Department of Health and Human Services

# OFFICE OF INSPECTOR GENERAL

# Home Dialysis Payment Vulnerabilities

**JANET REHNQUIST**
**Inspector General**

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# *OFFICE OF INSPECTOR GENERAL*

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# EXECUTIVE SUMMARY

## OBJECTIVE

To assess End Stage Renal Disease (ESRD) home dialysis billing processes and identify any vulnerabilities in Medicare payments.

## BACKGROUND

End Stage Renal Disease, characterized by a permanent loss of kidney function, is the only basis for entitlement to Medicare based on the presence of a specific medical diagnosis. The Centers for Medicare & Medicaid Services (CMS) is charged with the administration of the ESRD Program. By 2000, the ESRD Medicare population in the United States climbed to approximately 273,000, with Medicare expenditures reaching nearly $12 billion. In the next 10 years, the number of individuals with ESRD, as well as Medicare expenditures for this population, is projected to more than double.

A beneficiary may receive dialysis at a facility or at home. If a beneficiary chooses the latter, he or she must select one of two payment methods. In Method I, a dialysis facility will provide all necessary supplies and services. In Method II, a dialysis facility provides all necessary services and a durable medical equipment supplier furnishes all necessary supplies. Fiscal intermediaries (FIs) process claims for ESRD supplies and services for Method I, but only services for Method II. Durable medical equipment regional carriers (DMERCs) process durable medical equipment claims, including dialysis supply kits, for Method II beneficiaries. The FIs and DMERCs, which process claims for ESRD facilities and durable medical equipment (DME) suppliers, respectively, should match the home dialysis beneficiaries' method selection to the types of payment allowed.

In order to complete this inspection, we identified the population of home dialysis beneficiaries by reviewing every recorded CMS-382 submission, designating home dialysis and payment method, from late 1996 to mid-2001. Next, we reviewed the calendar year (CY) 2000 National Claims History File (NCH) to identify claims for all beneficiaries with a Medicare status code indicating ESRD.

## FINDINGS

Medicare and beneficiaries paid an additional $15.3 million for continuous cycling peritoneal dialysis (CCPD) under Method II when compared to Method I. Medicare also allowed claims without existing method selection data in the Common Working File (CWF), resulting in $9.5 million in incorrect payments.

### Medicare regulations for reimbursement for home dialysis are inconsistent

Medicare pays all dialysis modalities under all Methods equally, except for CCPD under Method II, where payments per month can be up to $484 more than the others. This premium resulted in additional annual payments of $12.2 million for Medicare and $3.1 million for beneficiaries in CY 2000. From CYs 1997 to 2000, there was a shift in both payment method and dialysis modality, with the majority of these beneficiaries now electing Method II, and an increasing proportion using the more expensive CCPD.

### Medicare allowed claims without an existing method selection

According to the Carrier Manual, a Medicare ESRD claim should only be paid if a method selection form is on file. If one does not exist, the claim should be denied. Medicare allowed $9.5 million for more than 12,000 home dialysis-related items in CY 2000 without a method selection designation in the CWF.

## RECOMMENDATIONS

We recommend that CMS:

- ❑ Change regulations to limit payments for Method II CCPD kits to that of Method I.
- ❑ Ensure that claims are not paid unless a valid method selection form has been recorded on the CWF.
- ❑ Review the $9.5 million in paid Medicare claims and collect any incorrect payments.

## AGENCY COMMENTS

In its written response to our report, CMS disagreed with the recommendation of changing regulations to limit payments for Method II CCPD supplies to that of Method I. The CMS believes the statute clearly intends that payment limits for CCPD supplies should be set at a higher level than under the composite rate methodology. We agree that the statute clearly allows a higher payment limit for CCPD supplies under Method II; however, the statute does not require paying the higher limit. Therefore, we continue to believe that CMS should reimburse suppliers consistently for the same dialysis supplies, irrespective of the method the beneficiary chooses.

The CMS agrees to take corrective action to ensure that claims are not paid unless a valid method selection form has been recorded on the CWF and that improper overpayments should be recovered. The full text of CMS's comments is included in Appendix B.

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# INTRODUCTION

## OBJECTIVE

To assess End Stage Renal Disease (ESRD) home dialysis billing processes and identify any vulnerabilities in Medicare payments.

## BACKGROUND

End Stage Renal Disease is characterized by a permanent and irreversible loss of kidney function requiring either kidney transplantation or regular dialysis treatments in order to survive. In 1972, amendments to Title XVIII of the Social Security Act extended Medicare Part A and Part B benefits to virtually all individuals with ESRD regardless of age.[1] The ESRD program is the only Medicare program for which entitlement is based on the presence of a specific medical diagnosis.

In 1973, the year in which the program was initiated, the number of eligible ESRD beneficiaries totaled 10,000. At the end of 2000, the ESRD Medicare population had climbed to approximately 273,000, with Medicare expenditures of nearly $12 billion.[2] The number of individuals with ESRD is expected to more than double by 2010, surpassing 660,000 individuals, with projected Medicare expenditures of $28 billion.[2]

### Home Dialysis

Dialysis treatments are utilized by 80 percent of ESRD beneficiaries; the remaining 20 percent receive transplants or withdraw from treatment. Dialysis may be performed either in a facility or in a home setting. Peritoneal dialysis, the most typical treatment modality for home dialysis patients, uses the body's own peritoneal membrane as the filter for screening toxins from the body. There are two forms of peritoneal dialysis: continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD).

Continuous ambulatory peritoneal dialysis. In CAPD, the dialysate solution is left in the peritoneal cavity for 4 to 6 hours. The process of draining the dialysate and replacing fresh solution takes approximately 30 minutes, and most patients change the solution 4 times a day.

[1] Individuals with ESRD, who are under age 65, may experience a 3-month waiting period prior to Medicare coverage. In addition, individuals who have coverage under an Employer's Group Health Plan may undergo a 30-month period in which Medicare acts as a secondary payer to the Group Health Plan.

[2] United States Renal Data System, retrieved from the World Wide Web: http://www.usrds.org/atlas.htm (August 30, 2001). MedPAC (Report to Congress: Medicare Payment Policy; March 2002). CMS ESRD Facility Survey Tables (OCSQ, CMS; August 2001).

Continuous cycling peritoneal dialysis. Although similar in function to CAPD, CCPD uses a machine to automatically fill and drain the dialysate from the abdomen. This process takes 12 hours and is performed overnight, allowing the machine to exchange the dialysate several times.

## Treatment and Method Selection

If a physician certifies that it is reasonable to expect that the beneficiary will complete the required self-dialysis training course and is able to self-dialyze at home on a regular basis, the beneficiary will complete the CMS-382 form and select either Method I or Method II for billing purposes. The beneficiary submits the CMS-382 form to his or her coordinating dialysis facility. This facility then forwards the form to the appropriate fiscal intermediary (FI). When the FI receives the completed form, it is supposed to enter the CMS-382 data, including the beneficiary's method selection, into its automated system and then transfer the data to CMS's Common Working File (CWF) within 30 days of receipt. The FIs and durable medical equipment regional carriers (DMERCs) use the CWF to process, edit, and screen claims, helping to ensure proper claims processing. (For a discussion of claims processing see Appendix A in this report.)

According to the Carrier Manual, beneficiaries who choose home dialysis must select a method for receiving necessary services and supplies. They can choose either Method I or Method II.

Method I. With Method I, a dialysis facility provides all equipment and support services for the home dialysis beneficiary. The facility is paid at the same composite rate it would receive for in-center treatments, regardless of whether the home beneficiary is performing hemodialysis, CAPD, or CCPD. The FIs process all Method I claims from facilities for supplies and ESRD-related services.

Method II. Method II was established as an alternative to Method I for beneficiaries who wish to make their own arrangements for supplies and equipment. The CMS believes that congressional intent in establishing Method II was to save the beneficiary money on coinsurance expenses by allowing beneficiaries to deal directly with suppliers. With Method II, a single durable medical equipment (DME) home dialysis supplier provides all necessary equipment and supplies for the home dialysis beneficiary while a dialysis facility provides services.[3] The supplier must report all items and services, which are furnished to the beneficiary, to the coordinating dialysis facility at least every 30 days, so that the facility can record the information in the beneficiary's record. The FIs process all ESRD service-related claims and the DMERCs process all supply claims.

[3] See Medicare Intermediary Manual 3166, 3167, 3170 for a detailed listing.

The DME supplier bills for equipment and supplies that it provides, with reimbursement limited to $1,490 per month, per beneficiary, for all treatment modalities except CCPD, which is limited to $1,974. In addition to supplier payments, Medicare pays the coordinating dialysis facility for services provided (e.g., maintaining documentation and arranging for lab tests).

## METHODOLOGY

### Pre-Inspection Activities

In order to gain a better understanding of ESRD, we reviewed relevant publications and held discussions with knowledgeable officials at CMS. We met with representatives from a local dialysis facility as well as an ESRD Network official to discuss billing and other related issues. Additionally, we reviewed documents published by advocacy and service groups, such as the ESRD Networks.

### Population Identification

The intended population for this inspection was to include beneficiaries listed in the Renal Beneficiary and Utilization System. However, efforts to select this population were compromised, due to data problems identified in our recent report "Problems Pervade the Renal Beneficiary and Utilization System" (OEI-07-01-00250). We, therefore, selected our population from a file CMS created for use in this inspection. This file was created from CMS-382 submissions to the CWF in late 1996 to mid-2001.

Using this CMS-382 file, the CMS Enrollment Database and the National Claims History (NCH) file, we extracted our population and ESRD claims for beneficiaries dialyzing as of January 1, 2000. The NCH file claims were identified using Medicare Status Codes and included all claims processed by FIs and DMERCs.

The inspection was broken into two parts: (1) identifying excess dollars paid for CCPD under Method II rather than under Method I, and (2) identifying home dialysis claims paid without an existing method selection on the CWF. Each of these parts followed the same procedure of: (1) analyzing the processes for paying ESRD-related claims,
(2) analyzing questionable payments, and (3) identifying dollars at risk in the Medicare program.

To identify excess dollars paid for CCPD under Method II, we calculated the amount that Medicare and beneficiaries actually paid, according to claims data, and then subtracted this amount from the maximum payment that would have been allowed under Method I.

For processing ESRD-related claims, we identified claims without CMS-382 forms on file. We also conducted a telephone survey with each FI and DMERC to understand what processes are in place to ensure the appropriate payment of ESRD-related claims. We asked which specific edits are being used and whether any contractors implemented specific practices to supplement these edits. In addition, we interviewed CMS staff to

determine what edits, procedures, and controls are in place to ensure accurate claims processing and payment.

In this study, allowed dollars are dollars Medicare allowed for a claim. Medicare typically pays 80 percent of the allowed amount after the beneficiary deductible. Unless otherwise indicated, we used the total allowed dollars to determine the effect on the Medicare program and beneficiaries. We did not conduct a medical record review.

We conducted this inspection in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

# FINDINGS

Medicare regulations for reimbursement for home dialysis are inconsistent, resulting in Medicare and beneficiaries paying $15.3 million more for CCPD under Method II than would have been paid for the same services and supplies under Method 1. Also, Medicare contractors allowed $9.5 million for claims without existing method selection data in the CWF. We recommend that CMS make a regulatory change to correct inequities in home dialysis payments, ensure that claims are not paid unless a valid method selection form is on record, and collect any incorrectly paid claims.

## Medicare regulations for reimbursement for home dialysis are inconsistent

Consistent with statutory requirements[4] and the CMS Carrier Manual, all dialysis kits for all modalities under Method I were paid up to the same rate of $1,490 per month in CY 2000. Under Method II, hemodialysis and CAPD were paid the same as in Method I, but the CCPD payment could be as much as $1,974 per month (a $484 premium) even though the supplies provided are the same as those supplied under Method I.

Medicare and beneficiaries paid a total of $62.2 million in CY 2000 for CCPD kits under Method II. If Medicare had paid for these same supplies at the maximum limit for Method I reimbursement, the total allowable amount would have been $49.9 million, a difference of $15.3 million. In 1992, CMS, formerly the Health Care Financing Administration (HCFA), referenced a 1989 congressional document which stated that by establishing Method II, beneficiaries would save money on coinsurance expenses because they could make their own arrangements.[5] However, beneficiaries paid at least an additional $3.1 million (20 percent coinsurance of $15.3 million) by choosing Method II CCPD over Method I CCPD. Medicare paid an additional $12.2 million for CCPD kits under Method II, which is $15.3 million less the $3.1 million beneficiary coinsurance.

The CMS (formerly the HCFA) expressed concern that Method II reimbursement, if left unchecked, would create an economic incentive for suppliers to encourage Method II selection.[6] MedPAC also stated that this incentive increased the use of CCPD from 3 to 5 percent of all forms of dialysis during 1993-1997.

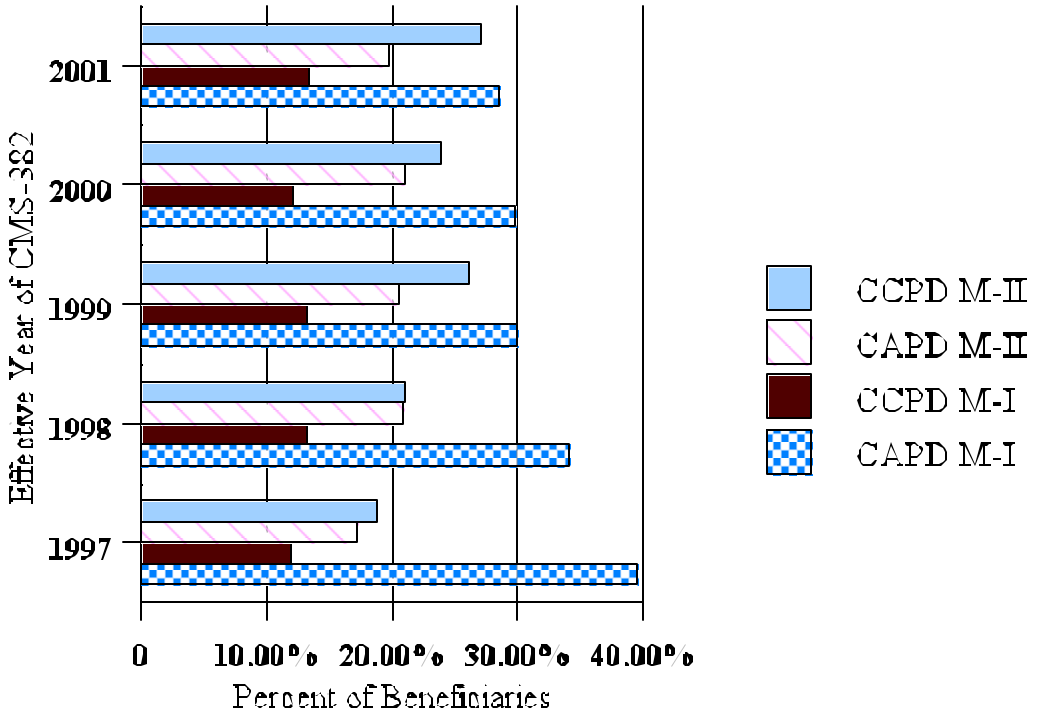
[4] Omnibus Budget Reconciliation Act of 1989

[5] 57 FR 54179 (November 17, 1992) ; Medicare and Medicaid Health Budget Reconciliation Amendments of 1989: 40 (Comm. Print 101-1)

[6] 54 FR 1247 (January 12, 1989)

Between CYs 1997 to 2000, there has been a trend from beneficiaries choosing Method I to choosing Method II and a trend from beneficiaries dialyzing under CAPD to dialyzing under CCPD. As shown in Chart 1 below, since 1997, the share of Method I and CAPD decreased 19 percent and 15 percent, respectively. During the same period, the share of Method II and CCPD increased 31 percent and 32 percent, respectively, meaning that such a trend will escalate the costs of ESRD for both Medicare and beneficiaries.

**Chart 1: Percentage of Beneficiaries Receiving Peritoneal Dialysis by Modality and Method**




## Medicare paid $9.5 million in claims without an existing method selection.

According to the Carrier Manual, no payment can be made for any home dialysis items or services for a beneficiary, unless a CMS-382 form has been filed.[7] This form indicates that a beneficiary has selected home dialysis, and whether the beneficiary has opted for either Method I or Method II.

In CY 2000, Medicare allowed $9.5 million for claims without a corresponding method selection recorded in the CWF. This amount is a combination of $8.9 million from more than 5,000 claims for home dialysis related items;[8] and $660,000 for more than

[7] This criteria was stated in 1990 and reiterated in various forms in 1991, 1993, and 1998.

[8] Codes A4650-A4927

7,000 facility claims of home dialysis support services[9] that were paid despite the lack of a recorded method selection from the CMS-382 form. The problem is systemic among all DMERCs and FIs.

The FIs and DMERCs are responsible for determining the appropriateness of payments by checking against the method selection designation in the CWF. In addition, the CWF maintains a consistency edit, RD 08, which functions to reject the claim in the absence of a valid method selection.[10] Once a claim is submitted, the CWF sends a trailer back to the contractor identifying the beneficiary's method selection and effective date. Fiscal intermediary billing specialists stated that if the CWF rejects claims without a method selection, the providers must submit additional information to support the claim. In the case of an RD-08 rejection, the provider must resubmit a CMS-382, which the FI will input into their own system as well as in the CWF. The DMERC staff stated that if there was no method selection on file in the CWF, the claim should be denied. The ESRD facility would then need to submit a CMS-382 to the FI. Nonetheless, claims are paid without the method selection recorded on the CWF. Therefore, the edit is not always working properly.

[9] Revenue Codes 825, 835, 845, 855

[10] Medicare Intermediary Manual: 3644.4 (11-92)

# CONCLUSION AND RECOMMENDATIONS

The current number of ESRD beneficiaries is 273,000, with annual expenditures of $12 billion. A projected doubling of the population in 10 years makes payment processes for dialysis significant. Current regulations caused Medicare and beneficiaries to pay an additional $15.3 million for CCPD under Method II in CY 2000. Also, Medicare contractors paid $9.5 million in claims without existing method selection data in the CWF. As such, we recommend that CMS:

- ❑ Change regulations to limit payments for Method II CCPD kits to that of Method I.
- ❑ Ensure that claims are not paid unless a valid method selection form has been recorded on the CWF.
- ❑ Review the $9.5 million in paid Medicare claims and collect any incorrect payments.

## AGENCY COMMENTS

In its written response to our report, CMS disagreed with the recommendation of changing regulations to limit payments for Method II CCPD supplies to that of Method I. The CMS believes the statute clearly intends that payment limits for CCPD supplies should be set at a higher level than under the composite rate methodology. We agree that the statute clearly allows a higher payment limit for CCPD supplies under Method II; however, the statute does not require paying the higher limit. Therefore, we continue to believe that CMS should reimburse suppliers consistently for the same dialysis supplies, irrespective of the method the beneficiary chooses.

The CMS agrees to take corrective action to ensure that claims are not paid unless a valid method selection form has been recorded on the CWF and that improper overpayments should be recovered. The full text of CMS's comments is included in Appendix B.

**APPENDIX A**

## Claims Processing

There are five basic steps in the claims payment process: 1) claims submission, 2) basic checks, 3) shared system processing, 4) querying the CWF, and 5) payment processing. When contractors receive claims for payment of ESRD services, they enter the claims information into their local system to perform basic checks, calculate the payment amount, and conduct consistency and utilization edits in order to measure compliance with the contractor's (i.e., FI, DMERC) guidelines. Contractors use their own local system to perform basic checks; but, to complete shared system processing, contractors use standardized CMS-approved software packages. The process is driven by the individual contractor's medical review guidelines and are based on CMS's national guidelines.

When contractors have finished processing the claim to the point of payment or denial, they must then query the CWF at one of the nationwide host sites. The FI or DMERC electronically forwards the claim to the CWF host site for edit checks and payment authorization.

For home dialysis beneficiaries, the FIs and DMERCs compare claims for ESRD supplies and equipment to the method selection information in CWF. The CWF host site then reviews the claim for consistency, entitlement, remaining benefits, deductible status, and duplicates of previously processed claims.

Within 24 hours of receiving the claim, the host site makes one of three payment determinations: pay the claim, reject the claim, or hold the claim to obtain missing information. When the host site authorizes the payment, the FI or DMERC pays the claim.

The CMS has made recent changes in policy, which affect claims processing. According to Program Memorandum B-01-56, supply kits were unbundled after January 1, 2002, and each individual item contained in the kit has now become a separate line item on each claim, thus requiring line-item billing. Also, the CMS recently released Program Memoranda AB-00-96 and AB-01-61, which requires FIs and DMERCs to determine the effective date, rather than the signed date, of the CMS-382 form in an attempt to reduce inappropriate payments.

**APPENDIX B**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid S

*Administrator*
Washington, DC 20201

**DATE:** MAR 21 2003

**TO:** Janet Rehnquist
Inspector General

**FROM:** Thomas A. Scully
Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: *Home Dialysis Payment Vulnerabilities* (OEI-07-01-00570)

Thank you for the opportunity to review and comment on the above-referenced draft report. The Centers for Medicare & Medicaid Services (CMS) appreciates OIG's efforts in assessing End-Stage Renal Disease (ESRD) home dialysis billing processes and identifying vulnerabilities in Medicare payments. According to OIG, the current number of ESRD beneficiaries is 273,000 with annual expenditures of $12 billion. A projected doubling of the population within 10 years makes payment processes for dialysis significant. The OIG indicates that current regulations caused Medicare and beneficiaries to pay an additional $15.3 million for continuous cycling peritoneal dialysis (CCPD) under Method II in calendar year 2000. Also, Medicare contractors paid $9.5 million in claims without existing method selection data in the Common Working File (CWF). Our responses to the recommendations are discussed below.

OIG Recommendation

The CMS should change regulations to limit payments for Method II CCPD kits to that of Method I.

CMS Response

We do not agree with this recommendation. Section 6203(b) of the Omnibus Budget Reconciliation Act of 1989 (Public Law 101-239), which became law on December 19, 1989, amended section 1881(b)(7) of the Social Security Act to provide that any Medicare payment for dialysis made under any payment method other than the composite payment rate (Method I) may not exceed the amount (or, in the case of CCPD, 130 percent of the amount) of the median payment that would have been made under the Method I (or composite) rate for hospital-based dialysis facilities. We believe the statute clearly intended that the payment limit for CCPD would be set at a higher level than under the composite rate methodology. Based on this directive, the limit on payment for CCPD under Method II was set at 130 percent of the median. We note that this is not a payment rate, but a monthly limit on payments to durable medical equipment suppliers based on actual supplies furnished.

With respect to payment for CCPD kits, we note that suppliers that furnish home dialysis equipment and supplies to Method II home dialysis patients can no longer bill for supply kits. Program Memorandum – Carriers, Transmittal B-01-56 (Payment for Home Dialysis Supplies

and Equipment) issued September 13, 2001, with an effective date of January 1, 2002, deleted the CCPD kit codes for billing purposes and requires the supplier to bill using existing and newly developed health care common procedure coding systems for individual dialysis supplies and equipment furnished to Medicare Method II CCPD home dialysis patients. This will enable us to ensure that we only pay for needed supplies actually furnished to home patients.

OIG Recommendation

The CMS should ensure that claims are not paid unless a valid method selection form has been recorded on the CWF.

CMS Response

We concur with this recommendation and will write a change request instructing the CWF or the durable medical equipment regional carriers' systems, as appropriate, to deny Method II claims when there is either no method selection on file or the method selection is any value other than 2.

OIG Recommendation

The CMS should review the $9.5 million in paid Medicare claims and collect any incorrect payments.

CMS Response

We agree that it is important that the beneficiary complete the form and it is entered on the CWF, and we have taken a number of steps to ensure that the intermediary posts this information timely. As always, CMS agrees that we should recover improper overpayments. However, we do not agree that the election information improperly posted on the CWF necessarily indicates that the claim is not payable. It would be inappropriate to cut off supplies to an ESRD beneficiary, or payment to a supplier, because a fiscal intermediary failed to enter the information timely.

We appreciate the effort that went into this report and the opportunity to review and comment on the issues it raises. We look forward to working with OIG on this and other issues pertinent to the ESRD program.

# ACKNOWLEDGMENTS

This report was prepared under the direction of Brian T. Pattison, Regional Inspector General for Evaluation and Inspections and Gina Maree, Assistant Regional Inspector General for Evaluation and Inspections in Kansas City. Other principal Office of Evaluation and Inspections staff who contributed include:

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