



U.S. OFFICE OF PERSONNEL MANAGEMENT
OFFICE OF THE INSPECTOR GENERAL
OFFICE OF AUDITS

Final Audit Report

Subject:

AUDIT OF INFORMATION SYSTEMS
GENERAL AND APPLICATION CONTROLS AT
CVS CAREMARK

Report No. 1H-01-00-10-057

Date: May 17, 2011

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UNITED STATES OFFICE OF PERSONNEL MANAGEMENT
Washington, DC 20415

Office of the
Inspector General

Audit Report

FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

CVS CAREMARK

SCOTTSDALE, ARIZONA
NORTHBROOK, ILLINOIS

Pharmacy Benefits Manager For:

CONTRACT 1039 – BLUECROSS BLUESHIELD ASSOCIATION, CODES 104, 105, 111, 112
CONTRACT 1146 – MAIL HANDLERS BENEFIT PLAN, CODES 414, 415, 454, 455
CONTRACT 1073 – RURAL CARRIER BENEFIT PLAN, CODES 381, 382
CONTRACT 1067 – NATIONAL ASSOCIATION OF LETTER CARRIERS, CODES 322, 321

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A handwritten signature in black ink, appearing to read "Michael R. Esser".

Michael R. Esser
Assistant Inspector General
for Audits



UNITED STATES OFFICE OF PERSONNEL MANAGEMENT
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Executive Summary

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This final report discusses the results of our audit of general and application controls over the information systems at CVS Caremark (Caremark).

Our audit focused on the claims processing applications used by Caremark to adjudicate Federal Employees Health Benefits Program (FEHBP) claims, as well as the various processes and information technology (IT) systems used to support these applications. We documented controls in place and opportunities for improvement in each of the areas below.

Security Management

Caremark has established a comprehensive series of IT policies and procedures to create an awareness of IT security. We verified that Caremark's policies and procedures are maintained on the company's intranet site in a manner that is easily accessible by employees.

Access Controls

We found that Caremark has implemented numerous physical controls to prevent unauthorized access to its facilities, as well as logical controls to prevent unauthorized access to its

information systems. However, we did note several opportunities for improvement related to Caremark's physical and logical access controls.

Configuration Management

Caremark has developed formal policies and procedures providing guidance to ensure that system software is appropriately configured and updated, as well as for controlling system software configuration changes.

Contingency Planning

We reviewed Caremark's business continuity plans and concluded that they contained most of the key elements suggested by relevant guidance and publications. We also determined that these documents are reviewed, updated, and tested on a periodic basis.

Claims Adjudication

Caremark has implemented many controls in its claims adjudication process to ensure that FEHBP claims are processed accurately. However, we recommended that Caremark implement several system modifications to ensure that its claims processing systems adjudicate FEHBP claims in a manner consistent with the OPM contract and other regulations.

Health Insurance Portability and Accountability Act (HIPAA)

Nothing came to our attention that caused us to believe that Caremark is not in compliance with the HIPAA security, privacy, and national provider identifier regulations.

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I. Introduction

This audit report details the findings, conclusions, and recommendations resulting from the audit of general and application controls over the information systems responsible for processing Federal Employees Health Benefits Program (FEHBP) claims by CVS Caremark (Caremark).

The audit was conducted pursuant to applicable FEHBP contracts; 5 U.S.C. Chapter 89; and 5 Code of Federal Regulations (CFR) Chapter 1, Part 890. The audit was performed by the U.S. Office of Personnel Management's (OPM) Office of the Inspector General (OIG), as established by the Inspector General Act of 1978, as amended.

Background

The FEHBP was established by the Federal Employees Health Benefits Act (the Act), enacted on September 28, 1959. The FEHBP was created to provide health insurance benefits for federal employees, annuitants, and qualified dependents. The provisions of the Act are implemented by OPM through regulations codified in Title 5, Chapter 1, Part 890 of the CFR. Health insurance coverage is made available through contracts with various carriers that provide service benefits, indemnity benefits, or comprehensive medical services.

Caremark is the pharmacy benefit manager responsible for processing prescription drug claims on behalf of the following FEHBP insurance carriers:

- Blue Cross Blue Shield Federal Employee Program (contract CS 1039);
- Mail Handlers Benefit Plan (contract CS 1146);
- Rural Carrier Benefit Plan (contract CS 1073); and
- National Association of Letter Carriers (contract CS 1067).

This was our first audit of Caremark's general and application controls. We also reviewed Caremark's compliance with the Health Insurance Portability and Accountability Act (HIPAA).

All Caremark personnel that worked with the auditors were particularly helpful and open to ideas and suggestions. They viewed the audit as an opportunity to examine practices and to make changes or improvements as necessary. Their positive attitude and helpfulness throughout the audit was greatly appreciated.

Objectives

The objectives of this audit were to evaluate controls over the confidentiality, integrity, and availability of FEHBP data processed and maintained in Caremark's IT environment.

We accomplished these objectives by reviewing the following areas:

- Security management;
- Access controls;
- Configuration management;
- Segregation of duties;

- Contingency planning;
- Application controls specific to Caremark's claims processing systems; and
- Health Insurance Portability and Accountability Act (HIPAA) compliance.

Scope

This performance audit was conducted in accordance with generally accepted government auditing standards issued by the Comptroller General of the United States. Accordingly, we obtained an understanding of Caremark's internal controls through interviews and observations, as well as inspection of various documents, including information technology and other related organizational policies and procedures. This understanding of Caremark's internal controls was used in planning the audit by determining the extent of compliance testing and other auditing procedures necessary to verify that the internal controls were properly designed, placed in operation, and effective.

The scope of this audit centered on the information systems used by Caremark to process prescription benefit claims for FEHBP members, with a primary focus on the Quantum Leap (QL) and Remote Electronic Claims Adjudication Process (RECAP) claims adjudication applications.

The on-site portion of this audit was performed in July and August of 2010. We completed additional audit work before and after the on-site visits at our office in Washington, D.C. The findings, recommendations, and conclusions outlined in this report are based on the status of information system general and application controls in place at Caremark as of October 1, 2010.

In conducting our audit, we relied to varying degrees on computer-generated data provided by Caremark. Due to time constraints, we did not verify the reliability of the data used to complete some of our audit steps but we determined that it was adequate to achieve our audit objectives. However, when our objective was to assess computer-generated data, we completed audit steps necessary to obtain evidence that the data was valid and reliable.

Methodology

In conducting this review we:

- gathered documentation and conducted interviews;
- reviewed Caremark's business structure and environment;
- performed a risk assessment of Caremark's information systems environment and applications, and prepared an audit program based on the assessment and the Government Accountability Office's (GAO) Federal Information System Controls Audit Manual (FISCAM); and
- conducted various compliance tests to determine the extent to which established controls and procedures are functioning as intended. As appropriate we used judgmental sampling in completing our compliance testing.

Various laws, regulations, and industry standards were used as a guide to evaluating Caremark's control structure. This criteria includes, but is not limited to, the following publications:

- Title 48 of the Code of Federal Regulations (CFR);
- Office of Management and Budget (OMB) Circular A-130, Appendix III;
- OMB Memorandum 07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information;
- Information Technology Governance Institute's CobiT: Control Objectives for Information and Related Technology;
- GAO's FISCAM;
- National Institute of Standards and Technology's Special Publication (NIST SP) 800-12, Introduction to Computer Security;
- NIST SP 800-14, Generally Accepted Principles and Practices for Securing Information Technology Systems;
- NIST SP 800-30, Risk Management Guide for Information Technology Systems;
- NIST SP 800-34, Contingency Planning Guide for Information Technology Systems;
- NIST SP 800-41, Guidelines on Firewalls and Firewall Policy;
- NIST SP 800-53 Revision 3, Recommended Security Controls for Federal Information Systems;
- NIST SP 800-61, Computer Security Incident Handling Guide;
- NIST SP 800-66 Revision 1, An Introductory Resource Guide for Implementing the HIPAA Security Rule; and
- HIPAA Act of 1996.

Compliance with Laws and Regulations

In conducting the audit, we performed tests to determine whether Caremark's practices were consistent with applicable standards. While generally compliant, with respect to the items tested, Caremark was not in complete compliance with all standards as described in the "Audit Findings and Recommendations" section of this report.

II. Audit Findings and Recommendations

A. Security Management

The security management component of this audit involved the examination of the policies and procedures that are the foundation of Caremark's overall IT security controls. We evaluated Caremark's ability to develop security policies, manage risk, assign security-related responsibility, and monitor the effectiveness of various system-related controls.

Caremark has implemented a series of formal policies and procedures that comprise a comprehensive security management program. These policies are readily available to all Caremark employees via the company's intranet site and are reviewed and updated on a regular basis. Caremark has also developed a thorough risk management methodology, and has procedures to document, track, and alleviate or accept identified risks. We also reviewed Caremark's human resources policies and procedures related to the security aspects of hiring, training, transferring, and terminating employees.

Nothing came to our attention to indicate that Caremark does not have an adequate security management program.

B. Access Controls

Access controls are the policies, procedures, and controls used to prevent or detect unauthorized physical or logical access to sensitive resources.

We examined the physical access controls of several Caremark facilities including a data center, a mail-order pharmacy, a Regional Order Creation Center, and several office buildings. We also examined the logical controls protecting sensitive data in Caremark's network environment and claims processing related applications.

The access controls observed during this audit include, but are not limited to:

- procedures for appropriately granting and revoking physical access privileges to the data center;
- multi-factor authentication requirements to enter the data center;
- procedures to monitor local and remote access to networks and applications;
- use of software tools to monitor and filter email and Internet activity; and
- adequate intrusion detection and incident response capabilities.

However, we did note several opportunities for improvement related to Caremark's physical and logical access controls.

1. Facility Physical Access Controls

The physical access controls at two Caremark office buildings were substantially weaker than controls typically implemented at other FEHBP contractor facilities.

We observed significant problems [REDACTED] at one facility. Although Caremark has a corporate policy prohibiting [REDACTED] and has issued educational reminders to its employees in an attempt to reduce it, there are no [REDACTED] in place to restrict this practice.

The other facility does not require [REDACTED]

[REDACTED] Although Caremark is not aware of any successful physical security breaches, we believe that the limited controls in place are insufficient, [REDACTED]

The draft audit report outlined specific physical access controls that are not implemented at the Caremark facilities, but are common at other FEHBP contractor facilities routinely visited by the OIG.

Failure to implement adequate physical access controls increases the risk that unauthorized individuals can gain access to Caremark facilities and the sensitive IT resources and confidential data they contain. NIST SP 800-53 Revision 3, Recommended Security Controls for Federal Information Systems, provides guidance for adequately controlling physical access to information systems containing sensitive data.

Recommendation 1

We recommend that Caremark review the physical access controls in place at its facilities and analyze the feasibility of implementing the controls outlined in the draft audit report.

CVS Caremark Response:

“Although we feel that our current security is sufficient, CVS Caremark concurs with the physical access controls recommendation and plans to [REDACTED] at the . . . operations centers no later than the conclusion of the [REDACTED]. [REDACTED] building entrances are also under video surveillance and are monitored in conjunction with the alarm systems on a 24/7 basis by our Corporate Security Operations Center.”

OIG Reply:

We acknowledge the steps Caremark is taking to address this audit recommendation. As part of the audit resolution process, we recommend that Caremark provide OPM's Audit Resolution staff with evidence that the access card controlled turnstiles have been installed.

2. Removal of System Access Privileges

Caremark's procedures for removing access privileges for terminated employees to the [REDACTED] could be improved.

We compared a list of Caremark employees terminated in 2010 to active user lists of five Caremark applications supporting the claims adjudication process. We also reviewed current Windows Active Directory users. We found no active accounts for terminated employees in four of the five applications or Active Directory. However, we discovered that 27 terminated employees still had active accounts in [REDACTED].

Users must be authenticated to the Caremark network in order to access [REDACTED]. However, users' [REDACTED] accounts are not synchronized with their Active Directory accounts. Therefore, an individual with an active [REDACTED] account could access the system from *any* Active Directory account, limiting the effectiveness of this compensating control.

The Federal Information System Controls Audit Manual (FISCAM) section 4.2 states that organizations should implement controls to ensure "prompt termination of access to the entity's resources and facilities...." Failure to promptly remove the system access of terminated employees increases the risk that unauthorized individuals can gain access to sensitive IT resources and the confidential data they contain.

Recommendation 2

We recommend that Caremark evaluate the procedures for removing [REDACTED] user accounts to determine why user access problems exist with this system when there were no issues with the other tested applications. Caremark should implement new controls to ensure that system access to [REDACTED] is promptly disabled following an employee termination.

CVS Caremark Response:

"CVS Caremark concurs with the recommendation for the removal of system access privileges for [REDACTED]. System access to the [REDACTED] system is maintained in the department that primarily uses the system. This includes both the Prior Authorization (PA) and Appeals department. During Q3 and Q4 2010, both department saw a number of personnel changes. Some of these changes were not executed in a timely manner to properly block and revoke access to the [REDACTED] system.

These departments have identified a new process to strengthen the communication between the PA and Appeals teams to ensure that all terminations are being communicated to the administrative team to properly deactivate access immediately. A monthly and quarterly review has been added to the process to ensure terminated employees do not remain on the [REDACTED] system. A report of all terminated employees will be run on a monthly

basis and compared to ██████ to verify access has been removed on all terminated employees. In addition, a quarterly reconciliation will be conducted by our Information Security team to verify that only valid staff has access to the ██████ system. We feel that these added controls will strengthen the terminated user process for ██████ and sufficiently address the auditors concerns.”

OIG Reply:

We acknowledge the steps Caremark is taking to address this audit recommendation. As part of the audit resolution process, we recommend that Caremark provide OPM’s Audit Resolution staff with evidence that the additional controls described by Caremark have been implemented.

C. Configuration Management

Caremark uses two primary claims adjudication systems to process FEHBP member claims: QL and RECAP. The QL system is housed on a mainframe environment with a z/OS operating platform. The RECAP system is housed on HP NonStop servers. We evaluated Caremark’s management of the configuration of QL and RECAP and determined that the following controls were in place:

- policies and procedures for ensuring that operating platforms are securely configured;
- controls for securely managing changes to the operating platforms and claims processing applications;
- controls for monitoring privileged user activity on the operating platform;
- procedures for routinely updating and patching the operating platforms; and
- procedures for monitoring configuration through vulnerability scans and periodic access review audits.

Nothing came to our attention to indicate that Caremark does not have adequate controls related to configuration management.

D. Contingency Planning

We evaluated Caremark’s contingency planning methodology to determine whether it contained adequate procedures for maintaining critical services for its customers should business operations be disrupted. The following elements of Caremark’s contingency planning program were reviewed:

- business continuity plans for several business units including claims processing, data center operations, and customer care;
- disaster recovery plan for the QL and RECAP claims processing system;
- disaster recovery plan tests conducted in conjunction with the recovery site; and
- emergency response procedures and training.

We determined that the service continuity documentation reviewed contained the critical elements suggested by NIST SP 800-34, “Contingency Planning Guide for IT Systems.”

Caremark has identified and prioritized the systems and resources that are critical to business operations, and has developed detailed procedures to recover those systems and resources.

Nothing came to our attention to indicate that Caremark has not implemented adequate controls related to contingency planning.

E. Claims Adjudication

The following sections detail our review of the applications and business processes supporting Caremark's claims adjudication process.

1. Claims Processing Controls

We evaluated the input, processing, and output controls associated with Caremark's claims adjudication systems. We determined that Caremark has implemented policies and procedures to help ensure that:

- claims processors are adequately trained;
- validated claims scheduled for payment were actually paid;
- claims are monitored as they are processed through the systems with real time tracking of the system's performance; and
- paper claims that are received in the mail room are tracked to ensure timely processing.

2. Enrollment

We evaluated Caremark's procedures for managing its enrollment databases containing data for members enrolled in the FEHBP insurance plans (Plans) it provides prescription benefits for, including:

- Blue Cross Blue Shield Federal Employee Program (FEP);
- Mail Handlers Benefit Plan (MHBP);
- Rural Carrier Benefit Plan (RCBP); and
- National Association of Letter Carriers (NALC).

Caremark maintains its enrollment databases with electronic update files that are routinely sent from the Plans. The update files only contain enrollment data for members that were added or removed from the Plan since the last file was sent.

Caremark conducts quarterly reviews of its FEP enrollment database to ensure its accuracy. However, Caremark does not conduct similar reviews for the MHBP, RCBP, and NALC Plans.

Although Caremark reviews each update file for MHBP, RCBP, and NALC, it does not review the full enrollment databases unless errors are detected in the update file at the time it is initially sent (missing fields, improper format, etc.). Therefore, any undetected errors in enrollment updates from these plans would remain in Caremark's database indefinitely, increasing the risk that prescription benefits are being paid for ineligible individuals.

Recommendation 3

We recommend that Caremark routinely reconcile the full enrollment databases for MHBP, RCBP, and NALC

CVS Caremark Response:

“CVS Caremark believes our current enrollment process with MHBP, RCBP and NALC is sufficient; however, we do recognize the value of the recommended additional control suggested by the OIG. In 2011, CVS Caremark will reach out to each of these FEHBP plans and discuss the options for enhancing the eligibility process.”

OIG Reply:

We acknowledge the steps Caremark is taking to address this audit recommendation. As part of the audit resolution process, we recommend that Caremark provide OPM’s Audit Resolution staff with evidence of its efforts to implement additional controls related to enrollment database reconciliation.

3. Debarment

Caremark’s procedures for maintaining its debarred provider database could be improved.

The provider information for all claims processed by Caremark is compared to the company’s debarred provider database, and any claims submitted by a debarred provider are appropriately denied. Caremark updates its provider database with monthly exclusion files issued by the United States Department of Health and Human Services (HHS) OIG and the General Services Administration (GSA). However, Caremark does not update its debarment database with the debarred provider listing maintained by OPM OIG.

Failure to update the debarment database with the OPM OIG exclusion list increases the risk that claims are being paid to providers that are debarred by OPM but not by HHS or GSA.

Recommendation 4

We recommend that Caremark implement procedures to routinely update its debarment database with OPM OIG’s debarred provider listing.

CVS Caremark Response:

“Our current process eliminates nearly all debarred providers and is sufficient. However, CVS Caremark concurs with the recommendation to utilize the OPM’s debarred provider listing. We are now receiving this listing from BCBSA on a regular periodic basis and expect to implement a process to routinely utilize the OPM Debarred Provider Listing by the end of the first quarter 2011.”

OIG Reply:

We acknowledge the steps Caremark is taking to address this audit recommendation. As part of the audit resolution process, we recommend that Caremark provide OPM's Audit Resolution staff with evidence that it is using the OPM debarred provider listing to update its debarment database.

4. Application Controls Testing

We conducted a testing exercise on Caremark's QL and RECAP claims adjudication applications. The exercise involved developing test claims that included realistic situations to present to Caremark claims adjudicators. The Caremark adjudicators entered the claims into the test claims processing environments, and the actual results produced by the systems were compared to our expected results.

The sections below document opportunities for improvement related to Caremark's application controls.

a) [REDACTED]

Caremark's QL and RECAP claims processing applications do not have the ability to detect prescriptions containing [REDACTED].

We submitted test claims into QL and RECAP for prescriptions written by [REDACTED]. The [REDACTED] for these providers had a valid structure [REDACTED] but they were not assigned [REDACTED]. We also submitted test claims that contained a [REDACTED] without an [REDACTED].

Both QL and RECAP suspended the claims containing [REDACTED] [REDACTED]. However, all claims with an [REDACTED] were processed and paid without encountering any system edits or suspensions, even though the [REDACTED] was not assigned to a [REDACTED].

Caremark representatives stated that it is the responsibility of the pharmacist filling the prescription to [REDACTED]. The "Provider Manual" that Caremark provides to pharmacies contains the following text:

"Identification of the Prescriber requires a [REDACTED] For all claims, including controlled substance prescriptions, [REDACTED] [REDACTED] may be submitted as permitted by State and Federal law."

This statement simply requires providers (pharmacies) to include the [REDACTED] a claim form; it does not state or imply that the provider must research [REDACTED].

We believe that it is the responsibility of Caremark to verify that prescriptions [REDACTED] prior to authorizing a claim for payment. A centralized method of verifying [REDACTED] would be more efficient than relying on the efforts of various pharmacies whose processes Caremark cannot control, and would also provide Caremark assurance that all claims are verified with consistent quality.

The weakness in the current control structure could be exploited by individuals [REDACTED]. If the pharmacist filling the prescription does not detect the anomaly, Caremark will pay benefits for the claim and the individual will gain unauthorized access to prescription drugs.

Caremark has demonstrated that it has the capability to verify [REDACTED] for validity, as this check is conducted for claims submitted through its mail-order system. We believe that consistent controls should be in place in the QL and RECAP systems.

Recommendation 5

We recommend that Caremark make the appropriate system modifications to the QL and RECAP systems in order to detect claims being processed with [REDACTED]

CVS Caremark Response:

“CVS Caremark disagrees with this recommendation for two central reasons: (1) a [REDACTED] is still in development; (2) this responsibility belongs to the dispensing pharmacist and his/her judgment. While the industry is moving in the direction of having a [REDACTED] which is complete and accurate, in our opinion, this objective has not yet been reached and member disruption could be significant. The dispensing pharmacists have a professional responsibility to review the FEHBP member’s prescription and determine its validity based on professional judgment and state and federal dispensing guidelines.

In 2011, CVS Caremark is offering an OIG debarred prescriber edit to our commercial and FEHBP clients. Clients can elect for the claims adjudication system to the reject claims written from prescribers debarred by the OIG.”

OIG Reply:

We believe that relying on the efforts of individual pharmacies to detect prescriptions [REDACTED] does not provide an adequate level of control. Although many pharmacies may have the resources to [REDACTED], Caremark has no way to ensure that this is being done on a consistent basis by the thousands of pharmacies in its provider network. A centralized method of verifying [REDACTED] would increase the efficiency and reliability of this process.

A current database of [REDACTED] is actively maintained by the Centers for Medicare and Medicaid Services. Caremark has demonstrated that it has the capability to verify [REDACTED] for validity, as this check is conducted for claims submitted through

its mail-order system. We continue to recommend that consistent controls should be in place in the QL and RECAP systems.

b) [REDACTED]

Caremark's QL and RECAP claims processing applications do not have the ability to detect claims for [REDACTED]

We submitted test claims into QL and RECAP for [REDACTED]. Both QL and RECAP processed and paid the claims without encountering any system edits or suspensions even though [REDACTED].

We performed a computer search to identify claims for [REDACTED] that were incurred and paid for BlueCross BlueShield FEP members. The computer search was based on pharmacy laws in all 50 states plus the District of Columbia, as outlined in the 2010 Survey of Pharmacy Law produced by the National Association of Boards of Pharmacy. The majority of state laws require drugs [REDACTED]. The following exceptions were incorporated into our search:

- States with [REDACTED] (excluded from search)
 - Alabama
 - California
 - Connecticut
 - District of Columbia
 - Georgia
 - Massachusetts
 - New Mexico
 - New York
 - South Dakota
- States with [REDACTED]
 - Idaho – [REDACTED]
 - Iowa – [REDACTED]
 - Maine – [REDACTED]
 - Oregon – [REDACTED]
 - South Carolina – [REDACTED]
 - Wyoming – [REDACTED]

For the period of July 21, 2007 through May 31, 2010, we identified 13,334 prescription drug claims totaling \$577,655 in payments (see table below for details) for prescriptions dispensed in violation of the applicable state law regarding [REDACTED]

<u>Year</u>	<u>Number of Unallowable Claims</u>	<u>Unallowable Claim Payments</u>
2007	1,367	\$67,704
2008	4,754	\$200,613
2009	4,795	\$200,325
2010	2,418	\$109,013
TOTAL	13,334	\$577,655

Caremark representatives stated that it is the responsibility of the pharmacist filling the prescription [REDACTED]. Caremark's Provider Manual contains the following text regarding the *Document Requirements of Original Prescriptions*:

"Prescription records must be [REDACTED] required by applicable Law; if applicable Law does not specify a [REDACTED] Caremark requires that prescription hard copies be [REDACTED]."

However, the high volume of claims paid by Caremark for [REDACTED] indicates that reliance on individual pharmacies to detect these claims is an insufficient control.

We believe that Caremark should modify its systems to alert pharmacies when they are attempting to submit a claim [REDACTED]. At a minimum, the alert should direct pharmacists to verify that they correctly transcribed [REDACTED] from the prescription into the claim form.

Caremark has demonstrated that it has the capability [REDACTED] [REDACTED]n, as this check is conducted for claims submitted through its mail-order system. We believe that consistent controls should be in place in the QL and RECAP systems.

Recommendation 6

We recommend that Caremark make the appropriate system modifications to the QL and RECAP systems to alert pharmacies when they submit claims for [REDACTED]

CVS Caremark Response:

"CVS Caremark disagrees with this recommendation. It is the dispensing pharmacy's responsibility to review each prescription and dispense according to State and Federal guidelines. Each State has separate and distinct pharmacy laws and regulations regarding [REDACTED] that the licensed pharmacists within that state are required to follow. Coding our adjudication systems to reject a claim based on individual state laws and guidelines would not be feasible or appropriate and it could potentially interfere with a member receiving proper therapy on a timely basis. It should be noted that CVS Caremark also monitors the pharmacy network through our pharmacy audit procedures. Reviewing for [REDACTED] is part of the audit program. CVS Caremark believes that this network monitoring process is a sufficient control to ensure [REDACTED]."

....

A review of these individual State pharmacy laws leads to two conclusions: (1) actual State laws are complex and diverse and applying [REDACTED] [REDACTED] for all is inappropriate; (2) given the above complexities and regulatory reliance on the professional discretion of pharmacists and/or prescribers means it is not practical to modify our adjudication system to reject claims in the manner recommended."

OIG Reply:

We acknowledge the fact that dispensing pharmacies have responsibility to review each prescription and dispense according to State and Federal guidelines. However, the high volume of claims paid by Caremark for [REDACTED] indicates that reliance on individual pharmacies is an insufficient control.

In each of the claims identified, an FEHBP member obtained a drug [REDACTED]. This creates a potentially dangerous situation for the member as use of this medication may no longer be safe [REDACTED]. We believe that the recommended system modification will enhance the well-being of FEHBP members and also ensure that Caremark will not continue to pay claims for prescriptions filled in violation of state laws.

Although pharmacy laws vary by state, there are a finite number of variations and it is reasonable for a nationwide PBM like Caremark to factor all of these laws into a modification of its claims adjudication system. In fact, similar controls currently exist in Caremark's mail-order claims system, indicating that the company has the ability to implement the recommended system edit. We continue to recommend that Caremark make the appropriate system modifications to the QL and RECAP systems to alert pharmacies when they submit claims for [REDACTED]

c) Toxic Acetaminophen Levels

Caremark's QL and RECAP claims processing applications do not have the ability to detect a series of claims containing a toxic level of acetaminophen (APAP) submitted for a single member.

Caremark is aware of the high risk of abuse with APAP and has implemented an "APAP Toxicity Program" to identify members whose prescription profile shows a toxic level of APAP usage. However, this program only reviews claims data on a post-payment basis, and does not prevent toxic levels of the drugs from being dispensed to its members.

We submitted a series of test claims for prescriptions containing APAP into QL and RECAP. The results of the test claims indicated that both systems will deny a single claim if the prescribed dosage is more than twice the recommended daily dosage as defined by the manufacturer of that specific drug. However, if APAP is distributed through a series of multiple claims, Caremark's systems cannot detect toxic levels of the ingredient. Our tests included 4 claims for 4 different drugs containing APAP submitted for a single member on the same day. Both QL and RECAP processed and paid all four claims without encountering any edits or warnings even though the total acetaminophen dosage for that member was 12,625 milligrams (mg) per day, well over the 5,000 mg per day considered toxic by Caremark's APAP Toxicity Program.

We believe that implementing preventive controls to detect claims containing toxic levels of APAP would reduce the level of fraud, waste, and abuse related to drugs containing this ingredient.

Recommendation 7

We recommend that Caremark make the appropriate system modifications to the QL and RECAP systems in order to detect a series of claims containing a toxic level of APAP.

CVS Caremark Response:

“CVS Caremark became aware of this issue and initiated a project to improve the controls over the ability to detect toxic levels of Acetaminophen in early 2010, well before the start of the OIG audit. The project was in the testing phase when the audit started and was fully implemented for BCBSA on February 1, 2011. These changes include the following:

1) Max Dose Edit: This is a hard edit that sends a message of "HD-Max Dose= X". This message will display when the dose on a single claim is 1.75 times greater than the FDB max dose.

2) Umbrella Limit: The umbrella limits allow for the following:

- 1) 750mg umbrella- All products containing 750mg of APAP are limited to 480 dosage units every rolling 90 days*
- 2) 650/660mg umbrella- All products containing 650 or 660mg of APAP are limited to 554 dosage units every rolling 90 days*
- 3) 500mg umbrella- All products containing 500mg of APAP are limited to 720 dosage units every rolling 90 days*
- 4) 325mg umbrella- All products containing 325mg of APAP, or less, are limited to 1,108 dosage forms every rolling 90 days*

In addition there is a “catch-all” umbrella limit that limits the total accumulated quantity of any combination of legend APAP containing products to less than 1,104 dosage units per rolling 90 days. These limits represent the maximum number of tablets it takes to have a daily dose greater than 4grams per day, every day for 90 days. This edit looks at all prescriptions in a rolling 90 day, rather than just single claims.

Also, both BCBSA and CVS Caremark monitors APAP toxicity and do focus on accumulation of multiple prescriptions for a total grams/day calculation. This program is a quarterly review on a look back of 120 days of member utilization. Once members are identified there is an outreach to educate them on the risks.”

OIG Reply:

We believe that the new umbrella limits added to QL and RECAP adequately address the audit recommendation. We will test the effectiveness of these controls as part of the next audit; no further action is required at this time.

F. Health Insurance Portability and Accountability Act

The OIG reviewed Caremark's efforts to maintain compliance with the security and privacy standards of HIPAA.

Caremark has implemented a series of IT security policies and procedures to adequately address the requirements of the HIPAA security rule. Caremark has also developed a series of privacy policies and procedures that directly addresses all requirements of the HIPAA privacy rule. The documents related to the HIPAA privacy and security rules are readily available to all Caremark employees via the company's intranet website. Caremark employees receive HIPAA-related training during new hire orientation, as well as annual refresher training.

Nothing came to our attention that caused us to believe that Caremark is not in compliance with the various requirements of HIPAA regulations.

III. Major Contributors to This Report

This audit report was prepared by the U.S. Office of Personnel Management, Office of Inspector General, Information Systems Audits Group. The following individuals participated in the audit and the preparation of this report:

- [REDACTED], Group Chief
- [REDACTED], Senior Team Leader
- [REDACTED], IT Auditor
- [REDACTED], IT Auditor
- [REDACTED], IT Auditor
- [REDACTED], IT Auditor



Appendix I

February 23, 2011

[REDACTED], Senior Team Leader
Information Systems Audits Group
Insurance Service Programs
Office of Personnel Management
1900 E Street, N.W., Room 6400
Washington, D.C. 20415

Re: OPM DRAFT EDP AUDIT REPORT: CVS/Caremark- Blue Cross Blue Shield
Retail Pharmacy Vendor - Audit Report Number 1H-01-00-10-057

Dear [REDACTED]:

This report is in response to the above-referenced U.S. Office of Personnel Management (OPM) Draft Audit Report detailing the results of your audit of the information systems general and application controls conducted at our offices during 2010. Your audit covered the general and application controls over the automated claims processing systems and other related computer –based systems at CVS Caremark. The following is a list of FEHBP insurance carriers included in your review:

- Blue Cross Blue Shield Federal Employee Program (contract CS 1039);
- Mail Handlers Benefit Plan (contract CS 1146);
- Rural Carrier Benefit Plan (contract CS 1073); and
- National Association of Letter Carriers (contract CS 1067).

We have reviewed your draft audit report in detail and commented on each of your recommendations below.

Section B. Access Controls – a) Facility Physical Access Controls

OIG Recommendation 1: We recommend that Caremark review the physical access controls in place at its facilities and analyze the feasibility of implementing the controls outlined in the report.

CVS Caremark Response: Although we feel that our current security is sufficient, CVS Caremark concurs with the [REDACTED] recommendation and plans to [REDACTED] at the [REDACTED]

Redacted by OPM/OIG operations centers no later than the conclusion of the [REDACTED]. The entrances to these facilities are currently monitored by security officers during business hours. The building entrances are also under video surveillance and are monitored in conjunction with the alarm systems on a 24/7 basis by our Corporate Security Operations Center.

Section B. Access Controls – b) Removal of System Access Privileges

OIG Recommendation 2: We recommend that Caremark evaluate the procedures for removing [REDACTED] user accounts to determine why user access problems exist with this system when there were no issues with the other tested applications. Caremark should implement new controls to ensure that system access to [REDACTED] is promptly disabled following an employee termination.

CVS Caremark Response: CVS Caremark concurs with the recommendation for the removal of system access privileges for [REDACTED]. System access to the [REDACTED] system is maintained in the department that primarily uses the system. This includes both the Prior Authorization (PA) and Appeals department. During Q3 and Q4 2010, both departments saw a number of personnel changes. Some of these changes were not executed in a timely manner to properly block and revoke access to the [REDACTED] system.

These departments have identified a new process to strengthen the communication between the PA and Appeals teams to ensure that all terminations are being communicated to the administrative team to properly deactivate access immediately. A monthly and quarterly review has been added to the process to ensure terminated employees do not remain on the [REDACTED] system. A report of all terminated employees will be run on a monthly basis and compared to [REDACTED] to verify access has been removed on all terminated employees. In addition, a quarterly reconciliation will be conducted by our Information Security team to verify that only valid staff has access to the [REDACTED] system. We feel that these added controls will strengthen the terminated user process for [REDACTED] and sufficiently address the auditors concerns.

Section E. Claims Adjudication – 2) Enrollment

OIG Recommendation 3: We recommend that Caremark routinely reconcile the full enrollment databases for MHBP, RCBP, and NALC.

CVS Caremark Response: CVS Caremark believes our current enrollment process with MHBP, RCBP and NALC is sufficient; however, we do recognize the value of the recommended additional control suggested by the OIG. In 2011, CVS Caremark will reach out to each of these FEHBP plans and discuss the options for enhancing the eligibility process.

Section E. Claims Adjudication – 3) Debarment

OIG Recommendation 4: We recommend that Caremark implement procedures to routinely update its debarment database with OPM OIG's debarred provider listing.

CVS Caremark Response: Our current process eliminates nearly all debarred providers and is sufficient. However, CVS Caremark concurs with the recommendation to utilize the OPM's debarred provider listing. We are now receiving this listing from BCBSA on a regular periodic basis and expect to implement a process to routinely utilize the OPM Debarred Provider Listing by the end of the first quarter 2011.

Section E. Claims Adjudication – 4) Application Controls Testing – a)

[REDACTED]

OIG Recommendation 5: We recommend that Caremark make the appropriate system modifications to the QL and RECAP systems in order to detect claims being processed [REDACTED].

CVS Caremark Response: CVS Caremark disagrees with this recommendation for two central reasons: (1) a [REDACTED] [REDACTED] is still in development; (2) this responsibility belongs to the dispensing pharmacist and his/her judgment. While the industry is moving in the direction of having [REDACTED] which is complete and accurate, in our opinion, this objective has not yet been reached and member disruption could be significant. The dispensing pharmacists have a professional responsibility to review the FEHBP member's prescription and determine its validity based on professional judgment and state and federal dispensing guidelines.

In 2011, CVS Caremark is offering an OIG debarred prescriber edit to our commercial and FEHBP clients. Clients can elect for the claims adjudication system to the reject claims written from prescribers debarred by the OIG.

Section E. Claims Adjudication – 4) Application Controls Testing – b)

[REDACTED]

OIG Recommendation 6: We recommend that Caremark make the appropriate system modifications to the QL and RECAP systems in order to deny [REDACTED] [REDACTED] from being processed and paid.

CVS Caremark Response: CVS Caremark disagrees with this recommendation. It is the dispensing pharmacy's responsibility to review each prescription and dispense according to State and Federal guidelines. Each State has separate and distinct pharmacy laws and regulations regarding [REDACTED] that the licensed pharmacists within that state are required to follow. Coding our adjudication

systems to reject a claim based on individual state laws and guidelines would not be feasible or appropriate and it could potentially interfere with a member receiving proper therapy on a timely basis. It should be noted that CVS Caremark also monitors the pharmacy network through our pharmacy audit procedures. Reviewing for [REDACTED] [REDACTED] is part of the audit program. CVS Caremark believes that this network monitoring process is a sufficient control to ensure the validity of the prescription documentation.

*****Redacted by OPM/OIG – not relevant to final audit report*****

A review of these individual State pharmacy laws leads to two conclusions: (1) actual State laws are complex and diverse and applying [REDACTED] for all is inappropriate; (2) given the above complexities and regulatory reliance on the professional discretion of pharmacists and/or prescribers means it is not practical to modify our adjudication system to reject claims in the manner recommended.

*****Redacted by OPM/OIG – not relevant to final audit report*****

Section E. Claims Adjudication – 4) Application Controls Testing – c) Toxic Acetaminophen Levels

OIG Recommendation 7 (draft report Recommendation 8): We recommend that Caremark make the appropriate system modifications to the QL and RECAP systems in order to detect a series of claims containing a toxic level of APAP.

CVS Caremark Response: CVS Caremark became aware of this issue and initiated a project to improve the controls over the ability to detect toxic levels of Acetaminophen in early 2010, well before the start of the OIG audit. The project was in the testing phase

when the audit started and was fully implemented for BCBSA on February 1, 2011. These changes include the following:

1) Max Dose Edit: This is a hard edit that sends a message of "HD-Max Dose= X". This message will display when the dose on a single claim is 1.75 times greater than the FDB max dose.

2) Umbrella Limit: The umbrella limits allow for the following:

- 1) 750mg umbrella- All products containing 750mg of APAP are limited to 480 dosage units every rolling 90 days
- 2) 650/660mg umbrella- All products containing 650 or 660mg of APAP are limited to 554 dosage units every rolling 90 days
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- 4) 325mg umbrella- All products containing 325mg of APAP, or less, are limited to 1,108 dosage forms every rolling 90 days

In addition there is a "catch-all" umbrella limit that limits the total accumulated quantity of any combination of legend APAP containing products to less than 1,104 dosage units per rolling 90 days. These limits represent the maximum number of tablets it takes to have a daily dose greater than 4grams per day, every day for 90 days. This edit looks at all prescriptions in a rolling 90 day, rather than just single claims.

Also, both BCBSA and CVS Caremark monitors APAP toxicity and do focus on accumulation of multiple prescriptions for a total grams/day calculation. This program is a quarterly review on a look back of 120 days of member utilization. Once members are identified there is an outreach to educate them on the risks.

After your review of our responses we would welcome any questions or additional 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,


Director of Client Audit




Cc: [REDACTED] Vice President of FEP Account Services
CVS/Caremark Corporation
[REDACTED], Director of FEP Account Services
CVS/Caremark Corporation
[REDACTED], Director Strategic Accounts
CVS/Caremark Corporation
[REDACTED], Coventry Health Care
[REDACTED], BlueCross BlueShield Federal Employee Program
[REDACTED], NALC Health Benefit Plan

Appendix II

March 7, 2011

██████████, Chief
Information Systems Audits Group
Insurance Service Programs
Office of Personnel Management
1900 E Street, N.W., Room 6400
Washington, D.C. 20415



**BlueCross BlueShield
Association**

An Association of Independent
Blue Cross and Blue Shield Plans
Federal Employee Program
1310 G Street, N.W.
Washington, D.C. 20005
202.942.1000
Fax 202.942.1125

**Reference: OPM DRAFT EDP AUDIT REPORT
CVS/Caremark- Blue Cross Blue Shield Retail Pharmacy Vendor
Audit Report Number 1H-01-00-10-057**

Dear ██████████

This report is in response to the above-referenced U.S. Office of Personnel Management (OPM) Draft Audit Report covering the Federal Employees' Health Benefits Program (FEHBP) Audit of Information Systems General and Application Controls for CVS Caremark's interface with the FEP claims processing system, access and security controls. This response is limited to those items related to the Blue Cross Blue Shield Federal Employment Program. Our comments regarding the findings in this report are as follows:

A. ACCESS CONTROLS

1. Facility Physical Access Controls

Recommendation 1

OIG recommended that CVS Caremark review the physical access controls in place at its facilities and analyze the feasibility of implementing the controls outlined in the report.

CVS/Caremark's Response to Recommendation 1

CVS Caremark agreed to this recommendation. The response to this recommendation is included the CVS Caremark's response.

2. Removal of System Access Privileges

Recommendation 2

OIG recommended that CVS Caremark evaluate the procedures for removing ██████████ ██████████ user accounts to determine why user access problems exist with this system when there were no

issues with the other tested applications. CVS Caremark should implement new controls to ensure that system access to ██████ is promptly disabled following an employee termination.

CVS/Caremark's Response to Recommendation 2

CVS Caremark agreed to this recommendation. The response to this recommendation is included the CVS Caremark's response.

B. Claims Adjudication

1. Provider Prescriber

Recommendation 5

OIG recommended that CVS Caremark make the appropriate system modifications to QL and RECAP systems in order to detect claims being processed with ██████████.

CVS/Caremark's Response to Recommendation 5

CVS Caremark disagreed with this recommendation. The response to this recommendation is included the CVS Caremark's response.

2. ██████████

Recommendation 6

OIG recommended that CVS Caremark make the appropriate system modifications to the QL and RECAP systems in order to deny ██████████ ██████████ from being processed and paid.

CVS/Caremark's Response to Recommendation 6

CVS Caremark disagreed with this recommendation. The response to this recommendation is included the CVS Caremark's response.

****** Redacted by OPM/OIG - not relevant to final audit report******

**** Redacted by OPM/OIG - not relevant to final audit report ****

3. Toxic Acetaminophen Levels

Recommendation 7(draft report Recommendation 8)

OIG recommended that CVS Caremark make the appropriate system modifications to the QL and RECAP systems in order to detect a series of claims containing a toxic level of APAP.

Response to Recommendation 7 (draft report Recommendation 8)

Prior to the start of this audit, FEP was working with CVS Caremark to implement measures to prevent toxic doses of APAP from being dispensed. FEP began working on this project in early 2010, and the necessary system changes were successfully implemented as of February 1, 2011. A detail response describing the system changes made to identify and prevent the dispensing of toxic APAP doses is included the CVS Caremark's response.

We appreciate the opportunity to provide our response to this Draft Audit Report and request that our comments be included in their entirety as an amendment to the Final Audit Report.

Sincerely,

[REDACTED]

Executive Director, Program Integrity

cc: [REDACTED], OPM
[REDACTED], CVS/Caremark
[REDACTED], FEP
[REDACTED], FEP