REPORT ON THE
MEDICARE DRUG DISCOUNT CARD
PROGRAM SPONSOR MCKESSON HEALTH SOLUTIONS
Report Number: A-06-06-00022

Maria Sharp
McKesson Health Solutions
4343 North Scottsdale Road, Suite 150
Scottsdale, Arizona 85251

Dear Ms. Sharp:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) final report entitled “Report on the Medicare Drug Discount Card Program Sponsor McKesson Health Solutions.” A copy of this report will be forwarded 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 the HHS action 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.

In accordance with the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, OIG reports issued to the Department’s grantees and contractors are made available to the public to the extent the information is not subject to exemptions in the Act that the Department chooses to exercise (see 45 CFR part 5).

Please refer to report number A-06-06-00022 in all correspondence.

Sincerely,

Gordon L. Sato
Regional Inspector General
For Audit Services

Enclosures
Direct Reply to HHS Action Official:

Cynthia Moreno
Director, Plan Oversight and Accountability Group
Centers for Medicare & Medicaid Services
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Mail Stop C4-23-07
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EXECUTIVE SUMMARY

BACKGROUND

Medicare Drug Discount Card Program and Transitional Assistance

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), section 1860D-31(a)(1), established a drug discount card program to provide eligible individuals with access to prescription drug discounts and transitional assistance (TA) subsidies. The program began in June 2004 and ended in December 2005 or when the beneficiary enrolled in the Medicare Part D drug program, whichever occurred first. However, if enrolled by December 2005, a beneficiary could have used the drug discount card through May 2006.

Section 1860D-31(h)(4) and (8) of the MMA required drug discount card sponsors to pass on negotiated prices to beneficiaries and ensure that beneficiaries were not charged more than the lower of the negotiated prices or the usual and customary prices.

The MMA, section 1860D-31(d)(2)(C), also required sponsors to provide a beneficiary’s TA balance to the pharmacy when a prescription was filled. Beneficiaries received a maximum TA subsidy of $600 per year for 2004 and 2005; the amount was prorated for 2005 based on when they enrolled in the program. Beneficiaries who enrolled in 2004 received the entire $600, regardless of the month they enrolled.1 The Centers for Medicare & Medicaid Services (CMS) added any amount not used in 2004 to the 2005 benefit.

To recoup claimed expenditure payments made to the pharmacies, sponsors withdrew funds from the Payment Management System. All claim expenditures and withdrawals should have been reported to CMS on the Transitional Assistance Monthly Expense and Reconciliation Report (TAMER).

The MMA, section 1860D-2(e)(2)(A), excludes specific drugs and drug classes from the definition of “covered Part D drug.” Any drug or class of drugs that is excluded should not have been purchased with TA funds. In August 2005, CMS issued a memo directing all drug discount card sponsors to determine whether they had used TA funds to pay for excluded drugs. The memo requested that sponsors repay CMS for any funds used for excluded drugs.

McKesson Health Solutions

McKesson Health Solutions (McKesson), a healthcare management organization in Scottsdale, Arizona, offered a drug discount card to eligible Medicare beneficiaries. McKesson submitted approximately $73 million in claims to CMS for TA expenditures from June 2004 through July 2005.

1All individuals whose applications were received in December 2004 were officially enrolled in January 2005. However, those individuals received the full TA entitlement for 2004 and 2005.
IntegriGuard

CMS contracted with IntegriGuard, LLC, to audit Medicare drug discount card programs. The program safeguard contractor reviewed a variety of issues, including enrollment, TA fund limits, and excluded drugs. We met with IntegriGuard and reviewed some of its workpapers in an effort to understand the program and develop audit areas.

Transition to Medicare Part D

CMS requires prescription drug plan (PDP) sponsors in the Part D program to ensure that:

- beneficiaries have access to drugs at negotiated prices,
- payments for beneficiaries and claims submitted to CMS are correct, and
- statutorily excluded drugs are not included in the program.

At the time of our audit, McKesson did not know whether it would participate in the Medicare Part D drug program. If McKesson participates, CMS will require it to follow the above requirements.

OBJECTIVES

Our objectives were to determine whether McKesson complied with Federal requirements to (1) ensure that beneficiaries did not exceed their TA limits, (2) apply TA funds only to covered drugs, (3) pass on negotiated prices to beneficiaries and offer the lower of the negotiated prices or the usual and customary prices, and (4) support the expenditures and withdrawals it reported to CMS.

SUMMARY OF FINDINGS

McKesson properly recorded on the TAMER the expenditures it made on behalf of beneficiaries and the withdrawals it made from the Payment Management System, as reflected on its bank deposit records, to recoup the expenditures. However, McKesson did not have proper procedures in place to ensure that it always complied with Federal requirements to:

- ensure that beneficiaries did not exceed their TA fund limits,
- apply TA funds only to covered drugs, and
- pass on negotiated prices to beneficiaries.

RECOMMENDATIONS

We recommend that McKesson:

- reimburse CMS for the $176,032 by which it exceeded TA fund limits;
- determine whether the amount McKesson reimbursed CMS for excluded drugs included any of the $135,494 in TA funds identified in the audit and reimburse the difference; and
- implement policies and procedures, if it continues as a PDP sponsor in Part D, to ensure that it (1) does not pay for statutorily excluded drugs with CMS funds and (2) offers negotiated prices to the beneficiaries.

MCKESSON HEALTH SOLUTIONS'S COMMENTS

In its written comments on our draft report, McKesson said that it would determine whether it agreed or disagreed with our first recommendation, disagreed with our second recommendation, and said that the third recommendation did not apply. After follow-up conversations, McKesson said that it will reimburse CMS $110,034 for excess TA payments it made to beneficiaries and that IntegriGuard identified in its audit. McKesson stated that IntegriGuard is conducting another audit of its TA expenditures and that McKesson will provide us with the results of the audit. McKesson also stated that it would determine how much of the $176,032 we identified is included in the amount identified by IntegriGuard.

McKesson stated that it will not reimburse CMS for the excluded drugs for which OIG believes it paid because CMS did not issue comprehensive guidance on identifying excluded drugs and, later, issued guidance without an effective date.

Additionally, McKesson stated that it is not participating in Medicare Part D as a PDP sponsor. McKesson’s comments are included in their entirety in the Appendix.

OFFICE OF INSPECTOR GENERAL’S RESPONSE

McKesson should submit its completed new reconciliation report on TA funds to us and CMS for review.

Also, we continue to believe that McKesson should reimburse CMS $135,494 for the TA funds it used to pay for excluded drugs.
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INTRODUCTION

BACKGROUND

Medicare Drug Discount Card Program and Transitional Assistance

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), section 1860D-31(a)(1), established a drug discount card program to provide eligible individuals with access to prescription drug discounts and transitional assistance (TA) subsidies. The program began in June 2004 and ended in December 2005 or when the beneficiary enrolled in the Medicare Part D drug program, whichever occurred first. However, if enrolled by December 2005, a beneficiary could have used the drug discount card through May 2006. The Medicare Part D program went into effect January 1, 2006. Like the drug discount card program, Medicare Part D provides discount drug coverage for Medicare-eligible individuals.

Under the drug discount card program, the Centers for Medicare & Medicaid Services (CMS) provided TA subsidies to low-income Medicare beneficiaries whose prescription drugs were not covered by Medicaid or another insurance plan. Eligible beneficiaries were entitled to $600 per year in 2004 and 2005; funds not used during 2004 were rolled over into 2005. Individuals who enrolled in 2004 were eligible for the entire $600 subsidy, regardless of when they enrolled in the program. Beneficiaries who enrolled in 2005 received a prorated subsidy based on the date they enrolled. When applying TA toward the purchase of prescription drugs, beneficiaries who had incomes at or below 100 percent of the poverty level paid a 5-percent coinsurance payment, and those with incomes between 101 and 135 percent of the poverty level paid a 10-percent coinsurance payment.

In addition, Medicare paid the annual drug discount card program enrollment fee, if any, charged by a sponsor for eligible beneficiaries.

Centers for Medicare & Medicaid Services Requirements

CMS required drug discount card sponsors to:

- obtain manufacturer discounts or rebates on brand name and generic drugs and share the savings with beneficiaries;
- enroll all eligible Medicare beneficiaries who applied to their programs and resided in their service areas;
- administer the TA program for all drug card program enrollees who applied for subsidies and met eligibility requirements;

1All individuals whose applications were received in December 2004 were officially enrolled in January 2005. However, those individuals received the full TA entitlement for 2004 and 2005.
• provide access to discounts on at least one brand name or generic prescription drug in each of the therapeutic drug classes, groups, and subgroups of prescription drugs Medicare beneficiaries commonly need; and

• charge CMS an annual enrollment fee of no more than $30 per beneficiary.

**Federal Requirements**

The MMA, sections 1860D-31(h)(4) and (8), required drug discount card program sponsors to pass on negotiated rates to beneficiaries and ensure that beneficiaries were not charged more than the lower of the negotiated prices or the usual and customary prices. Negotiated prices take into account any manufacturer rebates, pharmacy discounts, and pharmacy dispensing fees. Manufacturers base rebates on a periodically updated published price that includes the wholesale acquisition cost (WAC) and the average wholesale price (AWP). The usual and customary price is what the pharmacy normally charges for the drug if the beneficiary does not have insurance.

The MMA, section 1860D-31(d)(2)(C), also required sponsors to provide a beneficiary’s TA balance to the pharmacy when a prescription was filled.

To recoup claimed expenditure payments to pharmacies, sponsors withdrew funds from the Payment Management System. All claim expenditures and withdrawals should have been reported to CMS on the Transitional Assistance Monthly Expense and Reconciliation Report (TAMER).

The MMA, section 1860D-2(e)(2)(A), excludes specific drugs and drug classes from the definition of “covered Part D drug.” Any drug or class of drugs that is excluded should not have been purchased with TA funds. In August 2005, CMS issued a memo directing all drug discount card sponsors to determine whether they had used TA funds to pay for excluded drugs. The memo requested that sponsors repay CMS for any funds used for excluded drugs.

**McKesson Health Solutions**

McKesson Health Solutions (McKesson), a healthcare management organization in Scottsdale, Arizona, offered a drug discount card to eligible Medicare beneficiaries. McKesson submitted approximately $73 million in claims to CMS for TA expenditures from June 2004 through July 2005.

**IntegriGuard**

CMS contracted with IntegriGuard, LLC, to audit Medicare drug discount card programs. The program safeguard contractor reviewed a variety of issues, including enrollment, TA fund limits, and excluded drugs. We met with IntegriGuard and reviewed some of its workpapers in an effort to understand the program and develop audit areas.
Transition to Medicare Part D

CMS requires prescription drug plan (PDP) sponsors in the Part D program to ensure that:

- beneficiaries have access to drugs at negotiated prices,
- payments for beneficiaries and claims submitted to CMS are correct, and
- statutorily excluded drugs are not included in the program.

At the time of our audit, McKesson did not know whether it would participate in the Medicare Part D drug program. If McKesson participates, CMS will require it to follow the above requirements.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to determine whether McKesson complied with Federal requirements to (1) ensure that beneficiaries did not exceed their TA fund limits, (2) apply TA funds only to covered drugs, (3) pass on negotiated prices to beneficiaries and offer the lower of the negotiated prices or the usual and customary prices, and (4) support the expenditures and withdrawals it reported to CMS.

Scope

For the period June 2004 through July 2005, McKesson submitted TA expenditure claims to CMS totaling approximately $73 million. We limited our review of the drug discount card program to claims paid with TA subsidies.

We reviewed the drug prices McKesson negotiated with drug manufacturers and pharmacies for July 2004 (the second full month of the program) and May 2005 (the most current month that data were available when we started the audit). To determine whether McKesson offered beneficiaries the prices negotiated with drug manufacturers and pharmacies, we repriced the negotiated prices McKesson claimed on 200 sampled claims by using the pricing methodology set forth in its contracts.

As part of our audit, we:

- relied on the enrollment information IntegriGuard provided,
- used McKesson’s payment data,
- did not perform a detailed review of McKesson’s internal controls because the audit objectives did not require it, and
• did not review the $44 McKesson reimbursed CMS for excluded drugs to determine whether it was included in the $135,494 in excluded drugs we identified.

We performed our fieldwork at the McKesson office in Scottsdale, Arizona.

Methodology

To accomplish our objectives, we:

• met with IntegriGuard officials and reviewed some of their workpapers in an effort to understand the program and develop audit areas;

• obtained McKesson’s bank records to compare them to the amounts recorded as withdrawals on the TAMER;

• obtained the claim information to compare it to the expenditures recorded on the TAMER;

• reviewed McKesson’s policies and procedures regarding TA;

• selected the months of July 2004 and May 2005 to reprice a sample of claims and reviewed an unrestricted random sample of 100 claims for each of the 2 months;

• reviewed the contracts between McKesson and CMS, manufacturers, and pharmacies; and

• analyzed all claims during the period June 2004 through July 2005 to determine whether the drugs on the claims were excluded drugs and whether beneficiaries exceeded their TA fund limits.

We did not rely on IntegriGuard’s work because it (1) did not cover the same period as our review of TA, (2) did not use all of the criteria available to determine excluded drugs, and (3) did not include negotiated prices in its review. Additionally, in its report to CMS, IntegriGuard did not recommend that McKesson reimburse CMS for funds used to pay for excluded drugs and excess TA.

We conducted our review in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

McKesson properly recorded on the TAMER the expenditures it made on behalf on beneficiaries and the withdrawals it made from the Payment Management System, as reflected on its bank deposit records, to recoup the expenditures. However, McKesson
did not have proper procedures in place to ensure that it always complied with Federal requirements to:

- ensure that beneficiaries did not exceed their TA fund limits,
- apply TA funds only to covered drugs, and
- pass on negotiated prices to beneficiaries.


**TRANSITIONAL ASSISTANCE LIMITS**

**Federal Requirements**

The MMA, section 1860D-31(g)(2)(a), limited the TA subsidy amount a qualified beneficiary could receive to $600 during 2004 and $600 during 2005. CMS prorated the amount for 2005 based on the date the beneficiary enrolled in the program. Beneficiaries who enrolled in 2004 received the entire $600, regardless of the month they enrolled. CMS added any amount not used during 2004 to the 2005 benefit.

**Transitional Assistance Limits Exceeded**

For the period June 2004 through July 2005, McKesson allowed 1,093 beneficiaries to exceed their TA fund limits. For 2004, the amount exceeding the TA fund limits ranged from $1 to $1,102 for 462 beneficiaries. For 2005, the amount exceeding the TA fund limits ranged from $.30 to $1,200 for 688 beneficiaries. Some beneficiaries exceeded their TA fund limits in both years.

**Inadequate Procedures**

McKesson did not have adequate procedures in place to ensure that beneficiaries did not exceed their TA fund limits as required by the MMA.

**Excess Transitional Assistance Funds**

Because McKesson did not have adequate procedures in place to ensure that beneficiaries did not exceed their TA fund limits, McKesson overpaid $176,032 for 1,093 beneficiaries. Specifically, McKesson paid:

- $47,503 for 462 beneficiaries who exceeded their TA fund limits in 2004 and
EXCLUDED DRUGS

Federal Requirements

The MMA, section 1860D-2(e)(2)(A), excludes specific drugs and drug classes from the definition of "covered Part D drug." Regulations (CFR § 403.802) define covered Part D drug and state which drugs are included and excluded. Any drug that falls into one of the excluded classes of drugs cannot be purchased with TA funds.

In July 2004, CMS issued a list of two classes of excluded drugs; in November 2004, it issued an updated list that covered all classes of excluded drugs as of December 2004. CMS based the lists on the National Drug Code (NDC), which identifies each drug by a specific code. On August 29, 2005, CMS issued a memo directing all drug discount card sponsors to determine whether they had used TA funds to pay for excluded drugs. The memo specified which list to use for the appropriate period and requested that sponsors repay CMS for any funds used for excluded drugs.

Transitional Assistance Funds Used for Statutorily Excluded Drugs

From July 12, 2004, to July 31, 2005, McKesson charged CMS for 7,371 claims for drugs that were statutorily excluded from the drug discount card program and for which payment should not have been made.

Excluded Drug List Not Updated in a Timely Manner

McKesson paid for excluded drugs because it initially did not establish edits at the NDC level to correctly identify all of the excluded drugs, and it did not update the list of excluded drugs in its system in a timely manner.

Charged for Statutorily Excluded Drugs

Because McKesson initially did not have sufficient edits and did not update CMS's list of excluded drugs in a timely manner, CMS overpaid McKesson $135,494 for 7,371 claims. Using the guidelines that CMS issued to drug card sponsors on August 29, 2005, the breakdown of claims McKesson submitted to CMS for statutorily excluded drugs is:

- $103,883 for 5,922 claims made from July 12 through December 3, 2004; and
- $31,611 for 1,449 claims made from December 4, 2004, through July 31, 2005.

In September 2005, McKesson sent CMS a letter stating that since it did not issue the guidelines in a timely manner, McKesson should be required to reimburse CMS only for the $44 in TA funds McKesson concluded was used for excluded drugs.
NEGOTIATED PRICES

Federal Requirements

The MMA, sections 1860D-31(h)(4) and (8), required sponsors to pass on negotiated rates to beneficiaries and ensure that beneficiaries were not charged more than the lower of the negotiated prices or the usual and customary prices.

Federal regulations (42 CFR § 403.806(d)(6)) required sponsors to pass on a share of any discounts, rebates, or other price concessions to beneficiaries through negotiated prices. McKesson's contracts with drug manufacturers specified the amount of the rebates that McKesson should have passed on to the beneficiaries and what amount it should have kept.

Negotiated Prices Not Passed On to Beneficiaries

McKesson did not comply with Federal requirements and McKesson contracts to pass on negotiated prices to the beneficiaries and charge the lower of the negotiated prices or the usual and customary prices. The contracts specifically stated the amount of a rebate that should have been passed on to the beneficiaries.

Of the 200 claims we reviewed, 60 had the following errors related to negotiated prices:

- Fifty-five claims were calculated using an incorrect formula.
- For two claims, the dispensing fee and discount percentage were different from those the pharmacy contract specified.
- For three claims, the rebate percent was rounded to the wrong decimal place.

Inadequate Procedures

McKesson did not have adequate procedures in place to ensure that it complied with the MMA's requirements to pass on negotiated prices to beneficiaries. Specifically, McKesson incorrectly calculated all the claims from one pharmacy chain for July 2004, did not use the correct discount and dispensing fee on the July 2004 claims from another pharmacy chain, and incorrectly rounded the rebate percent for all claims involving a drug manufacturer.

Claims Billed Incorrectly

While the dollar amounts of these errors are not material, they could become material if McKesson becomes a Part D provider.
RECOMMENDATIONS

We recommend that McKesson:

- reimburse CMS for the $176,032 by which it exceeded TA fund limits;
- determine whether the amount McKesson reimbursed CMS for excluded drugs included any of the $135,494 in TA funds identified in the audit and reimburse the difference; and
- implement policies and procedures, if it continues as a PDP sponsor in Part D, to ensure that it (1) does not pay for statutorily excluded drugs with CMS funds and (2) offers negotiated prices to the beneficiaries.

MCKESSON HEALTH SOLUTIONS’S COMMENTS

In its written comments on our draft report, McKesson said that it would determine whether it agreed or disagreed with our first recommendation, disagreed with our second recommendation, and said that the third recommendation did not apply. After follow-up conversations, McKesson said that it will reimburse CMS $110,034 for excess TA payments it made to beneficiaries and that IntegriGuard identified in its audit. McKesson stated that IntegriGuard is conducting another audit of its TA expenditures and that McKesson will provide us with the results of the audit. McKesson also stated that it would determine how much of the $176,032 we identified is included in the amount identified by IntegriGuard.

McKesson stated that it will not reimburse CMS for the excluded drugs for which we believe it paid because CMS did not issue comprehensive guidance on identifying excluded drugs and, later, issued guidance without an effective date. CMS initially requested sponsors to exclude drugs based on categories McKesson said that it believed CMS left to each sponsor to interpret. McKesson said that CMS issued a list of NDC codes on November 4, 2004, without an effective date; therefore, McKesson did not implement the list until January 1, 2005. McKesson reimbursed CMS $44.35 for excluded drugs for which McKesson said it paid between January 1 and August 4, 2005.

Additionally, McKesson stated that it is not participating in Medicare Part D as a PDP sponsor. McKesson’s comments are included in their entirety in the Appendix.

OFFICE OF INSPECTOR GENERAL’S RESPONSE

McKesson should submit its completed new reconciliation report on TA funds to us and CMS for review. We spoke with McKesson officials and they said that they plan to work with IntegriGuard to determine the total funds spent that exceeded TA limits. Therefore, that is why the reconciliation was not completed by September 1, 2006, as stated in their response.
Also, we continue to believe that McKesson should reimburse CMS $135,494 for the TA funds it used to pay for excluded drugs. CMS issued a list of excluded drugs on July 12, 2004, covering benzodiazepines and barbiturates at the NDC level. CMS issued a revised list on November 4, 2004, that covered all excluded drug classes at the NDC level. Due to questions from sponsors, CMS issued a clarification in 2005 that made the November 4, 2004, list effective as of December 4, 2004.
August 15, 2006

Attn: Gordon L. Sato
Regional Inspector General for Audit Services
Office of Audit Services
1100 Commerce, Room 632
Dallas, TX 75242


McKesson has read the report and recommendations provided by the Office of Inspector General (OIG). OIG included 3 recommendations that McKesson will address individually.

1. OIG requests McKesson reimburse CMS for the $176,032 by which McKesson exceeded TA fund limits
   a. Based on the findings provided during the audit with IntegriGuard and the requested payment amount indicated in the A-06-06-00022 report, McKesson is conducting a full reconciliation of the difference which will be completed by September 15, 2006. McKesson will remit payment for the entire or partial amount based on the results. Please provide McKesson with the remit to address for payment.

2. OIG requests McKesson to determine whether the amount McKesson reimbursed CMS for excluded drugs included any of the $135,494 in TA funds identified in the audit and reimburse the difference
   a. McKesson did determine that the amount reimbursed to CMS was included in the $135,494. McKesson also maintains the position that the difference is not due to CMS due to the following reasons:
      - For claims paid between July 12, 2004 and November 3, 2004, McKesson has identified that the guidance provided to sponsors from CMS was not at the NDC level. CMS requested sponsors to exclude drugs based on categories (benzodiazepines and barbiturates), which was left to be interpreted by each sponsor. McKesson acted in accordance with CMS' request; therefore, we do not feel responsible to pay for excluded claims during this time period.
      - For claims paid between November 4, 2004 and August 4, 2005, McKesson did receive a file at the NDC level on November 4, 2004 from CMS, without an effective date. Since there was not a published effective date from CMS, the excluded drug list was not implemented until the new enrollment period of 2005. Therefore, McKesson holds no financial responsibility for claims processed between November 4, 2004 and December 31, 2004. McKesson does hold financial responsibility for claims processed between January 1, 2005 and August 4, 2005. The total amount of claims processed between this time period for excluded drug is $44.35. McKesson adjusted the TAMER by $44.35 on September 30, 2005.
      - Claims paid after August 4, 2005, CMS requests sponsors to be in compliance with the excluded drug list provided and shall not pay for any excluded drugs as referenced in 1860-D-2(e)(2). McKesson and other sponsors requested a more reasonable implementation lead time. CMS provided a required implementation date of September 14, 2005. McKesson completed the updates and do not have any claims paid for excluded drugs for this time period.

3. OIG requests McKesson implement policies and procedures, if it continues as a PDP sponsor in Part D, to ensure that McKesson (1) does not pay for statutorily excluded drugs with CMS funds and (2) offers negotiated prices to the beneficiaries.
   a. McKesson has chosen not to participate as a PDP sponsor in Part D.

Sincerely,

DeEtte Thomas
Vice President, Client Services