



August 9, 2010

Report Number: A-07-09-03136

Mr. Craig Bodway
Vice President, Compliance and Regulatory Affairs
Sterling Life Insurance Company
2219 Rimland Drive
Bellingham, WA 98226

Dear Mr. Bodway:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Sterling Life 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.

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

If you have any questions or comments about this report, please do not hesitate to call me at (816) 426-3591, or contact Dan Bittner, Audit Manager, at (515) 284-4674, extension 23, or through email at Dan.Bittner@oig.hhs.gov. Please refer to report number A-07-09-03136 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 & Medicaid Services
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Department of Health & Human Services

**OFFICE OF
INSPECTOR GENERAL**

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



Daniel R. Levinson
Inspector General

August 2010
A-07-09-03136

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 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

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. The Centers for Medicare & Medicaid Services (CMS), which administers Medicare, contracts with private prescription drug plans (Part D sponsors), which must apply to CMS to participate in the Part D program, to offer prescription drug benefits to eligible individuals.

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. Accordingly, CMS set forth regulations at 42 CFR § 423.504(b)(4)(vi) that require Part D sponsors to have a compliance plan. The compliance plan, which must be approved by CMS, articulates policies, processes, and procedures for Part D sponsors to detect, correct, and prevent FWA. Implementing a compliance plan includes conducting the activities described in the plan and developing comprehensive written procedures for activities referenced in the plan. The sponsors' compliance plans must contain the required components as set forth in these regulations; chapter 9 of CMS's *Prescription Drug Benefit Manual* contains further interpretation of the required components.

Sterling Life Insurance Company

Sterling Life Insurance Company (Sterling) is headquartered in Bellingham, Washington, and is a subsidiary of Munich-American Holding Corporation. Sterling became a Part D sponsor in 2006 and, during the period of this review, offered Part D drug plans in all 50 States and the District of Columbia. Sterling contracts with Express Scripts, Inc. (ESI), to provide pharmacy benefits management services including pharmacy auditing, claims processing, and formulary management.

OBJECTIVE

The objective of our review was to determine whether Sterling had adequate internal controls in place to detect, correct and prevent FWA in the Part D program during the period of July 1, 2007, through June 30, 2009.

SUMMARY OF FINDINGS

Sterling had several internal control weaknesses that compromised its ability to detect, correct and prevent FWA in the Part D program during the period of July 1, 2007, through June 30, 2009. Specifically:

- Sterling did not ensure that its employees completed compliance training pursuant to Federal regulations.
- Sterling did not require its contracted entities to provide compliance training to their employees as required by Federal regulations.
- Sterling did not perform monitoring activities of its contracted entities as required by Federal regulations.
- Sterling did not have a compliance committee pursuant to Federal regulations.

Sterling's Compliance Plan and its policies and procedures, if properly implemented, would enable Sterling to detect, correct and prevent FWA pursuant to Federal requirements. However, Sterling did not follow the provisions of its Compliance Plan and the policies and procedures pertaining to the compliance training of its employees and contracted entities, the monitoring of its contracted entities, and the designation of a compliance committee. As a result of these internal control weaknesses, Sterling compromised its ability to detect, correct and prevent FWA in the Part D program, and increased the risk that improper payments may have occurred.

RECOMMENDATIONS

We recommend that Sterling strengthen internal controls by following the provisions of its Compliance Plan by:

- establishing policies and procedures to maintain documentation to support that its employees completed compliance training pursuant to Federal regulations,
- revising its contracts to require that contracted entities provide compliance training to their employees as required by Federal regulations,
- adhering to its policies and procedures to monitor the activities of its contracted entities as required by Federal regulations, and

- adhering to its policies and procedures to establish a formal compliance committee pursuant to Federal regulations.

STERLING LIFE INSURANCE COMPANY COMMENTS

In written comments on our draft report, Sterling concurred with our recommendations and described corrective actions that it had implemented or planned to implement.

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

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INTRODUCTION

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. The Centers for Medicare & Medicaid Services (CMS), which administers Medicare, contracts with private prescription drug plans (Part D sponsors), which must apply to CMS to participate in the Part D program, to offer prescription drug benefits to eligible individuals.

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. Accordingly, CMS set forth regulations at 42 CFR § 423.504(b)(4)(vi) that require Part D sponsors to have a compliance plan. The compliance plan, which must be approved by CMS, articulates policies, processes, and procedures for Part D sponsors to detect, correct, and prevent FWA. Implementing a compliance plan includes conducting the activities described in the plan and developing comprehensive written procedures for activities referenced in the plan. The sponsors' compliance plans must contain the required components as set forth in these regulations; chapter 9 of CMS's *Prescription Drug Benefit Manual* contains further interpretation of the required components.

Sterling Life Insurance Company

Sterling Life Insurance Company (Sterling) is headquartered in Bellingham, Washington, and is a subsidiary of Munich-American Holding Corporation. Sterling became a Part D sponsor in 2006 and, during the period of this review, offered Part D drug plans in all 50 States and the District of Columbia. Sterling contracts with Express Scripts, Inc. (ESI), to provide pharmacy benefits management services including pharmacy auditing, claims processing, and formulary management.

Previous Office of Inspector General Work

The U.S. Department of Health & Human Services, Office of Inspector General, Office of Evaluation and Inspections (OEI), issued two reports regarding Part D sponsors' compliance plans and a third report that dealt more generally with the reporting of potential FWA on the parts of Part D sponsors. 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 as to the content of those plans. The second report, issued in October 2008 and entitled *Oversight of Prescription Drug Plan Sponsors' Compliance Plans* (OEI-03-08-00230), found that in calendar year 2007 CMS conducted only one audit of a Part D sponsor's compliance plan.

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 Part D sponsors identified in their reports of potential FWA.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objective of our review was to determine whether Sterling had adequate internal controls in place to detect, correct and prevent FWA in the Part D program during the period of July 1, 2007, through June 30, 2009.

Scope

We reviewed Sterling's internal controls that pertained to the detection, correction and prevention of FWA in the Part D program for the period of July 1, 2007, through June 30, 2009. We limited our review to Sterling's prescription drug plan, CMS contract number S4802. We did not test the claims processing edits that were in place to ensure that unallowable claims are properly rejected.

We conducted fieldwork at the corporate offices of Sterling in Bellingham, Washington, and of ESI in St. Louis, Missouri, and in our field office in Des Moines, Iowa, from September 2009 through March 2010.

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 Sterling and ESI officials to gain an understanding of both Sterling's FWA program and its internal controls to detect, correct and prevent FWA in the Part D program;
- reviewed Sterling's 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 Sterling's potential FWA cases for the period of July 1, 2007, through June 30, 2009;
- reviewed Sterling's contracts and requirements for its contracted entities that were responsible for the administration and delivery of the Part D program; and
- reviewed Sterling's compliance training documentation for 2007 and 2008.¹

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

Sterling had several internal control weaknesses that compromised its ability to detect, correct and prevent FWA in the Part D program during the period of July 1, 2007, through June 30, 2009. Specifically:

- Sterling did not ensure that its employees completed compliance training pursuant to Federal regulations.
- Sterling did not require its contracted entities to provide compliance training to their employees as required by Federal regulations.
- Sterling did not perform monitoring activities of its contracted entities as required by Federal regulations.
- Sterling did not have a compliance committee pursuant to Federal regulations.

¹ Sterling compiled its training documentation by calendar year. Therefore, the training documentation reviewed did not include information on training conducted in calendar year 2009.

Sterling's Compliance Plan and its policies and procedures, if properly implemented, would enable Sterling to detect, correct and prevent FWA pursuant to Federal requirements. However, Sterling did not follow the provisions of its Compliance Plan and the policies and procedures pertaining to the compliance training of its employees and contracted entities, the monitoring of its contracted entities, and the designation of a compliance committee. As a result of these internal control weaknesses, Sterling compromised its ability to detect, correct and prevent FWA in the Part D program, and increased the risk that improper payments may have occurred.

COMPLIANCE TRAINING FOR EMPLOYEES

Federal regulations at 42 CFR § 423.504(b)(4)(vi)(C) require that a Part D sponsor's compliance plan address effective training and education for the Part D sponsor's employees and its contracted entities. In addition, CMS guidance in the *Prescription Drug Benefit Manual*, chapter 9, § 50.2.3.1, states that Part D sponsors "... should maintain records of the time, attendance, topic and results of training."

Sterling's Compliance Plan requires that its employees complete compliance training and states, in Section IV (Training and Education), that "[e]ach member of Sterling's Workforce must receive initial and annual compliance training. Failure to comply with training requirements will result in disciplinary action, including possible termination." In addition, the Compliance Plan states that "[t]he Compliance Officer and appropriate Business Unit managers or supervisors, as applicable, shall document training of Sterling's Workforce and provide the documentation to the Compliance Officer. The documentation will include the time and date ... as well as listing Workforce members who attended (or otherwise received) the training."

Sterling did not follow the provisions of its Compliance Plan to ensure that its employees completed compliance training as required by Federal regulations. Notwithstanding the documentation requirements specified in its Compliance Plan, Sterling could not support with documentation that all of its employees completed compliance training. Sterling did not have proper procedures in place to ensure that each employee attended compliance training. Sterling retained sign-in sheets as documentation of the required training, but did not ensure that each of its employees attended the training. Thus, there is no assurance that all of Sterling's employees received appropriate compliance training.

COMPLIANCE TRAINING FOR CONTRACTED ENTITIES

Federal regulations at 42 CFR § 423.504(b)(4)(vi)(C) require that a Part D sponsor's compliance plan address effective training and education for the Part D sponsor's employees and its contracted entities. In addition, CMS guidance in the *Prescription Drug Benefit Manual*, chapter 9, § 50.2.3.2, states that (a) Part D sponsors should require that the contracted entities provide their own compliance training or, (b) where there are sufficient organizational similarities, Part D sponsors may choose to make their training programs available to the contracted entities.

In addition, Sterling's Compliance Plan requires, in Section IV (Training and Education), that its contracts include a provision that requires the contracted entities to provide compliance training to their employees.

Sterling did not follow the provisions of its Compliance Plan to ensure that the employees of its contracted entities received compliance training as required by Federal regulations. Specifically, Sterling did not contractually require its contracted entities to provide compliance training to their employees, as required by the Compliance Plan. Thus, there is no assurance that Sterling's contracted entities provided the required compliance training to their employees.

MONITORING OF CONTRACTED ENTITIES

Federal regulations at 42 CFR § 423.504(b)(4)(vi)(F) require that a Part D sponsor's compliance plan include procedures for effective internal auditing and monitoring. In addition, CMS guidance in the *Prescription Drug Benefit Manual*, chapter 9, § 40.1, emphasizes that Part D sponsors are ultimately responsible for ensuring that Federal requirements are met for any compliance functions delegated to contracted entities. In order to ensure that contracted entities are in compliance with Federal requirements, CMS guidance in Chapter 9, § 50.2.6.1.3, recommends that Part D sponsors have a plan in place to monitor and audit contracted entities' responsibilities and activities with respect to the administration and delivery of the Part D program.

In keeping with CMS guidance, Sterling's Compliance Plan addresses, in Section VII (Monitoring and Auditing), the monitoring of Sterling's contracted entities. In addition, Sterling's Vendor Oversight Policy identifies specific monitoring activities and requires that a compliance monitoring plan be in place for its contracted entities. Section IV of Sterling's Vendor Oversight Policy identifies specific areas to be addressed in the compliance monitoring plan, to include Federal requirements and contractual requirements.

Sterling did not follow the provisions of its Compliance Plan and policies and procedures relating to the monitoring of its contracted entities pursuant to Federal regulations. Specifically, Sterling did not have compliance monitoring plans in place to ensure that its contracted entities were in compliance with Federal and contractual requirements. Moreover, Sterling did not perform monitoring activities, as outlined in its Compliance Plan and policies and procedures, to ensure the ongoing compliance of its contracted entities. Thus, there is no assurance that Sterling's contracted entities were in compliance with Federal and contractual requirements.

FORMATION OF A COMPLIANCE COMMITTEE

Federal regulations at 42 CFR § 423.504(b)(4)(vi)(B) require that a Part D sponsor's compliance plan include the designation of a compliance officer and a compliance committee, both of whom are accountable to senior management. In addition, Sterling's Compliance Plan and policies and procedures require that Sterling establish a compliance committee. Sterling's Compliance Plan states, in Section II (Compliance Officer and Compliance Committee), that "Sterling will establish a Compliance Committee to advise the Compliance Officer and assist the Compliance Officer in implementation of this Compliance Plan.... The Compliance Committee will be accountable to senior management...."

Sterling did not follow the provisions of its Compliance Plan and policies and procedures relating to the designation of a compliance committee pursuant to Federal regulations.

Specifically, Sterling did not establish a formal compliance committee until May 2009. According to Sterling officials, an informal ad hoc committee served in place of a formal compliance committee. The absence of a formally designated compliance committee may have hindered Sterling's ability to effectively implement its Compliance Plan and communicate any potential risks associated with the Part D program to senior management.

RECOMMENDATIONS

We recommend that Sterling strengthen internal controls by following the provisions of its Compliance Plan by:

- establishing policies and procedures to maintain documentation to support that its employees completed compliance training pursuant to Federal regulations,
- revising its contracts to require that contracted entities provide compliance training to their employees as required by Federal regulations,
- adhering to its policies and procedures to monitor the activities of its contracted entities as required by Federal regulations, and
- adhering to its policies and procedures to establish a formal compliance committee pursuant to Federal regulations.

STERLING LIFE INSURANCE COMPANY COMMENTS

In written comments on our draft report, Sterling concurred with our recommendations and described corrective actions that it had implemented or planned to implement.

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

APPENDIX

APPENDIX: STERLING LIFE INSURANCE COMPANY COMMENTS

STERLING Life Insurance Company

Real People. Wise Choices.™

Sterling Life Insurance Company
2219 Rimland Drive
Bellingham, WA 98226

July 28, 2010

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

RE: Report Number A-07-09-03136

Dear Mr. Cogley:

Enclosed please find Sterling Life Insurance Company's (Sterling) response to the U.S. Department of Health and Human Services, Office of Inspector General (OIG) draft report entitled *Review of Sterling Life Insurance Company's Internal Controls to Guard Against Fraud, Waste and Abuse for the Medicare Part D Program*.

If you have any questions or comments please do not hesitate to call me at 360-392-9098, or contact Matthew Cooper, Compliance Analyst, at 360-392-9357, or through email at matthew.cooper@sterlingplans.com.

Sincerely,

Craig Bodway
Vice President, Compliance and Regulatory Affairs

Attachment

Sterling Life Insurance Company's response to the U.S. Department of Health and Human Services, Office of Inspector General (OIG) draft report entitled *Review of Sterling Life Insurance Company's Internal Controls to Guard Against Fraud, Waste and Abuse for the Medicare Part D Program* (Report Number A-07-09-03136)

Finding #1:

Sterling had several internal control weaknesses that compromised its ability to detect, correct and prevent FWA in the Part D program during the period of July 1, 2007, through June 30, 2009.

Sterling did not ensure that its employees completed compliance training pursuant to Federal regulations.

Recommendation:

We recommend that Sterling strengthen internal controls by following the provisions of its Compliance plan by establishing policies and procedures to maintain documentation to support that its employees completed compliance training pursuant to Federal regulations.

Response:

Sterling concurs with the recommendation. The Sterling Compliance Plan was implemented in January 2009 and revised in November 2009. The Compliance Plan contains policy and procedures outlining the training and education of Sterling's workforce. Elements of this training include, but are not limited to, an overview of the Part C and Part D programs; fraud, waste and abuse controls; privacy and security; and compliance training specialized for individual business units. The methods used to administer training were under development during the review period but have since been formalized. Initial and annual compliance training is administered by the Compliance Department and its effectiveness is measured through testing. Calendar year (CY) 2009 compliance training was completed in April 2010 and CY 2010 training will be conducted in September 2010, thence on an annual basis. The Compliance Department maintains employee records related to compliance training.

Finding #2:

Sterling had several internal control weaknesses that compromised its ability to detect, correct and prevent FWA in the Part D program during the period of July 1, 2007, through June 30, 2009.

Sterling did not require its contracted entities to provide compliance training to their employees as required by Federal regulations.

Recommendation:

We recommend that Sterling strengthen internal controls by following the provisions of its Compliance plan by revising its contracts to require that contracted entities provide compliance training to their employees as required by Federal regulations.

Response:

Sterling concurs with the recommendation. Sterling maintains oversight of contracted entities through the appointment of Vendor Relationship Managers who coordinate key functions and contract requirements between the parties. Upon request, Sterling's pharmacy benefit managers (PBMs) were able to provide documentary evidence of compliance training provided to their employees. The contract update process with Sterling's PBMs has been initiated and contracts will be amended to require contracted entities to provide compliance training to their employees.

Finding #3:

Sterling had several internal control weaknesses that compromised its ability to detect, correct and prevent FWA in the Part D program during the period of July 1, 2007, through June 30, 2009.

Sterling did not perform monitoring activities of its contracted entities as required by Federal regulations.

Recommendation:

We recommend that Sterling strengthen internal controls by following the provisions of its Compliance plan by adhering to its policies and procedures to monitor the activities of its contracted entities as required by Federal regulations.

Response:

Sterling agrees that it can improve its oversight of contracted entities. Sterling performed audits of its PBMs during the review period. Auditing of AmWins began on April 2, 2009, and was completed on June 10, 2009. ESI was audited in October 2008 and again, beginning in June 2009. This audit was finalized in September 2009. Auditing of both contracted entities addressed methods of controlling fraud, waste and abuse.

In an effort to further strengthen its oversight of contracted entities, Sterling implemented a program of vendor oversight in June 2009 and appointed Vendor Relationship

Managers tasked with the responsibility of overseeing and coordinating the key functions and contract requirements of Sterling's contracted entities. The oversight of Sterling's Part D PBMs was augmented with monitoring grids, which outline contractual and regulatory requirements and the methods used to meet them. The grids are used to identify potential gaps in meeting requirements before they occur. Vendor Relationship Managers report to Sterling senior management and the Compliance Officer.

Sterling will continue to utilize Vendor Relationship Managers and targeted audits to oversee and monitor the activities of its contracted entities.

Finding #4:

Sterling had several internal control weaknesses that compromised its ability to detect, correct and prevent FWA in the Part D program during the period of July 1, 2007, through June 30, 2009.

Sterling did not have a compliance committee pursuant to Federal regulations.

Recommendation:

We recommend that Sterling strengthen internal controls by following the provisions of its Compliance plan by adhering to its policies and procedures to establish a formal compliance committee pursuant to Federal regulations.

Response:

Sterling concurs with the recommendation and had modified its policies before the end of the period under review. Prior to October 2008, Sterling's Compliance Officer reported compliance matters on a quarterly basis to the Board of Directors, which is responsible for compliance oversight. The Compliance Office attended quarterly Board meetings and provided an oral report of compliance activities and oversight for the previous quarter, accompanied by a detailed written report. Since October 2008, Sterling's Compliance Officer submits a quarterly report to the Board of Directors Audit and Compliance Committee.

Sterling reorganized its management level Compliance Committee in April 2009 and held the first meeting of the reorganized committee in May 2009. Quarterly meetings have been held since that time. Duties of the Committee include but are not limited to: establishing standards of conduct and policies and procedures; performing a compliance risk assessment; and developing an annual internal audit plan.