DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

OFFICE OF AUDIT SERVICES, REGION IX
90 - 7TH STREET, SUITE 3-650
SAN FRANCISCO, CA 94103

July 12, 2012

Report Number: A-09-11-02023

Mr. Thomas S. Paul
Chief Executive Officer
United HealthCare Medicare & Retirement
9701 Data Park Drive
MN006-E010
Minnetonka, MN 55343

Dear Mr. Paul:

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 United HealthCare Medicare & Retirement*. 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-09-11-02023 in all correspondence.

Sincerely,

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

Enclosure

Direct Reply to HHS Action Official:

Mr. Timothy P. Love
Acting Deputy Director
Center for Medicare
Centers for Medicare & Medicaid Services
Mail Stop C3-20-11
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 UNITED HEALTHCARE MEDICARE & RETIREMENT

Daniel R. Levinson
Inspector General

July 2012
A-09-11-02023

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, 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.

United HealthCare Medicare & Retirement (United) contracted with CMS as a Part D sponsor to provide prescription drug benefits to eligible Part D beneficiaries. United provided prescription drug coverage to approximately 1 million beneficiaries and submitted to CMS over 9.7 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 United 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

United 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. United 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 in place to prevent refills of those drugs.

Of 94 judgmentally selected PDE records, 3 records represented unallowable partial fills. (There were no refills.) In addition, of 100 judgmentally selected PDE records (which included the 94 records reviewed for refills and partial fills), 18 records contained inaccurate data in certain fields when compared with the supporting documentation at the pharmacies. An additional 12 PDE records were inaccurate because they were for drugs that the pharmacies did not dispense to beneficiaries.

The claims processing system's edits were not adequate to identify unallowable partial fills to prevent submission of PDE records related to those prescriptions, ensure the accuracy of certain fields in the PDE records, or identify PDE records for drugs that pharmacies did not dispense to beneficiaries. In addition, United has not provided to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or submission of accurate claim information for Schedule II drugs.

RECOMMENDATIONS

We recommend that United:

- strengthen its controls to (1) prevent unallowable partial fills of Schedule II drugs, (2) ensure the accuracy of submitted PDE records, and (3) identify PDE records for drugs that pharmacies did not dispense to beneficiaries;

- 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;

- work with its pharmacies to ensure that appropriate reversals are processed for the 12 PDE records for drugs that pharmacies did not dispense to beneficiaries; and

- work with its pharmacies to determine whether there are additional PDE records for drugs that pharmacies did not dispense to beneficiaries and ensure that appropriate reversals are processed for those PDE records.

AUDITEE COMMENTS

In written comments on our draft report, United did not concur that it did not have specific controls to prevent unallowable partial fills or refills of Schedule II drugs or that its claims processing system's edits were not adequate to identify unallowable partial fills. United stated that the claims system correctly processed the three unallowable partial fills based on the patient's location in a long-term-care facility and the information provided by the pharmacy. Regarding our finding that 18 PDE records contained inaccurate data in certain fields, United did not concur on its overall ability to ensure the accuracy of PDE data that pharmacies prepare and submit to United. In addition, United disagreed that it was responsible for providing to pharmacies routine updates regarding Federal requirements. United concurred with our finding that 12 PDE records were inaccurate because they were for drugs that the pharmacies did not dispense to beneficiaries and provided information on corrective actions taken.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

Federal regulations make clear that, for a Schedule II drug to be partially filled, the total quantity dispensed must not exceed the total quantity prescribed. For two of the three unallowable partial fills, the pharmacy dispensed more than the total amount prescribed. For the third unallowable partial fill, the pharmacist did not create written documentation supporting that an oral authorization was received, as required by Federal regulations. Regarding United's statement that it is not able to ensure the accuracy of submitted PDE data, Federal regulations require the sponsor to provide certification as to the accuracy, completeness, and truthfulness of the claims data submitted for payment purposes. Nothing in United's comments caused us to revise our findings or recommendations.

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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, completeness, 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, physician, 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.

United HealthCare Medicare & Retirement and OptumRx

United HealthCare Medicare & Retirement (United) contracted with CMS as a Part D sponsor to provide prescription drug benefits to eligible Part D beneficiaries. United provided prescription drug coverage to approximately 1 million beneficiaries and submitted to CMS over 9.7 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 $1.26 billion.[2]

United contracted with OptumRx to provide PBM services beginning February 2007, including claims processing and adjudication, as well as preparation and submission of PDE records. As United's PBM, OptumRx processed prescription claims from pharmacies for each drug dispensing event. OptumRx 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. OptumRx used these data elements, as well as other Part D data, to create the PDE records and submitted the PDE records to CMS. OptumRx also performed audits of the data received from pharmacies. United maintained an oversight role in OptumRx's processes.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether United 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.

[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 $1.26 billion includes the amounts paid for original submissions of PDE records as well as any subsequent adjustments.

Scope

We limited our review to 8,180,629 PDE records for dates of service from January 1, 2008, through June 30, 2010, representing $1,038,274,795 paid for Schedule II drugs under United's four standalone prescription drug plans. 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 United 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 April 2011 to February 2012 and performed fieldwork at United's office in Minnetonka, Minnesota, and 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 United's contract with CMS regarding its roles and responsibilities as a Part D sponsor;
- reviewed United's contract with OptumRx regarding pharmacy contracting and processing of pharmacy claims;
- interviewed United officials regarding their monitoring and oversight of PDE data;
- obtained United's PDE records for Schedule II drugs for dates of service from January 1, 2008, through June 30, 2010 (processed by CMS through November 2010);
- analyzed the PDE records by beneficiary, prescription reference number, and fill number to determine that 565,287 PDE records represented potential refills and/or potential unallowable partial fills;
- selected a judgmental sample of 94 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 100 PDE records (which included the 94 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 United 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

United 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. United 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 in place to prevent refills of those drugs.

Of 94 judgmentally selected PDE records, 3 records represented unallowable partial fills. (There were no refills.) In addition, of 100 judgmentally selected PDE records (which included the 94 records reviewed for refills and partial fills), 18 records contained inaccurate data in certain fields when compared with the supporting documentation at the pharmacies. An additional 12 PDE records were inaccurate because they were for drugs that the pharmacies did not dispense to beneficiaries.

The claims processing system's edits were not adequate to identify unallowable partial fills to prevent submission of PDE records related to those prescriptions, ensure the accuracy of certain fields in the PDE records, or identify PDE records for drugs that pharmacies did not dispense to beneficiaries. In addition, United has not provided to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or 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. In the case of an emergency situation, a pharmacist may dispense Schedule II drugs upon receiving oral authorization from a prescribing practitioner, provided that, among other things, the prescription is immediately reduced to writing by the pharmacist and contains all information required in 21 CFR § 1306.05, except for the signature of the prescribing practitioner.

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 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.

UNALLOWABLE PARTIAL FILLS

Of 94 judgmentally selected PDE records, 3 records represented unallowable partial fills of Schedule II drugs. (There were no refills.)

- For two PDE records, the pharmacy dispensed more than the prescribed amount of the drug.

- For one PDE record, the pharmacy filled an emergency prescription for a drug without documenting oral authorization from the prescribing practitioner.

INACCURATE PRESCRIPTION DRUG EVENT DATA

Of 100 judgmentally selected PDE records (which included the 94 records reviewed for refills and partial fills), 18 records contained inaccurate data in certain fields. An additional 12 PDE

[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.

records were inaccurate because they were for drugs that the pharmacies did not dispense to beneficiaries.

Inaccurate Data in Certain Fields

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 18 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 dispense as written code indicating the prescriber's instructions regarding generic substitution did not match the prescriber's instructions on the prescription 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.

No Drugs Dispensed

Of 100 judgmentally selected PDE records, 12 records were inaccurate because they were for drugs that the pharmacies did not dispense to beneficiaries. OptumRX prepared these PDE records from claims submitted to United by four pharmacies. The pharmacies had no supporting documentation, such as physician-signed prescriptions and inventory logs showing that drugs had been dispensed. Although the pharmacies and United received payment for these drugs, no drugs were dispensed to beneficiaries.

INADEQUATE CONTROLS

OptumRx stated that the claims processing system had some edits in place to identify discrepancies and errors in pharmacy claims, but it relies on the pharmacy to enter accurate data for an allowable claim. However, 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 information provided by the pharmacies, the edits were not adequate to ensure the accuracy of certain fields in the PDE records or to identify PDE records for drugs that pharmacies did not dispense to beneficiaries.

United sends correspondence to its network pharmacies to remind them that they are contractually obligated to be familiar with Federal requirements related to Schedule II drugs. However, United has not provided to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or submission of accurate claim information for Schedule II drugs.

[4] All 18 PDE records had at least one of the types of inaccurate data shown.

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 United:

- strengthen its controls to (1) prevent unallowable partial fills of Schedule II drugs, (2) ensure the accuracy of submitted PDE records, and (3) identify PDE records for drugs that pharmacies did not dispense to beneficiaries;

- 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;

- work with its pharmacies to ensure that appropriate reversals are processed for the 12 PDE records for drugs that pharmacies did not dispense to beneficiaries; and

- work with its pharmacies to determine whether there are additional PDE records for drugs that pharmacies did not dispense to beneficiaries and ensure that appropriate reversals are processed for those PDE records.

AUDITEE COMMENTS

In written comments on our draft report, United did not concur that it did not have specific controls to prevent unallowable partial fills or refills of Schedule II drugs or that its claims processing system's edits were not adequate to identify unallowable partial fills. United stated that the claims system correctly processed the three unallowable partial fills based on the patient's location in a long-term-care facility and the information provided by the pharmacy.

Regarding our finding that 18 PDE records contained inaccurate data in certain fields, United acknowledged the importance of accurate data but did not concur on its overall ability to ensure the accuracy of PDE data that pharmacies prepare and submit to United. United stated that it is not able to validate the accuracy or completeness of underlying documentation or audit each claim submission in real time to ensure that accurate data are submitted. United added that OptumRx monitors claims submissions for possible improper billing patterns or questionable practices and that audits of selected pharmacies supplement this monitoring.

United disagreed that it was responsible for providing to pharmacies routine updates regarding Federal requirements. However, United concurred that when a particular issue or known

problem with network pharmacy claim submissions is identified, reminding pharmacies of the requirements is warranted. United stated that it accepts the recommendation to reach out to the pharmacy network through a communication on the subject of partial fills of Schedule II drugs. United also stated that it intends to provide communication to its network pharmacies on the importance of accurate data submission.

United concurred with our finding that 12 PDE records were inaccurate because they were for drugs that the pharmacies did not dispense to beneficiaries and stated that reversals for these records had been or would be processed. United also stated that additional PDE records for drugs not dispensed to beneficiaries were identified and reversed. United provided further information on corrective actions taken.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

Although the three unallowable partial fills were for patients residing in a long-term-care facility, Federal regulations make clear that, for a Schedule II drug to be partially filled, the total quantity dispensed must not exceed the total quantity prescribed. For 2 of the 3 unallowable partial fills, the pharmacy dispensed 360 pills, divided among 3 dispensings of 120 pills each, when only 120 pills were prescribed in total. In each instance, the pharmacy requested a new prescription from the doctor for 360 pills and overlooked that the doctor approved only 120 pills. For the third unallowable partial fill, the pharmacist did not create written documentation supporting that an oral authorization was received, as required by Federal regulations.

Regarding United's statement that it is not able to validate the accuracy or completeness of underlying documentation or ensure the accuracy of submitted PDE data, Federal regulations require the sponsor to provide certification as to the accuracy, completeness, and truthfulness of the claims data submitted for payment purposes.

Nothing in United's comments caused us to revise our findings or recommendations.

APPENDIX

APPENDIX: AUDITEE COMMENTS

UnitedHealthcare
MEDICARE & RETIREMENT

Contract Years 2008 - 2010
Office of Inspector General (OIG) Audit
UnitedHealthcare Response
Part D Fieldwork – PDE Data – Schedule II Drugs

A.1) OIG Findings – Unallowable Partial Fills and Inadequate Controls:

United 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.

United 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 in place to prevent refills of those drugs.

Of 94 judgmentally selected PDE records, 3 records represented unallowable partial fills of Schedule II drugs. (There were no refills.)

1. For two PDE records, the pharmacy dispensed more than the prescribed amount of the drug and allowed two additional dispensings.

RX_CLAIM_NUM	RX_CARDHOLDER_ID	RX_SERV_REF_NUM	RX_DOS_DT
101145349379002000	[redacted] *	9913254	4/24/2010
101256342718023000	[redacted]	9913254	5/5/2010

2. For one PDE record, the pharmacy filled an emergency prescription for a drug without documenting oral authorization from the prescribing practitioner.

RX_CLAIM_NUM	RX_CARDHOLDER_ID	RX_SERV_REF_NUM	RX_DOS_DT
091196329694018900	[redacted]	7870591	4/29/2009

The claims processing system's edits were not adequate to identify unallowable partial fills to prevent submission of PDE records related to those prescriptions, ensure the accuracy of certain fields in the PDE records, or identify PDE records for drugs that pharmacies did not dispense to beneficiaries. In addition, United has not provided to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or submission of accurate claim information for Schedule II drugs.

* **Office of Inspector General Note:** The deleted text has been redacted because it contained personally identifiable information.

OptumRx stated that the claims processing system had some edits in place to identify discrepancies and errors in pharmacy claims, but it relies on the pharmacy to enter accurate data for an allowable claim. However, 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 information provided by the pharmacies, the edits were not adequate to ensure the accuracy of certain fields in the PDE records or to identify PDE records for drugs that pharmacies did not dispense to beneficiaries.

United sends correspondence to its network pharmacies to remind them that they are contractually obligated to be familiar with Federal requirements related to Schedule II drugs. However, United has not provided to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or submission of accurate claim information for Schedule II drugs.

A.1 & A.2) OIG Recommendation:

We recommend that United:

1. strengthen its controls to (1) prevent unallowable partial fills of Schedule II drugs, (2) ensure the accuracy of submitted PDE records, and (3) identify PDE records for drugs that pharmacies did not dispense to beneficiaries;
2. 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;

A.1) Company Response to Findings and Corrective Action Requirements:

UnitedHealthcare (United) respectfully does **not concur to the issues noted:**

- United did not have specific controls to prevent unallowable partial fills or refills of Schedule II drugs.
- The claims processing system's edits were not adequate to identify unallowable partial fills to prevent submission of PDE records related to those prescriptions.

According to the Code of Federal Regulations (21 CFR section 1306.13, Partial filling of prescriptions), a prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. The 3 records that the OIG represented as a non-allowable partial fill were submitted by an LTCF. OptumRx's claims adjudication system correctly processed the claims based on the patient's location (LTCF) and information provided by the pharmacy. OptumRx's agreement with the pharmacy network requires the pharmacy to maintain and provide evidence to validate their adherence to documenting a patient's terminal illness or LTCF and to report accurate information to the PBM.

OptumRx requires the pharmacy to comply with state and Federal laws applicable to their business as independent contractor professionals in our pharmacy network, as noted in section 3.13 of our Pharmacy Network Agreement. In addition, OptumRx regularly sends to pharmacies amendments to the Pharmacy Network Agreement to comply with applicable new laws, including annual CMS Medicare Part D notice amendments. We respectfully disagree that it is the responsibility of OptumRx as a Pharmacy Benefit

Management (PBM) company to provide to pharmacies routine updates regarding Federal requirements; however we concur that upon the identification of a particular issue or known problem with our network pharmacy claim submissions that an action is warranted to clarify and remind pharmacies of the requirements and expectations. We accept the OIG's recommendation to reach out to the pharmacy network through a communication on the subject of partial fills of Schedule II controlled drugs.

We note that our system edits functioned correctly by restricting the use of medication to a specific day supply within a period of time. Two prescriptions with the same prescription number were correctly processed within eleven days apart (4/24/10, and 5/5/10), with a day supply of 12 and 5 days, respectively. The quantity usage of the first claim was greater than 75% on the day that the second claim processed. As stated in 21 CFR section 1306.13, an LTCF patient may receive a partial and incremental Schedule II fill of a single prescription over the course of a 60 day period from the issue date.

A.2) OIG Findings – Inaccurate Prescription Drug Event 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 18 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.

RX_CLAIM_NUM	RX_CARDHOLDER_ID	RX_SERV_REF_NUM	RX_DOS_DT
092325240975019	[redacted]	2377643	8/20/2009
092604398734058	[redacted]	2379300	9/17/2009
082463460710012	[redacted]	5131007	9/2/2008
100531318834003	[redacted]	2420242	2/22/10
082742712853012	[redacted]	685914	9/30/08
081995394492020	[redacted]	9383746	7/17/08
091103303323036	[redacted]	5311087	4/20/09
092643537263009	[redacted]	8660998	9/21/09
082616067176005	[redacted]	315156	9/17/08
091901643718034	[redacted]	7109498	7/08/09
083337053390015	[redacted]	1857534	11/28/08

- The dispense as written code indicating the prescriber's instructions regarding generic substitution did not match the prescriber's instructions on the prescription maintained at the pharmacy.

RX_CLAIM_NUM	RX_CARDHOLDER_ID	RX_SERV_REF_NUM	RX_DOS_DT
092443627055045900	[redacted]	4050604	9/1/2009
092263467709009900	[redacted]	4050604	8/14/2009
092333935122048900	[redacted]	4050604	8/21/2009
092143929564068900	[redacted]	4050604	8/2/2009
092383599767031900	[redacted]	4050604	8/26/2009
092203770484083900	[redacted]	4050604	8/8/2009

- 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.

RX_CLAIM_NUM	RX_CARDHOLDER_ID	RX_SERV_REF_NUM	RX_DOS_DT
091984704405022900	[redacted]	81708	7/17/2009

A.2) Company Response to Findings and Corrective Action Requirements:

OptumRx acknowledges the importance of accurate data in PDE records and the observations noted as "Inaccurate Prescription Drug Event Data." We provide the following further background to the OIG regarding the specific error examples

- **Fill number did not match Prescription** - The refill count code "01" is a self reported field submitted by the Pharmacy. There is no actual adjudication value to this field; therefore it is not possible to edit against whether this should be a "00" (indicating a zero refill or original prescription) or a "01" or a "02" (indicating 1 or more refills).
- **Dispense as written (DAW) code did not match the prescription** – DAW code is entered by the pharmacy at Point Of Sale (POS). The PBM does not have ability to view the hard copy of the prescription at POS when the claim is electronically adjudicated.
- **Day supply (DS) did not match the prescription** – The DS is entered by the pharmacy at POS. The Pharmacy Benefit Management (PBM) does not have ability to view the hard copy of the prescription at POS when the claim is electronically adjudicated.

Considering our role as administrator/adjudicator of pharmacy claims we respectfully do **not concur** with the OIG on our overall ability to ensure the accuracy of PDE data points that are prepared and submitted to us by pharmacies. As claims are submitted electronically and are adjusted in a real time basis, often with patients waiting to receive their medication, we do not receive nor do we have the ability to evaluate supporting documentation or records of either the prescriber or the pharmacy. We are not able to validate the accuracy or completeness of underlying documentation or essentially audit each claim submission in real time to ensure accurate data is submitted as part of the claim. The many system edits of our claims adjudication system, act as our primary reasonableness checkpoint, looking for inconsistent data parameters or other data discrepancies that should prevent a claim from adjudicating.

Prescribers and pharmacies have specific and unique requirements regarding their tasks and operations, and it is their responsibility to perform and adhere to the applicable requirements, such as signing prescription forms, indicating a patient's terminal illness status, or dispensing medication as written when called for. OptumRx monitors claims submissions received for possible improper billing patterns or questionable practices seeking to indentify common errors and points of particular concern, especially related to fraud, waste and abuse. Desktop and on-premises audits of selected pharmacies supplement this monitoring. Action may be taken against a particular pharmacy based on

their identified patterns and practice, up to and including potential termination from the OptumRx network.

We support our role and can reasonably act as a source of referral and information to regulatory agencies for their potential action against a prescriber or pharmacy, or to support their oversight and education efforts. We are able to provide generalized education to our pharmacies about expected practices, and to the extent we have knowledge of a particular problem to address such with them. In this case, we intend to provide a communication to our network pharmacies as a reminder of the importance of accurate data submission and their adherence to documentation requirements, to include the example data errors noted by the OIG.

B) OIG Findings – Inaccurate Prescription Drug Event Data:

No Drugs Dispensed
Of 100 judgmentally selected PDE records, 12 records were inaccurate because they were for drugs that the pharmacies did not dispense to beneficiaries. OptumRX prepared these PDE records from claims submitted to United by four pharmacies. The pharmacies had no supporting documentation, such as physician-signed prescriptions and inventory logs showing that drugs had been dispensed. Although the pharmacies and United received payment for these drugs, no drugs were dispensed to beneficiaries.

B) OIG Recommendation:

1. work with its pharmacies to ensure that appropriate reversals are processed for the 12 PDE records for drugs that pharmacies did not dispense to beneficiaries; and
2. work with its pharmacies to determine whether there are additional PDE records for drugs that pharmacies did not dispense to beneficiaries and ensure that appropriate reversals are processed for those PDE records.

B) Company Response to Findings and Corrective Action Requirements:

OptumRx states for the issue noted as "No Drugs Dispensed" concurrence to the 12 inaccurate PDE records.

OptumRx response to the OIG regarding this finding as follows:

We state concurrence with the Eight* OptumRx *(Mail Service Operation) inaccurate PDEs.

The following steps were taken immediately as corrective action:

- The eight duplicates were reversed on 6/15/2011 and the PDE records were corrected.

- A report was run to quantify the total impact and identify other duplicates incurred
- All identified duplicates were reversed in the claim system
- Verification checks were performed to ensure that PDE deletion records were accepted by CMS
- A root cause analysis was performed to identify that the issue resulted from a rare occasion whereby prescriptions that are cancelled after adjudication were not systematically reversed in our system. To address this, a batch process was implemented on 7/13/2011 to detect and report these situations. This process scans the database for prescriptions created during a specified date range for the previous week. When it encounters a prescription that is cancelled, it reviews the adjudication transactions to match "Accepted" reversal transactions with corresponding "Paid" billing transactions. Any prescription without the appropriate match to indicate the system reversed the claim is listed on the report and manually reversed.

We state concurrence to the four OptumRx (Retail Pharmacy Network) inaccurate PDEs.

The following steps were taken immediately as corrective action:

- The pharmacies were notified of the duplicate error.
- The three duplicates were reversed on 11/10/2011 and the PDE records were corrected and a note that the pharmacy was notified of the error was posted to the claim transaction.
- OptumRx will reverse the claim that the pharmacy could not provide supporting documentation to validate a drug was dispensed.
- A root cause analysis was performed on the three claims which identified that the issue was due to pharmacy billing errors that resulted in two paid claim records. In two instances the pharmacy submitted a first billing, but did not dispense the medication to the member/patient. The pharmacy should have reversed their first billing before submitting a second billing but did not, resulting in OptumRx's Refill-Too-Soon (RTS) edit appropriately preventing the second billing from processing. The pharmacies called into OptumRx's Help Desk since they were aware that no prior dispensing had occurred seeking a solution to permit dispensing of the medication at that time. Our Help Desk issued an "override" to the RTS edit permitting the internal control to be by-passed so that the medication could be dispensed. Our standard practice is to instruct the pharmacies to reverse prior billings in these situations. However, the pharmacies did not reverse their first billings.
- In the case of all claims, not just those for CIIs, Customer Service Advocates are trained to ask the pharmacy for all relevant information about a denied claim in order to determine what action is required. Plan guidelines and specific scenarios will determine the appropriate action, such as whether a reversal of a previous paid claim, a waiting period to resolve the RTS, an override of the current, denied claim, or some other action is necessary. Training material was modified on April 19, 2012 to

further clarify the process, including specific reference to controlled medications

- In the third instance, OptumRx validated that the lifted RTS was due to several states' declaration of a natural disaster. In these situations the edit is "lifted" to permit member/patient access to medications during the RTS crisis situation.
- A communication will be sent out to the pharmacy network to reinforce their contractual obligation to avoid duplication billing and maintain records and accounts of all transactions regarding covered Part D Prescription Drugs to Medicare Drug Plan Members.