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

September 20, 2011

Report Number: A-09-10-02046

Ms. Gay Ann Williams
Vice President, Legislative & Regulatory Compliance
Health Net, Inc.
21650 Oxnard Street
Woodland Hills, CA 91367

Dear Ms. Williams:

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 Health Net, Inc.* 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.

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If you have any questions or comments about this report, please do not hesitate to call me, or contact Shon Dormoy, Audit Manager, at (415) 437-8360 or through email at Shon.Dormoy@oig.hhs.gov. Please refer to report number A-09-10-02046 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, Maryland 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 HEALTH NET, INC.

Daniel R. Levinson
Inspector General

September 2011
A-09-10-02046

Office of Inspector General

http://oig.hhs.gov

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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, Health Net, Inc. (Health Net), provided prescription drug coverage to over 126,000 beneficiaries and submitted to CMS over 1.2 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 Health Net 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

Health Net did not have 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 as required by Federal regulations. Of 49 judgmentally selected PDE records, 7 records represented unallowable partial fills. (There were no refills.) In addition, of 67 judgmentally selected PDE records (which included the 49 records reviewed for refills and partial fills), 32 records contained inaccurate data when compared with the supporting documentation at the pharmacies.

The claims processing system had no edits to identify refills and unallowable partial fills by pharmacies 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, Health Net has not provided to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or adequate guidance on submitting accurate claim information for Schedule II drugs.

RECOMMENDATIONS

We recommend that Health Net:

- strengthen its controls to (1) prevent refills and 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.

HEALTH NET COMMENTS

In its written comments on our draft report, Health Net responded to our two recommendations. Regarding our first recommendation, Health Net agreed to enhance its retrospective audit practices to ensure that appropriate samples of claims for Schedule II drugs are included in all audits. Health Net concurred with our second recommendation and provided information on actions that it planned to take to address our recommendation. Health Net'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, 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.

Health Net, Inc., and CVS Caremark Part D Services, LLC

As a Part D sponsor, Health Net, Inc. (Health Net), provided prescription drug coverage to over 126,000 beneficiaries and submitted to CMS over 1.2 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 $178 million.[2] Health Net contracted with CVS Caremark Part D Services, LLC (Caremark), to provide PBM services beginning January 2008, including claims processing and adjudication, as well as preparation and submission of PDE records. Health Net maintained its own contracts with pharmacies until March 2009, when it switched to Caremark's pharmacy network.

As Health Net's PBM, Caremark processed prescription claims from pharmacies for each drug dispensing event. Caremark 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. Caremark used these data elements, as well as other Part D data, to create the PDE records. Caremark submitted the PDE records to CMS weekly. Caremark also performed audits of the data received from pharmacies. Health Net maintained an oversight role in Caremark'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] The amount paid to the pharmacies is on behalf of the sponsor, beneficiaries, and third parties. The $178 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 Health Net 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 1,167,889 PDE records for dates of service from January 1, 2008, through June 30, 2010, representing $161,423,861 paid for Schedule II drugs under Health Net'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 Health Net 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 November 2010 to August 2011 and performed fieldwork at Health Net's office in Rancho Cordova, California, 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 Health Net's contract with CMS regarding its roles and responsibilities as a Part D sponsor;
- reviewed Health Net's contract with Caremark regarding pharmacy contracting and processing of pharmacy claims;
- interviewed Health Net officials regarding their monitoring and oversight of PDE data;
- obtained Health Net's PDE records for Schedule II drugs for dates of service from January 1, 2008, through June 30, 2010 (processed by CMS through September 2010);

- analyzed the PDE records by beneficiary, prescription reference number, and fill number to determine that 55,454 PDE records represented potential refills and/or potential unallowable partial fills;

- selected a judgmental sample of 49 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 67 PDE records (which included the 49 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 Health Net 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

Health Net did not have 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 as required by Federal regulations. Of 49 judgmentally selected PDE records, 7 records represented unallowable partial fills. (There were no refills.) In addition, of 67 judgmentally selected PDE records (which included the 49 records reviewed for refills and partial fills), 32 records contained inaccurate data when compared with the supporting documentation at the pharmacies.

The claims processing system had no edits to identify refills and unallowable partial fills by pharmacies 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, Health Net has not provided to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or adequate guidance on submitting 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(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.

REFILLS AND UNALLOWABLE PARTIAL FILLS

Of 49 judgmentally selected PDE records, 7 records represented unallowable partial fills of Schedule II drugs. (There were no refills.)

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

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

INACCURATE PRESCRIPTION DRUG EVENT DATA

Of 67 judgmentally selected PDE records (which included the 49 records reviewed for refills and partial fills), 32 records contained inaccurate data. We considered data to be inaccurate when

[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.

certain fields in the PDE records did not match the supporting documentation that we reviewed at the pharmacies. The 32 PDE records contained the following inaccurate data:[4]

- The drug quantity dispensed did not match the quantity that was actually dispensed by the pharmacy.

- The days supply of the drug did not match the days supply of the drug actually dispensed by the pharmacy based on the prescriber's directions for use written on the prescription.

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

- The fill number did not match the number of refills or partial fills associated with the prescription as shown in the documentation 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).

- The prescription reference number did not match the reference number assigned to the prescription by the pharmacy.

INADEQUATE CONTROLS

Health Net stated that Caremark's monitoring efforts included the use of edits in its claims processing system to prevent payment for duplicate claims and to identify claims that had been resubmitted, adjusted, or deleted. However, there were no edits to identify refills and unallowable partial fills by pharmacies. In addition, Caremark's edits did not ensure the accuracy of certain fields in the PDE records based on information provided by the pharmacies.

Health Net also stated that Caremark sends correspondence to its network pharmacies on operational and procedural issues related to claims processing. However, Health Net has not provided to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or adequate guidance on submitting accurate claim information for Schedule II drugs.

CONCLUSION

Schedule II drugs have a high potential for abuse. Therefore, 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,

[4] All 32 PDE records had at least one of the types of inaccurate data shown.

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 Health Net:

- strengthen its controls to (1) prevent refills and 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.

HEALTH NET COMMENTS

In its written comments on our draft report, Health Net responded to our two recommendations:

- Regarding our first recommendation, Health Net agreed to enhance its retrospective audit practices to ensure that appropriate samples of claims for Schedule II drugs, especially those with refills, are included in all audits. Health Net stated that system edits are not available at the point-of-sale to regulate the issues identified in our findings.

- Health Net concurred with our second recommendation and provided information on actions that it planned to take to address our recommendation. Health Net stated that communication from a single Part D sponsor will have little impact on pharmacy practice and suggested that a much more effective approach would be to engage State and Federal agencies, such as State Boards of Pharmacy and the U.S. Department of Justice.

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

APPENDIX

APPENDIX: HEALTH NET COMMENTS

September 7, 2011

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

Re: Draft Report - *"Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Health Net, Inc., for the Period of January 1, 2008, through June 30, 2010."*
Report Number A-09-10-02046

Dear Ms. Ahlstrand,

Thank you for the opportunity to review and respond to the draft OIG report entitled *"Review of Medicare Part D Prescription Drug Event Data for Schedule II Drugs at Health Net, Inc., for the Period of January 1, 2008, through June 30, 2010."*

While we share the OIG's concerns around ensuring proper controls are in place when dispensing Schedule II drugs, we do have some concerns with the conclusions and recommendations contained within the draft report.

The report concludes that "Health Net did not have adequate controls to (l) 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 as required by Federal regulations." These conclusions were based upon findings developed as a result of reviewing documentation available at the network pharmacy that is not available for review or action within the electronic point-of-sale transaction model that supports our industry.

The current industry model, utilizing NCPDP data standards, does not allow Health Net (or any other Part D sponsor) to implement system edits to prevent the findings described in the report, with one exception. The vast majority of issues can only be discovered when a retrospective review/audit of documentation retained at the dispensing pharmacy is conducted. As a result, we believe the appropriate response is a re-examination of our "on-

site" and "desktop" audit functions. This re-examination will ensure that appropriate samples of claims for Schedule II drugs are reviewed for supporting documentation, refill history, and other issues identified in this report.

To reduce the probability that these issues occur, Health Net agrees that it would be beneficial to develop and distribute a pharmacy communication reminding pharmacies of the Federal Requirements related to (1) refills and partial fills of Schedule II drugs and (2) submission of accurate claim information for Schedule II drugs. We would like to suggest, however, that this communication from a single Part D sponsor will have little impact on pharmacy practice. A much more effective approach would be to engage the respective State Boards of Pharmacy, the U.S. Department of Justice's Drug Enforcement Division, or the OIG. We believe that communications and reminders from these sources will have a much higher potential to effectuate a change in Schedule II dispensing practices.

Please see a more detailed discussion of each OIG Finding and Recommendation in the attached pages.

Again, thank you for this opportunity to review the draft report. Health Net appreciates the effort put into reviewing these issues, and understands and supports the OIG's efforts to help reduce waste, abuse, and mismanagement.

If you have any questions regarding this response, please call me at (818) 676-8681.

Sincerely,

GayAnn Williams, Vice President
Medicare Compliance Officer
Health Net, Inc.

Cc: Jay Gellert, President and CEO
Patricia Clarey, Senior Vice President
John Sivori, President, Health Net Pharmacy Services

OIG Finding:

Health Net did not have adequate controls to prevent refills and unallowable partial fills of Schedule II drugs.

Of 49 judgmentally selected PDE records, 7 records represented unallowable partial fills of Schedule II drugs. (There were no refills.)

- For three 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 three PDE records, the drug was dispensed more than 60 days after the issue date of the prescription.
- For one PDE record, the drug was dispensed without a practitioner's written prescription.

OIG Recommendation:

Health Net should strengthen its controls to prevent refills and unallowable partial fills of Schedule II drugs.

Health Net Response:

As discussed above, the majority of these issues can only be discovered in a retrospective audit. Accordingly, Health Net agrees to enhance our retrospective audit practices to ensure appropriate samples of claims for Schedule II drugs, especially those with refills, are included in all audits. In addition, the issues identified above will be included in each Schedule II drug claim reviewed in the audit.

- Health Net is not aware of a patient's diagnosis from the claim as submitted, so cannot confirm that a patient is terminally ill in a point-of-sale transaction. Refills could be blocked at all non-LTC pharmacies pending confirmation of a diagnosed terminal illness, but we believe this could result in preventing access to services for a vulnerable population.
- Because the "issue date" of a prescription is included on pharmacy claims submitted to Health Net, an edit could be built and implemented to reject claims for secondary partial fills of Schedule II drugs that occur more than 60 days from the issue date. Unfortunately, current NCPDP data standards do not require this field to be included in the electronic claim submitted to a Plan and, consequently, the industry does not have an effective system edit available today that could reject these claims. However, the next release of the NCPDP standard (effective Jan 1, 2012) will require the "date written" field. Health Net recognizes this as an opportunity for increased compliance, but suggests that this issue needs to be addressed at the industry level. CMS involvement, by requiring all plans to develop and implement this edit, would be an effective tool to expand and reinforce compliance.

OIG Finding:

Health Net 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 67 judgmentally selected PDE records (which included the 49 records reviewed for refills and partial fills), 32 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. The 32 PDE records contained the following inaccurate data:

- The drug quantity dispensed did not match the quantity that was actually dispensed by the pharmacy.
- The days supply of the drug did not match the days supply of the drug actually dispensed by the pharmacy based on the prescriber's directions for use written on the prescription.
- 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 prescriber identifier did not match the prescriber information on the prescription maintained at the pharmacy.
- The fill number did not match the number of refills or partial fills associated with the prescription as shown in the documentation 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).
- The prescription number did not match the reference number assigned to the prescription by the pharmacy.

OIG Recommendation:

Health Net should strengthen its controls to ensure accuracy of submitted PDE records.

Health Net Response:

System edits are not available to regulate the issues indentified above at the point-of-sale. The findings listed above can only be discovered and addressed in a retrospective audit of documentation retained at the dispensing pharmacy. As a result, Health Net agrees to enhance our retrospective audit practices to ensure appropriate samples of claims for Schedule II drugs are included in all audits. The issues identified above will be routinely included in each Schedule II drug claim reviewed in the audit.

OIG Finding:

Health Net also stated that Caremark sends correspondence to its network pharmacies on operational and procedural issues related to claims processing. However, Health Net has not provided to pharmacies any guidance clarifying Federal requirements related to refills and partial fills of Schedule II drugs or adequate guidance on submitting accurate claim information for Schedule II drugs.

OIG Recommendation:

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

Health Net Response:

Health Net concurs and will develop and distribute a pharmacy communication reminding pharmacies of the Federal Requirements related to (1) refills and partial fills of Schedule II drugs and (2) submission of accurate claim information for Schedule II drugs.

We would suggest, however, that this communication from a single Part D sponsor will have little impact on pharmacy practice. A much more effective approach would be to engage the respective State Boards of Pharmacy, the U.S. Department of Justice's Drug Enforcement Division, or the OIG. The ultimate responsibility for ensuring the accuracy of prescription written for a Schedule II drug rests with the licensed dispensing pharmacist. He/she is the gate keeper at the point-of-service and it is his/her responsibility to ensure the Schedule II prescription is valid under state and federal laws prior to dispensing. We believe the most effective way to increase compliance is to direct communication and training to those individuals. We also believe that those communications and reminders will have more impact when distributed by the sources listed above.