DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date NOV 21 1997

From June Gibbs Brown
Inspector General

Subject Review of Clinical Laboratory Tests Performed by Independent Laboratories and Physicians (A-01-96-00509)

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 Independent and Physician Laboratories." The objective of this nationwide audit is to determine the adequacy of procedures and controls used by Medicare Carriers to process payments for clinical laboratory tests performed by independent and physician laboratories. Specifically, the audit is 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 by physicians. The attached report covers the 2-year period from July 1, 1993 through June 30, 1995. We estimate that nationwide, Medicare Carriers overpaid independent and physician laboratories about $50.2 million for chemistry, hematology, and urinalysis tests during the 2-year period. For the same period, an additional $30.8 million could have been saved if policies had been adopted to preclude payment for additional automated hematology indices.

We recommended that the Health Care Financing Administration (HCFA) direct Medicare Carriers to implement procedures and controls to ensure that clinical laboratory tests are appropriately grouped together, not duplicated for payment purposes, and are actually ordered by physicians. We also recommended that HCFA consider eliminating separate reimbursement for additional indices and that the identified potential overpayments be recovered through coordination with applicable investigative agencies who are presently active in this area.

Officials in your office have generally concurred with our recommendations and have 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-01-96-00509 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 INDEPENDENT LABORATORIES AND PHYSICIANS

JUNE GIBBS BROWN
Inspector General

NOVEMBER 1997
A-01-96-00509

SUMMARY

BACKGROUND

This report presents the results of our nationwide audit of clinical laboratory services performed by independent and physician laboratories. The audit follows up on the Health Care Financing Administration's (HCFA's) efforts to initiate corrective action regarding unbundled and duplicate charges within single claims involving chemistry and hematology tests. This area was addressed in our prior review entitled "Medicare Part B Payments by Carriers for Chemistry Tests and Hematology Profiles Performed by Independent and Physician Laboratories" (CIN: A-01-94-00513), issued May 3, 1994. The audit also covers the same type payments occurring among more than one claim and also includes urinalysis tests.

OBJECTIVE

The objective of the audit was to determine the adequacy of procedures and controls used by Medicare Carriers to process payments for clinical laboratory tests performed by independent and physician 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 by physicians.

SUMMARY OF FINDINGS

Our audit showed that Medicare Carriers did not always have adequate controls to detect and prevent inappropriate payments for laboratory tests. Contrary to applicable laws, regulations, and local Carrier reimbursement policies, Medicare Carriers 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, received, or needed by a physician. As a result, we estimate that nationwide, Medicare Carriers overpaid independent and physician laboratories about $50.2 million for chemistry, hematology, and urinalysis tests during the 2-year period from July 1, 1993 to June 30, 1995. For the same period, an additional $30.8 million could have been saved if policies had been adopted to preclude payment for additional automated hematology indices, (additional indices are calculated tests based upon information obtained from primary tests with an automated hemogram). Such policies have already been adopted by over half of the Carriers under this review because their studies showed that the indices were medically unnecessary or over-utilized and were merely a by-product of automated analyses.

Since our prior review (CIN: A-01-94-00513), several Medicare Carriers implemented procedures and edits to prevent payment for unbundled and duplicate tests. However, procedures and controls are still needed to ensure that payments for 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.

RECOMMENDATIONS

We are recommending that HCFA direct Medicare Carriers to (1) implement procedures and controls to ensure that clinical laboratory tests are appropriately grouped together and not duplicated for payment purposes and (2) recover potential overpayments in coordination with applicable investigative agencies. We are also recommending that HCFA establish policies to ensure that Medicare provider billings are limited to those clinical laboratory tests that physicians actually order. Finally, we recommend that HCFA consider eliminating separate reimbursement for additional indices on the basis that additional indices are a by-product of analyses 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. Regarding our recommendation relating to Medicare provider billings reflecting physicians orders, HCFA stated that it does not believe it has the authority to require laboratories to set up their order forms in a government-prescribed manner. The HCFA already has a requirement (42 CFR 410.32) that all diagnostic tests must be ordered by the attending physician. In this regard, HCFA suggested that OIG consider including this recommendation in its model compliance plan for laboratories.

OIG RESPONSE

We agree that HCFA does not have the authority or the need to prescribe specific order forms. However, HCFA should ensure that, until procedures are established to preclude payment for additional indices, Medicare contractors are aware that such payments are allowable only if the attending physician requests the additional indices. This is particularly important during post-payment reviews. For subsequent periods, HCFA has agreed to revise coding instructions to indicate that additional indices are not valid for Medicare and to remove these codes from fee schedules.

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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. Depending on the number of tests performed on behalf of a beneficiary on the same day by the same provider, the services may be billed to Medicare on one (single) or more claims (multiple).

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.

Hematology tests 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.

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. While claims for clinical laboratory tests performed on an outpatient hospital basis are processed by Medicare fiscal intermediaries, claims for clinical laboratory services provided by independent laboratories and physicians are processed for payment by a Medicare Carrier (Carrier). 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 have 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 Carriers to process payments for clinical laboratory tests performed by

independent and physician 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 instances of potential overpayment for claims paid during the period July 1993 through June 1995. Instances of potential overpayment occur when a Carrier pays an independent or physician laboratory for unbundled or duplicative tests provided on behalf of a beneficiary on the same day whether payment is based on one (single) or more (multiple) claims. To obtain a population of potential overpayments, we extracted payments applicable to selected chemistry, hematology and urinalysis tests from Health Care Financing Administration's (HCFA's) Five Percent Sample Standard Analytical File, for the period of audit. Using a series of computer applications applied to our extract of the five percent file, we identified those instances in which selected tests could have been grouped but were billed separately or duplicatively. Our extract and match resulted in identifying a population of 652,234 instances that met our criteria for review. The population of instances involved individual line charges amounting to $12,259,265. Since the extract and match were based on a five percent file, we estimate that nationwide, a population of about 13 million instances would meet our extract and match criteria for review. Individual line charges for this population of instances to be reviewed are estimated to be about $245 million. Further detail of this estimate is contained in APPENDIX A.

In order to test the reliability of HCFA's Sample Standard Analytical File, we compared the payment data to source documents (i.e., billings and remittance advices) for 1,392 randomly selected instances of potential overpayment from 16 randomly selected Carriers. Eight Carriers were selected to evaluate overpayments resulting from single claims and eight Carriers were selected to evaluate overpayments resulting from multiple claims.

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 and appropriate Medicare fee schedule. The resulting difference was identified as an overpayment. We also determined by questionnaires, 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 instances of potential overpayment. Since our

sample was taken from a population which represented a 5 percent statistical file, the results were multiplied by 20. 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 16 Carriers.

Our review of the internal controls at each Carrier 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 16 Carriers' policies, procedures, and instructions to providers related to the billing of clinical laboratory services. We also reviewed Carrier documentation relating to manual, automated paneling, and duplicate claim detection edits for chemistry, hematology, and urinalysis tests. We did not assess the completeness of HCFA's 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 Carrier payments involving chemistry and hematology tests within single claims. This area was addressed in our prior review entitled "Medicare Part B Payments by Carriers for Chemistry Tests and Hematology Profiles Performed by Independent and Physician Laboratories" (CIN: A-01-94-00513), issued May 3, 1994.

The audit was conducted between March 1996 and February 1997 at the HCFA central office, the Blue Shield of Massachusetts and our regional Office of Audit Services in Boston, Massachusetts. We also contacted the 16 Carriers selected in our sample and sent questionnaires to 285 physicians listed in HCFA's file as being responsible for ordering additional indices.

FINDINGS AND RECOMMENDATIONS

Our audit showed that Carriers did not always have adequate controls to detect and prevent inappropriate payment for laboratory tests. Contrary to applicable laws, regulations, and local Carrier reimbursement policies, Carriers 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, received, or needed. As a result, we estimate that, for the 2-year period from July 1, 1993 to June 30, 1995, Carriers nationwide overpaid independent and physician laboratories about $50.2 million for chemistry, hematology, and urinalysis tests (APPENDIX D). For the same period, an additional $30.8 million could have been saved if policies had been adopted to preclude payment for additional automated hematology indices. Eight of the 16 Carriers in our review have already adopted such policies because their studies showed that the indices were medically unnecessary or over-utilized and were merely a by-product of analyses performed on automated equipment (APPENDIX E).

Some Carriers implemented procedures and edits to prevent payment for several types of unbundled and duplicate tests. However, most Carriers generally needed procedures and controls to ensure that payments for clinical laboratory tests were proper. The HCFA recognized that uniform payment policies and procedures should be followed by all Carriers. Accordingly, HCFA introduced a correct coding initiative to standardize applicable codes that need to be grouped together for billing purposes. The audit also showed that the program overpaid for additional indices because the Carriers did not have procedures to 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 Five Percent Sample Standard Analytical File for the period July 1993 through June 1995. Using a series of computer applications, we identified those instances 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 population of 652,234 instances for review. Since the extract and match were based on a 5 percent file, we estimate that nationwide, about 13 million instances met our extract and match criteria for review. Further detail of this estimate is contained in APPENDIX A.

We selected a statistical sample of 1,392 potential overpayments from 16 randomly selected Carriers. Eight Carriers were selected to evaluate overpayments resulting from single claims and eight Carriers were selected to evaluate overpayments resulting from multiple claims. We also identified those instances involving hematology tests with additional indices to determine their medical necessity. A discussion of reimbursement requirements and details of our review of both single and multiple claims for each type of clinical laboratory service follows.

CLINICAL LABORATORY SERVICES REIMBURSEMENT REQUIREMENTS

In regard to establishing fee schedules, Section 1833(h)(2)(A)(i) of the Social Security Act authorizes 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 5114.1.L of the Medicare Carriers Manual.

Medicare claims for clinical laboratory services are reimbursed based on fee schedules and are subject to the guidelines published by HCFA in its Medicare Carriers Manual. Medicare pays the lesser of the national limit as published by HCFA annually, an individual Carrier fee schedule, providing that it does not exceed HCFA's national limit, or the actual charge for the service, providing that the service is reasonable and necessary.

Section 5114 of the Medicare Carriers Manual states that:

> "This section sets out payment rules for diagnostic laboratory services, i.e.,
> (1) outpatient clinical diagnostic laboratory tests subject to the fee schedule, and
> (2) other diagnostic laboratory tests...."

Section 5114.1L.1 continues on to list those tests which can be and are frequently performed as panels on automated multichannel equipment. Our review also identified three additional tests that HCFA has allowed Carriers the option of adding to their list of chemistry panel tests (APPENDIX B). Section 5114.1L.2 also directs Carriers 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.

Based on the above criteria, Medicare providers are required to group 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.

Section 7103.1B of the Medicare Carriers Manual discusses duplicate payments and provides that if an overpayment to a supplier is caused by multiple processing of the same charge (e.g., through overlapping or duplicate bills), the supplier does not have a reasonable basis for assuming that the total payment it received was correct and thus should have questioned it. The supplier is, therefore, at fault and liable for the overpayment.

CHEMISTRY TESTS

The audit showed that, of 480 sample items related to chemistry claims containing potential unbundling or duplication, 267 or 56 percent were found to be overpaid (APPENDIX D). These claims resulted in overpayments amounting to $2,410. As a result, we estimate that, nationwide, Carriers overpaid independent and physician laboratories about $25.2 million for unbundled or duplicated chemistry tests during the audit period. The following schedule summarizes the breakout of overpaid claims occurring between instances involving one claim and multiple claims.

Sample Strata	Universe of Potential Overpayments	Sample Size	Items Overpaid	Estimated Overpayments
Single	232,276	240	128	$15,828,200
Multiple	166,177	240	139	9,364,940
Totals	398,453	480	267	$25,193,140

All Carriers reviewed needed to make additions or refinements to their claims processing systems to ensure that chemistry claims were properly grouped together for reimbursement purposes. For example, several Carriers adopted policies to reimburse for groups of two or more automated chemistry panel tests, but allowed payments for individual tests of less than three. Likewise, Carriers that adopted a policy to group the three optional chemistry tests did not preclude payment when these tests were billed individually. Further, a hepatic function panel, which contains five chemistry panel tests, was not always treated as automated tests that were subject to being grouped for reimbursement purposes.

For the reasons discussed above, we believe procedures and controls need to be further refined. The results of our review of single claims showed that overpayments continued to occur for chemistry tests in the same manner as reported in our prior report titled, "Medicare Part B Payments by Carriers for Chemistry Tests and Hematology Profiles Performed by Independent and Physician Laboratories" (CIN: A-01-94-00513), issued May 3, 1994. These overpayments continued despite HCFA's agreement with our prior report recommendations and indication that corrective action would be taken. The prior review addressed overpayments occurring within single claims. In as much as our current review also involved multiple claims, we believe that corrective action should also cover overpayments involving two or more claims.

HEMATOLOGY TESTS

For hematology tests, we verified that 293 of 459 sample items (64 percent) were overpayments (APPENDIX D). These claims resulted in overpayments amounting to $2,189. As a result, we estimate that, nationwide, Carriers overpaid independent and physician laboratories about $23.1 million for unbundled or duplicated hematology tests during the audit period. The following schedule summarizes the breakout of overpaid claims occurring between instances involving one claim and multiple claims.

Sample Strata	Universe of Potential Overpayments	Sample Size	Items Overpaid	Estimated Overpayments
Single	296,429	240	129	$22,112,720
Multiple	29,057	219	164	996,040
Totals	325,486	459	293	$23,108,760

As with chemistry tests, all Carriers 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. As with overpayments discussed in chemistry, hematology overpayments also continued to occur in the same manner as reported in the prior report and, as currently reported, occurred in instances involving more than one claim. As discussed below, the Carriers also overpaid for additional indices that were not ordered, not received, or unneeded by physicians or because edits were not in place to preclude payment when a Carrier adopted a nonpayment policy.

Additional Automated Hematology Indices Of the 459 hematology claims reviewed in the sample, 285 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 Carriers' locally adopted payment policies.

To determine the medical necessity of additional indices, we sent 285 questionnaires to physicians who were listed on the beneficiary record as the "***referring 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. Of the 285 questionnaires, physicians responded to 222. We found that in 99 of the 222 responses, physicians indicated that they either did not order, receive, 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.

In those cases where physicians provided documentation of laboratory order forms, we found that laboratories usually provided the additional indices as part of a complete blood count. We noted that, overall, laboratories did not provide the opportunity for the physicians to order additional indices separately. Laboratory order forms did not provide a separate space or line on the form to enable the physicians to order the additional indices, if necessary. Instead, the physicians were provided the additional indices and the 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 physicians 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 be reimbursed based on a specific physician order and not on the assumption that a physician needs the additional indices. Accordingly, as a minimum, Carriers should be required to establish procedures to reimburse for additional indices in only those instances in which physician need is indicated and documented. In addition, Carriers should be required to establish edits to preclude payment for additional indices when a nonpayment policy is adopted locally.

Procedure Code Used for Reimbursement

Further analysis of potential overpayments for additional indices cast some 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 26 percent of the independent or physician providers accounted for over 75 percent of the additional indices billed and reimbursed. This concentration of overpayments is further demonstrated, in that, only 2 percent of the independent or physician providers accounted for 33 percent of the additional indices billed and reimbursed (see Figure 1). This suggests that at least in some cases, billings may be driven more by billing practices rather than medical need.

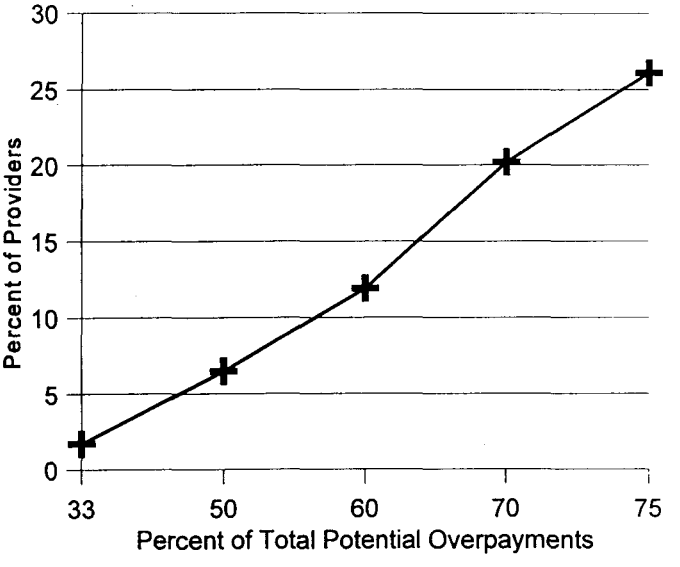

Figure 1 - Relationship between percent of providers and their share of overpayments for additional indices.

Similar results were indicated in our prior reviews of additional indices reimbursed in the Medicaid program. In one state, we identified four hospital outpatient laboratories and four independent laboratories that accounted for 99 percent and 95 percent respectively of the claims involving additional indices billed in the entire

state. The Medicaid 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.

Such belief is shared by the Medical Directors of several Carriers that adopted policies not to pay for additional indices. Of the 16 Carriers included in our sample, 8 Carriers have adopted policies to either stop making separate payment for these additional indices or pay only based on a documented need. Seven of the eight Carriers had this policy in effect during all or part of our audit period. These policies were based on Carrier studies that show additional indices were seldom clinically useful or overutilized and were merely a by-product of analyses performed on automated equipment which produces the hematology tests and calculates and measures all indices simultaneously. Further review of policies in other Carriers showed that such non-payment policies have been adopted at an additional 22 Carriers.

Nevertheless, responses to our questionnaire did show that physicians in 123 of 222 responses received, ordered and used the additional indices in the diagnosis of their patients. In most cases, the specialties of these physicians were hematology or oncology. Of the 123 cases that indicated a need for additional hematology indices, 87 involved orders that were self-referrals to the physicians' own laboratories.

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.

For the period of review, an additional $30.8 million could have been saved if policies had been adopted to preclude payment for additional automated hematology indices (APPENDIX E).

URINALYSIS TESTS

Our review of urinalysis tests showed that 433 of 453 (96 percent) were found to be overpayments resulting from duplication (APPENDIX D). These claims resulted in overpayments amounting to $1,621. As a result, we estimate that, nationwide, Carriers overpaid independent and physician laboratories about $1.9 million for unbundled or duplicated urinalysis tests during the audit period. The following schedule summarizes the breakout of overpaid claims occurring between instances involving one claim or multiple claims.

Sample Strata	Universe of Potential Overpayments	Sample Size	Items Overpaid	Estimated Overpayments
Single	25,991	240	237	$1,698,400
Multiple	4,999	213	196	172,540
Totals	30,990	453	433	$1,870,940

All Carriers reviewed needed to make additions or refinements to 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.

CARRIER POLICIES AND PROCEDURES

Based on our review, most Carrier policies and procedures did not always ensure proper payment of chemistry, hematology, and urinalysis claims submitted by independent and physician laboratories. Most Carriers attempted to prevent some types of 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, policies and related procedures controls to prevent duplicate payment for hematology and urinalysis tests varied widely between Carriers and, generally did not address all types of duplicate billing and payment discussed in this report.

With regard to additional automated hematology indices, we noted that 8 of the 16 Carriers randomly selected in our review had established policies to either deny payment for the additional indices or pay only in cases of documented medical necessity. However, related procedures and controls were not always in place to implement the Carriers' non-payment policies. The other Carriers continue to routinely pay for these services or deny based on intermittent post-payment review.

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 "Medicare Part B Payments by Carriers for Chemistry Tests and Hematology Profiles Performed by Independent and Physician Laboratories" (CIN: A-01-94-00513). In a memorandum, dated June 30, 1994, HCFA indicated that corrective actions would be taken. Such actions were to include: discussing the reported findings with involved parties and regional offices; reinforcing Carrier manual guidelines; developing edit specifications; installing edits; and determining and recovering overpayments.

Through the "National Correct Coding Policy Manual for Part B Medicare Carriers," effective January 1, 1996, HCFA has attempted to assure that uniform payment policies and procedures are followed by all Carriers and to promote accurate coding and reporting of services by physicians. The manual describing the initiative cites the lack of consistency or uniformity among Carriers in correct coding edits due to (1) individual Carrier discretion and established priorities and (2) Carrier problems with the identifying component parts of comprehensive procedures. In this regard, the "National Correct Coding Initiative" sets out to develop correct coding methodologies and to control improper coding that caused inappropriate increases of payments in Part B claims.

We reviewed the sections of the correct coding manual relating to the pathology and laboratory services and found that many issues that caused overpayments discussed in this audit still need to be addressed. Specifically:

- only 38 of the 68 codes included in our review are incorporated in the correct coding manual;

- the initiative compares pairs of codes and does not address groups of codes which should be paneled for billing purposes; and

- the manual does not require Carriers to develop specifications for installing edits to prevent payment of unbundled or duplicate claims.

The HCFA personnel have stated that the corrective action plan has not been completed and that overpayments identified as part of our prior audit have not been systematically identified for recovery.

RECOMMENDATIONS

We are recommending that HCFA:

- direct Carriers to (1) implement procedures and controls to ensure that clinical laboratory tests are appropriately grouped together and not duplicated for payment purposes, and

(2) recover potential overpayments estimated at $50.2 million from providers. As discussed in the OTHER MATTERS section of this report, HCFA should also coordinate recovery efforts with applicable investigative agencies;

- establish policies to ensure that Medicare provider billings reflect only those clinical laboratory tests, specifically additional indices, that physicians actually order; in this regard, (1) laboratories should provide physicians the opportunity to order such services separately, and (2) Carriers should only reimburse additional indices when medical necessity is properly documented and establish edits to preclude payment for additional indices when a nonpayment policy is adopted locally; and

- consider eliminating separate reimbursement for additional indices on the basis that (1) additional indices are a by-product of analyses performed on automated equipment which produces the hematology tests and calculates and measures all indices simultaneously, and (2) the possibility that these additional indices are medically unnecessary.

HCFA COMMENTS

In its written comments on our draft audit report (APPENDIX F), HCFA concurred with all OIG recommendations. Regarding our recommendation relating to Medicare provider billings reflecting physicians orders, HCFA stated that it does not believe it has the authority to require laboratories to set up their order forms in a government-prescribed manner. The HCFA already has a requirement (42 CFR 410.32) that all diagnostic tests must be ordered by the attending physician. In this regard, HCFA suggested that OIG consider including this recommendation in its model compliance plan for laboratories.

OIG RESPONSE

We agree that HCFA does not have the authority or the need to prescribe specific order forms. However, HCFA should ensure that, until procedures are established to preclude payment for additional indices, Medicare contractors are aware that such payments are allowable only if the attending physician requests the additional indices. This is particularly important during post-payment reviews. For subsequent periods, HCFA has agreed to revise coding instructions to indicate that additional indices are not valid for Medicare and to remove these codes from fee schedules.

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 Carriers' 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 overbilling warrants further review. This is necessary to determine whether overpayments to these providers are based on insufficient internal controls or adoption of aberrant marketing or billing practices or whether the providers are involved in some form of potentially fraudulent activity.

The Department of Health and Human Services, Office of Inspector General, Office of Investigations, in cooperation with the U.S. Attorneys' Office of the Department of Justice are currently involved in a number of investigations involving overbilling 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 of high profile laboratories 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

SINGLE CLAIMS CARRIER	INSTANCES OF POTENTIAL OVERPAYMENT (5 PERCENT FILES)	INSTANCES OF POTENTIAL OVERPAYMENT (POPULATION) (X 20)
Blue Cross and Blue Shield of Florida, Inc.	19,154	383,080
Health Care Service Corp. (MI)	14,503	290,060
IASD Health Services Corporation	6,110	122,200
Blue Cross and Blue Shield of Michigan	30,739	614,780
Blue Shield of Western New York	8,603	172,060
Blue Cross Blue Shield of North Dakota	5,671	113,420
Connecticut General Life Insurance Company/Equicor (N.C.)	13,908	278,160
MetraHealth (CT)	18,941	378,820
Total Sample	117,629	2,352,580
Total For All Carriers (single claims)	554,696	11,093,920
MULTIPLE CLAIMS CARRIER		
Blue Shield of California	12,931	258,620
Health Care Service Corp. (IL)	2,067	41,340
Blue Cross and Blue Shield of Kansas	423	8,460
Xact Medicare Services	10,474	209,480
Blue Cross and Blue Shield of Texas	3,495	69,900
Triple-S Incorporated	1,346	26,920
Aetna Life Insurance Company	592	11,840
Transamerica Occidental Life Insurance Company	7,774	155,480
Total Sample	39,102	782,040
Total For All Carriers (multiple claims)	97,538	1,950,760
Grand Total	652,234	13,044,680

5 PERCENT FILE ESTIMATE TOTAL (X 20)

	INSTANCES	AMOUNT	INSTANCES	AMOUNT
SINGLE	554,696	$10,192,863	11,093,920	$203,857,260
MULTIPLE	97,538	2,066,402	1,950,760	41,328,040
TOTAL	652,234	$12,259,265	13,044,680	$245,185,300

The resulting extract from the five percent Sample Standard Analytical File totaled 652,234 instances of potential overpayments. Multiplying by a factor of 20 resulted in a nationwide estimate of 13,044,680 claims. This total reflects an unduplicated count since a claim can contain more than one type of potential overpayment. Our computer program stratified each potential overpayment into one of three error categories by Carrier. The first category consisted of 312,839 instances of potentially unbundled chemistry panel tests. The second category consisted of 310,911 instances of potentially duplicate hematology tests or unneeded additional indices. The third category consisted of 28,484 claims with potentially duplicate urinalysis profile and tests.

SAMPLE METHODOLOGY

This report covers Medicare payments for clinical laboratory services provided between July 1, 1993 through June 30, 1995.

To obtain a population of potential overpayments, we extracted applicable payments for selected chemistry, hematology and urinalysis tests from HCFA's Five Percent Sample 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 HCFA's Common Procedure Coding System (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 instance is a potential payment error in which the Carriers 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 1,392 instances of potential overpayments involving claims for clinical laboratory services in the 16 Medicare Carriers selected for audit. The instances of potential overpayments were stratified into the clinical laboratory service categories of chemistry, hematology, and urinalysis for both single and multiple claims. For each sampled instance, we requested and reviewed supporting documentation from the Carrier consisting of copies of physician or independent laboratory claims and related paid claims history. Our review disclosed 993 potential overpayments out of the 1,392 instances 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 dollar value of paid claims containing potential overpayments at each Carrier (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 CAPT 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

ESTIMATE OF POTENTIAL OVERPAYMENTS
(Sample Instances)

CARRIER SINGLE CLAIMS	CHEMISTRY		HEMATOLOGY		URINALYSIS		TOTAL	
	SAMPLE SIZE	SAMPLE ERROR	SAMPLE SIZE	SAMPLE ERROR	SAMPLE SIZE	SAMPLE ERROR	SAMPLE SIZE	SAMPLE ERROR
00590-FL	30	28	30	30	30	30	90	88
00623-MI	30	15	30	11	30	30	90	56
00640-IA	30	0	30	19	30	30	90	49
00710-MI	30	17	30	14	30	30	90	61
00801-NY	30	30	30	12	30	30	90	72
00820-ND	30	18	30	7	30	28	90	53
05535-NC	30	1	30	27	30	30	90	58
10230-CT	30	19	30	9	30	29	90	57
TOTALS	240	128	240	129	240	237	720	494

CARRIER MULTIPLE CLAIMS	CHEMISTRY		HEMATOLOGY		URINALYSIS		TOTAL	
	SAMPLE SIZE	SAMPLE ERROR	SAMPLE SIZE	SAMPLE ERROR	SAMPLE SIZE	SAMPLE ERROR	SAMPLE SIZE	SAMPLE ERROR
00542-CA	30	30	30	13	30	30	90	73
00621-IL	30	18	30	30	30	30	90	78
00650-KS	30	2	9	8	3	3	42*	13
00860-PA	30	15	30	27	30	25	90	67
00900-TX	30	24	30	15	30	25	90	64
00973-PR	30	14	30	29	30	24	90	67
01390-WA	30	17	30	30	30	30	90	77
02050-CA	30	19	30	12	30	29	90	60
TOTALS	240	139	219	164	213	196	672	499

*Only 42 potential overpayments were identified by our random sample match.

CARRIER TOTALS	CHEMISTRY		HEMATOLOGY		URINALYSIS		TOTAL	
	SAMPLE SIZE	SAMPLE ERROR	SAMPLE SIZE	SAMPLE ERROR	SAMPLE SIZE	SAMPLE ERROR	SAMPLE SIZE	SAMPLE ERROR
SINGLE	240	128	240	129	240	237	720	494
MULTIPLE	240	139	219	164	213	196	672	499
TOTAL	480	267	459	293	453	433	1392	993

ESTIMATE OF POTENTIAL OVERPAYMENTS

(Dollars)

	SAMPLE ESTIMATE OF POTENTIAL OVERPAYMENTS	PRECISION* (+ - percent)	TOTAL ESTIMATE OF POTENTIAL OVERPAYMENTS (X 20)	
CHEMISTRY				
SINGLE	$ 791,410	70.62%	$15,828,200	
MULTIPLE	468,247	21.09%	9,364,940	
TOTAL CHEMISTRY				$25,193,140
HEMATOLOGY				
SINGLE	$1,105,636	40.71%	$22,112,720	
MULTIPLE	49,802	39.26%	996,040	
TOTAL HEMATOLOGY				$23,108,760
URINALYSIS				
SINGLE	$ 84,920	72.44%	$ 1,698,400	
MULTIPLE	8,627	59.95%	172,540	
TOTAL URINALYSIS				$ 1,870,940
ALL CATEGORIES				
SINGLE	$1,981,966	22.95%	$39,639,320	
MULTIPLE	526,676	18.92%	10,533,520	
TOTAL ESTIMATED OVERPAYMENT				$50,172,840

*Based on 90 percent confidence level

ESTIMATE OF POTENTIAL SAVINGS
(additional automated hematology indices)

CARRIER (Single Claims)	SAMPLE SIZE*	CLAIMS W/ALLOWABLE INDICES	CARRIER (Multiple Claims)	SAMPLE SIZE	CLAIMS W/ALLOWABLE INDICES
00590-FL	30	0	00542-CA	30	15
00623-MI	30	19	00621-IL	30	0
00640-IA	30	11	00650-KS	9	0
00710-MI	30	16	00860-PA	30	0
00801-NY	30	22	00900-TX	30	14
00820-ND	30	23	00973-PR	30	0
05535-NC	30	3	01390-WA	30	0
10230-CT	30	21	02050-CA	30	19
TOTAL	240	115	TOTAL	219	48

		SAMPLE ESTIMATE OF POTENTIAL OVERPAYMENTS AND SAVINGS*	PRECISION** (+ - percent)	TOTAL ESTIMATE OF POTENTIAL OVERPAYMENTS AND SAVINGS (X 20)
HEMATOLOGY	SINGLE	$1,513,414	34.95%	$30,268,280
	MULTIPLE	29,065	94.04%	581,300
TOTAL HEMATOLOGY				$30,849,580

*Assumes all payments for additional indices are in error, i.e., all Carriers 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

Deputy Administrator
Washington, D.C. 20201

DATE: OCT 13 1997

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle NMD
Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Review of Clinical Laboratory Tests Performed by Independent Laboratories and Physicians," (A-01-96-00509)

We reviewed the above-referenced report that examines whether certain chemistry, hematology, and urinalysis tests were appropriately grouped together in a panel or profile and not duplicated for Medicare payment purposes. It also examines whether certain additional automated hematology indices paid by the Medicare program were ordered by physicians.

This audit follows-up on corrective actions taken by the Health Care Financing Administration (HCFA) regarding unbundled and duplicate charges within single claims involving chemistry and hematology tests.

The audit found that Medicare carriers did not always have adequate controls to detect and prevent inappropriate payments for laboratory tests. Contrary to applicable laws, regulations, and local carrier reimbursement policies, Medicare carriers reimbursed providers for claims involving: (1) unbundled and/or duplicate chemistry, hematology, and urinalysis tests which should have been grouped together and paid at a lesser amount; and (2) additional indices that were not ordered, received, or needed by a physician. As a result, OIG estimates that nationwide, Medicare carriers overpaid independent and physician laboratories about $50.2 million for chemistry, hematology, and urinalysis tests during the 2-year period ending June 30, 1995. For the same period, OIG estimates that an additional $30.8 million could have been saved if policies had been adopted to preclude payment for additional automated hematology indices.

HCFA concurs with all OIG report recommendations. Our detailed comments are as follows:

OIG Recommendation

HCFA should direct carriers to implement procedures and controls to: (1) ensure that clinical laboratory tests are appropriately grouped together and not duplicated for payment purposes; (2) recover potential overpayments estimated at $50.2 million from providers; and (3) delay or suspend such recoveries pending completion of ongoing investigations or investigative actions that have resolved such matters.

HCFA Response

We concur. Changes were made to the correct coding initiative edits effective July 1, 1997, which should address the hemoglobin and urinalysis problems mentioned in the report.

We are also working with the regional offices and carriers to correct situations where tests may not be correctly processed and/or duplicate checked. This task is tied into a project that will eliminate the existing codes for automated chemistry panels (80002 - 80019 and G0058 - G0060), and substitute specific billing by laboratories for four new chemistry panels and individual billing for tests not included in the four new panels. This project will require contractors to bundle tests for payment purposes, but will allow them and us to know which specific tests were performed. This task is to be operational by January 1, 1998.

Beginning for services performed on or after January 1, 1998, HCFA will require ordering physicians to identify the individual automated tests ordered, or use the four Current Procedure Terminology (CPT) panel codes which specifically identify the tests in each panel. This requirement, when implemented by the contractors' systems, will allow ease in duplicate checking of tests.

We will also be including requirements that carriers must unbundle tests and/or panels for duplicate checking and then bundle tests for pricing. As another part of this project, we are building test cases for the carriers' systems to test their abilities to correctly process the new panels and all automated chemistry tests, and existing organ and disease panels that include any automated tests, to avoid duplicate payments. We believe this project will include most, if not all, of the situations in the report.

We will review OIG work papers and take action as necessary to recover any overpayments as deemed appropriate.

OIG Recommendation

HCFA should establish policies to ensure that Medicare provider billings reflect only those clinical laboratory tests, specifically additional indices, that physicians actually order. In this regard, laboratories should provide physicians the opportunity to order such services separately. Carriers should only reimburse additional indices when medical necessity is properly documented, and establish edits to preclude payment for additional indices when a nonpayment policy is adopted locally.

HCFA Response

We concur. However, we do not believe HCFA has the authority to require laboratories to set up their order forms in a government-prescribed manner. We suggest that OIG consider including this recommendation in its model compliance plan for laboratories.

HCFA already has a requirement (42 CFR 410.32) that all diagnostic tests must be ordered by the attending physician. We believe any laboratory that provides additional indices on the basis of an order for a complete blood count would not meet the requirement of 42 CFR 410.32. Therefore, since it is implicit for any claim for any diagnostic test (including indices, other clinical laboratory tests, or any other diagnostic test) that the test was ordered by the attending physician, if the test was in fact not ordered, then the service was not provided as claimed and constitutes a false representation of a material fact. As such, it would seem that it is a violation of sections 1128(A)(a)(1)(A) and (B) and sections 1128(B)(a)(1) and (2) of the Social Security Act. While Medicare must assume that billed services are in fact ordered or the claims processing system would collapse (the alternative is to get hard copy documentation and review every laboratory order), where it is found that claims contain services that were not ordered, the case should be developed as a false claim.

OIG audit staff should refer the cases uncovered as a result of this audit to their Office of Investigations.

OIG Recommendation

HCFA should consider eliminating separate reimbursement for additional indices on the basis that additional indices are a by-product of analyses performed on automated equipment that produces the hematology tests and calculates and measures all indices simultaneously, and the possibility that these additional indices are medically unnecessary.

HCFA Response

We concur. Based on the report finding that additional hemogram indices (CPT codes 850029 and 85030) are not test results but rather, calculations using the results of tests that were already billed, 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.