accordingly, we recommend using an overnight traceable mail carrier.

The request for a hearing must be sent to the CMS Hearing Office at the following address:

Benjamin Cohen
CMS Hearing Officer
Office of Hearings
ATTN: HEARING REQUEST
Centers for Medicare & Medicaid Services
2520 Lord Baltimore Drive
Suite L
Mail Stop: LB-01-22
Baltimore, MD 21244-2670
Phone: 410-786-3169
Email: Benjamin.Cohen@cms.hhs.gov

A courtesy copy of the request should also be sent to the following CMS Official:

Patricia Axt
Director, Division of Compliance Enforcement
Program Compliance and Oversight Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop: C1-22-06
Baltimore, MD 21244
Email: Trish.Axt@cms.hhs.gov
FAX: 410-786-6301

CMS will consider the date the Office of Hearings receives the e-mail or the date it receives the fax or traceable mail document, whichever is earlier, as the date of receipt of the request. The request for a hearing must include the name, fax number and e-mail address of the contact within SSIC (or an attorney who has a letter of authorization to represent the organization) with whom CMS should communicate regarding the hearing request.

Pursuant to 42 C.F.R. §§ 423.507(b)(3) and 423.509(c) this notice also informs SSIC of its opportunity to correct the deficiencies stated in this notice. According to our regulations, SSIC is solely responsible for the identification, development and implementation of its Corrective Action Plan and for demonstrating to CMS that the underlying deficiencies have been corrected and are not likely to recur.

Please note that we are closely monitoring your organization and SSIC may also be subject to other applicable remedies available under law, including the imposition of additional sanctions, penalties, or other enforcement actions as described in 42 C.F.R. Part 423, Subparts K and O.

CMS believes these issues to be of such a serious nature that if left uncorrected, CMS will consider taking action to immediately terminate SSIC's contract.

If you have any questions about this notice, please call or email the enforcement contact provided in your email notification.

Sincerely,

**/s/**

Gerard J. Mulcahy
Acting Director
Program Compliance and Oversight Group

Enclosures:
Attachment A – Corrective Action Template

cc: James McCaslin, CMS/CMHPO/Region III
Tamara McCloy, CMS/CMHPO/Region III
Kathleen Dombrowski, CMS/CMHPO/Region III
John Whalen, CMS/CMHPO/Region III

**Silverscript Insurance Company (SSIC)**
**Corrective Action Plan**
**For: January 15, 2013 CMS Intermediate Sanctions (Suspension of Enrollment and Marketing) for Contract Number S5601**
**Submission Date: [insert date]**
**Version Number: [insert version #]**

## Part I

Instructions: For each of the deficiencies cited in the sanction notice, please use the template below to provide ***brief*** summary description of what caused the deficiency, the actions being taken to correct each deficiency and ensure it is not likely to recur, and the projected timeframe for correction.

Part I must not exceed 30 pages.

**Part D Benefit**

**SSIC's deficiencies:**

1. **Failure to use point of service systems to adjudicate claims in a timely and efficient manner, in violation of 42 C.F.R. § 423.505(b)(17).**

**What Caused the Deficiency to Occur?**

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

**What Specific Actions Will Be Taken To Correct the Deficiency?**
[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

*[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged) noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action*

*process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to all beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]*

**What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur?**

[For this heading, enter a brief summarized statement of what specific mechanisms will be instituted to ensure the deficiency is not likely to recur.]

**What is the Projected Timeframe for Correction of the Deficiency?**

[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

2. **Failure to process enrollments in a manner consistent with the requirements stated at 42 C.F.R. Subpart B, in violation of 42 C.F.R. § 423.505(b)(2).**

**What Caused the Deficiency to Occur?**

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

**What Specific Actions Will Be Taken To Correct the Deficiency?**

[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

*[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged) noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to all beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]*

**What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur?**

[For this heading, enter a brief summarized statement of what specific mechanisms will be instituted to ensure the deficiency is not likely to recur.]

**What is the Projected Timeframe for Correction of the Deficiency?**
[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

3. **Failure to properly administer the Low Income Subsidy (LIS) benefit, and in doing so, failure to charge LIS qualified members the reduced cost sharing amounts to which they are entitled, in violation of 42 C.F.R. § 423.800(b).**

**What Caused the Deficiency to Occur?**

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

**What Specific Actions Will Be Taken To Correct the Deficiency?**
[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

*[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged) noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to all beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]*
**What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur?**
[For this heading, enter a brief summarized statement of what specific mechanisms will be instituted to ensure the deficiency is not likely to recur.]

**What is the Projected Timeframe for Correction of the Deficiency?**
[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

**PART II**

Instructions: Using the projected timeframes provided above, create a timeline reflecting all planned corrective action. This timeline will be a detailed outline of a plan of action to correct all noted deficiencies. It should include (at a minimum) milestones with actions planned, projected completion dates, and accountable parties.

| **Deficiency # (from Part I)** | **Milestone/Activity Description** | **Accountable Parties** | **Projected Completion Date** |
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**Corrective Action Documentation Submitted By:**

**[Name]**
**[Title]**
**[Company]**
**[Address]**
**[Phone Number]**
**[Email Address]**

**(Signature)** **(Date)**