Memorandum

Date NOV 16 1998

From June Gibbs Brown
Inspector General

Subject Review of Clinical Laboratory Tests Performed by Hospital Outpatient Department Laboratories (A-01-96-00527)

To Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

Attached are two copies of the Department of Health and Human Services, Office of Inspector General's report entitled, "Review of Clinical Laboratory Tests Performed by Hospital Outpatient Department Laboratories." The objective of this nationwide audit was to determine the adequacy of procedures and controls used by Medicare fiscal intermediaries (FIs) to process payments for clinical laboratory tests performed by hospital outpatient department laboratories. Specifically, the audit was designed to determine whether certain chemistry, hematology, and urinalysis tests were appropriately grouped together (bundled into a panel or profile) and not duplicated for Medicare payment purposes and whether certain additional automated hematology indices paid by the Medicare program were ordered and/or needed by physicians.

The attached report covers the 2-year period from January 1, 1994 through December 31, 1995. We estimate that nationwide, Medicare FIs overpaid hospital outpatient department laboratories about $43.6 million for chemistry, hematology, and urinalysis tests during the 2-year period. For the same period, an additional $15.6 million could have been saved if policies had been developed to preclude payment for additional automated hematology indices. About 75 percent of the claims containing these overpayments and potential savings were billed by less than 20 percent of the hospitals reviewed.

Our audit also showed that the Health Care Financing Administration (HCFA) has taken some corrective action with regard to the processing of claims for chemistry tests since the time of our last review of this issue, the results of which were included in a memorandum to the HCFA Administrator dated April 1994 (CIN A-01-93-00520). We found that HCFA and the FIs implemented edits for many of the chemistry claims that are subject to unbundling and duplication. These corrective actions resulted in a significant decrease in the number of potential overpayment claim situations. We estimate that the edits have resulted in the avoidance of $37.2 million of potential chemistry overpayments during the 2-year audit period. However, as our current audit indicated, additional improvements are needed to eliminate the remainder of the overpayment situations identified in our review.

We recommended that HCFA direct Medicare FIs to (1) implement additional procedures and controls to ensure that all clinical laboratory tests performed by hospital outpatient department laboratories are appropriately grouped together and not duplicated for payment purposes and (2) recover overpayments. We also recommended that HCFA consider eliminating separate reimbursement for additional hematology indices. Officials in your office generally concurred with our recommendations, as discussed on page 12 of the attached report, and agreed to take corrective action. We appreciate the cooperation given us in this audit.

We would appreciate your views and the status of any further action taken or contemplated on our recommendations within the next 60 days. If you have any questions please contact 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-01-96-00527 in all correspondence relating to this report.

Attachments

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF CLINICAL LABORATORY TESTS PERFORMED BY HOSPITAL OUTPATIENT DEPARTMENT LABORATORIES

JUNE GIBBS BROWN
Inspector General

NOVEMBER 1998
A-01-96-00527

SUMMARY

BACKGROUND

This report presents the results of our nationwide audit of Medicare reimbursement for clinical laboratory tests performed by hospitals as an outpatient service. The audit follows up on the Health Care Financing Administration's (HCFA) efforts to initiate corrective action regarding unbundled and duplicative charges involving chemistry and hematology tests. This area was addressed in our prior review entitled "Nationwide Review of Laboratory Services Performed by Hospitals as an Outpatient Service" (CIN A-01-93-00520), issued in April 1994. The current audit also covers the same type payments involving urinalysis tests.

OBJECTIVE

The objective of the audit was to determine the adequacy of procedures and controls used by Medicare fiscal intermediaries (FIs), to process payments for clinical laboratory tests performed by hospital outpatient department laboratories. The audit was designed to determine whether certain chemistry, hematology, and urinalysis tests were appropriately grouped together and not duplicated for Medicare payment purposes and whether certain additional automated hematology indices paid by the Medicare program were ordered and/or needed by physicians.

SUMMARY OF FINDINGS

Our audit showed that Medicare FIs did not always have adequate controls to detect and prevent inappropriate payment for laboratory tests. Contrary to applicable laws, regulations, and Medicare reimbursement policies, Medicare FIs reimbursed providers for claims involving (1) unbundled and/or duplicate chemistry, hematology, and urinalysis tests that should have been grouped together and paid at a lesser amount and (2) additional hematology indices that were not ordered and/or needed by a physician. As a result, we estimate that nationwide, Medicare FIs overpaid hospital outpatient department laboratories about $43.6 million for chemistry, hematology, and urinalysis tests during the 2-year period from January 1, 1994 through December 31, 1995. For the same period, an additional $15.6 million could have been saved if policies had been developed to preclude payment for additional automated hematology indices, (additional indices are calculated tests based upon information obtained from primary tests with an automated hemogram). About 75 percent of the claims containing these overpayments and potential savings were billed by less than 20 percent of the hospitals reviewed. Policies establishing nonpayment of additional indices have been developed by many Medicare contractors. These Medicare contractors have conducted studies that show that the additional indices were medically unnecessary or over-utilized and were merely a by-product of automated analysis.

Since our prior review (CIN A-01-93-00520), HCFA and Medicare FIs implemented procedures and edits to prevent payment for unbundled and duplicate tests related to most chemistry tests subject to bundling that are performed on multichannel automated

equipment. This resulted in a significant decrease in the number of potential overpayments for chemistry claims. We estimate that, for the 2-year audit period, savings of about $37.2 million accrued to the Medicare program because of the edits. Also, effective October 1996, HCFA issued additional instructions requiring FIs to implement payment edits for other chemistry multichannel tests and urinalysis tests. However, procedures and controls are still needed to ensure that payments for all other clinical laboratory tests are proper. This includes ensuring that additional indices are paid based on a physician order instead of an assumption that the additional indices are medically necessary each time a physician orders hematology profiles.

In addition to our review of clinical laboratory tests performed by hospital outpatient department laboratories, we also performed a separate audit of such services performed by independent laboratories and physicians. The results of that audit identified overpayment problems similar to those described in this report and were included in our report issued on November 21, 1997 under CIN A-01-96-00509.

RECOMMENDATIONS

We are recommending that HCFA direct Medicare FIs to (1) implement additional procedures and controls to ensure that all clinical laboratory tests performed by hospital outpatient department laboratories are appropriately grouped together and not duplicated for payment purposes, and (2) recover overpayments. We also recommended that HCFA consider eliminating separate reimbursement for additional indices on the basis that additional indices are a by-product of analysis which produces the hematology tests and calculates and measures all indices simultaneously.

HCFA COMMENTS

In its written comments on our draft audit report (APPENDIX F), HCFA concurred with all Office of Inspector General (OIG) recommendations. However, HCFA offered some technical comments regarding our use of information related to Medicare contractor studies which analyzed both FI and carrier reimbursement policies. The HCFA felt that this leads to confusion because this report deals with an FI based issue. The response also questions our citation of Medicare Intermediary Manual instructions which have been modified since the period of our audit. The HCFA suggested that we remove these references from the report.

OIG RESPONSE

The Medicare contractor studies were cited in the report because these studies formed a major part of the basis on which we recommended a change to reimbursement policy related to additional hematology indices, a recommendation which HCFA agreed to implement. The citation of the Medicare Intermediary Manual instructions, that were effective during the audit period, supported our conclusion that certain costs audited were unallowable. We believe that our disclosure of the studies and instructions is consistent with OIG policies and procedures to report the attributes of the findings developed in the report and is in accordance with generally accepted government auditing standards.

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INTRODUCTION

BACKGROUND

Clinical laboratory services include chemistry, hematology, and urinalysis tests. Chemistry tests involve the measurement of various chemical levels in the blood while hematology tests are performed to count and measure blood cells and their content. Urinalysis tests involve the measurement of certain components of the sample, which may also include a microscopic examination.

Chemistry tests frequently performed on automated equipment are grouped together and reimbursed at a panel rate. Chemistry tests are also combined under problem-oriented classifications (referred to as organ panels). Organ panels were developed for coding purposes and are to be used when all of the component tests are performed. Many of the component tests of organ panels are also chemistry panel tests. For example, when HCFA's Common Procedure Coding System (HCPCS) 80058 (hepatic function panel, which contains five chemistry panel tests) is billed along with one or more other automated panel tests, the tests must be regrouped and reimbursed based on the total number of automated panel tests.

Hematology tests that are grouped and performed on an automated basis are classified as profiles. Automated profiles include hematology component tests such as hematocrit, hemoglobin, red and white blood cell counts, platelet count, differential white blood cell counts, and a number of indices. Indices are measurements and ratios calculated from the results of hematology tests. Examples of indices performed as part of the hematology profile are red blood cell width, red blood cell volume, and platelet volume.

A complete urinalysis includes testing for components and a microscopic examination. However, providers can perform different levels of urinalysis by testing for those components requested. A urinalysis may be ordered by the physician as a complete test which includes microscopy, a urinalysis without the microscopy or the microscopy only. A duplicate payment occurs when a complete urinalysis with microscopy exam (81000), and a separate urinalysis test (81002, 81003 or 81015), are both present on the claim. The separate urinalysis test is considered a duplicate payment.

Part B of Title XVIII of the Social Security Act (Medicare Supplementary Medical Insurance), as amended, covers clinical laboratory services performed at hospitals, physicians' practices, or independent laboratories. Claims for clinical laboratory tests performed on an outpatient hospital basis are processed by Medicare FIs. The FIs reimburse all claims for clinical laboratory services based on Medicare fee schedules subject to guidelines published in the FI Medicare Manual. Medicare pays 100 percent of the fee schedule amount or actual charge for the laboratory service (whichever is lower), provided that the service is reasonable and necessary for the diagnosis or treatment of an illness or injury.

OBJECTIVE, SCOPE, AND METHODOLOGY

We conducted our nationwide audit in accordance with generally accepted government auditing standards. The objective of the audit was to determine the adequacy of procedures and controls used by FIs to process payments for clinical laboratory tests performed by hospital outpatient department laboratories. Specifically, the audit was designed to determine whether certain chemistry, hematology, and urinalysis tests were appropriately grouped together (bundled into a panel or profile) and not duplicated for Medicare payment purposes. The audit was also designed to determine whether certain additional automated hematology indices, (additional indices are calculated tests based upon information obtained from primary tests with an automated hemogram), paid by the Medicare program were ordered, received, and medically necessary.

We reviewed claims containing potential overpayment for claims paid during the period January 1994 through December 1995. Claims containing potential overpayment occur when an FI pays a hospital outpatient department laboratory for unbundled or duplicative tests provided on behalf of a beneficiary on the same day. Claims containing potential overpayment also occur when an FI pays for additional indices that are not ordered or needed by a physician. To obtain a population of potential overpayments, we extracted payments applicable to selected chemistry, hematology, and urinalysis tests from HCFA's 100 Percent Standard Analytical File for the period of audit. Using a series of computer applications applied to our extract, we identified those claims in which selected tests could have been grouped but were billed separately or duplicatively. Our extract and match resulted in identifying a nationwide population of 9,568,703 claims that met our criteria for review. The scope of our review included 2,573,373 of these claims as detailed in APPENDIX A.

In order to test the reliability of HCFA's 100 Percent Standard Analytical File, we compared the payment data to source documents (i.e., billings, remittance advices, and other payment documentation), for 720 randomly selected claims containing potential overpayment from 8 randomly selected FIs.

For each sample claim selected, we determined whether an overpayment actually occurred. We analyzed each claim by comparing amounts actually paid against amounts that should have been paid based on the proper billing codes, Medicare reimbursement practices, and appropriate Medicare fee schedule. The resulting difference was identified as an overpayment. We also determined by questionnaires sent to 211 physicians, whether physicians ordered, received, and needed additional indices. We considered payments for such additional indices that were not ordered, received, and needed as an overpayment. An example of the methodology used to calculate an overpayment is contained in APPENDIX B.

We projected the total dollar amount of overpayments using a variable sample appraisal methodology. Our estimate was based on a statistical projection of the results of our sample

and extrapolated to the universe of claims containing potential overpayments. Details of the methodology used in selecting and appraising the sample are also contained in APPENDIX B.

The chemistry, hematology, and urinalysis tests that were part of our review are listed in the "Physicians' Current Procedural Terminology (CPT)" manual and contained in APPENDIX C. APPENDIX A provides detailed information on the scope of our review at each of the eight FIs.

Our review of the internal controls at each FI was limited to an evaluation of that part of the claims processing function that related to the processing of claims for clinical laboratory services. Specifically, we reviewed each of the eight FIs' policies, procedures, and instructions to providers related to the billing of clinical laboratory services. We also reviewed FI documentation relating to manual and automated paneling and duplicate claim detection edits for chemistry, hematology, and urinalysis tests. We did not assess the completeness of HCFA data files nor did we evaluate the adequacy of the input controls.

In conducting our audit, we also followed up on HCFA's efforts to initiate corrective action to ensure accurate FI payments involving chemistry and hematology tests, which were the scope of the prior review. This area was addressed in our prior review entitled "Nationwide Review of Laboratory Services Performed by Hospitals as an Outpatient Service" (CIN A-01-93-00520), issued in April 1994.

Our current audit was conducted at the HCFA central office and Blue Cross of Massachusetts, as well as, through contact with the other seven FIs selected in our sample.

A separate audit of clinical laboratory services provided by independent laboratories and physicians has also been performed. The results of that audit were included in our report issued on November 21, 1997 under CIN A-01-96-00509.

FINDINGS AND RECOMMENDATIONS

Our audit showed that FIs did not have adequate controls to detect and prevent all inappropriate payments for clinical laboratory tests performed by hospital outpatient department laboratories. Contrary to applicable laws, regulations, and Medicare reimbursement practices, FIs reimbursed providers for claims involving (1) unbundled and/or duplicate chemistry, hematology, and urinalysis tests that should have been grouped together and paid at a lesser amount, and (2) additional indices that were not ordered and/or medically unnecessary. As a result, we estimate that, for the 2-year period from January 1, 1994 to December 31, 1995, FIs nationwide overpaid hospital outpatient department laboratories by about $43.6 million for chemistry, hematology, and urinalysis tests (APPENDIX D). For the same period, we estimate that another $15.6 million (APPENDIX E) could be saved if policies are developed to preclude payment for additional indices. Medicare contractor studies showed that the additional indices were medically unnecessary or over-utilized and were merely a by-product of analysis performed on

automated equipment. About 75 percent of the claims containing these overpayments and potential savings were billed by less than 20 percent of the hospitals reviewed.

Our review disclosed that, in response to recommendations included in our prior nationwide report on this issue, HCFA and the FIs implemented procedures and edits to prevent payment for unbundled and duplicate claim situations for most chemistry tests. These edits became operational at most FIs between April and July 1994. As a result, we found that the number of potential overpayments for chemistry claims decreased significantly. We estimated that because of these edits, savings of about $37.2 million accrued to the Medicare program during the 2-year audit period. However, HCFA and the FIs did not establish edits to ensure proper payments for certain other chemistry tests and for most hematology and urinalysis tests included in the scope of our review of claims submitted by hospital outpatient department laboratories. The review also showed that the program overpaid for additional indices because the FIs did not ensure that payments were made for only those additional indices that were ordered, received, and needed.

In order to perform our audit, we extracted payments applicable to selected chemistry, hematology, and urinalysis tests from HCFA's 100 Percent Standard Analytical File for the period January 1994 to December 1995. Using a series of computer applications, we identified those claims in which selected tests could have been grouped together for billing purposes but were billed separately or duplicatively. Our extract and match resulted in identifying a nationwide population of 9,568,703 claims containing potential overpayments. The scope of our review included 2,573,373 of these claims as detailed in APPENDIX A.

We selected a statistical sample of 720 potential overpayments from 8 randomly selected FIs. We also identified those claims involving hematology tests with additional indices to determine their medical necessity. A discussion of reimbursement requirements and details of our review for each type of clinical laboratory service follows.

CLINICAL LABORATORY SERVICES REIMBURSEMENT REQUIREMENTS

Regarding the establishment of fee schedules, section 1833(h)(2)(A)(i) of the Social Security Act authorized the Secretary to make "...adjustments as the Secretary determines are justified by technological changes." While this section does not specifically address grouping of automated laboratory tests into panels, bundling rules are addressed in section 3628 J. of the *Medicare Intermediary Manual.* These bundling rules are also addressed in section 437 of the *Medicare Hospital Manual*, the manual provision that furnishes billing procedure guidance to hospitals.

Medicare claims for clinical laboratory services, including those claims submitted by hospital outpatient departments, are reimbursed based on fee schedules. The fee schedules are subject to the guidelines published by HCFA in its *Medicare Intermediary Manual.* Medicare pays the lesser of the national limit as published by HCFA annually, the individual fee schedule, or the actual charge for the service, providing that the service is reasonable and necessary.

Section 3628 of the *Medicare Intermediary Manual* refers to those tests which can be and are frequently performed as panels on automated equipment. Our review also identified three additional tests that HCFA allowed FIs the option of adding to their list of chemistry panel tests (APPENDIX C). Section 3628 also directs FIs to make payment at the lesser amount for the panel if the sum of the payment allowance for the separately billed tests exceeds the payment allowance for the panel that includes these tests.

With respect to the clinical laboratory claims submitted by hospital outpatient department laboratories for tests performed on automated equipment, FIs are required to utilize the carrier fee schedule and also follow the practices in effect for the carriers' locality. Specifically, paragraph J of section 3628 stated that FIs are to:

> "...Install edit procedures to identify situations where the provider bills individual tests where billing for the automated battery would be appropriate based upon carrier practices in your area."

Similarly, section 437 J of the *Medicare Hospital Manual* referred to the automated blood chemistry tests which must be bundled when billed. Based on the above criteria, Medicare providers should have grouped certain hospital outpatient laboratory tests into the applicable panel and profile test codes when the tests are performed for the same patient on the same date of service.

CHEMISTRY TESTS

The audit showed that, of 240 sample items related to chemistry claims containing potential unbundling or duplication, 212 (88 percent) were overpaid (APPENDIX D). These claims resulted in overpayments amounting to $2,780.11. As a result, we estimate that, nationwide, FIs overpaid hospital outpatient department laboratories about $17.6 million for unbundled or duplicated chemistry tests during the audit period. Our estimate is based on projection of the sample results to the universe of 1,748,442 claims containing potential chemistry overpayments.

Our review disclosed that about 67 percent of all potential chemistry overpayments were related to services provided prior to July 1994. This occurred because claims processing edits were implemented around July 1994 addressing many of the chemistry claim overpayment situations disclosed in our prior audit of clinical laboratory claims processed by FIs (CIN A-01-93-00520). It is apparent that the edits prevented inappropriate payment of many chemistry tests that can be performed on automated multichannel equipment. We estimated that savings of about $37.2 million accrued to the Medicare program because of these edits. The corrective actions implemented by HCFA and the FIs are discussed in detail in the Prior Audit Finding section of this report.

With respect to those claims with dates of service subsequent to July 1994, we found that the FIs need to make additional refinements to their claims processing systems to ensure that all other chemistry claims are properly grouped together for reimbursement purposes. About

75 percent of the remaining chemistry overpayments were related to separate reimbursement of organ panel tests, such as HCPCS 80058 (hepatic function organ panel), when billed with another chemistry panel test code. However, we noted that HCFA has since addressed this overpayment billing situation by further revising the *Medicare Intermediary Manual* Part 3 - Claims Processing. The revision, effective October 4, 1996, required the implementation of additional claims processing edits to ensure that all organ panel tests are bundled and reimbursed under the appropriate panel code. This was also addressed in section 437 of the *Medicare Hospital Manual.*

The corrective action taken by HCFA in July 1994 and the additional revisions effective in October 1996 should eliminate most of the potential overpayment situations identified in our review. We did not review any claims paid since the latest revisions to the reimbursement policies. However, we believe that HCFA should monitor the FIs to ensure that they have, in fact, implemented all reimbursement policy revisions for the chemistry panel tests.

HEMATOLOGY TESTS

For hematology tests, we verified that 139 of 240 sample items (58 percent), were overpayments (APPENDIX D). These claims resulted in overpayments amounting to $846.06. As a result, we estimate that, nationwide, FIs overpaid hospital outpatient department laboratories about $21.3 million for duplicated or medically unnecessary hematology tests during the audit period. Our estimate is based on projection of the sample results to the universe of 6,720,975 claims containing potential hematology overpayments.

The sample claims found to be overpayments included (1) 115 claims which included reimbursement for additional indices when they were not ordered and/or medically necessary, and (2) 24 claims which included duplicate reimbursement of a hematology profile and a component of the profile.

We found that all FIs reviewed needed to make additions or refinements to their claims processing systems to ensure that the tests contained in hematology profiles were not duplicated for reimbursement purposes. In this regard, edits were necessary to preclude providers from receiving payments for hematology profiles each of which contained tests that were duplicative of each other. Our review disclosed that hematology overpayments continued to occur in the same manner as reported in the prior report. As discussed below, the FIs also overpaid for additional indices that were not ordered and/or needed by physicians.

Additional Automated Hematology Indices

Of the 240 hematology claims reviewed in the sample, 215 sample items involved payment for additional indices. Since additional indices are interpreted to supplement indices already provided in a hematology profile, additional indices are not duplicative. Accordingly, our review of additional indices was limited to determining the medical necessity of the additional indices and whether payment conformed to the FIs' payment policies.

To determine the medical necessity of additional indices, we sent questionnaires to physicians who were listed on the hospital outpatient payment record as the "***attending physician***" for claims containing additional indices. The primary purpose of the questionnaire was to specifically determine whether the physician ordered, received, and needed the additional indices. For the 215 sample items involving payment of additional indices, we sent 211 questionnaires (addresses for 4 physicians could not be found) and received 154 responses. We found that in 115 of the 154 responses, physicians indicated that they did not order and/or need the additional indices that were paid by the Medicare program. Accordingly, we considered these additional indices as overpayments in our overall sample. Non-responses to our questionnaires were not considered to be in error. As a result, we believe our calculation of potential overpayments in the hematology area is conservative. Nevertheless, the impact of non-responses related to claims containing additional indices is discussed in the following section of this report which addresses potential savings.

In those cases where physicians did not order and/or need the additional indices, we found that the laboratory usually provided the additional indices as part of a complete blood count. We noted that, overall, laboratories did not provide the opportunity for the physician to order additional indices separately. Laboratory order forms did not provide a separate space or line on the form to enable the physician to order the additional indices if necessary. Instead, the physician was provided the additional indices and laboratories billed separately even though the physicians had not indicated their need for the additional indices. For physicians that indicated a need for the additional indices, we found that examples of the laboratory ordering forms they used also did not provide the physician the opportunity to order the additional indices separately.

Since the additional indices are represented by a separate CPT code and reimbursed separately, we believe that laboratories should have been reimbursed based on a specific physician order and not on the assumption that a physician needs the additional indices.

Procedure Code Used For Reimbursement

Further analysis of potential overpayments for additional indices cast doubt on whether there is a valid medical need for such tests. We found that reimbursement for additional indices is concentrated among relatively few providers rather than spread among a broad range of providers. In our review, only 27 percent of the hospital outpatient laboratories accounted for 75 percent of the additional indices billed and reimbursed (Figure 1). This suggests that at least in some cases, billings may be driven more by billing practices rather than medical need.

Similar results were indicated in other OIG, Office of Audit Services reviews. Our recent review of clinical laboratory claims submitted by independent laboratories and physicians and processed for payment by Medicare carriers (CIN A-01-96-00509) disclosed that over

75 percent of the additional indices claims were billed by only 26 percent of these providers. In other prior reviews of additional indices reimbursed in the Medicaid program, we found that in one state, four hospital outpatient laboratories and four independent laboratories accounted for 99 percent and 95 percent, respectively, of the claims involving additional indices billed in the entire state. The Medicaid State agency performed follow-up reviews at three of the hospital outpatient laboratories and one independent laboratory and found no ordering support for the additional indices reimbursed. We believe that, if there is a valid need for additional indices, such a majority of ordering, billing, and reimbursement would not be confined to so few providers.

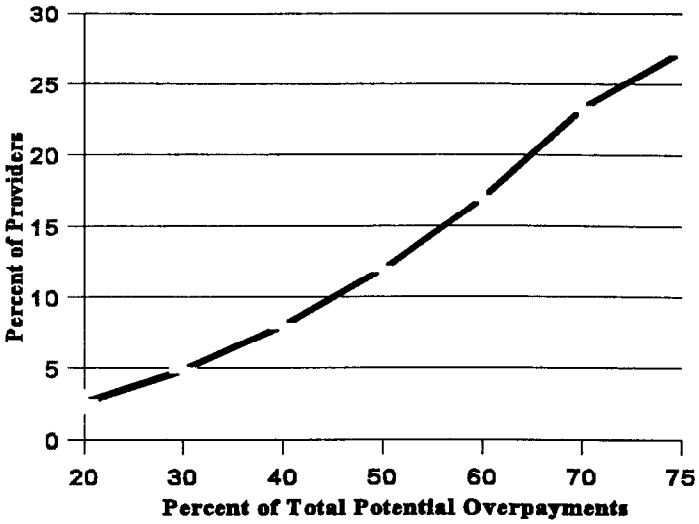

Figure 1 - Relationship between percent of providers and their share of overpayments.

We surveyed Medicare carriers nationwide and found that, in total, 38 of 52 carriers responsible for processing Medicare claims had developed policies to either deny separate payment for additional indices or only pay based on a documented need. These policies were based on carrier studies that show additional indices were seldom clinically useful or were over utilized and were merely a by-product of analysis performed on automated equipment which produces the hematology tests and calculates and measures all indices simultaneously.

Responses to our physician questionnaire regarding the ordering of additional indices appear to support the decision of most carriers to pay only when medically necessary. We found that physicians for 115 of 154 responses received, did not specifically order and/or need the additional indices in the diagnosis of their patients. In those cases where the physician did indicate that the indices were ordered, the physician provided comments that indicated that the patient for whom the indices were ordered was diagnosed with cancer or had complex medical problems that necessitated the need to monitor the patients' blood levels more closely than normal.

Of particular note, one response to our questionnaire included correspondence between the hospital and the FI. The correspondence indicated that the hospital outpatient laboratory that provided the services for the sample claim recently performed an analysis of its billing practices for additional indices. The hospital's review determined that it was incorrectly billing the additional indices HCPCS code (85029) along with a Complete Blood

Count (CBC) HCPCS (85023 and 85027). According to a letter to the FI, dated November 12, 1996, the hospital indicated that:

> "...The instrumentation, Coulter STKS, used to perform a CBC, automatically performs and reports the additional indices. In reviewing this issue, we determined that only a select group of physicians had utilized information provided by this analysis...."

As a result of their review, the hospital refunded $404,070 to the FI for overpayments identified for the period July 1993 to February 1996. The hospital indicated that it has discontinued billing for the additional indices.

While opinions differ as to the medical necessity of additional indices, the additional indices are the result of an automated hemogram and the calculated values are presented in laboratory results whether or not the physician orders them. The HCFA could consider eliminating separate reimbursement for additional indices on the basis that the additional indices are medically unnecessary. However, more compelling reasons to eliminate their reimbursement is that (1) the additional indices are a by-product of automated equipment which produces the hematology tests and calculates all indices simultaneously, and (2) such charges are the result of a billing practice to maximize revenue as evidenced by the fact that most billings are made by a few providers.

We believe that the results of our surveys, as noted above, provide significant evidence to support the need for documenting medical necessity of additional indices before Medicare reimburses providers for their cost. For the period of review, we estimate that, in addition to overpayments made for unnecessary additional indices, an additional $15.6 million (APPENDIX E) could have been saved if policies had been developed to preclude payment for additional automated indices. This statistical estimate is based on claims containing additional indices that we determined to be allowable because the physician did not respond to our questionnaire or the physician's response indicated that he/she requested and/or needed the additional indices.

URINALYSIS TESTS

Our review of urinalysis tests showed that 239 of 240 sample items (99 percent) were overpaid (APPENDIX D). These claims resulted in overpayments amounting to $812.59. As a result, we estimate that, nationwide, FIs overpaid hospital outpatient department laboratories about $4.8 million for unbundled or duplicated urinalysis tests during the audit period. Our estimate was based on projection of the sample results to the universe of 1,099,286 claims containing potential urinalysis overpayments .

All eight FIs included in our sample did not have edits in their claims processing systems to ensure that the urinalysis tests were properly grouped together and were not duplicated for reimbursement purposes. For the most part, duplication occurred because a urinalysis microscopic examination was billed simultaneous with a urinalysis which already included a

microscopy, both services being provided on the same day. Likewise, proper grouping did not occur when other urinalysis without microscopy was billed simultaneously with the individual microscopic examination performed on the same day. Urinalysis tests were not covered in our prior review.

As previously noted, HCFA and the FIs have implemented new claims processing edits, effective October 1996, that include controls to identify and prevent payment of duplicate urinalysis tests of the type identified in our review. We did not test the edits to determine if they were working properly. However, we believe that HCFA should monitor the FI claim payments for urinalysis tests to ensure that these edits have been implemented and prevent the overpayment situations found in our review.

FISCAL INTERMEDIARY POLICIES AND PROCEDURES

Based on our review, most FI policies and procedures did not always ensure proper payment of chemistry, hematology, and urinalysis claims submitted by hospital outpatient laboratories. Most FIs attempted to prevent unbundling of chemistry claims. However, policies and related procedures and controls were not consistently applied to preclude payment for all forms of chemistry unbundling on a nationwide basis. Likewise, FIs did not have controls to prevent duplicate payment for hematology and urinalysis tests and payment for medically unnecessary additional indices.

Overall, we believe that the FIs policies and procedures for the period of our review were not adequate to identify and prevent the overpayment situations noted in our review. However, HCFA and the FIs have since implemented edits to address the unbundling/duplicative overpayment situations for chemistry and urinalysis tests. Corrective action is still needed for processing duplicate and medically unnecessary hematology claims.

PRIOR AUDIT FINDINGS

As part of our audit, we followed up to determine the adequacy of HCFA's response to recommendations made in a prior audit entitled, "Nationwide Review of Laboratory Services Performed by Hospitals as an Outpatient Service" (CIN A-01-93-00520). We found that HCFA began to take corrective action on the problems found during the last review prior to the issuance of the nationwide report. In a memorandum dated January 31, 1994, HCFA officials set forth a plan of corrective action. Included in this plan of action was the establishment of edits to address the reimbursement problems related to hospital outpatient claims for clinical laboratory services. Specifically, we found that HCFA and the FIs developed edits to identify and prevent payment of many unbundled and duplicate multichannel chemistry tests. These edits were implemented at various times during the period April to July 1994. The edits resulted in a significant decrease in the number of potential overpaid chemistry claims identified through our computer analysis. The potential overpayments declined from 726,219 in the first quarter of 1994 to 77,485 in the fourth quarter of 1995.

Accordingly, we estimated the amount of savings that accrued to the Medicare program as a result of HCFA's corrective action. To do this, we made a judgement that the first quarter of 1994 best represents the number of chemistry claims that would have been paid had no edits been implemented for the entire audit period. Using this rate of potential overpayments for all eight quarters reviewed, we determined the potential savings effect of the edits as follows:

Year	Quarter	Estimated Claims Overpaid (w/o Edits)	Potential Claims Overpaid (Identified)	Overpaid Claims Avoided
1994	1st	726,219	726,219	-0-
	2nd	726,219	437,114	289,105
	3rd	726,219	113,666	612,553
	4th	726,219	93,043	633,176
1995	1st	726,219	103,479	622,740
	2nd	726,219	103,515	622,704
	3rd	726,219	93,921	632,298
	4th	726,219	77,485	648,734
	Total overpaid claims avoided:			4,061,310

Our sample methodology was designed to create a population of only potential errors, thus, all 240 chemistry sample claims were potential errors from which our average overpayment was taken. Our statistical sample results for the chemistry sample claims determined that the average overpayment amount per chemistry claim was $9.16. This was based on total estimated potential overpayments for all FIs ($16,009,005) divided by the population of claims overpaid by all FIs (1,748,442). As calculated above, the estimated number of claims that would have been avoided (4,061,310) represented the difference between the potential overpaid claims in each of the 8 quarters reviewed and number of claims overpaid in the quarter immediately before edits were implemented. Multiplying the estimated number of claims avoided (4,061,310) by the average overpayment per chemistry claim ($9.16), the total savings accrued to the program amounts to an estimated $37,201,599.

RECOMMENDATIONS

We are recommending that HCFA:

- direct FIs to (1) implement procedures and controls to ensure that clinical laboratory tests performed by hospital outpatient department laboratories are appropriately grouped together and not duplicated for payment purposes, and

(2) recover overpayments estimated at $43.6 million from providers. As discussed in the OTHER MATTERS section of this report, HCFA should also coordinate recovery efforts with applicable investigative agencies; and

- consider eliminating separate reimbursement for additional indices on the basis that (1) additional indices are calculated tests based upon information obtained from primary tests with an automated hemogram, and (2) the possibility that these additional indices are medically unnecessary. A similar recommendation is included in our report, issued under CIN A-01-96-00509, on our review of clinical laboratory tests performed by independent laboratories and physicians.

HCFA COMMENTS

In its written comments on our draft audit report (APPENDIX F), HCFA concurred with all OIG recommendations. In this regard, HCFA instituted new coding procedures and will remove additional indices codes from Medicare fee schedules.

The HCFA response also included technical comments regarding our use of certain information and references in our report. In this regard, HCFA felt that our inclusion of information related to Medicare contractor studies which analyzed policies of both FIs and carriers leads to confusion of an FI based issue. The HCFA suggested that we remove this section from the report (contained on page 3). The HCFA also felt that our reference to the Medicare Intermediary Manual, section 3628 J (contained on page 5), should be eliminated because this section no longer contains the specific instructions that FIs should use carrier practices to implement reimbursement edits.

OIG RESPONSE

In regard to our references to Medicare contractor studies, we were using factual data gathered during the audit to illustrate our point that automated hematology indices have been determined by both FIs and carriers to be generally medically unnecessary and merely a by-product of analyses done on automated equipment. We believe that these studies provided a major part of our basis for recommending that HCFA consider eliminating separate reimbursement for the additional hematology indices, a recommendation that HCFA agreed to implement.

Relative to our use of section 3628 J of the Medicare Intermediary Manual, we noted that, for the period of our audit (Calendar Years 1994 and 1995), this criteria specifically instructed FIs to install edits for processing clinical laboratory claims based on the local carrier's practices. The citation of the Medicare Intermediary Manual instructions, that were effective during the audit period, also supported our conclusion that certain costs audited were unallowable. The HCFA revised the criteria subsequent to the audit period.

We believe that our disclosures of the studies and instructions applicable during the audit period are consistent with OIG policies and procedures to report the attributes of the findings developed during the audit and is in accordance with generally accepted government auditing standards. Accordingly, we believe that our use of the data included in the report was appropriate to support our conclusions and recommendations.

OTHER MATTERS

As in all our recent audits involving potentially unbundled or duplicated claims for clinical laboratory services, we found that most of the overpayments identified were made to a relatively small percent of laboratory providers. While FIs' policies and procedures did not always ensure that proper payments were made in accordance with applicable laws, regulations, and guidelines, overpaid laboratory providers were ultimately responsible for billing the Medicare program for such claims. The frequency by which some of these laboratory providers far exceeded others in such over billing warrants further review. This is necessary to determine whether overpayments to these providers were the result of insufficient internal controls, adoption of aberrant marketing or billing practices or some form of potentially fraudulent activity.

The Department of Health and Human Services, OIG, Office of Investigations, in cooperation with the US Attorneys' Office of the Department of Justice are currently involved in a number of investigations involving over billing which has occurred at a number of laboratories. Because of their interest and our concern to not impede or duplicate their investigative activity, we are providing these investigative agencies with the results identified in our audit. Pending their investigation and disposition, we will provide detailed results of our audit to HCFA for further recovery action at the laboratory providers.

APPENDICES

DETAILED SCOPE OF AUDIT

(Fiscal Intermediaries Selected for Review and Sample Population)

Fiscal Intermediary	Claims Containing Potential Overpayments (Population)
Blue Cross and Blue Shield of Florida, Inc.	345,161
IASD Health Services Corporation	205,857
Blue Cross and Blue Shield of Massachusetts, Inc.	355,915
Blue Cross and Blue Shield of Mississippi, Inc.	173,148
Blue Cross and Blue Shield of North Carolina, Inc.	374,497
Independence Blue Cross	33,702
VERITUS Inc.	467,404
Mutual of Omaha	617,689
Total	2,573,373

SAMPLE METHODOLOGY

This report covers Medicare payments for clinical laboratory services provided between January 1, 1994 through December 31, 1995.

To obtain a population of potential overpayments, we extracted applicable payments for selected chemistry, hematology, and urinalysis tests from HCFA's 100 Percent Standard Analytical File for the period of audit. The extract included all claims containing:

- chemistry panels and panel tests for chemistry procedure codes listed in the CPT manual (APPENDIX C);
- hematology profiles and component tests normally included as part of a hematology profile for hematology procedure codes listed in the CPT manual (APPENDIX C); and
- urinalysis and component tests listed in the CPT manual (APPENDIX C).

We then performed a series of computer applications to identify all records for the same individual for the same date of service with HCPCS line item charges for:

- more than one chemistry panel; a chemistry panel and at least one individual panel test; or two or more panel tests;
- more than one automated hematology profile under different profile codes; more than one unit of the same profile; a component normally included as part of a profile in addition to the profile; or additional indices and a profile; and
- a complete urinalysis test which includes microscopy; a urinalysis without microscopy; or a microscopy only.

Each claim is a potential payment error in which the FIs paid providers for clinical laboratory tests (on behalf of the same recipient on the same date of service) which were billed individually instead of as part of a group, or were duplicative of each other. An example of an overpayment follows.

SAMPLE METHODOLOGY

Example of an Overpayment

Test Code	Test Name	Units	Paid Amount
Individual Test Codes			
82040	Albumin (chemistry test)	1	$7.00
82465	Cholesterol (chemistry test)	1	$6.47
84478	Triglycerides (chemistry test)	1	$8.54
Total Paid			$22.01
Panel Test Code			
80003	for any 3 clinical, chemistry, automated, multichannel, panel tests	1	$10.85
Difference in Amounts Paid is an Overpayment:			**$11.16**

On a randomly selected basis, we examined 720 claims containing potential overpayments involving clinical laboratory services in the 8 Medicare FIs selected for audit. The claims containing potential overpayments were stratified into the clinical laboratory service categories of chemistry, hematology, and urinalysis claims. For each sampled claim, we requested and reviewed supporting documentation from the FI consisting of copies of hospital outpatient laboratory claims and related paid claims history. Our review disclosed 590 potential overpayments out of the 720 claims examined.

To quantify the potential overpayments for unbundled chemistry panel tests, duplicate hematology profile tests, and unbundled or duplicate urinalysis tests, we utilized a multistage sample based on probability-proportional-to-size weighted by the number of paid claims containing potential overpayments at each FI (see APPENDIX D).

PHYSICIANS' CURRENT PROCEDURAL TERMINOLOGY MANUAL CODES

Chemistry Panel CPT Code Description	CPT Codes
1 or 2 clinical chemistry automated multichannel test(s)	80002
3 clinical chemistry automated multichannel tests	80003
4 clinical chemistry automated multichannel tests	80004
5 clinical chemistry automated multichannel tests	80005
6 clinical chemistry automated multichannel tests	80006
7 clinical chemistry automated multichannel tests	80007
8 clinical chemistry automated multichannel tests	80008
9 clinical chemistry automated multichannel tests	80009
10 clinical chemistry automated multichannel tests	80010
11 clinical chemistry automated multichannel tests	80011
12 clinical chemistry automated multichannel tests	80012
13-16 clinical chemistry automated multichannel tests	80016
17-18 clinical chemistry automated multichannel tests	80018
19 or more clinical chemistry automated multichannel tests	80019
General Health Panel	80050
Hepatic Function Panel	80058

Chemistry Panel Test CPT Code Description Subject to Paneling (34 CPT Codes)	CPT Codes
Albumin	82040
Albumin/globulin ratio	84170
Bilirubin Total OR Direct	82250
Bilirubin Total AND Direct	82251
Calcium	82310, 82315, 82320, 82325
Carbon Dioxide Content	82374
Chlorides	82435
Cholesterol	82465
Creatinine	82565
Globulin	82942
Glucose	82947
Lactic Dehydrogenase (LDH)	83610, 83615, 83620, 83624
Alkaline Phosphatase	84075
Phosphorus	84100
Potassium	84132
Total Protein	84155, 84160
Sodium	84295
Transaminase (SGOT)	84450, 84455

PHYSICIANS' CURRENT PROCEDURAL TERMINOLOGY MANUAL CODES

Transaminase (SGPT)	84460, 84465
Blood Urea Nitrogen (BUN)	84520
Uric Acid	84550
Triglycerides *	84478
Creatinine Phosphokinase (CPK) *	82550, 82555
Glutamyltranspetidase, gamma *	82977

Hematology Component Test CPT Code Description	CPT Codes
Red Blood Cell Count (RBC) only	85041
White Blood Cell Count (WBC) only	85048
Hemoglobin, Colorimetric (Hgb)	85018
Hematocrit (Hct)	85014
Manual Differential WBC count	85007
Platelet Count (Electronic Technique)	85595

Additional Hematology Component Tests - Indices	CPT Codes
Automated Hemogram Indices (one to three)	85029
Automated Hemogram Indices (four or more)	85030

Hematology Profile CPT Code Description	CPT Codes
Hemogram (RBC, WBC, Hgb, Hct and Indices)	85021
Hemogram and Manual Differential	85022
Hemogram and Platelet and Manual Differential	85023
Hemogram and Platelet and Partial Automated Differential	85024
Hemogram and Platelet and Complete Automated Differential	85025
Hemogram and Platelet	85027

Urinalysis and Component Test CPT Code Description	CPT Codes
Urinalysis	81000
Urinalysis without microscopy	81002, 81003
Urinalysis microscopic only	81015

* HCFA designated chemistry panel tests that can be bundled at carriers' option

APPENDIX D

NATIONWIDE ESTIMATE OF POTENTIAL OVERPAYMENTS

(Includes Results of Claims Sampled)
(For the Period January 1994 Through December 1995)

FISCAL INTERMEDIARY	CHEMISTRY		HEMATOLOGY		URINALYSIS		TOTAL	
	SAMPLE SIZE	SAMPLE ERROR	SAMPLE SIZE	SAMPLE ERROR	SAMPLE SIZE	SAMPLE ERROR	SAMPLE SIZE	SAMPLE ERROR
00090-FL	30	30	30	18	30	30	90	78
00140-IASD	30	18	30	22	30	30	90	70
00200-MA	30	29	30	18	30	30	90	77
00230-MS	30	25	30	13	30	30	90	68
00310-NC	30	26	30	17	30	30	90	73
00362-IND	30	27	30	16	30	30	90	73
00363-VER	30	30	30	20	30	30	90	80
52280-M/O	30	27	30	15	30	29	90	71
TOTALS	240	212	240	139	240	239	720	590

	ESTIMATE OF POTENTIAL OVERPAYMENTS	PRECISION* (+ - percent)
CHEMISTRY	$ 17,590,041	33.62
HEMATOLOGY	21,278,350	21.63
URINALYSIS	4,764,376	35.27
TOTAL ESTIMATED OVERPAYMENTS	$ 43,632,767	13.91

*Based on 90 percent confidence level

NATIONWIDE ESTIMATE OF POTENTIAL SAVINGS

(Includes Results of Sampled Claims that Contain Additional Automated Hematology Indices) (For the Period January 1994 Through December 1995)

FISCAL INTERMEDIARY	SAMPLE SIZE	CLAIMS WITH ALLOWABLE INDICES
00090-FL	30	12
00140-IASD	30	8
00200-MA	30	12
00230-MS	30	17
00310-NC	30	13
00362-IND	30	13
00363-VER	30	10
52280-M/O	30	15
TOTAL	240	100

	ESTIMATE OF POTENTIAL SAVINGS*	PRECISION** (+ - percent)
HEMATOLOGY	$ 15,551,928	32.68

* Assumes all payments for additional indices are in error, i.e., all FIs adopt a payment policy not to pay for additional indices.

** Based on 90 percent confidence level

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

IG	
EAIG	
SAIG	
PDIG	✓
DIG-AS	
DIG-EC	
DIG-EI	
DIG-OI	
DIG-MP	
AIG-LC	
OGC/IG	✓
ExecSec	✓
Date Sent	10-14

DATE: OCT 13 1998

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle NMD
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Review of Clinical Laboratory Tests Performed by Hospital Outpatient Department Laboratories," (A-01-96-00527)

We reviewed the above-referenced report that examines the adequacy of procedures and controls used by Medicare fiscal intermediaries (FIs) to process payments for clinical laboratory tests performed by hospitals as an outpatient service. The audit follows up on the Health Care Financing Administration's (HCFA's) efforts to initiate corrective action regarding unbundled and duplicative charges involving chemistry and hematology tests.

HCFA concurs with the OIG recommendations. Our detailed comments follow:

OIG Recommendation

HCFA should direct FIs to: (1) implement procedures and controls to ensure that clinical laboratory tests performed by hospital outpatient department laboratories are appropriately grouped together and not duplicated for payment purposes; and (2) recover overpayments estimated at $43.6 million from providers. As discussed in the Other Matters section of the report, HCFA should also coordinate recovery efforts with applicable investigative agencies.

HCFA Response

We concur. Beginning January 1, 1998, new codes were instituted which identify each automated multi-channel test performed. Along with the new coding, we require that all contractors have a duplicate detection capability to ensure that no duplicate payments are made. This process is new and an addition to existing duplicate checking capabilities. A QR modifier also was included in order to allow the payment of duplicate services when there is medical justification for the tests to be performed more than once on the same day.

We agree that HCFA should recover overpayments. However, we cannot verify the validity of the estimated $43.6 million in overpayments until the OIG furnishes us the identity of the intermediaries and providers that are subject to the audit finding. Upon

receipt of this information, we will instruct the intermediaries to notify their respective providers of the possible re-opening of claims. We will coordinate any recovery activity with the Department of Justice through our Office of General Counsel.

OIG Recommendation

HCFA should consider eliminating separate reimbursement for additional indices on the basis that: (1) additional indices are calculated tests based upon information obtained from primary tests with an automated hemogram; and (2) the possibility that these additional indices are medically unnecessary.

HCFA Response

We concur. We will revise our coding instructions to indicate that these codes are not valid for Medicare and we will remove them from our fee schedule.

Technical Comments

Use of the word "contractors" in the Findings and Recommendations Section - The Findings and Recommendations Section states that "Our audit shows that FIs did not have adequate controls to detect and prevent all inappropriate payments for clinical laboratory tests performed by hospital outpatient department laboratories." The paragraph continues to discuss FI reimbursement policies. However, the next to the last sentence discusses Medicare contractor studies which analyze policies of both intermediaries and carriers, and leads to confusion of this FI based issue. We suggest that the last two sentences of the first paragraph in this section be removed from the report.

Reference to Medicare Intermediary Manual Section 3628J - The Clinical Laboratory Services Reimbursement Requirements Section of the report also contains language that confuses the FI issue. The report cites Medicare Intermediary Manual Section 3628J which at one time may have indicated FIs should install edits based upon carrier practices. However, this section no longer contains instructions that the FI should use carrier practices to implement reimbursement edits. Where such carrier policy was stated in carrier local medical review policy, the FI was not responsible for implementing similar policies and edits. We suggest that the fourth paragraph of this section be eliminated.