DEPARTMENT OF HEALTH & HUMAN SERVICES **Office of Inspector General**

Office of Audit Services, Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

December 14, 2011

Report Number: A-09-11-02028

Ms. Amy Jampel
Vice President of Medicare Programs
Hawaii Medical Service Association
10-Medicare Programs Departments
P.O. Box 860
Honolulu, HI 96808-0860

Dear Ms. Jampel:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Hawaii Medical Service Association*. 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, or contact Doug Preussler, Audit Manager, at (415) 437-8360 or through email at Doug.Preussler@oig.hhs.gov. Please refer to report number A-09-11-02028 in all correspondence.

Sincerely,

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

Enclosure

Direct Reply to HHS Action Official:

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

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICARE PART D PRESCRIPTION DRUG EVENT DATA FOR SCHEDULE II DRUGS AT HAWAII MEDICAL SERVICE ASSOCIATION

Daniel R. Levinson
Inspector General

December 2011
A-09-11-02028

Office of Inspector General

http://oig.hhs.gov

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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

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

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

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

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

As a Part D sponsor, Hawaii Medical Service Association (HMSA) provided prescription drug coverage to 119 beneficiaries and submitted to CMS 403 PDE records for Schedule II drugs for dates of service from January 1, 2008, through June 30, 2010. HMSA contracted with Argus Health Systems, Inc., through December 2009 and Medco Health Solutions, Inc., beginning January 2010 to provide PBM services, including claims processing and adjudication as well as preparation and submission of PDE records.

OBJECTIVE

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

SUMMARY OF FINDING

HMSA had adequate controls to prevent refills and unallowable partial fills of Schedule II drugs. Of 10 judgmentally selected PDE records, no records represented refills or unallowable partial fills. However, HMSA did not have adequate controls to ensure the accuracy of the PDE records submitted for Schedule II drugs as required by Federal regulations. Of the 10 PDE records, 2 records contained inaccurate data when compared with the supporting documentation at the pharmacy.

The PBMs' claims processing systems did not have edits to ensure the accuracy of the PDE records. In addition, HMSA has not provided to pharmacies adequate guidance clarifying Federal requirements related to submitting accurate claim information for Schedule II drugs.

RECOMMENDATIONS

We recommend that HMSA:

- strengthen its controls to ensure the accuracy of submitted PDE records and

- issue adequate guidance to its pharmacies clarifying Federal requirements related to submission of accurate claim information for Schedule II drugs.

HAWAII MEDICAL SERVICE ASSOCIATION COMMENTS

In written comments on our draft report, HMSA concurred with our finding and recommendations and provided information on actions that it planned to take to address the recommendations. HMSA's comments are included in their entirety as the Appendix.

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INTRODUCTION

BACKGROUND

Medicare Part D

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

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

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

Prescription Drug Event Data

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

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

Controlled Substances

The Controlled Substances Act (CSA), 21 U.S.C. §§ 801–971, established five schedules based on the medical use acceptance and the potential for abuse of the substance or drug. Schedule I,

which includes drugs or substances that have no currently accepted medical use and a high potential for abuse, is the most restrictive, and Schedule V is the least restrictive.

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

Pursuant to 21 CFR § 1306.12(a), Schedule II prescription drugs may not be refilled. However, 21 CFR § 1306.13(b) provides that Schedule II drugs for patients residing in a long-term-care facility and for the terminally ill may be partially filled as long as the total quantity dispensed does not exceed the total quantity prescribed.[1] Under this provision, Schedule II prescriptions for these patients are valid for a period not to exceed 60 days from the issue date.[2]

Hawaii Medical Service Association, Argus Health Systems, Inc., and Medco Health Solutions, Inc.

As a Part D sponsor, Hawaii Medical Service Association (HMSA) provided prescription drug coverage to 119 beneficiaries and submitted to CMS 403 PDE records for Schedule II drugs for dates of service from January 1, 2008, through June 30, 2010. For these PDE records, pharmacies were paid $14,934.[3] HMSA contracted with Argus Health Systems, Inc. (Argus), through December 2009 and Medco Health Solutions, Inc. (Medco), beginning January 2010 to provide PBM services, including claims processing and adjudication as well as preparation and submission of PDE records. HMSA maintained its own contracts with pharmacies and established a policy that disallowed partial fills of Schedule II drugs.

As HMSA's PBMs, Argus and Medco processed prescription claims from pharmacies for each drug dispensing event. Argus and Medco used their claims software to process prescription claims at the point of sale, which included implementing a series of edits and calculating certain data elements. Argus and Medco used these data elements, as well as other Part D data, to create PDE records. Argus and Medco submitted PDE records to CMS weekly and biweekly, respectively. Argus and Medco also performed audits of the data received from pharmacies. HMSA maintained an oversight role in Argus' and Medco's PBM processes.

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

[2] Federal regulations (21 CFR § 1306.13(a)) also permit the partial filling of a prescription for a Schedule II drug if the pharmacist is unable to supply the full quantity prescribed. The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist may not dispense any further quantity without a new prescription.

[3] The amount paid to the pharmacies is on behalf of the sponsor, beneficiaries, and third parties. The $14,934 includes the amounts paid for original submissions of PDE records as well as any subsequent adjustments.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

We limited our review to 287 PDE records for dates of service from January 1, 2008, through June 30, 2010, representing $12,203 paid for Schedule II drugs under HMSA's one standalone prescription drug plan. We excluded from our review PDE records that were (1) for noncovered Part D drugs under the prescription drug plan, (2) deleted, (3) plan-to-plan reconciliations, (4) subsequently adjusted, or (5) submitted in a nonstandard format.

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

We conducted our audit from May to August 2011 and performed fieldwork at HMSA's office in Honolulu, Hawaii, and at selected pharmacies.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed HMSA's contract with CMS regarding its roles and responsibilities as a Part D sponsor;
- reviewed HMSA's contracts with Argus and Medco regarding processing of pharmacy claims;
- reviewed HMSA's contracts with selected pharmacies regarding submission of claims;
- interviewed HMSA officials regarding their monitoring and oversight of PDE data;
- obtained HMSA's PDE records for Schedule II drugs for dates of service from January 1, 2008, through June 30, 2010 (processed by CMS through March 2011);

- analyzed the PDE records by beneficiary, prescription reference number, and fill number to determine whether the records represented potential refills and/or potential unallowable partial fills;

- selected a judgmental sample of 10 PDE records and reviewed the supporting documentation at the pharmacies that submitted those claims to identify refills and unallowable partial fills and to determine the accuracy of certain fields in the PDE records; and

- shared the results of our audit with HMSA officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our finding and conclusions based on our audit objective.

FINDING AND RECOMMENDATIONS

HMSA had adequate controls to prevent refills and unallowable partial fills of Schedule II drugs. Of 10 judgmentally selected PDE records, no records represented refills or unallowable partial fills. However, HMSA did not have adequate controls to ensure the accuracy of the PDE records submitted for Schedule II drugs as required by Federal regulations. Of the 10 PDE records, 2 records contained inaccurate data when compared with the supporting documentation at the pharmacy.

The PBMs' claims processing systems did not have edits to ensure the accuracy of the PDE records. In addition, HMSA has not provided to pharmacies adequate guidance clarifying Federal requirements related to submitting accurate claim information for Schedule II drugs.

FEDERAL REQUIREMENTS FOR SPONSORS

Pursuant to 42 CFR § 423.505(k), the sponsor must provide certification as to the accuracy, completion, and truthfulness of the claims data submitted. For every individual drug claim transaction at the pharmacy, the Part D sponsor or its PBM prepares a PDE record.

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

INACCURATE PRESCRIPTION DRUG EVENT DATA

Of 10 judgmentally selected PDE records, 2 records contained inaccurate data. We considered data to be inaccurate when certain fields in the PDE records did not match the supporting documentation that we reviewed at the pharmacies. For the two records that contained inaccurate data, the prescriber identifier did not match the prescriber information on the prescription maintained at the pharmacy. Specifically, the pharmacy provided its own identification number for the prescriber identifier field rather than the prescribing physician's identification number.

INADEQUATE CONTROLS

Argus' and Medco's monitoring efforts included the use of edits in their claims processing systems to prevent payment for duplicate claims and to identify claims that had been resubmitted, adjusted, or deleted. However, the edits did not ensure the accuracy of the prescriber identifier field in the PDE records based on information provided by the pharmacy. HMSA stated that the edits for the prescriber identifier field ensured that a prescriber's identification number was active; however the edits did not ensure that the prescriber's identification number matched the identification number of the physician on the prescription.

HMSA stated that Argus and Medco sent correspondence to HMSA's network pharmacies on operational and procedural issues related to claims processing. However, HMSA has not provided to pharmacies adequate guidance clarifying Federal requirements on submitting accurate claim information for Schedule II drugs.

CONCLUSION

Schedule II drugs have a high potential for abuse. Adequate controls to ensure the accuracy of data in submitted PDE records is essential to program integrity. Without adequate controls, Part D sponsors cannot properly oversee the dispensing and monitoring of Schedule II drugs.

RECOMMENDATIONS

We recommend that HMSA:

- strengthen its controls to ensure the accuracy of submitted PDE records and

- issue adequate guidance to its pharmacies clarifying Federal requirements related to submission of accurate claim information for Schedule II drugs.

HAWAII MEDICAL SERVICE ASSOCIATION COMMENTS

In written comments on our draft report, HMSA concurred with our finding and recommendations and provided information on actions that it planned to take to address the recommendations. HMSA's comments are included in their entirety as the Appendix.

APPENDIX

APPENDIX: HAWAII MEDICAL SERVICE ASSOCIATION COMMENTS

HMSA

Blue Cross Blue Shield of Hawaii

An Independent Licensee of the Blue Cross and Blue Shield Association

NOV 2 2 2011

November 21, 2011

Report: A-09-11-02028

Office of Inspector General
Office of Audit Services, Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

Dear Sirs:

This is in response to the Office of Inspector General Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Hawaii Medical Service Association (HMSA) for CMS Contract No. S3994 which resulted in one audit finding and two recommendations.

Finding
HMSA did not have adequate controls to ensure the accuracy of Prescription Drug Event (PDE) records submitted for Schedule II drugs as required by Federal regulations. Of the ten PDE records, two records contained inaccurate data when compared with the supporting documentation of the pharmacy. For the two records that contained inaccurate data, the prescriber identifier did not match the prescriber information on the prescription at the pharmacy. Specifically, the pharmacy provided its own NPI number for the prescriber identifier field rather than the prescribing physician's NPI number.

The PBM's claims processing systems did not have adequate edits in place to ensure the accuracy of the prescriber identifier field in the PDE records based on the information provided by the pharmacy. The edits did not ensure that the prescriber's identification matched the identification of the physician on the prescription. In addition, HMSA has not provided to pharmacies adequate guidance clarifying Federal requirements related to submitting accurate claim information for Schedule II drugs.

Recommendations:

- Strengthen its controls to ensure the accuracy of submitted PDE records and
- Issue adequate guidance to its pharmacies clarifying Federal requirements related to submission of accurate claim information for Schedule II drugs.

Corrective Action Plan:
HMSA concurs with the finding and recommendations.

Hawaii Medical Service Association | 818 Keeaumoku St. • P.O. Box 860 Honolulu, HI 96808-0860 | (808) 948-5110 | Branch offices located on Hawaii, Kauai and Maui | Internet address www.HMSA.com

HMSA's PBM vendor will review and confirm the validity of each prescriber identifier before submission of PDE records beginning January 1, 2012. When an identifier is not provided by the pharmacy or is determined to be invalid for a given prescription claim, HMSA's PBM vendor will work with the pharmacy to obtain the correct identifier. If no valid identifier is obtained, the PDE record will not be submitted to the Centers for Medicare and Medicaid Services (CMS). HMSA will implement an audit process in 2012 with our independent claims auditor to ensure that PDE records have correct NPI prescriber identifiers.

A special communication will be sent to all HMSA network pharmacies clarifying Federal and State requirements related to accurate claim submissions for Schedule II drugs. The communication will remind pharmacies that complete accuracy and truthfulness are required when submitting claims and provide them with the example of a pharmacy inappropriately submitting the pharmacy's NPI number instead of the prescribing physician's NPI number. This mailing will go out by December 15, 2011 and will also be posted online in the pharmacy section of HMSA's provider portal by December 15, 2011. In addition, a reminder will be sent to participating pharmacies annually in an HMSA pharmacy newsletter.

An individual letter will be sent to the pharmacy identified as inappropriately submitting their pharmacy NPI number in place of the prescriber NPI number. The letter will restate and clarify the requirements and point to the specific inappropriate submissions. This letter will be sent by December 15, 2011.

HMSA's PBM vendor will issue a reminder to its network pharmacies no later than December 31, 2011 that, as already stated in the PBM's Pharmacy Services Manual, pharmacies must submit valid prescriber identifiers, and that HMSA's PBM will continue to audit submissions to ensure that accurate information is transmitted. The PBM vendor will follow-up with network pharmacies when identifiers cannot be validated.

If there are any questions regarding this letter, please contact me directly at (808) 948-6597 or email me at amy_jampel@HMSA.com.

Sincerely,

/Amy Jampel/

Amy Jampel
Vice President
Medicare Programs Department