Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICARE PART D PRESCRIPTION DRUG EVENT DATA FOR SCHEDULE II DRUGS AT HUMANA INSURANCE COMPANY

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Lori A. Ahlstrand
Regional Inspector General

October 2012
A-09-12-02031

Office of Inspector General

https://oig.hhs.gov

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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 third-party administrator 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 third-party administrator 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, completeness, 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.

Humana Insurance Company (Humana) contracted with CMS as a Part D sponsor to provide prescription drug benefits to eligible Part D beneficiaries. Humana provided prescription drug coverage to almost 500,000 beneficiaries and submitted to CMS over 4.1 million PDE records for Schedule II drugs for dates of service from January 1, 2008, through June 30, 2010.

OBJECTIVE

Our objective was to determine whether Humana 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 FINDINGS

Humana did not have adequate controls to (1) prevent unallowable partial fills of Schedule II drugs and (2) ensure the accuracy of certain fields in the PDE records submitted for Schedule II drugs as required by Federal regulations. Humana did not have specific controls to prevent refills of Schedule II drugs; however, the pharmacies that we visited either did not allow refills or had edits to prevent refills of those drugs.

Of 53 judgmentally selected PDE records, 16 records represented unallowable partial fills. (There were no refills.) In addition, of 64 judgmentally selected PDE records (which included the 53 records reviewed for refills and partial fills), 29 records contained inaccurate data in certain fields when compared with the supporting documentation at the pharmacies. An additional two PDE records were missing pharmacy documentation, which prevented us from determining the accuracy of the data in the records.

The claims processing system's edits were not adequate to identify unallowable partial fills to prevent submission of PDE records related to those prescriptions nor did it have edits to ensure the accuracy of certain fields in the PDE records. In addition, during the audit period, Humana did not provide to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or adequate guidance regarding the submission of accurate claim information for Schedule II drugs.

RECOMMENDATIONS

We recommend that Humana:

- strengthen its controls to (1) prevent unallowable partial fills of Schedule II drugs and (2) ensure the accuracy of submitted PDE records and

- issue guidance to its pharmacies clarifying Federal requirements related to (1) refills and partial fills of Schedule II drugs and (2) submission of accurate claim information for Schedule II drugs.

AUDITEE COMMENTS

In written comments on our draft report, Humana concurred with part of our first recommendation (that it strengthen its controls to prevent unallowable partial fills of Schedule II drugs) and concurred with our second recommendation. Humana also provided information on actions that it had taken or planned to take to address these recommendations. Although Humana did not explicitly concur with part of our first recommendation (that it strengthen its controls to ensure the accuracy of submitted PDE records), Humana stated that it would enhance

its pharmacy audit process to include a review of all PDE data elements that are based upon the pharmacy's submitted claim. Humana'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) or third-party administrator to manage or administer the prescription drug benefit on the sponsor's behalf. PBM or third-party administrator 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 third-party administrator 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, completeness, and truthfulness of the claims data submitted for payment purposes.

A Part D sponsor or its third-party administrator 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, physician, pharmacy, drug, prescription reference number, and fill number; (2) the dates that the prescription was filled and the PDE record was processed; and (3) the prescription drug cost and other payment information.

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.

Humana Insurance Company, Argus Health Systems, and Humana Pharmacy Solutions

Humana Insurance Company (Humana) contracted with CMS as a Part D sponsor to provide prescription drug benefits to eligible Part D beneficiaries. Humana provided prescription drug coverage to almost 500,000 beneficiaries and submitted to CMS over 4.1 million 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 approximately $438 million.[2]

Humana contracted with Argus Health Systems, Inc. (Argus), a third-party administrator, to provide claims processing services for Humana's Medicare Prescription Drug Benefit Program beginning March 2005. These services included claims adjudication, as well as creation of PDE records. Argus processed prescription claims from pharmacies for each drug dispensing event. Argus used its claims software to process prescription claims at the point of sale, which included implementing a series of edits and calculating certain data elements. Argus used these data elements, as well as other Part D data, to create the PDE records and transmit them to Humana. Humana submitted the PDE records to CMS monthly. Argus also performed audits of the data received from pharmacies. Humana oversaw Argus's claims processing services.

Humana Pharmacy Solutions (HPS) serves as the PBM for Humana's Medicare Part D business. HPS provides a network of pharmacies and routinely performs pharmacy audits.

[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] The amount paid to the pharmacies is on behalf of the sponsor, beneficiaries, and third parties. The $438 million 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 Humana 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 3,558,714 PDE records for dates of service from January 1, 2008, through June 30, 2010, representing $367,730,117 paid for Schedule II drugs under Humana'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 Humana 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 February to June 2012 and performed fieldwork at selected pharmacies.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CMS officials about the Federal requirements related to Schedule II drugs;
- reviewed Humana's contract with CMS regarding its roles and responsibilities as a Part D sponsor;
- reviewed Humana's contract with Argus regarding processing of pharmacy claims;
- interviewed Humana officials regarding their monitoring and oversight of PDE data;
- obtained Humana's PDE records for Schedule II drugs for dates of service from January 1, 2008, through June 30, 2010 (processed by CMS through November 2011);
- analyzed the PDE records by beneficiary, prescription reference number, and fill number to determine that 112,815 PDE records represented potential refills and/or potential unallowable partial fills;

- selected a judgmental sample of 53 PDE records and reviewed the supporting documentation at the pharmacies that submitted those claims to identify refills and unallowable partial fills;

- selected a judgmental sample of 64 PDE records (which included the 53 PDE records reviewed for refills and partial fills) and reviewed the supporting documentation at the pharmacies that submitted those claims to determine the accuracy of certain fields in the PDE records; and

- shared the results of our audit with Humana 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 findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATIONS

Humana did not have adequate controls to (1) prevent unallowable partial fills of Schedule II drugs and (2) ensure the accuracy of certain fields in the PDE records submitted for Schedule II drugs as required by Federal regulations. Humana did not have specific controls to prevent refills of Schedule II drugs; however, the pharmacies that we visited either did not allow refills or had edits to prevent refills of those drugs.

Of 53 judgmentally selected PDE records, 16 records represented unallowable partial fills. (There were no refills.) In addition, of 64 judgmentally selected PDE records (which included the 53 records reviewed for refills and partial fills), 29 records contained inaccurate data in certain fields when compared with the supporting documentation at the pharmacies. An additional two PDE records were missing pharmacy documentation, which prevented us from determining the accuracy of the data in the records.

The claims processing system's edits were not adequate to identify unallowable partial fills to prevent submission of PDE records related to those prescriptions nor did it have edits to ensure the accuracy of certain fields in the PDE records. In addition, during the audit period, Humana did not provide to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or adequate guidance regarding the submission of accurate claim information for Schedule II drugs.

FEDERAL REQUIREMENTS

Federal Regulations for Schedule II Drugs

Pursuant to Federal regulations (21 CFR § 1306.12(a)), Schedule II prescription drugs may not be refilled. A separate prescription is required if a physician wishes to authorize continuation of a patient's use of a Schedule II drug beyond the amount specified on the first prescription.

However, Federal regulations (21 CFR § 1306.13(b)) allow for a prescription for a Schedule II drug written for a patient in a long-term-care facility or for a patient with a medical diagnosis documenting a terminal illness to be filled in partial quantities to include individual dosage units. Under this provision, a Schedule II drug may be partially filled as long as the total quantity dispensed does not exceed the total quantity prescribed. The prescription is valid for a period not to exceed 60 days from the issue date.[3]

Pursuant to 21 CFR § 1306.11, 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.

Federal Regulations and Guidance for Sponsors

Pursuant to 42 CFR § 423.505(d), the sponsor agrees to maintain, for 10 years, records and documents that are sufficient to accommodate periodic auditing of data and to enable inspection of the quality, appropriateness, and timeliness of services performed under the contract with CMS. In addition, pursuant to 42 CFR § 423.505(k), the sponsor must provide certification as to the accuracy, completeness, and truthfulness of the claims data submitted. For every individual drug claim transaction at the pharmacy, the Part D sponsor or its third-party administrator 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.

UNALLOWABLE PARTIAL FILLS

Of 53 judgmentally selected PDE records, 16 records represented unallowable partial fills of Schedule II drugs. (There were no refills.)

- For 13 PDE records, the drug was dispensed without a practitioner's written prescription.

- For two PDE records, the drug was dispensed to a beneficiary who was neither a patient in a long-term-care facility nor a patient with a medical diagnosis documenting a terminal illness.

- For one PDE record, the drug was dispensed more than 60 days after the issue date of the prescription.

[3] 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.

INACCURATE PRESCRIPTION DRUG EVENT DATA

Of 64 judgmentally selected PDE records (which included the 53 records reviewed for refills and partial fills), 29 records contained inaccurate data in certain fields. An additional two PDE records were missing pharmacy documentation, which prevented us from determining the accuracy of the data in the records.

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. The 29 PDE records contained the following inaccurate data:[4]

- The fill number did not match the number of fills associated with the prescription as shown in the documentation maintained at the pharmacy.

- The days supply of the drug did not match the number of days associated with the prescription as shown in the documentation maintained at the pharmacy.

- The prescriber identifier did not match the prescriber information on the prescription maintained at the pharmacy.

- The prescription origin code did not match the type of prescription that was presented at the pharmacy (i.e., written, telephone, electronic, or fax).

Missing Documentation

Of 64 judgmentally selected PDE records, 2 records were not supported by physician-signed prescriptions. The pharmacy was not able to provide us with any supporting documentation, such as physician-signed prescriptions, refill requests, or drug delivery receipts. Therefore, we were not able to determine the accuracy of the data in the PDE records.

INADEQUATE CONTROLS

Although Argus's claims processing system had some edits in place to identify discrepancies and errors in pharmacy claims, Argus relies on the pharmacy to enter accurate data for an allowable claim. The edits were not adequate to identify unallowable partial fills by pharmacies to prevent submission of PDE records related to those prescriptions. In addition, based on our review of information provided by the pharmacies, we determined that the edits were not adequate to ensure the accuracy of certain fields in the PDE records.

HPS sends correspondence to its network pharmacies to remind them that they are contractually obligated to follow Federal requirements. However, during the audit period, HPS did not provide to pharmacies any guidance clarifying Federal requirements related to refills and partial

[4] All 29 PDE records had at least one of the types of inaccurate data shown.

fills of Schedule II drugs or adequate guidance regarding the submission of accurate claim information for Schedule II drugs.

CONCLUSION

Schedule II drugs have a high potential for abuse. Therefore, having adequate controls to prevent refills and unallowable partial fills, while ensuring that an adequate and uninterrupted supply is available for legitimate medical needs, is a valuable program integrity safeguard. In addition, having 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 Humana:

- strengthen its controls to (1) prevent unallowable partial fills of Schedule II drugs and (2) ensure the accuracy of submitted PDE records and

- issue guidance to its pharmacies clarifying Federal requirements related to (1) refills and partial fills of Schedule II drugs and (2) submission of accurate claim information for Schedule II drugs.

AUDITEE COMMENTS

In written comments on our draft report, Humana concurred with part of our first recommendation (that it strengthen its controls to prevent unallowable partial fills of Schedule II drugs) and concurred with our second recommendation. Humana also provided information on actions that it had taken or planned to take to address these recommendations. Although Humana did not explicitly concur with part of our first recommendation (that it strengthen its controls to ensure the accuracy of submitted PDE records), Humana stated that it would enhance its pharmacy audit process to include a review of all PDE data elements that are based upon the pharmacy's submitted claim. Humana's comments are included in their entirety as the Appendix.

APPENDIX

APPENDIX: AUDITEE COMMENTS

Humana

500 West Main Street
Louisville, KY 40202
Law Department
Humana.com

September 20, 2012

Ms. Lori A. Ahlstrand
Regional Inspector General for Audit Services
Department of Health and Humana Services
Office of Inspector General
Office of Audit Services, Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

Dear Ms. Ahlstrand:

RE: Report Number: A-09-12-02031

Enclosed is Humana's response to the U.S. Department of Health and Human Services, Office of Inspector General (OIG), draft report entitled *Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Humana Insurance Company*.

Please let me know if you have questions or require additional information.

Sincerely,

C. Brooks Newman

Brooks Newman
Director & Medicare Compliance Officer
Humana Inc.

Office of Inspector General

Review of Medicare Part D Prescription Drug Event Data
For Schedule II Drugs at Humana Insurance Company

Response – September 20 2012

UNALLOWABLE PARTIAL FILLS

OIG Finding

Humana did not have adequate controls to prevent unallowable partial fills of Schedule II drugs as required by Federal regulations.

Of 53 judgmentally selected PDE records, 16 records represented unallowable partial fills of Schedule II drugs. (There were no refills.)

- For 13 PDE records, the drug was dispensed without a practitioner's written prescription.
- For two PDE records, the drug was dispensed to a beneficiary who was neither a patient in a long-term-care facility nor a patient with a medical diagnosis documenting a terminal illness.
- For one PDE record, the drug was dispensed more than 60 days after the issue date of the prescription.

OIG Recommendation

OIG recommends that Humana strengthen its controls to prevent unallowable partial fills of Schedule II drugs.

Humana Response

Humana concurs with the OIG's recommendation and is in the process of implementing a new point-of-sale edit to prevent unallowable partial fills of Schedule II drugs. The new edit will also prevent long-term care refill or partial fill claims for a Schedule II drug received with a Date of Service more than 60 days after the Date Written. The pharmacy will receive a message stating the reason for denial.

INACCURATE PRESCRIPTION DRUG EVENT DATA

OIG Finding

Humana did not have adequate controls to ensure the accuracy of certain fields in the PDE records submitted for Schedule II drugs as required by Federal regulations.

Of 64 judgmentally selected PDE records (which included the 53 records reviewed for refills and partial fills), 29 records contained inaccurate data in certain fields. An additional two PDE records were missing pharmacy documentation, which prevented us from determining the accuracy of the data in the records.

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. The 29 PDE records contained the following inaccurate data:

- The fill number did not match the number of fills associated with the prescription as shown in the documentation maintained at the pharmacy.
- The days supply of the drug did not match the number of days associated with the prescription as shown in the documentation maintained at the pharmacy.
- The prescriber identifier did not match the prescriber information on the prescription maintained at the pharmacy.
- The prescription origin code did not match the type of prescription that was presented at the pharmacy (i.e., written, telephone, electronic, or fax).

Of 64 judgmentally selected PDE records (which included the 53 records reviewed for refills and partial fills), 29 records contained inaccurate data in certain fields.

Missing Documentation

Of 64 judgmentally selected PDE records, 2 records were not supported by physician-signed prescriptions. The pharmacy was not able to provide us with any supporting documentation, such as physician-signed prescriptions, refill requests, or drug delivery receipts. Therefore, we were not able to determine the accuracy of the data in the PDE records.

OIG Recommendation

OIG recommends that Humana strengthen its controls to ensure the accuracy of submitted PDE records

Humana Response

The current National Council for Prescription Drug Programs (NCPDP) pharmacy transaction standards do not support Humana (or any Part D plan sponsor) implementing effective adjudication edits preventing all possible data errors like many of those identified in the OIG's report. In many cases the only reasonable, available data validation method for PDE record components based upon pharmacy-submitted information is review through a retrospective audit process. Humana's current pharmacy audit process includes review of many pharmacy submitted transaction fields for accuracy. Humana will enhance its pharmacy audit process to include review of all PDE data elements that are based upon the pharmacy's submitted claim. Humana will continue to review and optimize the volume of claims reviewed as part of Humana's pharmacy audit process where PDE data elements are reviewed for accuracy.

INADEQUATE CONTROLS

Although Argus's claims processing system had some edits in place to identify discrepancies and errors in pharmacy claims, Argus relies on the pharmacy to enter accurate data for an allowable claim. The edits were not adequate to identify unallowable partial fills by pharmacies to prevent submission of PDE records related to those prescriptions. In addition, based on our review of information provided by the pharmacies, we determined that the edits were not adequate to ensure the accuracy of certain fields in the PDE records.

HPS sends correspondence to its network pharmacies to remind them that they are contractually obligated to follow Federal requirements. However, during the audit period, HPS did not provide to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or adequate guidance regarding the submission of accurate claim information for Schedule II drugs.

OIG Recommendation

The OIG recommends that Humana issue guidance to its pharmacies clarifying Federal requirements related to (1) refills and partial fills of Schedule II drugs and (2) submission of accurate claim information for Schedule II drugs.

Humana Response

Humana concurs with the OIG's recommendation and will issue guidance to its network pharmacies biannually clarifying federal requirements related to refills and partial refills of Schedule II drugs. The guidance will also remind pharmacies of the importance of monitoring pharmacy claims for accuracy and compliance with federal and state laws, rules and regulations before submitting claims to Humana for reimbursement, especially when filling prescriptions and submitting claims for Schedule II drugs. In addition, Humana will include this guidance and clarification in its 2013 Humana Pharmacy Solutions Pharmacy Provider Manual.