JAN 24 1996

June Gibbs Brown
Inspector General

Follow-up Report to "Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests" (A-09-93-00056)

Bruce C. Vladeck
Administrator —
Health Care Financing Administration

Attached are two copies of our final report on the follow-up review to our audit entitled, "Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests." The objective of our follow-up review was to evaluate the actions taken by the Health Care Financing Administration (HCFA) to implement the recommendations made in our January 1990 report (A-09-89-00031).

Our 1990 audit report disclosed that Medicare, which pays for laboratory tests based on fee schedules, was paying nearly twice as much as physicians pay for the same tests. Much of the difference was attributable to the way in which Medicare reimbursed organ or disease related panels (panels), or groups of tests, ordered as a package by physicians. While laboratories offered panels to physicians at greatly reduced prices, Medicare usually paid the fee schedule rates for the individual tests.

In our 1990 report, we recommended that HCFA: (1) seek legislation to bring the Medicare fee schedule allowances in line with the prices physicians pay for tests purchased from independent clinical laboratories, (2) develop policies and procedures to more appropriately reimburse panels, and (3) work with contractors to further streamline the processing of laboratory claims.

Although our follow-up has found that, generally, Medicare continues to pay clinical laboratories more than physicians pay for the same tests, recent legislation will further reduce the Medicare fee schedules. The Omnibus Budget Reconciliation Act of 1993 will reduce the fee schedule to 76 percent of the national average by 1996. We are, therefore, recommending that HCFA periodically evaluate the national fee schedule to ensure that it is in line with the prices physicians pay for clinical laboratory services.

We also found that Medicare policies are not sufficient to control the billing of panel tests. We found that panels are still generally being billed as individual tests to Medicare and that the utilization of laboratory services has continued to increase. Our
original recommendation to develop policies and procedures to more appropriately reimburse panels remains valid. We are also recommending that HCFA study the reinstatement of the beneficiary coinsurance and deductible provisions for clinical laboratory services as a means of controlling utilization and require carriers to analyze provider practices for aberrancies in billing and utilization.

Further, as a result of enhancements to the electronic media claims system, the coordination between carriers and independent laboratories appears to be improving. Therefore, we have no new recommendations regarding the processing of laboratory claims.

The HCFA has concurred with most of our recommendations and has taken, or agreed to take, corrective action. The HCFA did not concur with our recommendation to reinstate coinsurance and deductibles for laboratory services. We have considered HCFA’s comments and have incorporated them, as appropriate, in our final report. We appreciate the cooperation given us in this audit.

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. Please advise us, within 60 days, on actions taken or planned on our recommendations. Copies of this report are being sent to other interested Department officials.

To facilitate identification, please refer to Common Identification Number A-09-93-00056 in all correspondence relating to this report.

Attachments
FOLLOW-UP REPORT TO
"CHANGES ARE NEEDED IN THE WAY
MEDICARE PAYS FOR CLINICAL
LABORATORY TESTS"

JUNE GIBBS BROWN
Inspector General

JANUARY 1996
A-09-93-00056
EXECUTIVE SUMMARY

This review is a follow-up of our report entitled, "Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests" (A-09-89-00031, January 1990). In that report, we stated that (1) Medicare was paying more than physicians for the same tests (dual pricing), (2) groups of related tests, called panels were billed and paid for at unreduced individual test rates (unbundling), and (3) claims processing needed to be streamlined.

Since our original report was issued, the national fee schedule amounts have been reduced and further reductions are scheduled by law. Although Medicare is still being charged and is paying more than physicians for the same tests, the Omnibus Budget Reconciliation Act (OBRA) of 1993, when fully implemented, should reduce the higher profit rates from Medicare billings.

Panel tests remain a problem, although the Health Care Financing Administration (HCFA) has standardized and set national ceilings for organ or disease related panels. Nevertheless, custom panels - packages developed by the laboratory that do not correspond with defined organ and disease panels - are still generally being billed as individual tests to Medicare. Current Medicare guidelines do not address the problem of custom panels as a marketing mechanism of the laboratory industry nor the problem of the industry billing the contents of the custom panels individually. Also, HCFA's policies have not emphasized the medical necessity element in the processing of claims for clinical laboratory services. In our opinion, these conditions have contributed to a significant increase in the utilization of laboratory services.

In our 1990 report, laboratory representatives said that it cost more to bill and obtain reimbursement from Medicare for laboratory services. Since then, enhancements in the electronic media claims system have addressed many problems cited by the laboratories. These enhancements have streamlined the system by making the process of handling electronic claims much more timely and efficient.

We are recommending that HCFA periodically evaluate national fee schedule amounts. We are also recommending that HCFA develop a method to pay panels at less than full price for the individual tests, study reinstating the beneficiary coinsurance, and require carriers to monitor providers to detect aberrations in utilization and billing.

In a written response to a draft of this report, HCFA concurred with all but one of the recommendations. The HCFA did not agree to study the reinstatement of beneficiary coinsurance because it was not proposed in the President's Fiscal Year 1996 budget statement.
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INTRODUCTION

BACKGROUND

History of Laboratory Fee Schedules

Third-party payers are not charged competitive prices

Independent laboratories have traditionally operated with two price lists: one that applies to insurance companies or other third-party payers (including Medicare), and a second list of prices that applies to physicians and other health providers. Independent laboratories depend on physicians to refer patients for testing, and physicians can negotiate prices that are reflective of a highly competitive market. However, these competitive market forces do not apply for third-party payers. Independent laboratories have no incentive to bill third-party payers at discounted rates. Therefore, the prices which are charged to third-party payers are usually substantially higher than charges to physicians.

Laboratories used a two-tiered pricing system

We previously discussed this two-tiered pricing situation, which we termed discriminatory pricing, in an audit report to HCFA, dated March 8, 1982 ("Despite Years of Attention: Clinical Laboratory Tests Still Cost Medicare/Medicaid Too Much" - ACN 15-20150). In this report, we showed how the Medicare allowances for laboratory tests, which at the time were based on what providers charged the program, exceeded the going market prices that physicians were paying for the same tests. We recommended that Medicare (and Medicaid) take advantage of these competitive market prices and that HCFA not allow laboratories to charge Medicare (and Medicaid) more than they charge physicians for the same tests.

A task force was established to study the problem

In response to our report, HCFA established a task force in 1982 with representatives of the laboratory industry to explore possible reforms to the way in which Medicare paid for clinical laboratory services. The task force's study and report, which was issued February 15, 1984, led to a major legislative change--converting Medicare reimbursement for most laboratory tests to fee schedules.

The HCFA task force recommended setting Medicare fee schedule amounts at less than the then prevailing charges because it believed that the prices billed to Medicare did not reflect a competitive market. The task force assumed that "the discounted prices of transactions between physicians and independent laboratories reasonably
The Congress mandated fee schedules—The Deficit Reduction Act of 1984 established the Medicare fee schedule payment methodology. The fee schedules went into effect in July 1984 for clinical laboratory tests reimbursed under Part B of the Medicare program. The fee schedule rates applied to tests performed on outpatients, whether done in physician offices, independent clinical laboratories, or hospital laboratories. Tests done on hospital inpatients were not subject to fee schedules, but paid through either fixed hospital rates or based on reasonable costs by Medicare.

Under the fee schedules, Medicare allowances for laboratory services varied by geographic location. Different allowances were set by each contractor (carrier) who processed and paid Medicare Part B claims billed by physicians or independent laboratories. For outpatient services, hospital laboratories generally submitted Part B claims to other contractors, called fiscal intermediaries, who paid according to these carrier set fees. In general, the fees were established at 60 percent of the Medicare prevailing rate during a base period at each carrier, and were periodically updated to reflect inflation. Hospital laboratories were initially paid at 62 percent of the prevailing rate.

Medicare payments for laboratory tests under the fee schedules had to be on the basis of assigned claims. Under this system, providers billing the program had to accept the fee schedule allowance as payment in full. In addition, the usual Medicare Part B deductible and coinsurance were waived, relieving beneficiaries of any liability for cost sharing on claims for which Medicare made payment.

At the time Medicare fee schedules were originally being developed, we expressed concern to HCFA over setting the rates at 60 percent of the Medicare prevailing rates. Based on our limited review of prices available to physicians, we concluded that 60 percent of the Medicare prevailing rate might be too high.

The Congress, also concerned about the appropriate levels of Medicare reimbursement for laboratory tests, requested the General Accounting Office (GAO) to perform two studies of the Medicare fee schedules. In the first of these studies (HRD-88-32, December 1987), the GAO reported that the fee schedules, as initially set, did not produce any significant program savings, although beneficiaries saved an estimated $313 million due to waived cost sharing on claims for laboratory services. The second study (HRD-91-59, June 1991)
involved an analysis of providers’ costs and revenues. It found that the laboratories’ cost to perform the tests and bill the Medicare program did not support the Medicare fee schedule rates. In fact, the laboratories lost money on discount customers but made up the loss with profits from third parties such as Medicare.

The Congress established fee schedule payment caps

The Congress first modified the fee schedule allowances, effective July 1, 1986, by imposing national ceilings, or payment caps, on what individual carriers could pay. These ceilings were initially set at 115 percent of the median of all carrier rates. Each carrier paid the lowest of the national fee schedule amount, its fee schedule amount, or the laboratory’s charge.

In its Fiscal Year 1988 legislative program, HCFA proposed a reduction in Medicare payment rates for laboratory services, citing previous studies by the Inspector General and GAO. In response to this proposal, the Congress mandated specific reductions in the rates, effective April 1, 1988. Certain tests, including automated chemistries and other commonly performed tests, were reduced by 8.3 percent. In addition, the national ceilings were limited to the median of all fee schedule allowances, instead of 115 percent of the median as was previously used.

Prior Report Findings

Our prior report (CIN: A-09-89-00031, January 1990) found that, for a statistical sample of claims, the Medicare criteria for paying laboratory claims were not adequate to protect the program from excessive charges. Our detailed review of 4,120 billings to 211 physicians revealed that the Medicare payment rates were about 90 percent more than the amounts which were actually paid by physicians. Of the 26 independent clinical laboratories we surveyed, 19 had established separate price lists for their physician and other health provider customers. While the price lists for physicians showed lower rates than those billed to Medicare and other third-party payers, we found that most physicians were given additional discounts from the price lists.

The Medicare rates did not exceed the physician prices on all tests. Medicare paid more for common, high-volume services such as panels and automated chemistries but paid less for certain low-volume tests such as human immunodeficiency virus antibody. Some of the most dramatic differences in prices in our sample occurred when physicians ordered custom panels - packages developed by the laboratory that do
Medicare was being overcharged for panels—Laboratories said it cost more to bill Medicare. Even though custom panels or packages of tests were common, Medicare did not ensure that reasonable prices were paid, that is that Medicare benefitted from the package discount. For the most part, Medicare paid for panels as individual tests at the full fee schedule allowances. Also, no national ceilings were set for any of the billing codes established for packages billed as panels. Medicare, unlike physicians, generally did not benefit when standard panels tests were ordered from the laboratories. For the 1,525 panels in our sample, Medicare was paying an average of 176 percent more than the physicians for the same tests.

Laboratories said it cost more to bill Medicare. When we asked laboratory representatives why they charged Medicare more than physicians, the most common response was that it cost more to bill and obtain reimbursement from Medicare. As an example, representatives at one laboratory showed us a stack of checks they had just received from Medicare. The laboratory, they explained, had billed for some 500 Medicare patients, using a single computer tape. Instead of issuing just one check for the entire billing, as its physician customers did, the laboratory’s carrier had paid with a separate check for each patient. The carrier’s use of separate checks for each patient obviously was inefficient and unnecessary from the perspective of both the laboratory and the Medicare program.

Laboratories overlooked the fact that Medicare was a large volume payer. We also noted that, although the laboratories provided evidence that Medicare needed to simplify the way in which it processed and paid claims, they overlooked the fact that Medicare was a large volume payer of tests. Because Medicare was such a large volume payer of tests, we believed a strong case could be made for Medicare paying less than physicians. We had based this opinion, in part, on a 1987 Smith Barney Research report on the clinical laboratory industry which estimated that Medicare represented 10 to 20 percent of the total testing performed.

SCOPE OF AUDIT

Our audit was made in accordance with generally accepted government auditing standards. The primary purpose of our review was to evaluate the actions taken by HCFA to implement the
recommendations made in our report entitled, "Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests" (A-09-89-00031).

The objectives of the review were to determine if HCFA:

- proposed legislation to make across-the-board adjustments in Medicare laboratory fee schedules to bring them in line with the prices which laboratories charge in a competitive marketplace;
- developed policies and procedures, including any needed legislative changes, to ensure that the program benefits from reduced prices when panels are ordered on behalf of Medicare patients; and
- worked with carriers to further streamline the processing of Medicare claims for laboratory services.

To accomplish the first objective, we obtained and evaluated the legislative proposals and legislation passed to adjust the fee schedule. We determined if the proposed legislation and any associated program memoranda would serve as corrective actions. We determined if there had been other changes to the Medicare program that would affect pricing. We also determined if prices were now more in line with what laboratories charge their physician clients. We inquired whether the use of the Office of Inspector General (OIG) sanction authority as suggested by HCFA was a practical solution to the problem.

To accomplish the second objective, we obtained and evaluated the program memoranda issued to the carriers. We reviewed the results of HCFA’s survey of carrier profiles that was performed in response to our prior report. The purpose of the survey was to determine the carriers’ policies relating to the definition and pricing of profiles. We obtained the original and revised panel codes as of April 1, 1993 (80050 through 80092) and determined what changes had been made. We reviewed the instructions sent to carriers and determined if HCFA told the carriers to properly associate the tests and individual components of each panel. We reviewed current industry practices of major laboratory chains.

To accomplish the final objective, we reviewed the increased use of electronic claims processing and its simplification of the billing
process. We also reviewed the new Common Working File and evaluated its implications for laboratory claims.

Other than the issues discussed in the FINDINGS AND RECOMMENDATIONS section of this report, we found no instances of noncompliance with applicable laws and regulations. For those items not tested, nothing came to our attention to cause us to believe that untested items would produce different results.

Our field work was performed between March 1993 and September 1995.
FINDINGS AND RECOMMENDATIONS

DUAL PRICING

Medicare is still paying more than physicians for the same tests. Medicare is being charged and is continuing to pay independent laboratories more than physicians pay laboratories for the same tests. However, when the OBRA of 1993 is fully implemented, it will reduce the national Medicare fee cap to 76 percent of the median of carrier prices. This reduction, according to a GAO report, will reduce the higher profit rates from Medicare billings.

1993 OBRA will further reduce fee caps. In response to our original report, HCFA said it would consider gradual reductions in the national ceiling. Based on the HCFA proposal, the Congress implemented reductions in the national ceiling. Since our report was originally issued, the national fee ceiling has been reduced from 100 percent of the median of the carriers' prices. The OBRA of 1993 reduced the national Medicare fee cap from 84 percent to 80 percent of the median in 1995 and to 76 percent in 1996.

The reduction to 76 percent in 1996 was based on a review performed by GAO. In its report (HRD-91-59, June 1991), GAO found that Medicare has been subsidizing the costs of tests run by the independent laboratories for their other customers. The report concluded that if the national cap were set at 76 percent of the median of the fee schedules, the laboratories would lose the financial advantage from Medicare. However, these reductions to the fee schedule do not address the problems of increased utilization of laboratory services.

Section 1128 sanction authority. The HCFA's response to our January 1990 report suggested that OIG could solve the problem of dual pricing by exercising its sanction authority in section 1128(b)(6) of the Social Security Act. However, in this instance, this sanction authority is not the preferred mechanism to efficiently protect program resources. Rather, HCFA should consider policy changes that will address the underlying issues involved in dual pricing, unbundling, and overutilization of clinical laboratory services.
Dual Pricing - Recommendation

As HCFA continues to implement the provisions of OBRA 1993, it needs to address the problem of excessive charges to the Medicare program. We recommend that HCFA periodically evaluate the national fee schedule to ensure that it is in line with the prices that physicians pay for clinical laboratory tests.

HCFA Comments

The HCFA concurred with this recommendation.

UNBUNDLING

Our January 1990 report found that the Medicare policies were not sufficient to control the billing of custom panels. During our review of a statistical sample of claims, we found that 37 percent of orders from physicians were for custom panels. These custom panels were generally offered to the physicians at specially discounted prices. Most of these panels were, however, billed to the Medicare program as individual tests, not as a panel. As a result, Medicare reimbursed for the tests at significantly higher rates than the discounted rates charged to physicians. For the panels in the sample, Medicare paid, on average, 176 percent more than the physicians paid for the tests.

Based on the Social Security Act, section 1862, no payment can be made for items and services that are not reasonable or necessary. The Medicare Carriers Manual (MCM) recognizes specially designed battery or profile tests (chemistry profiles) provided by independent laboratories to enable their physician clients to evaluate a patient's condition or the patient's response to a prescribed course of treatment. The MCM also recognizes that some tests in the battery may not be medically necessary and, therefore, not covered. The MCM provides that if only some tests in a battery are covered, payment cannot exceed the amount that would have been paid if the covered tests had been ordered individually from the laboratory. The same section also states that "In no event, however, may payment for the covered tests exceed the payment allowance for the battery." The MCM further states that "...the cost of a battery of tests is ordinarily low as compared with the costs of tests performed individually...."
HCFA surveyed carriers about organ or disease related panels

No similar rules have been set for panels. Until July 1993, no specific national limitation amounts had been set. The only comments in the MCM were that the individual tests that comprise the panels were subject to the national limitation and, where applicable, to the adjusted fee schedule. The carriers were to ensure that the payment allowance for the panels did not exceed the lower of the sum of the applicable fee schedule amounts for the individual tests in the panels or the sum of the fee schedule amount established for the panels by the carrier. These criteria are inadequate and do not prevent Medicare from being overcharged for panels nor from paying for tests that are not medically necessary.

The HCFA initially responded to our 1990 report by advising each carrier to (1) determine the tests included in each panel; (2) ensure that the amount paid for the panels does not exceed the sum of the fee schedule amounts or national limitations, if lower, of the individual tests; and (3) report the test content and payment allowance for the common panels to HCFA for possible establishment of national limitations on those panels with standard definitions.

Although HCFA requested detailed reporting about the contents of the organ panels from the carriers, the carriers did not fully comply with the request. The HCFA did not follow up to get the information for all of the carriers nor did it do anything with the information to monitor the carriers’ administration of the organ/disease panels. Our Philadelphia Region has recently found that the Pennsylvania carrier had been setting the price for some panels at a level higher than the component tests. For example, the lipid panels were overpaid as much as $11.37 per test in Pennsylvania. Our report (A-03-93-00025, issued August 2, 1993) identified potential overpayments of $12.6 million for organ or disease related panels processed by one carrier in its five service areas for the 28-month period ended April 30, 1993.

Based on current surveys of major laboratory chains, we found that, generally, custom panels are still being billed as individual tests to Medicare. For example, a custom panel consisting of a chemistry profile, ferritin and cholesterol was billed by a laboratory in 1992 to its physician clients for $16.00 or less, but billed to Medicare for $64.75. Medicare was allowing $47.80 for the three tests.

Laboratories still billing panels as separate tests

Physicians were misled into ordering expensive tests

A recent review at one major laboratory chain demonstrates why this is a significant problem. The laboratory was using custom panels with inexpensive price tags to market tests to its physician clients.
For example, the tests added to the chemistry profile in its basic custom custom panel were advertised as "at no additional costs to you [the physician]." Thus, the physicians were misled into ordering the custom panel instead of the simple chemistry profile because the patient could potentially benefit from the additional screening tests that were "free."

The ordering physicians were not aware that some of the tests in the custom panel were billed separately to Medicare. Therefore, tests that were not medically necessary were being routinely ordered by the physicians and paid for by the Medicare program. There was no identification on the claim that each test was or was not separately ordered by the physician.

Unfortunately for the Medicare program, the tests generally are not free, nor may all of the tests be medically necessary. One laboratory pled guilty to criminal false claims against the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) and refunded about $110 million to the Medicare, Medicaid, and CHAMPUS programs for its marketing practices for custom panels.

Since the period covered by our 1990 report, the utilization of laboratory services has significantly increased. One of the main reasons for the increased activity could be the increased use of custom panel packages to sell more laboratory tests. Although the national fee schedule has been reduced (limiting the maximum reimbursement for individual tests) the average amount billed per beneficiary has gone up. The laboratories may have compensated for lower prices by getting physicians to order more tests, thus increasing utilization. (See attached EXHIBIT.)

The accompanying chart shows that for the period 1986 through 1993 the Medicare population remained essentially flat, increasing by only 14 percent, whereas the frequency of testing increased 96 percent (125.5 million to 245.4 million tests billed). The increasing frequency of testing was one of the main reasons the allowed charges rose by 162 percent ($1,054 million to $2,765 million allowed).

Although the physician orders the clinical laboratory tests, the laboratory bills the Medicare program directly. As a result, the physician generally does not have knowledge of how the tests are billed to Medicare.
Further, the Medicare beneficiary has no incentive to control this jump in utilization because there is no deductible or coinsurance for clinical laboratory services and Medicare pays 100 percent of the allowed charge. In addition, the carriers have reduced or eliminated the notices that they send to beneficiaries concerning the payments made on their behalf for clinical laboratory services. If the beneficiary paid the 20 percent coinsurance or received a notice of the amount paid on their behalf, there might be an additional control on utilization.

To address these issues, in 1993 HCFA established a new unit dedicated to detecting Medicare fraud. This unit is currently studying the laboratory industry and its abusive practices. This unit will be issuing directives to the carriers about how to identify and control abusive practices and may also recommend changes to the program depending on their findings. The unit has already issued alerts to the carriers about the abuses of panel billing.

Together with the American Medical Association, HCFA has defined panel codes in the 1993 version of the physicians' Current Procedural Terminology (CPT) numbers, 80050-80092. These defined panels actually list the component tests for the panels and HCFA set prices on the national fee ceiling based on the component test prices. However, HCFA does not mandate the use of the panel numbers and allows providers to bill the components separately.

**Unbundling - Recommendations**

We had initially recommended that HCFA develop policies and procedures, including any needed legislative changes, to ensure that the program benefits from reduced prices when panels are ordered on behalf of Medicare patients. This recommendation remains valid.

We further recommend that HCFA:

1. develop a methodology and legislative proposal to address paying for tests ordered as custom panels at substantially less than the full price for individual tests;
2. study reinstating the coinsurance and deductible provisions for laboratory services as a means of controlling utilization; and

3. require the carriers to analyze provider practices for aberrations in billing and utilization.

**HCFA Comments and OIG Response**

For recommendation one, HCFA concurred to the extent Medicare continues to recognize custom panels. HCFA also encouraged OIG assistance in the effort.

For recommendation two, HCFA did not concur because the President's Fiscal Year 1996 budget statement includes no proposal for coinsurance or deductibles for laboratory tests. We continue to believe that beneficiary coinsurance, a standard provision of the Medicare program, should be reconsidered as a means of controlling laboratory utilization.

For recommendation three, HCFA concurred.

**STREAMLINE PROCESSING**

In our 1990 report, laboratories' representatives disclosed that it cost more to bill and obtain reimbursement from Medicare for laboratory services. Since that time, the enhancements in the electronic media claims seem to have addressed many of the problems identified by the laboratories. Generally, independent clinical laboratories now use electronic means to file claims with Medicare. Also, the coordination between carriers and independent clinical laboratories appears to be improving.

The independent laboratories are paid the lower of the amount billed, the local carrier fee schedule or a national fee schedule limitation. The laboratory is required to bill using the CPT-4 coding system for uniformity.

The HCFA has been promoting and streamlining the electronic media claims. The system now requires that the carriers have the capability to accommodate online status query of claims from the provider. "Clean" electronic claims (those without significant problems) must be paid between 14 and 30 days after receipt. Effective in 1993, the
carriers began to provide electronic fund transfer payments directly to the providers’ bank accounts with electronic remittance advice.

**Streamline Processing - Recommendations**

Enhancements in the electronic media claims system have addressed many problems cited in our 1990 report. We have no new recommendations in this area.

--- **HCFA TECHNICAL: COMMENTS AND OIG RESPONSE**

The HCFA comments raised several questions about physicians’ office laboratories (POLs), specifically whether or not the report covered them. Although HCFA raises some interesting questions about potential overutilization in POLs, our Scope section specifically states that this report is only intended to address the corrective actions taken by HCFA to our earlier report. That report’s stated objective was "...to compare Medicare payment rates for clinical laboratory tests to the prices which large commercial laboratories charged physicians." It was not intended to address POLs.
EXHIBIT
MEDICARE LABORATORY TESTS
All values expressed in millions

Based on carrier Part B payments only
APPENDIX
DATE   AUG 16  1995
FROM    Bruce C. Vladeck
        Administrator
TO      June Gibbs Brown
        Inspector General

We reviewed the above-referenced draft report which discusses the reimbursement of clinical laboratory services under Medicare Part B. Our detailed comments are attached.

Thank you for the opportunity to review and comment on this draft report.

Attachment
Health Care Financing Administration (HCFA) Comments on
Office of Inspector (OIG) Draft Report: Followup Report to "Changes Are Needed in the
Way Medicare Pays for Clinical Laboratory Tests"
(A-09-93-00056)

DUAL PRICING

OIG Recommendation 1
HCFA should ensure that the section of the Omnibus Budget Reconciliation Act (OBRA) of 1993
with provisions for independent laboratories is fully implemented.

HCFA Response
We concur. However, we are concerned that the recommendation could be misconstrued to
imply that we are not properly implementing the OBRA provisions. There is nothing to suggest
that HCFA has failed or will fail to implement the provisions, and for this reason we suggest that
this recommendation be dropped from the report.

OIG Recommendation 2
HCFA should periodically evaluate the national fee schedule to ensure that the fee schedule is in
line with the prices that physicians pay for clinical laboratory tests.

HCFA Response
We concur. In addition, we welcome OIG's offer of assistance as HCFA does not have access to
laboratory or physician records that would allow us to determine prices laboratories charge other
customers or what physicians are paying for laboratory tests.

UNBUNDLING

Recommendation 1
HCFA should require laboratories to identify on the Medicare claim form all tests ordered as part
of a custom panel.

HCFA Response
We are concerned that the use of custom panels has contributed to increased utilization of lab
tests and are evaluating what changes should be made in our payment and coverage policies for
custom panels, including whether we should continue to recognize tests that have been ordered as
part of a custom panel. We believe, however, that the pricing issue should be addressed as part of an
overall strategy on dual pricing. While this recommendation is feasible, it cannot be accomplished
until all custom panels can be defined. Once the panel sizes are determined then standard systems
changes can be developed, scheduled, and installed within each contractor's standard system or
within the Medicare Transaction System.
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Due to limitations on the Medicare/Medicaid Health Insurance Common Claim Form (HCFA-1500), as well as internal record formats of the HCFA contractors' standard systems, we are limited to the number of tests (i.e., line items) that can be billed on a single claim. We are limited to six lines of coding on the HCFA-1500. Each line represents a lab test. Therefore, any custom panel which has more than six laboratory tests will require a second or possibly a third claim form.

Most standard systems are limited to 11 lines of input on the internal claims records. These records include the input, suspense, and history records. Whenever a claim exceeds 11 lines of code, a second claim record will be required. Regardless of how the claim is submitted (paper or electronically) extensive systems changes must be made to link all claims within the system for processing and review of provider practices for aberrancies in billing and utilization as recommended by the OIG.

**Recommendation 2**
HCFA should develop a methodology and legislative proposal to address paying for tests ordered as custom panels at substantially less than the full price for individual tests.

**HCFA Response**
We concur to the extent that we continue to recognize custom panels. The development of an appropriate price should be addressed as part of an overall strategy to deal with dual pricing. We would welcome the assistance of OIG in this effort, including a review of what legislative changes may be appropriate to the sanction authority in section 1128 of the Social Security Act.

**Recommendation 3**
HCFA should study reinstating the coinsurance and deductible provisions for laboratory services as a means of controlling utilization.

**HCFA Response**
We do not concur. The President's Fiscal Year (FY) 1996 budget statement includes no proposal for coinsurance or deductibles for laboratory tests.

**Recommendation 4**
HCFA should require the carrier to analyze provider practices for aberrancies in billing and utilization.

**HCFA Response**
We concur. We note that in FY 1993 carriers were required to establish an infrastructure to implement Focused Medical Review (FMR). To implement FMR carriers are expected to develop computer systems and the ability to analyze claims data, identify inappropriate patterns of practice and utilization, decide whether patterns are appropriate, and then find the most effective course for resolving problems which result from inappropriate patterns. In 1994, as part of their FMR efforts, carriers were required to develop methods to profile physicians' ordering and referring patterns. We will continue doing that in FYs 1995 and 1996.
Technical Comments

It is not clear whether this report speaks only to independent laboratory (IL) billing or if it includes physicians’ office laboratories (POLs), which are a major provider of lab services under Medicare. If it does not already address the provision of laboratory services by POLs, it might be interesting to determine how POL billing practices compare to ILs and if the same recommendations apply to that scenario.

On page 10 of the report, it is indicated that utilization of laboratory services has increased significantly. The paragraph goes on to indicate that ILs are the primary cause. POLs have also dramatically increased test volume. Do they unbundle also? What restraints can be instituted concerning POL utilization and Medicare billing on tests ordered by the physician and performed by the POL?

On pages 10 and 11, a statement is made that physicians generally do not have knowledge of how tests are billed to Medicare. Since many physicians provide laboratory testing in their offices, we are not sure this statement is correct. In fact, information from the 1993 Part B Medicare Annual Data Report indicates that POLs bill and receive a substantial amount under Medicare for diagnostic laboratory tests.

Although the report cited increases in utilization through 1992 as evidence of continuing problems, our actuary’s office has asked us if we have an explanation of why utilization has slowed between 1992 and 1993 and may actually be on a negative trend. We suggest that before issuing this report in final OIG review and analyze the current trends in utilization.