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Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives

September 1997

MEDICARE DIALYSIS PATIENTS

Widely Varying Lab Test Rates Suggest Need for Greater HCFA Scrutiny

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Health, Education, and
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The Honorable William M. Thomas
Chairman, Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Mr. Chairman:

Dialysis treatments annually extend the lives of the more than 200,000 people with permanent and irreversible loss of kidney function. For these end-stage renal disease (ESRD) patients, the predominant payer for dialysis and other medical services is Medicare. Medicare's ESRD program is rapidly growing; between 1984 and 1994, enrollment more than doubled to about 279,000, while expenditures more than trebled to $8.4 billion.

We reported to you in 1995 on enrollment patterns and payment practices for dialysis patients.[1] During the review leading to the report, we also observed that patients of some renal dialysis facilities received many more laboratory tests than other patients. Medicare deems 16 laboratory tests as routine for dialysis patients and includes them in the bundle of services for which it pays a lump sum.[2] For any of the roughly 1,350 other procedure codes for laboratory tests that physicians can order, Medicare pays the performing clinical laboratory separate amounts according to a fee schedule.[3]

After discussions with your office about the anomalous patterns of test rates we observed for dialysis patients, you asked us to explore this matter further. Specifically, you asked us to determine (1) the extent to which the rates for providing laboratory tests to Medicare patients varied among dialysis facilities; (2) the appropriateness of these rates; (3) reasons for the variation; and (4) the adequacy of the reviews that the Health Care Financing Administration (HCFA), the agency administering Medicare, performs to examine laboratory test claims.

[1]Medicare: Enrollment Growth and Payment Practices for Kidney Dialysis Services (GAO/HEHS-96-33, Nov. 22, 1995).

[2]Under Medicare's billing system, approximately 50 different procedure codes are used to bill for the 16 laboratory tests.

[3]Throughout this report, "laboratory tests" and "tests" refer to tests not bundled into the dialysis rate and therefore separately billable. In some circumstances, tests included in the bundled rate can also be billed separately, but these tests were not included in our study.

To do this work, we reviewed HCFA's 1994 and 1995 billing data (the latest data available) for Medicare patients who received dialysis treatments at freestanding facilities. We did not conduct a formal reliability assessment of the data, but we did check them against other published data to ensure that they contained the correct number of facilities and patients.

We included only renal dialysis facilities with at least 50 patients and patients who used one dialysis facility in a given year. We then determined how many tests each patient received while attending the dialysis facility and identified the laboratories where the tests were performed. In the absence of explicit practice guidelines or specific standards, we assessed the medical necessity and appropriate frequency of laboratory tests on the basis of discussions with renal disease experts, including officials from the National Institutes of Health (NIH), the National Renal Administrators Association (NRAA), and the Renal Physicians Association (RPA). (See app. I for a complete description of our scope and methodology.)

Results in Brief

Despite the large volume of laboratory services provided to ESRD patients, HCFA does not scrutinize the level of laboratory tests ordered for patients receiving dialysis. Our study of 2.8 million laboratory services for patients treated at 766 freestanding dialysis facilities in 1994 showed that clinically similar patients received laboratory tests at widely disparate rates. Compared to the median facility's average of 56 tests per patient per year, patients of one facility averaged 224 tests for the year, whereas patients of another averaged 9 tests that year.

This variation suggests that, at one extreme, Medicare may be paying for an excessive number of tests; at the other, patients may not be receiving the tests needed to adequately monitor their condition. Renal disease experts we consulted found questionable usage rates for 20 of 34 individual laboratory tests identified in two data samples. They determined that many of these tests provided to patients at the 100 facilities with the highest average number of tests ordered per patient were either provided too often or ordered for an implausibly large proportion of patients. In contrast, low rates of laboratory tests for patients of some facilities were also found. For example, although laboratory tests need to be conducted for a variety of factors relating to renal desease, the experts whom we interviewed suggested the need for a minimum of eight tests yearly just to check blood iron levels. Nevertheless, patients of some facilities we reviewed received an average

of only nine tests in total, indicating that they are not being adequately tested for all conditions.

The nature of fee-for-service reimbursement does not give physicians adequate incentives to be judicious in ordering tests. In addition, the likelihood of excessive testing may increase when a company owns both a dialysis facility and a laboratory and includes unnecessary tests in standing orders—a list of tests to be ordered for most patients treated at that facility. These and other physician-related factors, such as the physician's knowledge of the latest testing techniques and medical practice differences, help explain the wide variation in laboratory test rates for dialysis patients, including the low rates of tests ordered.

Neither HCFA nor its claims-processing contractors analyze claims data that would reveal the dramatic variation in test rates found in our study. As a result, neither knows if Medicare is paying for unnecessary tests for some patients or if other patients receive too few tests to ensure high-quality treatment. Furthermore, because claims for tests are submitted by the laboratories performing the tests, contractors' reviews of claims data would likely identify the laboratories and not the test rate patterns found when the data are arrayed by the patient's ordering physician or dialysis facility. Without knowledge of these patterns, HCFA has no indication of whether laboratory claims made on behalf of ESRD patients receiving dialysis are for an appropriate level of tests.

Without a process for identifying the physicians who order tests for dialysis patients and for notifying contractors of providers whose test order rates are aberrant, HCFA is unable to identify physicians who order unneeded or inadequate numbers of tests. In addition, the Congress may wish to consider making the ordering physician liable for recovery of payments made to laboratories when the physician has been notified of a pattern of inappropriately high testing rates.

Background

Medicare covers dialysis and related services for patients suffering from ESRD, the stage of kidney impairment that is considered irreversible and requires either regular dialysis or a kidney transplant to maintain life. Dialysis is the process of cleansing excess fluid and toxins from the blood of patients whose kidneys do not function. Renal failure can result not only directly from specific kidney disease, such as nephritis, but also indirectly from other diseases, such as diabetes and hypertension.

Virtually all persons with ESRD are eligible for the Medicare program and for all Medicare-covered services, not just dialysis services.[4] In 1994, about 222,000 patients received dialysis services, while about 10,000 patients received a kidney transplant. In that year, there were 1,795 freestanding dialysis facilities and 731 hospital-based dialysis facilities.

The two general modes of dialysis treatment, hemodialysis and peritoneal dialysis, can be performed at a renal facility or at home. In hemodialysis, blood is cycled from the patient's body through a dialysis machine that filters out body waste before returning the blood to the patient. Peritoneal dialysis uses the lining of the patient's abdomen (the peritoneal membrane) to filter blood. Eighty-two percent of patients on dialysis receive hemodialysis treatments at a renal facility.

Generally, an ESRD patient receives three hemodialysis treatments a week, and Medicare pays freestanding dialysis facilities a flat payment, or composite rate, that averages $126 for each treatment.[5] This rate covers a bundle of services and supplies, including dialysis and 16 laboratory tests, that are routinely provided to each patient. All laboratory tests not included in the bundle are separately billed by the laboratories performing the tests, with payment based on a HCFA fee schedule.[6]

To date, attention on laboratory tests for dialysis patients has focused on laboratory tests included in the composite rate. In October 1996, the Department of Health and Human Services (HHS) Inspector General found duplicate payments for routine laboratory tests that were paid both as part of the composite rate and as a separately billed claim.[7] Given a sample of 800 claims for laboratory tests, the Inspector General estimated that $6.3 million of $12.8 million that Medicare paid for these tests should not have been separately reimbursed. In effect, Medicare paid twice for these tests.

[4]To be eligible for ESRD coverage, a patient generally must have been on dialysis for 3 months and must be (1) entitled to a monthly insurance benefit under title II of the Social Security Act (or an annuity under the Railroad Retirement Act), (2) fully or currently insured under Social Security, or (3) the spouse or dependent child of a person who meets at least one of the first two requirements.

[5]The average dialysis payment rate for freestanding facilities is $126. The rate can range from a minimum of $117 to a maximum of $139 per facility depending on regional wage variations.

[6]In addition to the 16 routine laboratory tests included in the composite rate, HCFA considers 5 other laboratory tests routine but separately billable. Medicare will pay for these tests, outside the composite rate, at frequencies cited in HCFA's manuals. Our data exclude all these tests.

[7]Department of Health and Human Services, Office of Inspector General, Review of Separately Billable End Stage Renal Disease Laboratory Tests, A-01-96-00513 (Oct. 1996).

Laboratory Test Rates Vary Markedly for Patients in Different Dialysis Facilities

Our examination of 766 freestanding facilities showed that, despite the similarity of their patient populations, patients of some facilities received on average many more laboratory tests per year than others. Table 1 shows the distribution of various test rates among the facilities in our study.[8] At the extremes were patients of a dialysis facility who received tests an average of 224 times per year and those of a facility who averaged only 9 tests per year. In the middle were patients of a facility who averaged 56 tests per year.[9]

Table 1: Distribution of Laboratory Test Rates for Patients of Freestanding Dialysis Facilities, 1994

Facility ranked by average number of tests provided annually per patient	Average number of tests provided	Ratio of tests provided to median facility
Top	224	4:1
100th (87th percentile)	86	1.5:1
383rd (median)	56	1:1
666th (13th percentile)	29	.5:1
Bottom	9	.16:1

Notably, patients of facilities averaging the largest numbers of tests annually and those averaging around the median number of tests had characteristics that were similar both demographically and clinically. Using a June 1996 version of HCFA's ESRD Program Medical Management and Information System (PMMIS), we examined the characteristics of patients of the 100 highest ranking facilities and of the 100 facilities that ranked around the middle.[10] In the top 100 facilities and the middle 100 facilities, patients shared the characteristics shown in table 2.

[8]To determine patient testing levels, we grouped patients by the facility where they received dialysis and calculated how many tests a facility's patients received on average. We used HCFA's billing data to determine how many laboratory tests all patients of each facility received while they were attending the facility. We divided this total by the number of weeks the patients attended the facility to get the average number of tests received per patient per dialysis week. Multiplying this result by 52, we arrived at the average yearly number of tests each patient would have received if he or she had attended the facility for an entire year.

[9]HCFA's billing data for 1995 showed similar testing rate patterns. At the extremes were patients of a facility who averaged 161 tests per year and those who averaged 8 tests per year. In the middle were patients of facilities averaging 69 tests per year.

[10]We found demographic and clinical information in PMMIS for about 70 percent of the patients in the top and middle 100 facilities (see app. I).

Table 2: Patient Characteristics in Top and Middle 100 Facilities, 1994

Patient characteristic	Facilities 1-100	Facilities 336-435
Mean age in years	63.7	62.9
% male	60	58.9
% white	51	49.3
% patients with diabetes as primary reason for dialysis	32	32
% patients with kidney failure as primary reason for dialysis	15	16
% patients with hypertension	33	32
Mortality rates (%) January 1994 through June 1996	42.2	41.7
% patients with at least one kidney transplant received January 1994 through June 1996	11.3	11.3

Despite the similarity in patient characteristics, our data showed that compared to patients in the middle 100 facilities, many patients in the top 100 facilities received certain individual laboratory tests nine times as frequently.

Test Rate Disparities Indicate Inappropriate Levels of Test Ordering

The large differences in the rates of tests ordered suggest that there may be both excessive use, with some patients receiving tests too often or receiving tests that may not be necessary at all, and underuse, with patients receiving too few tests to ensure appropriate monitoring of their condition. In the absence of formal criteria or guidelines on proper testing levels for laboratory tests, we asked several renal disease experts to examine our test rate data in detail.[11] The experts reviewed usage rates for 34 individual laboratory tests from two data samples and questioned the usage rates for 20 tests. The first sample included the average yearly number of tests provided to patients across the 100 highest ranking facilities; for another perspective, the second sample included average yearly tests provided to patients of 6 randomly selected facilities.[12] For a complete list of tests that the experts reviewed, see appendix II. For a list of the tests the experts found questionable, see appendix III.

[11]The National Kidney Foundation is developing treatment guidelines for ESRD patients. The draft guidelines address improving patient survival, reducing patient morbidity, increasing efficiency of care, and improving quality of life for dialysis patients. However, the guidelines do not specify levels for laboratory tests.

[12]The first sample consisted of 13 individual laboratory tests that at least 100 patients of the top 100 facilities received at least twice as often as patients of the middle 100 facilities. The second sample included 26 high-frequency tests provided to patients of six dialysis facilities that we selected at random. Because 5 tests appeared in both samples, the total of individual tests reviewed was 34.

Excessive Rates Composed of Tests Rarely Needed or Ordered Too Frequently

The experts found that many of the tests reviewed appeared to be either rarely necessary or ordered too frequently. Table 3 shows a few examples of tests the experts deemed to have been provided inappropriately.

Table 3: Examples of Tests Experts Found Ordered Inappropriately

Procedure code	Name	Use rate	Experts' comments
Tests deemed rarely medically necessary			
82307	Calciferol (vitamin D)	Provided to 3% of patients (247) in our top-100 facility sample.	Rarely, if ever, needed.
82652	Dihydrozy vitamin D, 1, 25-	Provided to 5% of patients (384) in our top-100 facility sample.	Rarely, if ever, needed.
83937	Osteocalcin (bone g1a protein)	Provided to 20% of patients (1,738) in our top-100 facility sample.	No value for dialysis patients.
84134	Prealbumin	Provided to 96% of patients at one facility and 88% of patients at another in our 6-facility sample.	Rarely, if ever, needed. Provided to implausibly large proportion of patient population.
Tests provided too frequently			
82746	Folic acid, serum	Provided to 40% of patients in the top-100 facility sample.	Should be given to a maximum of 15 percent of patients.
83970	Parathormone (parathyroid hormone)	Provided 10 times to 92% of patients at one facility in our 6-facility sample.	Test should be given about 4 times a year.
85730	Thromboplastin time, partial (PTT); plasma or whole blood	Provided 11.5 times to 87% of patients at one facility in our 6-facility sample.	Should be provided, at most, 4 times a year.
86296	Hepatitis A antibody (HAAb); IgG and IgM	Provided over 3 times to 3% of patients (280) in the top-100 sample.	Test should be given a maximum of once a year.

The experts noted that, although any test might be valid for any one individual, they could find no plausible reason for giving certain tests to the large numbers of patients we identified. For example, some of the experts had never ordered a test that measures the absorption of calcium in bone. Nevertheless, this test, 83937, osteocalcin (bone g1a protein), was provided three times per patient per year to 20 percent of the patients in

the top-ranked 100 facilities. Several experts questioned the test's value for dialysis patients, noting that its appropriateness for them was uncertain.

The experts also found the value of vitamin D tests, 82307, calciferol vitamin D, and 82652, dihydrozy vitamin D, 1, 25-, to be dubious. Because dialysis patients do not produce vitamin D, their physicians provide it to them, therefore making the monitoring of vitamin D levels unnecessary. In our data samples, one of these tests was provided to 5 percent of the patients in the top 100 facilities about 8 times a year, and the other test was provided to 3 percent of the patients about 10 times a year. One expert had rarely ordered these tests in his 18-year career, and a second, who had been practicing for more than 16 years, believed he may have ordered these tests twice. A third expert said that most of the physicians at facilities where he is the medical director would not give the test at any time.

Several experts noted that they had never ordered 85730, thromboplastin time, partial (PTT); plasma or whole blood, a test to determine the effect of the drug heparin, which is given to dialysis patients to prevent blood clotting. Nonetheless, 87 percent of the patients at one dialysis facility received this test 11 times a year. In comparison, 30 percent of the patients at another facility and 25 percent of the patients at a third facility received it twice a year, while 44 percent of the patients at a fourth facility received it 2.5 times a year.

Finally, with respect to 84134, prealbumin, a test that indicates malnourishment, three experts said it was rarely needed and should be provided to few patients. Nevertheless, in our six-facility sample, 96 percent of patients of one facility and 88 percent of patients of a second facility received this test 11 times a year. These rates compare with 16 percent of patients of the middle-ranked 100 facilities averaging five tests per year.

The experts also identified tests that are not unusual for dialysis patients to receive but were nevertheless given too often. Two experts, for instance, believed that the number of patients who received the 82746, folic acid, serum, test was very high. Forty percent of the patients in the top 100 facilities received this test four times per year. One expert said that fewer than 15 percent of all patients should receive this test ever or that often, and another believed it was needed only rarely.

Two experts also identified a problem with the ordering of 86296, hepatitis A antibody (HAAb); IgG and IgM. This test was provided to about 3 percent of the patients in the top 100 facilities who received it an average of three times per year. One expert said the test was rarely needed and was certainly not needed three times per year per patient.

Two experts found that 83970, parathormone (parathyroid hormone), a test to check for a hormone that regulates calcium and phosphorus metabolism, was given much too often. One expert noted that the test should be given about twice a year, and the other observed that the medical condition for which this test is performed would not change for 2 to 3 months after a change in therapy, so that testing before that time would not be useful. At one facility, however, 92 percent of the patients received the test an average of 11 times a year—nearly once a month.

Low Test Rates Appear to Be Inconsistent With Common Medical Practice

The data also show that some patients received tests not covered under the composite rate at rates dramatically below the median. Some, for example, received on average 9 tests in total for the year, compared with patients of the median facility, who averaged 56 per year. An RPA official and other experts noted that, to monitor the blood levels of just one substance—iron—dialysis patients should receive at least eight tests yearly (two different tests provided quarterly).[13] In affirming the importance of iron-level testing, one expert suggested these iron tests be included in the routine test bundle reimbursed through the composite rate.

Financial Incentives and Other Physician-Related Factors May Explain Wide Variation in Test Rates

Financial incentives as well as lack of knowledge and differences in medical practices may help explain the wide variation we found in the rates of laboratory tests provided. The experts we consulted cited these factors as possible reasons for inappropriate test levels.

The financial incentive to bill for as many tests as possible is inherent in the fee-for-service payment arrangement for laboratory tests, making laboratory ownership an important factor. For example, when a single company owns one or more dialysis facilities and a laboratory, there is an opportunity to increase overall revenues by directing more laboratory tests to the company-owned laboratory. As the experts pointed out, facilities can influence the tests physicians order through the development

[13]Iron and iron-binding capacity tests, identified by HCFA Common Procedure Codes 83540 and 83550, respectively. A third test, serum ferritin (82728), was also identified as necessary but is not included in our example because it is a test not requiring specific medical justification under the ESRD program.

of "standing orders," which are a list of tests periodically performed on all patients unless the ordering physician overrides them.

Former hospital billing practices illustrate the potential to use standing orders to pad claims for laboratory services. Before Medicare and other insurers implemented prospective payment systems for inpatient hospital care—namely, the payment of flat fees for certain diagnoses regardless of the volume of services provided—many problems were identified with hospitals' standing orders for laboratory tests given to patients upon admission. The standing orders often included tests that were not medically necessary for most patients, but all patients received them, and their insurers were billed for those excess tests.

The use of standing orders could account for the presence, in our 1994 data sample, of more than 40 percent of a chain's facilities in the top-ranked 100 facilities in terms of tests ordered.[14] It may also explain our study's finding that about 90 percent, on average, of the patients of at least 23 facilities in this chain received a prealbumin test from 11 to 12 times per year—a test that experts considered to be needed plausibly for only a small fraction of patients. The medical director of one of these facilities confirmed that prealbumin was in the facility's standing order.

The potential for overordering tests inherent in the joint ownership arrangement is consistent with information provided to us by a facility's former medical director. He told of a company official who once cautioned him that unless the company's profits from laboratory tests increased (the company owned both the facility and the laboratory), a reduction in the facility's nursing staff would be necessary.

The experts we interviewed attributed most of the unneeded tests, as well as the underprovision of tests, to a lack of knowledge on the part of the ordering physicians. They believed that the physicians were either not keeping abreast of current scientific knowledge or misguided about the frequency at which a test should be ordered. As a result, physicians could fail to order the tests needed or not be in a position to challenge the inclusion of tests in standing orders that might not be appropriate.

The experts also believed that some of the unneeded tests they identified could have resulted from differences among physicians in professional judgment regarding which tests are needed and how often they are

[14]Likewise, in our 1995 sample, a substantial portion of this chain's facilities reappeared in the top-ranked 100 facilities.

needed. Divergent opinions could be the product of differences in medical school training or continuing education. For example, an NIH nephrologist indicated that, contrary to the views of the experts we interviewed, he believes that the prealbumin test (code 84134) should not be limited to very few patients. In contrast, he agreed that it is not necessary to receive this test nearly once a month as did patients of some facilities in our sample. In addition, legitimate medical practice differences could be reflected in standing orders developed by different medical directors.

Current Payment Procedures Make It Difficult to Hold Appropriate Providers Accountable for Overordering

HCFA officials informed us that neither HCFA nor its claims-processing contractors perform the analyses necessary to determine the rates at which dialysis patients receive laboratory tests. As a result, neither knows if Medicare is paying for unnecessary tests for patients who receive numerous tests or if patients who receive few tests are receiving high-quality treatment. HCFA relies largely on its contractors to monitor claims data for inappropriate, erroneous, or otherwise unnecessary payments. The contractors' reviews of paid claims (postpayment review) generally are conducted in accordance with a HCFA policy known as focused medical review, under which contractors are instructed to examine claims to identify either services likely to be overused or providers likely to be overbilling.

Normally, the provider that bills Medicare is also the one that orders or controls the provision of the service. With laboratory tests, however, this is often not so. While a physician must always order tests, they are frequently performed by an independent clinical laboratory. Under Medicare rules, physicians bill for their personal services (such as the office visit when the test was ordered), and the laboratory bills for the test itself. Under the normal analysis methods carriers use, if anyone is identified for excessive test usage rates, it would likely be the laboratory and not the physician ordering the tests.

Our study identifies patients' test rates by the facility at which they have been dialyzed, by test types, and by test frequencies. Arraying the data by facility allowed us to observe test rates in conjunction with ownership ties, recognizing that laboratories and facilities can have a common owner and that ordering physicians are often a dialysis facility's medical director. To replicate such an analysis, HCFA could examine contractor data for laboratory claims. These claims identify the ordering (or referring) physician. Using these claims data, HCFA could profile (or identify) physicians who order many more tests than their peers. Profiling would

allow HCFA to observe usage rates nationwide, single out facilities or physicians (or both) whose test order rates are aberrant, and notify the contractors who process these providers' claims. The contractor's health professionals could then review the provider's practices and, if excessive or insufficient testing were identified, notify the provider of this fact through educational letters.

With regard to physicians' ordering excessive tests, as discussed above, they do not have a financial incentive to scrutinize the necessity of tests they order when the testing is done at independent clinical laboratories. In addition, if the laboratory actually performs the tests a physician orders, Medicare will pay for unnecessary tests because the laboratory is only complying with the physicians' orders.[15] One way to give physicians an incentive to review their test-ordering practices more closely would be to hold them financially responsible for unnecessary tests (done by independent laboratories) that they order after having been notified that individual tests are inappropriate, perhaps through the educational letters mentioned above.

Conclusions

Insufficient use of the proper tests can compromise the quality of ESRD patients' care, while the excessive or inappropriate use of tests can result in unnecessary Medicare payments. The seriousness of both extremes calls for HCFA to monitor laboratory test rates for patients receiving dialysis treatments. Although the data are available, HCFA does not examine them in a way that would reveal relative test usage rates.

Our analysis of these data, in consultation with renal disease experts, reinforces concerns that both excessive and insufficient testing are occurring. The distribution of test rates across facilities included in our study suggests that financial incentives and differences in individual physicians' professional judgment could account for the wide variation. The experts noted that our study's testing patterns warrant further investigation. Therefore, we believe that HCFA should perform the data analyses needed to examine test rate variation and identify physicians whose rates of test orders are out of line with average rates.

Because independent laboratories that perform the excessive tests doctors order are generally not held liable for repayment, Medicare does not have a way to recover the costs of such tests. Making ordering physicians

[15]However, if common ownership, kickbacks, or conspiracies are involved, the laboratory could be subject to civil or criminal penalties.

financially responsible in such cases after they have been notified of the inappropriateness of particular tests would be a way to induce physicians to review more closely the necessity of the tests they order, including those ordered through standing orders.

Matter for Congressional Consideration

The Congress may wish to consider making the ordering physician liable for the recovery of payments made to laboratories when the physician continues to order tests that are not medically necessary or are provided too frequently, after having been notified of a pattern of such inappropriately high testing rates.

Recommendation to the Administrator of HCFA

We recommend that, to assist contractors in their efforts to determine the appropriateness of laboratory tests ordered for Medicare dialysis patients, the HCFA Administrator profile physicians ordering laboratory tests for dialysis patients and notify the contractors of the providers whose test order rates are aberrant. The Administrator should instruct the contractors to review these cases and carefully scrutinize ordering physicians who order too many or too few tests.

Agency Comments

We requested comments from HCFA but none were received. However, HCFA staff provided technical corrections, which we incorporated.

As arranged with your office, unless you publicly announce the contents of this report earlier, we plan no further dissemination until 30 days after its issue date. At that time, we will send copies of this report to the Secretary of Health and Human Services, the Administrator of HCFA, appropriate congressional committees, and other interested parties. We will also make copies available to others upon request.

If you or your staff have any questions, please call me at (202) 512-6806 or William Scanlon, Director of the Health Financing and Systems issue area, at (202) 512-7114. Other contributors to this report include Scott Berger, Jack Brennan, Tom Dowdal, Hannah Fein, Jonathan Ratner, Don Snyder, and Vanessa Taylor.

Sincerely yours,

Richard L. Hembra
Assistant Comptroller General

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Abbreviations

ESRD	end-stage renal disease
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
NIH	National Institutes of Health
NRAA	National Renal Administrators Association
PMMIS	Program Medical Management and Information System
RPA	Renal Physicians Association

Objectives, Scope, and Methodology

Our objective was to determine whether patients of some dialysis facilities receive many more than the average number of laboratory tests and, if so, to determine what the Health Care Financing Administration (HCFA) should do to help ensure that dialysis patients receive only necessary tests. We limited our analysis to end-stage renal disease (ESRD) outpatients who attended only one freestanding facility and to facilities having at least 50 patients. Our resulting sample included 766 facilities with 67,767 patients in 1994 and 819 facilities with 72,100 patients in 1995. Medicare paid $35.9 million for laboratory tests for these patients in 1994 and $40.6 million in 1995. We eliminated hospital-based facilities from our study after learning that many hospital-based laboratories do not submit bills to Medicare for dialysis patients, making it impossible for us to determine how many tests patients of these facilities received.

We used HCFA data to determine how many laboratory tests patients of each facility received during the period they received dialysis. We included only tests from the 80000 series of services as shown in HCFA's Common Procedure Coding System. We excluded approximately 50 procedure codes from the 80000 series for the 16 laboratory tests that are included in the composite rate (that is, tests provided to every dialysis patient at a frequency cited in HCFA's manuals), and 5 tests (7 procedure codes) that are provided at a stated frequency but are reimbursed in addition to the composite rate. We reviewed HCFA manuals and met with a HCFA official to identify the tests and their related procedure codes included in these two categories.

We used a June 1996 version of HCFA's Program Medical Management and Information System (PMMIS) file to compare patient demographic characteristics. We were able to match about 70 percent of our claims sample with PMMIS. Thus, demographic information discussed in this report is based on the smaller number of patients. We calculated facility average percentage of patients by age, race, gender, initial medical reason for being placed on dialysis, mortality rates, and transplant rates.

We interviewed HCFA officials responsible for ESRD policy development and implementation for laboratory testing, as well as research and analysis and information systems management; officials at several HCFA carriers and regional offices and an intermediary; officials at one end-stage renal disease network office; an official at a state health department; and representatives of national renal organizations of administrators and nurses. We also visited two freestanding dialysis facilities.

We met with four renal disease experts to review the testing rates and comment on their reasonableness and to obtain their views on the causes of the variation in rates. We also discussed our results with officials, including nephrologists, from the National Institutes of Health (NIH), National Renal Administrators Association (NRAA), and Renal Physicians Association (RPA).

We conducted our work in accordance with generally accepted government auditing standards except that we did not verify the accuracy of HCFA's computerized files. However, we did check the data that HCFA provided against other published HCFA data to ensure that they contained the correct number of facilities and patients.

Thirty-Four Tests the Experts Reviewed

Procedure code	Description
80002	Profile on automated multichannel equipment, 2 clinical chemistry tests[a]
80003	Profile on automated multichannel equipment, 3 clinical chemistry tests[a]
80007	Profile on automated multichannel equipment, 7 clinical chemistry tests
80009	Profile on automated multichannel equipment, 9 clinical chemistry tests[a]
80019	Automated multichannel tests, 19 or more clinical chemistry tests[a]
80061	Lipid panel, which must include cholesterol, serum, total (82465); lipoprotein, direct measurement, high-density cholesterol (HDL cholesterol) (83718); triglycerides (84478)
80162	Digoxin
82307	Calciferol (vitamin D)[a]
82465	Cholesterol, serum, total[a]
82607	Cyanocobalamin (vitamin B-12)[a]
82652	Dihydrozy vitamin D, 1, 25-[a]
82746	Folic acid, serum[a]
83540	Iron[a]
83550	Iron-binding capacity[a]
83718	Lippoprotein, direct measurement; high-density cholesterol (HDL cholesterol)[a]
83937	Osteocalcin (bone g1a protein)[a]
83970	Parathormone (parathyroid hormone)[a]
84134	Prealbumin[a]
84460	Transferase; alanine amino (ALT) (SGPT)[a]
84466	Transferrin
84478	Triglycerides
85007	Blood count; manual differential WBC count (includes RBC morphology and platelet estimation)
85027	Hemogram and platelet count, automated
85029	Additional automated hemogram indexes (e.g., red cell distribution width (RDW), mean platelet volume (MPV), red blood cell histogram, platelet histogram, white blood cell histogram); one to three indexes
85044	Reticulocyte count, manual
85045	Reticulocyte count, flow cytometry
85730	Thromboplastin time, partial (PTT); plasma or whole blood[a]
86296	Hepatitis A antibody (HAAb); IgG and IgM[a]
86302	Hepatitis C antibody[a]

(continued)

Procedure code	Description
86317	Immunoassay for infectious agent antibody, quantitative, not elsewhere specified
87040	Culture, bacterial, definitive; blood (includes anaerobic screen)
87070	Culture, bacterial, definitive; any other source
88305	Surgical pathology, gross and microscopic examination[a]
89051	Cell count, miscellaneous body fluids (e.g., CSF, joint fluid, except blood)

[a]Tests experts found to have been provided too often or of questionable value for ESRD patients. See app. III for additional details.

Twenty Tests Experts Reviewed and Found Provided Too Often or of Questionable Value

Procedure code	Name	Use rate[a]	Experts' comments
80002	Profile on automated multichannel equipment, 2 clinical chemistry tests	Provided to 93% of patients at one facility and 76% at another in our 6-facility sample.	Three-fourths of the patients receiving this test at one facility is far too many.
80003	Profile on automated multichannel equipment, 3 clinical chemistry tests	Provided to 33% of patients (2,826) 10 times per year in our top-100 facility sample.	Not consistent with expert's medical practice.
80009	Profile on automated multichannel equipment, 9 clinical chemistry tests	Provided to 13% of patients (1,127) 4 times per year in our top-100 facility sample.	Not consistent with expert's medical practice.
80019	Automated multichannel tests, 19 or more clinical chemistry tests	Provided to 52% of patients (4,432) in our top-100 facility sample.	Because 12 of these tests are included in the bundle, it was ordered for an unlikely number of patients.
82307	Calciferol (vitamin D)	Provided to 3% of patients (247) in our top-100 facility sample.	Rarely, if ever, needed.
82465	Cholesterol, serum, total	Provided to 71% of patients at one facility in our 6-facility sample.	Reasonable for only a few patients, not for almost three-fourths of patients at one facility.
82607	Cyanocobalamin (vitamin B-12)	Provided to 39% of patients (3,307) 3.5 times per year in our top-100 facility sample.	Should be provided once a year to less than 15 percent of patients.
82652	Dihydrozy vitamin D, 1, 25-	Provided to 5% of patients (384) in our top-100 facility sample.	Rarely, if ever, needed.
82746	Folic acid, serum	Provided to 42% of patients in our top-100 facility sample.	Indicated for a maximum of 15% of patients.
83540	Iron	In our 6-facility sample, provided to 96% and 88% of patients at 2 facilities 11.4 times, 88% of patients at a third facility 7 times, and 82% of patients at a fourth facility 10.4 times.	Provided too frequently. Need one test every 3 months for stable patients—about 75% of population.
83550	Iron-binding capacity	In our 6-facility sample, provided to 92% of patients at one facility 11 times and 82% of patients at each of 2 other facilities 8 and 12 times.	Provided too frequently. Need one test every 3 months for stable patients—about 75% of population.
83718	Lipoprotein, direct measurement; high-density cholesterol (HDL cholesterol)	Provided 11.4 times per year to 96% of patients at one facility and 88% at another in our 6-facility sample.	Provided to implausibly large proportion of patient population. About 5% of patients may need this test once a month.
83937	Osteocalcin (bone g1a protein)	Provided to 20% of patients (1,738) in our top-100 facility sample.	No value for dialysis patients.
83970	Parathormone (parathyroid hormone)	Provided 10.5 times to 92% of patients at one facility in our 6-facility sample.	Should be given once or twice a year at most.

(continued)

Procedure code	Name	Use rate[a]	Experts' comments
84134	Prealbumin	Provided to 96% of patients at one facility and 88% of patients at another facility in our 6-facility sample.	Provided to implausibly large proportion of patient population.
84460	Transferase; alanine amino (ALT) (SGPT)	Provided 9 times a year to 4% of patients (321) in the top-100 facility sample.	Should be part of a multichannel panel, not given separately. Too many patients received this test.
85730	Thromboplastin time, partial (PTT); plasma or whole blood	Provided 11.5 times to 87% of patients at one facility in our 6-facility sample.	Should be provided, at most, 4 times a year.
86296	Hepatitis A antibody (HAAb); IgG and IgM	Provided 3 times a year to 3% of patients (280) in the top-100 facility sample.	Should be given a maximum of once a year.
86302	Hepatitis C antibody	Provided to 83% of patients at one facility in our 6-facility sample.	Provided to far too many patients.
88305	Surgical pathology, gross and microscopic examination	Provided 2 times a year to 28% of patients at one facility in our 6-facility sample.	Provided to an implausibly large proportion of patient population. Needed very rarely—perhaps once a year for 2% or 3% of all patients.

[a]8,526 patients in the top 100 facilities.

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