

**Memorandum**

Date . JAN 24 2001

From *Michael Mangano*
Michael Mangano
Acting Inspector General

Subject Review of Separately Billed End Stage Renal Disease Hospital Outpatient Laboratory Tests Included in the Composite Rate (A-01-99-00506)

To Michael McMullan
Acting Principal Deputy Administrator
Health Care Financing Administration

Attached are two copies of our final audit report entitled, "Review of Separately Billed End Stage Renal Disease Hospital Outpatient Laboratory Tests Included in the Composite Rate." The objective of our review was to determine whether hospital outpatient laboratory services provided to end stage renal disease (ESRD) beneficiaries and billed separately from the ESRD dialysis facility composite rate were reimbursed in accordance with Medicare requirements.

Our assessment of the payment system for billed laboratory services provided to ESRD beneficiaries identified a control weakness with the reimbursement for these tests. Specifically, our analysis showed that hospital laboratories were reimbursed separately for laboratory services which were included in the dialysis facility's composite rate. We also found that contrary to the "50 percent rule", separate payments were made for additional profile tests performed in conjunction with the monthly testing included in the composite rate¹. Other errors identified in our review included improper coding, unbundled claims, and lack of documentation to support the services claimed. Based on a statistical sample, we estimate that \$6.1 million was improperly paid to hospital laboratories for laboratory services provided to ESRD beneficiaries during Calendar Years (CY) 1995 through 1997.

As a result of our request to providers for information on the claims in our sample, three providers initiated internal reviews of their ESRD billing practices. Two providers with completed reviews identified a total of \$475,860 in improper payments for laboratory services covered under the composite rate. The first provider concluded a refund of \$205,854 was due the Medicare program for the period April 1, 1995 through July 22, 1999 and the second provider stated that it intended to return \$270,006 to the Medicare program for the period January 1, 1995 through June 30, 1999. The third provider requested entry into the Office of Inspector General's voluntary disclosure program.

¹If 50 percent or more of the laboratory tests performed as a profile of tests are included in the composite rate, then the entire profile is considered to be included in the composite rate.

We recommended that the Health Care Financing Administration (HCFA) require fiscal intermediaries (FI) to provide education to all ESRD providers and hospital laboratories explaining proper Medicare billing practices relating to claims for laboratory services provided to ESRD beneficiaries, including which laboratory tests are included in the composite rate, the frequencies at which these tests are included, and the "50 percent rule"; monitor providers' billing for laboratory tests outside the composite rate; and conduct detailed post-payment reviews to determine if reimbursement was proper.

Based on our estimate that \$6.1 million was improperly paid to hospital laboratories for laboratory services provided to ESRD beneficiaries during CYs 1995 through 1997, implementation of our recommendations should lead to future savings of more than \$2 million per year.

In response to our draft report, HCFA officials stated that they concur with our recommendations and have proposed corrective actions to address the issues. The HCFA also stated that they "plan to eliminate the 50 percent rule and set up a system for paying non-composite rate tests that are part of a panel at the unit price for a 22-panel test (currently 76 cents per test). Providers would only be required to bill for the non-composite rate tests in the panel even though these panels would include a number of composite rate tests as well. This change would eliminate the contractor burden of enforcing the 50 percent rule, but would ensure that we do not overpay for panel tests that include composite rate tests."

Based on clarification from HCFA officials, we understand that HCFA's intent is to pay for medically necessary chemistry automated multichannel profile tests (which are not to be included in the composite rate payment) at either the 76 cents unit price for a 22 test profile, the incremental cost of performing additional chemistry profile tests, or some other amount to be determined. The HCFA's proposed payment policy pertains to (1) the 12 chemistry profile tests when performed in excess of designated composite rate testing frequencies and (2) the 10 additional profile tests not designated for inclusion in the composite rate payment for dialysis services.

Please advise us within 60 days on actions taken or planned on our recommendations. If you have any questions, please call me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 786-7104.

To facilitate identification, please refer to Common Identification Number A-01-99-00506 in all correspondence relating to this report.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF SEPARATELY BILLED END
STAGE RENAL DISEASE HOSPITAL
OUTPATIENT LABORATORY TESTS
INCLUDED IN THE COMPOSITE RATE**



Inspector General

JANUARY 2001

A-01-99-00506

EXECUTIVE SUMMARY

The objective of our review was to determine whether hospital outpatient laboratory services provided to end stage renal disease (ESRD) beneficiaries and billed separately from the ESRD dialysis facility composite rate were reimbursed in accordance with Medicare requirements.

Our assessment of the payment system for hospital outpatient laboratory services billed on behalf of ESRD beneficiaries identified a control weakness with the reimbursement for these services. We found that 240 of 400 patient months in our statistical sample contained payments for laboratory services which did not meet Medicare reimbursement requirements. Specifically, our analysis showed that hospital laboratories were reimbursed separately for laboratory services which were included in the dialysis facility's composite rate. We also found that contrary to the "50 percent rule", separate payments were made for additional profile tests performed in conjunction with the monthly testing included in the composite rate. Other errors identified in our review included improper coding, unbundled claims, and lack of documentation to support the services claimed.

As a result of our request to providers for information on the claims in our sample, three providers initiated internal reviews of their laboratory billing practices for ESRD beneficiaries. Two providers with completed reviews identified a total of \$475,860 in improper payments for laboratory services covered under the composite rate. The first provider concluded a refund of \$205,854 was due the Medicare program for the period April 1, 1995 through July 22, 1999 and the second provider stated that it intended to return \$270,006 to the Medicare program for the period January 1, 1995 through June 30, 1999. The third provider requested entry into the Office of Inspector General's (OIG) voluntary disclosure program.

These problems occurred because:

- hospital billing departments did not follow Medicare billing guidelines.
- the nature of the Medicare billing systems do not allow Medicare fiscal intermediaries (FI) to develop edits to ascertain on a prepayment basis whether the tests billed were included in the composite rate.

Based on a statistical sample, we estimated that \$6.1 million was improperly paid to hospital laboratories for services provided to ESRD beneficiaries during Calendar Years (CY) 1995 through 1997.

We recommended that the Health Care Financing Administration (HCFA) require all FIs to:

- (1) Provide education to ESRD providers and hospital laboratories explaining proper billing practices for claims for laboratory services provided to ESRD beneficiaries, including which laboratory tests are included in the composite rate, the frequencies at which these tests are included, and the "50 percent rule";

- (2) Monitor providers' billing for laboratory tests outside the composite rate and conduct detailed post-payment reviews to determine if reimbursement was proper.

Based on our estimate that \$6.1 million was improperly paid to hospital laboratories for laboratory services provided to ESRD beneficiaries during CYs 1995 through 1997, implementation of our recommendations should lead to future savings of more than \$2 million per year. The value of post-payment reviews is demonstrated by the results of the provider reviews discussed above.

In response to our draft report, HCFA concurred with our recommendations and proposed corrective actions to address the issues. However, HCFA also stated that they plan to eliminate the "50 percent rule."

Based on clarification from HCFA officials, we understand that HCFA's intent is to pay for medically necessary chemistry automated multichannel profile tests (which are not to be included in the composite rate payment) at either the 76 cents unit price for a 22 test profile, the incremental cost of performing additional chemistry profile tests, or some other amount to be determined. The HCFA's proposed payment policy pertains to (1) the 12 chemistry profile tests when performed in excess of designated composite rate testing frequencies and (2) the 10 additional profile tests not designated for inclusion in the composite rate payment for dialysis services.

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INTRODUCTION

BACKGROUND

Health Insurance for the Aged and Disabled (Medicare), Title XVIII of the Social Security Act, as amended, is a broad program of health insurance that is administered by HCFA. Medicare provides coverage for eligible persons suffering from kidney failure under its ESRD benefit.

The HCFA utilizes a prospective method of payment for dialysis services. Under this system, HCFA establishes a composite rate per dialysis treatment to reimburse hospital based (HB) dialysis and free standing (FS) dialysis facilities. The Medicare program pays 80 percent of the composite rate and the remaining 20 percent (coinsurance) is the responsibility of the ESRD beneficiary. The composite rate is a comprehensive payment for all services related to dialysis treatment except for bad debts, physician patient care services, blood, and certain drug and laboratory services that are separately billable. The HCFA designates laboratory tests that are included in the composite rate and specifies the frequencies at which such tests are included (per treatment, weekly, monthly or quarterly). When laboratory tests are performed at these frequencies, they cannot be billed separately. However, when any of these tests are performed at a frequency greater than specified, the additional tests are separately billable and are covered provided they are medically justified. In addition, laboratory tests not included as part of the facility's composite rate may be billed separately.

The HCFA guidelines also provide limitations on separately billed laboratory tests when they are performed as part of a chemistry automated multichannel profile of tests. Specifically, if 50 percent or more of the laboratory tests performed as a profile of tests are included in the composite rate, then the entire profile is considered to be included in the composite rate. In this instance, no separate payment is made for those laboratory tests outside the composite rate. We make reference to this throughout our report as the "50 percent rule."

Medicare FIs are responsible for processing claims for laboratory services submitted by hospitals or HB dialysis facilities.

SCOPE

Our review was conducted in accordance with generally accepted government auditing standards. The objective of our review was to determine whether hospital outpatient laboratory services provided to ESRD beneficiaries and billed separately from the ESRD dialysis facility composite rate were reimbursed in accordance with Medicare requirements. More specifically, we determined if duplicate payments were made by FIs to hospitals for laboratory services provided to ESRD beneficiaries that were already included in the composite rate payment for dialysis services. This objective also involved reviewing profiles of tests for the "50 percent rule." To accomplish our objective, we:

- ◆ Used HCFA's National Claims History file to extract CYs 1995 through 1997 paid claims for laboratory services provided to ESRD beneficiaries.
- ◆ Identified 55 FIs that processed 1,077,855 patient months of laboratory services that have the potential to be included in the composite rate. These laboratory services were valued at approximately \$18.5 million and were submitted by 5,717 hospital laboratories.
- ◆ Limited our sample population to 836 hospital laboratories with at least 300 patient months of laboratory services that had the potential to be included in the composite rate (chemistry automated multichannel profiles, profile tests, hemoglobins, hematocrits, automated platelet counts, and blood drawing). Fifty-three FIs processed 858,395 patient months of laboratory services of this type valued at approximately \$15.2 million. In this manner, our review covered about 83 percent of the billed laboratory services that had the potential to be covered by the ESRD composite rate.
- ◆ Employed a multistage statistical sampling approach to randomly select 8 FIs from a population of 53 FIs. We further randomly selected 50 patient months from each of the 8 FIs for a total sample of 400 patient months. See APPENDICES I and II for sample methodology and list of laboratory services extracted.

As part of our examination, we obtained an understanding of the internal control structure surrounding billing and processing of laboratory claims for ESRD beneficiaries. In this regard, we requested that each sampled FI and hospital laboratory provide us with their policies and procedures applicable to processing ESRD claims for separately billed composite rate laboratory services. We specifically requested copies of instructions and Medicare Policy Bulletins made available by FIs to hospital providers of ESRD laboratory services concerning billing for composite rate and separately billable laboratory services.

We concluded, however, that our consideration of the internal control structure could be conducted more efficiently by expanding substantive audit tests, thereby placing limited reliance on the hospitals' and FIs' internal control structures. We did not include as part of our review a determination of the medical necessity of separately billed claims for laboratory services.

We requested the following documentation relating to each of the 400 sampled items directly from the hospitals that provided the laboratory services:

- (1) Copies of the claim(s) for the sampled laboratory services as submitted to the FI.
- (2) Copies of remittance advices which accompanied payment for the sampled services.

- (3) Copies of written physician and standing orders and related requisitions for the laboratory services under review and identification of the dialysis facility which requested the services listed and to which the laboratory test results were sent.
- (4) Copies of laboratory reports including exact dates of service for all blood tests performed during the month the sampled items were provided.

We used a variable appraisal program to estimate the dollar impact of improper payments in the total population. In completing our review of the sample, we established a reasonable assurance on the authenticity and accuracy of the data. Our review, however, was not directed toward assessing the completeness of the file from which the data was obtained.

We conducted our review from November 1998 to October 1999 at the Health Care Financing Audit Division headquarters in Baltimore, Maryland and the Boston regional OIG.

Laboratory tests included in the composite payment rate are provided by hospital laboratories for patients undergoing outpatient dialysis at HB dialysis facilities and payment is included in the hospital's composite payment rate. For laboratory services provided by hospital laboratories performed in connection with dialysis treatments provided by FS dialysis facilities, the hospital bills the dialysis facility and is paid out of the FS dialysis facility's composite rate payment.

To verify payment and relationship of services to dialysis treatment sessions, we reviewed copies of the claims, remittance advices, physician orders, laboratory requisitions, and test results. By reviewing these documents, we were able to determine whether the selected billed laboratory service was provided at a frequency above that included in the dialysis composite payment rate or was totally unrelated to the dialysis treatment.

FINDINGS AND RECOMMENDATIONS

Our assessment of the payment system for laboratory services billed on behalf of ESRD beneficiaries identified a control weakness with the reimbursement for these services. As a result of reviewing the sample of 400 patient months of billed hospital laboratory services valued at \$6,392, we found that 240 patient months included claims for laboratory services valued at \$2,709 that were improperly paid. Specifically, our analysis showed that hospital laboratories were reimbursed separately for laboratory services which were included in each facility's composite rate. We also found that contrary to the "50 percent rule", separate payments were made for additional profile tests performed in conjunction with the monthly testing included in the composite rate. Other errors identified in our review included coding and unbundling errors and a lack of documentation (absence of reports showing test results) to support the services claimed. Based on a statistical sample, we estimate that approximately \$6.1 million was improperly paid to hospitals for laboratory services provided to ESRD beneficiaries during CYs 1995 through 1997.

As noted below, in many cases, hospitals billed Medicare for laboratory services that were the responsibility of the FS dialysis facilities. Of 240 patients with errors in a sample month, 142 were treated at HB dialysis facilities and 98 were treated at FS dialysis facilities.

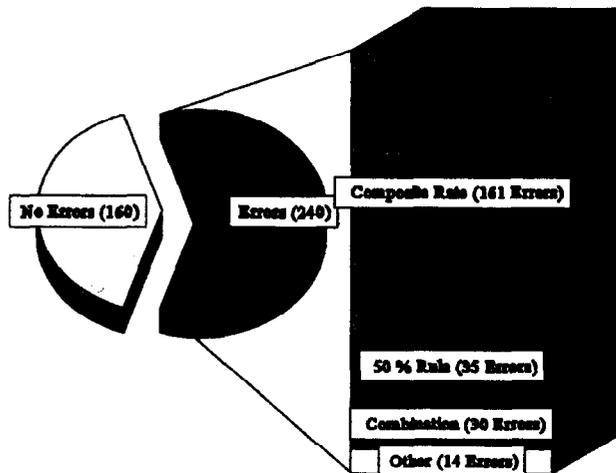


Figure 1 - Results of Claims Analysis

Figure 1 presents the results of our analysis of the claims contained in the sample of 400 patient months. We found various conditions in which hospital laboratories were improperly reimbursed for laboratory services. Specifically, we found that 240 out of 400 patient months of billed services for ESRD beneficiaries contained improper payments. We classified the errors into four conditions: laboratory services included in the composite rate, “50 percent rule”, combination, and other categories.

Errors Relating to Laboratory Services Included in the Composite Rate

Specific clinical laboratory services and testing frequencies routinely included in composite rate payments for dialysis services depend on the type of dialysis treatment. Our sample of patient months included patients treated by hemodialysis, continuous cycling peritoneal dialysis (CCPD), and continuous ambulatory peritoneal dialysis (CAPD).

Our review identified providers that billed Medicare for laboratory services included in the composite rate which were performed at or below the designated composite rate testing frequencies. Because the services were not conducted above the frequencies specified under the composite rate, separate reimbursement was improper. This type of error occurred

in 161 of the patient months under review and consisted of payments for chemistry automated multichannel profile tests (Chemistry Profile Tests), blood urea nitrogen (BUN) tests, hemoglobin and hematocrit tests (Hematology), and blood drawing services (Venipunctures) with a payment error valued at \$1,669.

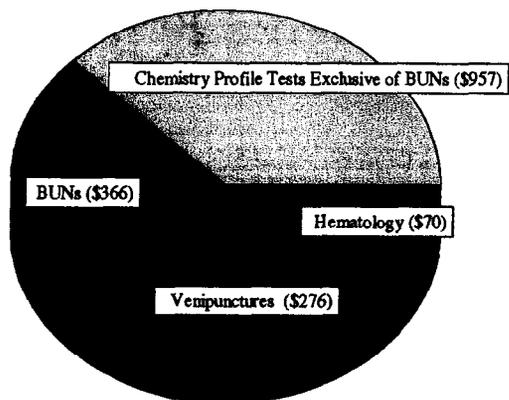


Figure 2 shows the sample errors for the types of laboratory services improperly paid because they were already included in the composite rate payments for dialysis treatments. Because our sample unit was a patient month containing one or *more* laboratory services routinely included in the composite rate at designated frequencies, a sampled patient month could contain more than a single category of error. In this regard, the sum of the patient months described below by service types would be greater than the total of 161 patient months containing such errors.

Figure 2 - Sample Errors

Sections E204.3 of the Medicare Hospital Manual and 3167.3 and 3171.2 of the Medicare Intermediary Manual designate and list laboratory tests and their frequencies (per dialysis treatment, weekly, monthly or quarterly) that are included in the dialysis composite rate calculations for hemodialysis, CCPD, and CAPD patients. When laboratory tests are performed at or below these frequencies, they cannot be billed separately to the Medicare program.

Chemistry Profile Tests Exclusive of Blood Urea Nitrogens

We found that 71 patient months contained payment errors valued at \$957 for chemistry profiles or individual profile tests designated as routinely included at weekly or monthly frequencies in the composite rate payment for dialysis treatments. (See APPENDIX II for a complete list of chemistry profile tests routinely included at weekly and monthly frequencies in the composite rate payment for dialysis services.)

Blood Urea Nitrogens

Because of HCFA clarification regarding frequency of BUN profile tests included in the composite rate, we determined the amount of sample errors associated with BUNs separately from other chemistry profile tests.

Both section E204.3 of the Medicare Hospital Manual and section 3167.3 of the Medicare Intermediary Manual state that the composite rate payment includes an allowance for one BUN test per week. Due to refinement to the BUN testing protocol for ESRD hemodialysis patients (it became standard practice to perform pre- and post-dialysis BUNs during one session per month followed by one additional BUN test during the next dialysis session.), HCFA stated in a policy clarification letter dated January 14, 1994 that the composite rate payment for dialysis treatments includes an allowance for BUN tests at a rate of 4 per month or 13 per calendar quarter.

We found 53 patient months contained improper payments valued at \$366 for BUNs provided at or below the designated composite rate testing frequency of four per month.

Hematology

Section E204.3 of the Medicare Hospital Manual and section 3167.3 of the Medicare Intermediary Manual state that for hemodialysis and CCPD patients, all hemoglobin and hematocrit tests performed incident to dialysis treatments are included in the dialysis composite rate calculations. Section 3171.2 of the Medicare Intermediary Manual states that for CAPD patients, hemoglobin and hematocrit tests performed monthly are included in the composite rate.

We found 14 patient months contained improper payments valued at \$70 for hemoglobin and hematocrit tests performed below the designated composite rate testing frequencies associated with the type of dialysis treatment provided.

Venipunctures

Section 437E of the Medicare Hospital Manual, "Billing for Clinical Diagnostic Laboratory Services" states that special rules apply when specimen collection services (venipunctures) are furnished to dialysis patients. The specimen collection fee is not separately payable for any patients dialyzed in the facility or for any patients dialyzed at home under reimbursement Method I (under reimbursement Method I, the dialysis facility responsible for monitoring home treatments receives the composite rate payment associated with dialysis services). Payment for this service is included under the ESRD composite rate for separately billable laboratory tests as well as those included in the composite rate. Fees for taking specimens in the hospital setting, but outside of the dialysis unit for use in performing laboratory tests not included in the ESRD composite rate, may be paid separately.

We found 55 patient months contained improper payments valued at \$276 for venipuncture services associated with collection of specimens for dialysis related laboratory testing furnished to patients in hospital and dialysis units.

Errors Relating to the “50 percent rule”

Section 2711.1 of the Provider Reimbursement Manual provides the payment instructions specific to separately billable ESRD tests. It not only provides when laboratory tests are separately billable but also provides limitations on all separately billable tests when they are performed as part of a chemistry automated multichannel profile of tests. Specifically, if 50 percent or more of the tests performed as a chemistry multichannel profile are included in the composite rate, then the entire profile is considered to be included in the composite rate. In this instance, no separate payment is made for the additional profile tests outside the composite rate. This is referred to as the “50 percent rule.”

Our review identified providers improperly billing Medicare for additional automated multichannel tests performed in conjunction with the monthly profile of chemistry tests included in the composite rate routinely covering ESRD patients undergoing dialysis. Errors relating to the “50 percent rule” occurred in 35 of the patient months under review. The value of “50 percent rule” errors for the 35 patient months totaled \$315.

An improper payment based on the “50 percent rule” occurs when a provider performs and bills for one or more additional chemistry automated multichannel profile tests separately where the profile tests included in the dialysis composite rate payment make up more than 50 percent of the profile. For example, a provider performed a monthly chemistry profile consisting of 19 tests. Ten of the chemistry profile tests performed were designated in Medicare Guidelines (section E204.3 of the Medicare Hospital Manual and sections 3167.3 and 3171.2 of the Medicare Intermediary Manual) as tests which were included in the composite rate monthly and two as tests that have a stated frequency of one per week or four per month for inclusion in the composite rate. These 12 tests were included in the dialysis composite rate payment and were not separately billable. In accordance with the “50 percent rule”, the remaining seven tests were non-billable.

Combination Errors

Thirty of the 240 patient months with errors contained 2 types of errors. The value of the 30 errors totaled \$540. These errors consisted of:

- ◆ Nineteen patient months concerning laboratory services included in the dialysis composite rate payment and improper payments for additional chemistry profile tests in violation of the “50 percent rule.”
- ◆ Nine patient months concerning laboratory services included in the dialysis composite rate payment and improper payments for other types of errors.

- ◆ Two patient months contained improper payments for additional profile tests in violation of the “50 percent rule” and other types of errors.

The other errors mentioned above are similar to the errors described below.

Other Errors

We categorized 14 patient months as other errors that did not pertain to the composite rate or the “50 percent rule”. The value of the errors in the 14 patient months totaled \$186. The claims in this category involved providers unbundling claims (six errors), providers billing incorrect Physicians Current Procedural Terminology codes (four errors), and the absence of reports containing test results (four errors).

Specifically:

- ◆ The unbundling errors consisted of payments at the individual test price for automated multichannel profile tests submitted under a range of dates. The FIs had no basis to roll the individual tests into the appropriate profile without exact dates of service. Because of the range of dates submissions, OIG’s other unbundling reviews requiring matches on exact dates of service would not detect this type of unbundling error.
- ◆ The incorrect coding errors consisted of instances where providers billed for a chemistry profile with a higher number of chemistry automated multichannel tests than were actually provided.
- ◆ The remaining errors related to missing laboratory reports and the lack of a response from one provider.

As a result of reviewing the 400 patient months of billed laboratory services provided by hospital laboratories, we found that claims for 240 patient months of laboratory services valued at \$2,709 were improperly paid. The estimated dollar impact of improper payments for the population was \$6.1 million with a precision of this estimate at the 90 percent confidence level of +/- 12.71 percent.

Reasons for Improper Payments

These improper payments occurred because hospital billing departments did not follow Medicare billing guidelines. Another reason for the overpayments surrounded the control procedures in place at the Medicare FIs which were responsible for processing claims for hospital outpatient laboratory services provided to ESRD beneficiaries. Because of the nature of the Medicare billing systems, edits to identify potential improper laboratory claims were not possible on a prepayment basis. In this regard, providers were instructed only to bill Medicare for separately

billable laboratory services, and not to include any laboratory services included in the dialysis composite rate payment on the bill. Inasmuch as FIs were not apprised of the frequencies relating to all laboratory services provided which were included in the composite rate, FIs were unable to ascertain whether the tests billed were included in the composite rate. The FI would need to know the frequency at which the tests were performed during the month in order to make the determination as to whether the tests were included in the composite rate or are, in fact, separately billable. Because of these weaknesses, only a post-payment or pre-payment manual review would determine whether the separately billed laboratory services were included in the composite rate, met the "50 percent rule", or were indeed separately billable.

Provider Internal Reviews

As a result of our request to providers for information on the claims in our sample, three providers initiated internal reviews of their billing practices relating to laboratory services provided to ESRD dialysis beneficiaries:

- ◆ One provider concluded that certain laboratory services covered under the composite rate had been billed separately and paid by the FI for the period April 1, 1995 through July 22, 1999. Further, laboratory services eligible for payment outside the composite rate were billed with insufficient diagnosis code information to support test results. Although detailed research on selected records indicated that some billing was properly documented, the provider considered the claims to be nonreimbursable. As such, the provider concluded a refund of \$205,854 was due the Medicare program for the period April 1, 1995 through July 22, 1999. The provider apprised us that a check was submitted to the FI for \$205,854 on September 8, 1999. We have not verified if this is an appropriate refund amount.
- ◆ A second provider also determined that certain laboratory services covered under the composite rate and provided to patients at two of its dialysis facilities were incorrectly paid by its FI. This provider stated that it intended to return \$270,006 to the Medicare program for the period January 1, 1995 through June 30, 1999. We have not verified if this is an appropriate refund amount.
- ◆ The third provider requested entry into the OIG's voluntary disclosure program.

Recommendations

We recommended that HCFA require all FIs to:

- (1) Provide education to ESRD providers and hospital laboratories explaining proper billing practices for claims for laboratory services provided to ESRD

beneficiaries, including which laboratory tests are included in the composite rate, the frequencies at which these tests are included, and the “50 percent rule.”

- (2) Monitor providers’ billing for laboratory tests outside the composite rate and conduct detailed post-payment reviews to determine if reimbursement was proper.

Based on our estimate that \$6.1 million was improperly paid to hospital laboratories for laboratory services provided to ESRD beneficiaries during CYs 1995 through 1997, implementation of our recommendations should lead to future savings of more than \$2 million per year. The value of post-payment reviews is demonstrated by the results of the provider reviews discussed above.

Auditee’s Comments

In its comments to our draft report, HCFA officials stated that they concur with our recommendations and have proposed corrective actions to address the issues.

Recommendation #1

The HCFA stated that they will share the results of the OIG review with FIs so that they can educate providers about proper billing practices. The HCFA will also request that the FIs perform data analysis to identify providers who were billing inappropriately and take appropriate corrective actions which could involve pre-payment or post-payment reviews.

The HCFA also stated that they plan to eliminate the “50 percent rule” and set up a system for paying non-composite rate tests that were part of a chemistry profile at the unit price for a 22 test profile. Providers would separately bill for the non-composite rate profile tests even though those profiles would include a number of composite rate tests as well. The HCFA maintained that this change would eliminate the contractor burden of enforcing the “50 percent rule”, but would ensure that they do not overpay for panel tests that include composite rate tests.

Additional OIG Comments

Based on clarification from HCFA officials, we understand that HCFA’s intent is to pay for medically necessary chemistry automated multichannel profile tests which are not to be included in the composite rate payment at either the 76 cents unit price for a 22 test profile, the incremental cost of performing additional chemistry profile tests, or some other amount to be determined. The HCFA’s proposed payment policy pertains to (1) 12 chemistry profile tests when performed in excess of designated composite rate testing frequencies and (2) the 10 additional profile tests not designated for inclusion in the composite rate payment for dialysis services. (See APPENDIX II.) In all cases, medical necessity is requisite for Medicare reimbursement.

Recommendation #2

HCFA stated that they are in the process of developing systems modifications to monitor providers' billing for laboratory tests outside the composite rate. These modifications include a special billing modifier for composite rate tests which would serve as an attestation from the billing entity that the tests qualify for separate billing based on frequency and medical justification. Payment would automatically be denied for composite rate tests that did not have this modifier. In addition, contractors would have the ability to monitor the frequency of billing by certain providers to assess the need for further review.

APPENDIX III to this report contains the complete text of HCFA's comments on the OIG's draft report.

APPENDICES

METHODOLOGY OF STATISTICAL SAMPLE SELECTION

Using a database containing CYs 1995, 1996, and 1997 services provided to ESRD beneficiaries by hospital laboratories, we performed a computer application to extract claims for laboratory services routinely included in the composite rate payment for dialysis treatments. See APPENDIX II for a list of laboratory services extracted.

We identified 55 FIs that processed 1,077,855 patient months of laboratory services that have the potential to be included in the composite rate. A patient month represents a calendar month in which separately billed laboratory services routinely included in the composite rate were provided to an ESRD patient undergoing dialysis. These laboratory services were valued at approximately \$18.5 million and were submitted by 5,717 hospital laboratories. We limited our sample population to 836 hospital laboratories with at least 300 patient months of laboratory services that had the potential to be included in the composite rate (chemistry automated multichannel profiles, profile tests, hemoglobins, hematocrits, automated platelet counts, and blood drawing). Fifty-three FIs processed 858,395 patient months of laboratory services of this type valued at approximately \$15.2 million. In this manner, our review covered about 83 percent of the billed laboratory services that have the potential to be included in the ESRD composite rate.

Our review employed a multistage statistical sampling approach based on probability-proportional-to-size weighted by dollar value of estimated payments for separately billed laboratory services routinely included in the composite rate at each of 53 FIs during CYs 1995 through 1997. The first stage consisted of a random selection of eight FIs. The second stage consisted of a random selection of 50 patient months containing separately billed laboratory services routinely included in the composite rate for each of the 8 FIs.

As a result of reviewing the 400 patient months of billed laboratory services provided by hospital laboratories, we found that claims for 240 patient months of laboratory services valued at \$2,709 were improperly paid. The estimated dollar impact of improper payments for the population is \$6.1 million with a precision of this estimate at the 90 percent confidence level of +/- 12.71 percent. All random selections and estimations were made using the Office of Audit Services' Statistical Software dated February 1995.

CLINICAL LABORATORY SERVICES EXTRACTED FOR REVIEW

FOR HEMODIALYSIS, CCPD, AND CAPD PATIENTS

CHEMISTRY PROFILES: 80002 through 80019, 80058

<u>PROFILE TESTS INCLUDED IN THE COMPOSITE RATE</u>	<u>CPT CODE</u>
• Albumin	82040
• Calcium	82310
• Carbon Dioxide	82374
• Chloride	82435 (Note)
• Creatinine	82565
• Lactic Dehydrogenase (LDH)	83615
• Alkaline Phosphatase	84075
• Phosphorous	84100
• Potassium	84132
• Total Protein	84155, 84160
• Aspartate Amino Transferase (SGOT/AST)	84450
• Blood Urea Nitrogen (BUN)	84520

ADDITIONAL PROFILE TESTS

• Bilirubin Total, Direct	82250, 82251
• Cholesterol	82465
• Creatine Kinase (CPK)	82550
• Glucose	82947
• Gamma Glutamyltransferase (GGT)	82977
• Sodium	84295 (Note)
• Transaminase (SGPT/ALT)	84460, 84465
• Uric Acid	84550, 84555
• Triglycerides	84478

(Note) For CAPD patients, Sodium is designated as a profile test included monthly in the composite rate and Chloride is an additional profile test:

<u>HEMATOLOGY TESTS INCLUDED IN COMPOSITE RATE</u>	<u>CPT CODE</u>
• Hematocrit	85013, 85014
• Hemoglobin	85018
• Automated Platelet Count (component of complete blood count)	85595

Routine Venipuncture 36415, G0001



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OFFICE OF INSPECTOR
GENERAL

The Administrator
Washington, D.C. 20201

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DATE: MAY 31 2000

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle
Administrator

SUBJECT: Office of the Inspector General (OIG) Draft Report: "Review of Separately Billed End Stage Renal Disease (ESRD) Hospital Outpatient Laboratory Tests Included in the Composite Rate" (A-01-99-00506)

We appreciate the opportunity to comment on this draft report regarding ESRD hospital outpatient laboratory tests included in the composite rate. The OIG found that hospital laboratories were being reimbursed separately for laboratory services which are included in the dialysis facility's composite rate. The OIG also found that, contrary to our guidelines, separate payments were made for additional profile tests performed in conjunction with the monthly testing included in the composite rate. Other errors identified by the OIG included improper coding, unbundled claims, and lack of documentation to support the services claimed. In addition, based on a statistical sample, OIG estimates that \$6.1 million was improperly paid to hospital laboratories for laboratory services provided to ESRD beneficiaries during Calendar Years 1995 through 1997.

The OIG recommended that HCFA require Fiscal Intermediaries (FI) to educate providers on proper billing practices in this area and require FIs to better monitor provider's billings. **

HCFA concurs with the OIG's recommendations. We are working with the FIs to ensure that they are working with the provider community to increase awareness of Medicare rules. In addition, we will establish a system which will be easier for the contractors to enforce. Furthermore, we are in the process of developing systems modifications to improve the ability of the FIs to monitor provider's billings. Due to delays caused by

** Office of Inspector General Note - Comments have been deleted since they are not applicable to the recommendations made in the final report.

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Y2K, we are only now implementing the changes associated with the Balanced Budget Refinement Act of 1999. **

Attached are our comments to the specific recommendations. We look forward to continuing our work with your office to assure that hospital outpatient laboratory services provided to ESRD beneficiaries and billed separately from the ESRD dialysis facility composite rate are reimbursed in accordance with Medicare requirements.

Attachment

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Comments of the Health Care Financing Administration on the OIG Draft Report:
“Review of Separately Billed End Stage Renal Disease (ESRD) Hospital Outpatient
Laboratory Tests Included in the Composite Rate” (A-01-99-00506)

OIG Recommendation No. 1

The Health Care Financing Administration (HCFA) should require all Fiscal Intermediaries (FIs) to provide education to ESRD providers and hospital laboratories explaining proper billing practices for claims for laboratory services provided to ESRD beneficiaries, including which laboratory tests are included in the composite rate, the frequencies at which these tests are included, and the 50 percent rule.

HCFA Response

We concur. FIs are required to work with the provider community and with beneficiary groups to increase awareness of Medicare rules. HCFA routinely alerts intermediaries to new issues for use in provider education. Also, intermediaries independently initiate educational activities when they become aware of common claims errors.

We will share the results of this OIG ESRD study with the FIs so that they can educate providers about proper billing practices. When we share this report with the FIs, we will request that they perform data analysis to identify providers who are billing inappropriately. If the FIs discover improper billing practices, they will take the appropriate corrective actions, which could involve prepayment or postpayment reviews.

With respect to the 50 percent rule, we plan to eliminate this rule and set up a system for paying non-composite rate tests that are part of a panel at the unit price for a 22-panel test. Providers would only be required to bill for the non-composite rate tests in the panel even though these panels would include a number of composite rate tests as well. This change would eliminate the contractor burden of enforcing the 50 percent rule, but would ensure that we do not overpay for panel tests that include composite rate tests.

We will be incorporating the need for this ESRD-related training in the contractors' 2001 budget performance requirements.

OIG Recommendation No. 2

HCFA should require all FIs to monitor providers' billing for laboratory tests outside the composite rate and conduct detailed post-payment reviews to determine if reimbursement was proper.

HCFA Response

We concur. Based on earlier OIG findings, we were in the process of developing systems modifications to address these problems. These modifications included a special billing modifier for composite rate tests which would serve as an attestation from the billing entity that the tests qualify for separate billing based on frequency and medical justification. Payment would automatically be denied for composite rate tests that did not have this modifier. In addition, contractors would have the ability to monitor the frequency of billing by certain providers to assess the need for further review. **

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