Memorandum

JAN 23 1995

Date

June Gibbs Brown

From Inspector General

Subject Review of Chemistry Tests Performed on Automated Laboratory Equipment (A-01-93-00521)

To Bruce C. Vladeck
Administrator
Health Care Financing Administration

Attached is our report entitled, "Review of Chemistry Tests Performed on Automated Laboratory Equipment." The objective of our review was to identify chemistry tests which should be paid as a panel but are not currently required to be paneled by the Health Care Financing Administration (HCFA).

This is the fourth in a recent series of reports to you concerning unbundled chemistry and hematology tests. Two of the prior reports involve compliance issues while the other relates to HCFA's policy. One of the compliance reports (A-01-93-00520) was issued in final on April 26, 1994. The review concerned payments by intermediaries to hospitals for unbundled and duplicate charges for chemistry and hematology tests performed as an outpatient service. The other compliance review (A-01-94-00513) was issued to your office on May 3, 1994. This report contained findings similar to the first report but involved payments by carriers to independent laboratories and physicians. The third report (A-01-94-00512) concerning Medicare payment guidelines was issued to your office on June 17, 1994. This review disclosed that the Medicare program is paying higher amounts for claims containing fewer than three chemistry tests and unbundled hematology tests.

This report, the fourth, presents the completed results of our review of chemistry tests performed on automated laboratory equipment (A-01-93-00521). We alerted you to the preliminary results of this review in a memorandum dated May 12, 1994, and issued our draft report on September 30, 1994.

The attached report shows that the Medicare Part B program is paying single test payment rates for chemistry tests commonly performed on automated laboratory equipment. The payment of single test rates for chemistry tests that should be paid as a panel results in increased costs to the Medicare program.

Single test payment rates are paid because HCFA's guidelines regarding chemistry tests subject to paneling have not been updated to add tests as laboratory technology has

advanced. This review identified 10 tests which are appropriate for paneling, but are not on the list of chemistry tests that should be paneled. Savings to the Medicare program would be about $216 million annually if the 10 tests identified were included as panel tests nationwide.

We are recommending that HCFA:

- Update its guidelines by expanding the national list of chemistry panel tests to include the 10 automated chemistry tests identified by our audit; and

- Establish a process whereby advances in technology and laboratory practices are periodically reviewed to further update the national list.

In response to our draft report, HCFA officials generally concurred with the two recommendations in our report. The full text of HCFA's comments is presented as an Attachment to this report.

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 call me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 966-7104. Copies of this report are being sent to other interested Department officials.

To facilitate identification, please refer to Common Identification Number A-01-93-00521 in all correspondence related to this report.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF CHEMISTRY TESTS PERFORMED ON AUTOMATED LABORATORY EQUIPMENT

JUNE GIBBS BROWN
Inspector General

JANUARY 1995
A-01-93-00521

EXECUTIVE SUMMARY

Background

Chemistry tests are clinical laboratory services requested by physicians in order to diagnose and treat patients. The Physicians' Current Procedural Terminology (CPT) manual lists chemistry tests which are commonly performed on automated laboratory equipment (referred to in this report as panel tests). The Health Care Financing Administration (HCFA) guidelines incorporate the panel tests included in the CPT manual and require that these panel tests be grouped together (bundled) for payment purposes. In addition, HCFA's Carriers Manual provides that other chemistry tests available in a carrier's service area and commonly performed on automated laboratory equipment be reimbursed as panel tests. However, HCFA guidelines allow carriers to determine which additional tests should be added to carrier specific panel test lists.

Objective

To Identify Chemistry Tests That Should Be Paid As A Panel But Are Not Currently Required To Be Paneled By HCFA

Results of Review

Based upon claims information and responses to questionnaires by hospital and independent laboratories related to 18 tests identified for review, 10 are available in all carrier service areas and are commonly performed on automated equipment. In our opinion, these 10 chemistry tests should be paid as panel tests. However, HCFA's guidelines which specify chemistry tests that should be paneled by all carriers have not been updated to add tests as technology has advanced. Further, HCFA's guidelines have not been followed by some carriers. In this regard, some carriers have appropriately added chemistry tests available in their service areas to their carrier specific lists while others have not.

The Medicare Part B program, through its fiscal intermediaries (FI) and carriers, is paying single test payment rates for chemistry tests which are commonly performed on automated laboratory equipment. The payment of single test rates for chemistry tests that should be paid as panel tests results in increased costs to the Medicare program. We estimate that savings to the Medicare program would be about $216 million annually if the 10 chemistry tests were paid as panel tests nationwide.

We are recommending that HCFA:

-- Update its guidelines by expanding the national list of chemistry panel tests to include the 10 automated chemistry tests identified by our audit. We estimate that HCFA would save about $216 million annually if the 10 chemistry tests recommended in our report are added to the national list of chemistry panel tests. In commenting to our draft report, HCFA did not agree with 2 of the 10 tests recommended for paneling. If HCFA only adds 8 of the 10 tests to the national list of chemistry panel tests, we estimate that savings of $130 million annually would be realized.

-- Establish a process whereby advances in technology and laboratory practices are periodically reviewed to update the national panel test list.

HCFA's Comments and OIG's Response

In response to our draft report, HCFA officials generally concurred with the two recommendations in the report. In response to the first recommendation, HCFA officials recognized the need to initiate changes in the payment policy for automated panel tests and are in the process of making such changes. However, they did not agree with 2 of the 10 tests, high density lipoprotein (HDL) and iron binding capacity (IBC), we recommended for addition to the list. In response to the second recommendation, HCFA officials agreed to a periodic review of tests for inclusion in the listing of automated panel tests. (The entire text of HCFA's comments is contained in Attachment IV.)

We appreciate HCFA's efforts to add tests to the listing of chemistry panel tests; however, HCFA should reconsider its decision not to add the HDL and IBC tests when expanding the list. Providers who answered our questionnaire stated that both tests are performed on automated equipment along with other panel tests. Further, 95 percent of responding providers who perform the test in their laboratories stated that they performed the HDL test using automated equipment while 98 percent of such providers replied that they performed the IBC test using automated equipment. Since these two tests are normally performed on automated equipment, we recommend that HCFA include them in their listing of panel tests.

Other Matters

In addition to expanding the national list of panel tests to include the 10 tests commonly performed on automated equipment, HCFA should also consider other tests disclosed in our review. In many of the 8 States reviewed, tests other than the 10 cited above were commonly performed on automated laboratory equipment and available in their respective service areas. Even though we did not recommend adding the tests to the panel test list, HCFA may further review these tests and consider them to be panel tests. (See the Other Matters Section of this report.)

This report is the fourth in a recent series concerning unbundled chemistry and hematology tests. Two of the prior reports involve compliance issues while the other relates to HCFA policy. In response to our prior reports, HCFA officials agreed to institute our recommendations and to work with the OIG in correcting the findings regarding unbundled chemistry and hematology tests. In addition, HCFA has issued a nationwide critical task order to develop uniform system edits for laboratory services.

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INTRODUCTION

BACKGROUND

Part B of Title XVIII of the Social Security Act (Medicare Supplementary Medical Insurance), as amended, includes coverage for clinical laboratory services. Claims for clinical laboratory services performed by hospitals as an outpatient service are processed for payment by FIs. Claims for clinical laboratory services performed by physicians and independent laboratories are processed by carriers.

Generally, claims for clinical laboratory services are reimbursed based on fee schedules and are subject to guidelines published by HCFA in its Carriers Manual. Medicare pays the lower of the fee schedule amount or the actual charge for the service, provided that the service is reasonable and necessary. The beneficiary associated coinsurance and deductible provisions do not apply to clinical laboratory services.

Chemistry tests are clinical laboratory services requested by physicians in order to diagnose and treat patients. The CPT manual lists chemistry tests which are commonly performed on automated laboratory equipment (referred to as panel tests). Current HCFA guidelines incorporate the 19 panel tests included in the Calendar Year (CY) 1993 CPT manual and require that these 19 panel tests be bundled for payment purposes. The HCFA guidelines also instruct carriers to bundle other chemistry tests commonly performed on automated equipment and available in their respective service areas and periodically update their carrier specific lists of chemistry panel tests.

In addition to the automated chemistry panel tests, the CPT manual lists other tests which are 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. The 1992 CPT manual lists 31 organ panels (subsequently reduced to 9 in the 1993 CPT manual). For 2 of the organ panels, lipid and thyroid, all of the component tests are either included in the CPT manual as chemistry panel tests or identified by our review as 1 of the 10 tests that should be added to the national chemistry panel list.

SCOPE OF AUDIT

Our review was conducted in accordance with generally accepted government auditing standards. Our objective was to identify chemistry tests which should be paid as a panel but are not currently required to be included in the list of automated panel tests by HCFA.

To accomplish our objective, we:

-- identified automated chemistry tests which are not currently included in the CPT manual list of automated panel tests;

-- utilized HCFA's 1992 Five Percent Sample Beneficiary Standard Analytic File to extract Medicare Part B claims which contained at least one of the tests identified;

-- excluded claims submitted by physicians from the sample population;

-- randomly selected 8 from a universe of 50 States and extracted claims submitted by hospital and independent laboratories located in those 8 States;

-- randomly selected 320 claims (40 in each State) submitted by hospital laboratories from a population of 254,771 claims containing potential panel tests, and 320 claims (40 in each State) submitted by independent laboratories from a population of 563,063 claims containing potential panel tests;

-- requested that each of the 275 providers which submitted at least 1 of the 640 sample claims complete a questionnaire regarding the equipment used and the tests performed on automated equipment in its laboratory;

-- reviewed the claim history for each sample claim to quantify the savings;

-- utilized a two-stage ratio estimate to project the amount of savings to the population; and

-- utilized the results of a survey of all carriers by our Office of Audit Services in Region III regarding clinical laboratory tests added to their carrier specific lists.

In addition, we estimated the CY 1992 Medicare payments for the 18 tests and 2 organ panels included in our review. To estimate the 1992 Medicare payments, we determined the number of times that each of the tests appeared on one of the claims recorded to the 1992 Five Percent Sample Beneficiary Standard Analytic File. Based on the number of times each of the above tests appeared in the universe, we computed the estimated payments using the 1992 national limitation fee schedule payment for each test. The resulting payments were then multiplied by 20 as the data was drawn from HCFA's 1992 Five Percent Sample Beneficiary Standard Analytic File.

Our review of internal controls was limited to intermediary and carrier guidelines related to the billing for chemistry panel tests. Our review was limited to claims recorded to HCFA's Five Percent Sample Beneficiary Standard Analytic File for dates of service during CY 1992. The reliability of computer generated output was tested by comparing data to source documents for the sampled claims. We did not, however, assess the completeness of the HCFA data files, nor did we evaluate the adequacy of the input controls. Details of the methodology used in selecting and appraising the sample are contained in Attachment I of this report. This review was performed between August 1993 and April 1994 in Boston, Massachusetts.

FINDINGS AND RECOMMENDATIONS

Based upon claims information and responses to questionnaires by hospital and independent laboratories, 10 of the 18 tests identified for review are available in all carrier service areas and commonly performed on automated equipment. In our opinion, these 10 tests should be included in the national panel test list.

TABLE I

ESTIMATED CY 1992 MEDICARE PART B PAYMENTS FOR POTENTIAL PANEL TESTS

TEST	ESTIMATED PAYMENTS
1. AMYLASE (AMY)	$9,740,700
2. CREATINE PHOSPHOKINASE (CPK)	8,321,580
3. TRIGLYCERIDES (TRIG)	13,479,880
4. MAGNESIUM (MAG)	14,374,380
5. GLUTAMYLTRANSFERASE, GAMMA (GGT)	8,344,520
6. HIGH DENSITY LIPOPROTEIN (HDL)	67,585,260
7. THYROXINE (T4)	50,646,540
8. IRON	28,934,100
9. T3 UPTAKE (T3U)	24,812,800
10. IRON BINDING CAPACITY (IBC)	26,410,440
1. LIPID PANEL	27,107,400
2. THYROID PANEL	31,500,960
SUBTOTAL	$311,258,560
11. AMMONIA (NH3)	1,164,280
12. LIPASE (LIP)	1,813,860
13. ACID PHOSPHATASE (ACP)	1,816,480
14. LACTATE (LAC)	58,420
15. CHOLINESTERASE	185,360
16. GLUCOSE-6-PD	167,220
17. APOLIPOPROTEIN	8,694,920
18. BILE ACIDS	98,960
TOTAL	$325,258,060

The HCFA has not established a process whereby advances in technology and laboratory practices are periodically reviewed to update the national panel test list. Their guidelines instruct carriers to bundle other chemistry tests commonly performed on automated equipment and available in their respective service areas. However, HCFA guidelines have not been consistently followed by carriers. Some carriers have added chemistry tests to their carrier specific panel test lists while others have not.

We estimate that $216 million would be saved annually by Medicare if the 10 chemistry tests commonly performed on automated equipment by hospital and independent laboratories nationwide were paid as panel tests. The Medicare Part B program is paying single test payment rates for chemistry tests which are available in all carrier service areas and commonly performed on automated laboratory equipment. The payment of single test rates for chemistry tests that should be paid as panel tests results in increased costs to the Medicare program.

Table I shows Medicare Part B payments to hospitals and independent laboratories for the 18 tests and 2 related organ panels that we estimate to be $325 million for CY 1992. Of this $325 million, the 10 tests and the 2 panels commonly performed on automated equipment account for $311 million (96 percent). The remaining 8 tests account for $14 million or 4 percent of the total. The 18 chemistry tests were identified from a listing of tests and equipment in the July 26, 1993 Federal Register entitled, "Compiled List of Clinical Laboratory Test Systems, Assays, and Examinations Categorized by Complexity." In addition to the 18 tests there are 2 organ panels which contain only chemistry panel tests. One of the two organ panels is a lipid panel consisting of three chemistry tests: cholesterol, HDL and triglycerides. Cholesterol is 1 of the tests already subject to paneling and HDL and triglycerides are among the 18 tests included in this review. The other organ panel is a thyroid panel made up of two chemistry tests: thyroxine and T3 uptake. Both of these tests were included in this review.

CHEMISTRY TESTS NOT ON PANEL LIST

HCFA's National Panel Test List Has Not Been Updated and Carriers Have Not Consistently Added Tests To Their Panel Lists

Current HCFA procedures do not provide for periodic updates to the national list of panel tests to reflect advances in laboratory technology. Our review identified 37 chemistry tests that are performed on automated laboratory equipment. Of these 37 tests, 19 have been recognized by HCFA as panel tests. (For a listing of the tests and related CPT codes, see Attachment II.) As such, HCFA requires that reimbursement for any combination of these 19 tests performed for a patient on the same date be limited to the fee schedule amount for the panel. Of the remaining 18 chemistry tests (37 - 19), we found that 10 are also available in all carriers' service areas and commonly performed on automated equipment. If these tests were recognized as panel tests by HCFA, the national list of chemistry panel tests could be updated to as many as 29.

In accordance with HCFA instructions, some carriers have updated their respective chemistry panel lists to include automated tests that are available in their service areas. We found, however, that other carriers have not. Of the 40 carriers surveyed, 34 had added at least 1 chemistry test to the panel lists for their service areas, while 6 had not added any tests. Specifically, the survey showed that 3 tests (CPK, GGT, and triglycerides) had been added to the panel test list by 32 carriers.

We believe that HCFA should update its guidelines to expand the national list of chemistry tests subject to paneling to ensure that a consistent payment standard is used by all carriers for commonly performed tests.

AUTOMATED CHEMISTRY TESTS

Tests Available In The Carrier's Service Area And Normally Performed On Automated Equipment Should Be Paid As Panel Tests

The Medicare Carriers Manual, section 5114.1 L.2, entitled, "Separately Billed Tests That Are Commonly Part of Automated Battery Test," requires that carriers identify tests which are available in their service area and commonly performed on automated equipment and make payment for such tests at lower panel rates. The Carriers Manual does not provide further guidance on how carriers are to identify such tests and leaves this process to the individual carrier's judgment.

We defined a test as available in all carriers' service areas if at least 70 percent of responding providers nationwide performed the test in their laboratories. If a test was identified by a hospital or independent laboratory as performed on their premises, we then considered whether the test was commonly performed on automated equipment. Our determination of whether the test was commonly performed on automated equipment was based on providers' responses; whether tests identified in our sample were performed manually or used automated equipment. A definition of automated equipment was included in the questionnaire. As defined in the Federal Register dated February 28, 1992 entitled, "Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988," automated equipment is an instrument or test system in which all analytical processes, including sample and reagent uptake, sample/reagent interaction, chemical/biological analysis, result calculation and result readout are mechanized.

RESULTS OF QUESTIONNAIRE

Provider Replies Show 10 Chemistry Tests Are Available In Carrier Service Areas

Of the 275 providers selected in our nationwide random sample of Medicare claims, 268 providers, or 97 percent, responded (185 hospital and 83 independent laboratories). As shown in Table II, for each of the first 10 tests at least 70 percent of respondents performed the tests in their own laboratories. In addition, for each test, at least 89 percent of those performing the tests in their laboratories reported that they performed the tests on automated equipment. For example, 98 percent of the 268 providers which replied to our questionnaire performed the amylase (AMY) test in their laboratories. As to the manner in which this test was performed, 100 percent of those which performed the test in their laboratories did so on automated equipment. However, of the 40 carriers surveyed, only 1 had added AMY to its panel test list.

TABLE II

ANALYSIS OF PROVIDER RESPONSES TO OIG QUESTIONNAIRE
BY SITE WHERE TEST PERFORMED AND BY METHOD OF TESTING USED

TEST	PERCENTAGE OF RESPONDING PROVIDERS WHICH PERFORM TEST IN OWN LAB	PERCENTAGE OF THOSE PROVIDERS PERFORMING TEST IN OWN LAB WHICH USE AUTOMATED EQUIPMENT
1. AMYLASE (AMY)	98%	100%
2. CPK	98%	100%
3. TRIGLYCERIDES (TRIG)	98%	100%
4. MAGNESIUM (MAG)	95%	100%
5. GGT	94%	100%
6. HDL	93%	95%
7. THYROXINE (T4)	88%	90%
8. IRON	86%	100%
9. T3 UPTAKE (T3U)	83%	89%
10. IBC	80%	98%
11. AMMONIA (NH3)	69%	98%
12. LIPASE (LIP)	66%	98%
13. ACID PHOSPHATASE (ACP)	55%	94%
14. LACTATE (LAC)	45%	99%
15. CHOLINESTERASE	19%	92%
16. GLUCOSE-6-PD	15%	36%
17. APOLIPOPROTEIN	12%	100%
18. BILE ACIDS	2%	75%

Column 2 of the table shows the percentage of providers which perform the test in their own laboratories compared to all providers which responded to the questionnaire. Those providers which do not perform the test in-house send the test to a reference laboratory.

Column 3 of the table only includes providers which responded that they perform the test in their own laboratories. The percentage is the number of providers which use an automated testing method.

As shown in Tables III and IV, provider responses to the questionnaire were analyzed for each of the eight States individually. For each of the 10 tests, at least 50 percent of providers in each of the 8 States responded that they perform the test in their laboratories. In fact, as shown in Table III, for 7 of the States, at least 73 percent of the providers performed each of the 10 tests in their laboratories. Also, as shown in Table IV, for each of the 10 tests, at least 71 percent of the providers which performed the tests in their laboratories performed the tests using automated equipment.

Using the prior example, Table III shows that the AMY test was performed in 96 percent of responding laboratories in Connecticut. Further, Table IV shows that of those Connecticut providers which perform the AMY test in their laboratories, 100 percent use automated equipment. Similarly, in each of the 8 States, a majority of providers generally performed most of the 10 tests in their laboratories using automated equipment.

TABLE III

ANALYSIS BY STATE FOR CHEMISTRY TESTS PERFORMED IN-HOUSE
BY PROVIDERS RESPONDING TO OIG QUESTIONNAIRE

	AMY	CPK	GGT	IRON	IBC	HDL	MAG	T4	TRIG	T3U
CONNECTICUT	96%	92%	92%	100%	96%	96%	96%	81%	100%	73%
FLORIDA	98%	100%	96%	96%	90%	98%	92%	90%	98%	86%
HAWAII	100%	100%	100%	57%	50%	79%	86%	50%	93%	50%
MINNESOTA	96%	100%	78%	85%	74%	93%	100%	96%	100%	74%
MISSISSIPPI	100%	97%	83%	73%	73%	83%	87%	80%	93%	80%
NEW HAMPSHIRE	100%	100%	100%	84%	74%	100%	100%	89%	100%	89%
PENNSYLVANIA	98%	100%	100%	90%	73%	90%	100%	93%	100%	90%
TEXAS	98%	98%	98%	84%	84%	96%	96%	96%	100%	94%

Responses shown in Table III are the percentage of providers performing the test in their own laboratories as compared to the total number of providers which responded to the questionnaire. Those providers which do not perform the test in-house, send the test to a reference laboratory.

TABLE IV

ANALYSIS BY STATE FOR CHEMISTRY TESTS PERFORMED IN-HOUSE
ON AUTOMATED EQUIPMENT BY PROVIDERS RESPONDING TO OIG QUESTIONNAIRE

	AMY	CPK	GGT	IRON	IBC	HDL	MAG	T4	TRIG	T3U
CONNECTICUT	100%	100%	100%	100%	96%	84%	100%	86%	100%	79%
FLORIDA	100%	100%	100%	100%	100%	98%	100%	91%	100%	91%
HAWAII	100%	100%	100%	100%	100%	100%	100%	71%	100%	86%
MINNESOTA	100%	100%	100%	100%	90%	92%	100%	92%	100%	90%
MISSISSIPPI	100%	100%	100%	100%	100%	96%	100%	100%	100%	100%
NEW HAMPSHIRE	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
PENNSYLVANIA	100%	100%	100%	100%	97%	95%	100%	92%	100%	89%
TEXAS	100%	100%	100%	100%	98%	96%	100%	84%	100%	83%

Responses in Table IV are shown as the percentage of providers performing the test on automated laboratory equipment as compared to the total number of providers which responded that they perform the test in their own laboratories. Those providers which do not perform the test on automated equipment use a manual testing method.

SAVINGS TO MEDICARE

Estimated Savings of $216 Million Annually Could Be Realized
By Including 10 Commonly Performed Tests As Panel Tests Nationwide

We estimate that intermediaries and carriers reimbursed hospital and independent laboratories $311 million in CY 1992 for the 10 commonly performed chemistry tests and the 2 organ panels. Of this $311 million, the Medicare program could save an estimated $216 million annually if the 10 tests were added to HCFA's national list of chemistry panel tests. Our results indicate that the list of panel tests could be expanded to as many as 29 tests. In calculating the estimated savings, we allowed an additional payment of $ .52 per test for each test over 19.

Our estimate of $216 million in Medicare savings is based on a sample of 640 claims. Of the 640 sample claims, 444 claims (221 from hospitals and 223 from independent laboratories) contained a combination of tests that would result in savings if the 10 tests were

bundled as panel tests instead of paid at single test payment rates. The remaining 196 claims would not result in savings. See Attachment I for details on the methodology used to calculate the savings.

SUMMARY

The Medicare program is paying single test payment rates for chemistry tests commonly performed on automated laboratory equipment. The payment of single test rates for chemistry tests that should be paid as a panel results in increased costs to the Medicare program. Single test payment rates were paid because HCFA's guidelines regarding which chemistry tests should be subject to paneling have not been updated to add tests as laboratory technology has advanced. Although HCFA's policy is to have carriers identify tests in their service areas which are appropriate for paneling and add such tests to their panel lists, a survey of carriers found that policy was not followed by some carriers. We believe that HCFA must periodically review and expand the national listing of chemistry tests subject to paneling to ensure consistent application of its bundling policy. Our review identified 10 tests which are appropriate for paneling, but are not on the national list of chemistry tests that should be paneled. Savings to the Medicare program would be about $216 million annually if the 10 tests identified were included as panel tests.

RECOMMENDATIONS

We are recommending that HCFA:

- Update its guidelines by expanding the national list of chemistry panel tests to include the 10 automated chemistry tests identified by our audit. We estimate that HCFA would save about $216 million annually if the 10 chemistry tests recommended in our report are added to the national list of chemistry panel tests. In commenting to our draft report, HCFA did not agree with 2 of the 10 tests recommended for paneling. If HCFA only adds 8 of the 10 tests to the national list of chemistry panel tests, we estimate that savings of $130 million annually would be realized.

- Establish a process whereby advances in technology and laboratory practices are periodically reviewed to further update the national list.

In addition to expanding the national list of panel tests to include the 10 commonly performed tests recommended in this report, upon further review, HCFA may consider other tests noted in this report to be panel tests. (See Other Matters.)

HCFA'S COMMENTS AND OIG'S RESPONSE

In response to our draft report, HCFA officials generally concurred with the two recommendations in the report. In response to the first recommendation, HCFA officials recognized the need to initiate changes in the payment policy for automated panel tests and is in the process of making such changes. However, they did not agree with 2 of the 10 tests

we recommended for addition to the list. It is HCFA's belief that the HDL and IBC tests should be excluded from consideration as prospective automated panel tests because both are two-step process tests. Further, HCFA believes these two tests get preprocessed and are not done along with other panel tests.

In response to the second recommendation, HCFA officials agreed to a periodic review of tests for inclusion in the listing of automated panel tests. (The full text of HCFA's comments is contained in Attachment IV.)

We appreciate HCFA's efforts to add tests to the listing of chemistry panel tests; however, HCFA should reconsider its decision not to add HDL and IBC tests when expanding the list. We agree that both tests involve a two-step process; however, we believe that the degree of automation should be the deciding factor, not the number of steps involved in the test. This would be consistent with HCFA's criteria which requires that chemistry tests commonly performed on automated laboratory equipment be reimbursed at the panel test rate. Our discussions with Center for Disease Control physicians and provider officials disclosed that equipment currently in use in many laboratories is capable of performing both steps of the two-step process (including preprocessing) in an automated manner along with other panel tests. Based on this information, we defined an automated test as stated in the Federal Register (see page 5 of this report) and asked each of the 275 hospital and independent laboratories whether the HDL and IBC tests were performed in an automated manner in their laboratories. The results of the questionnaire are provided in Table II. As shown, HDL and IBC are performed in an automated manner by 95 percent and 98 percent, respectively, of responding providers who perform the test in their laboratories. Accordingly, we recommend that HCFA include these two tests in expanding the national list of chemistry panel tests.

In addition to addressing our two recommendations, HCFA made two separate "Technical Comments" to our draft report. The first comment related to the terminology in our report. In this regard, HCFA officials stated that the word "panel" has been used for the word "profile" in our report. The second of these comments related to physician office laboratory claims. Specifically, HCFA officials were concerned that physician office laboratory claims were excluded from the sample population to identify chemistry tests which should be paid as a panel and, hence, would also be excluded from claims edits.

With regard to HCFA's first technical comment, the OIG recognizes the conflict in terminology between the CPT manual and our report. However, we chose to use the terminology as defined in our report to coincide with that of HCFA's Carriers Manual. Our review was based on 1992 claims and common terminology at that time in HCFA's Carriers Manual referred to automated chemistry tests as "battery or panel" tests and referred to organ or disease panels as "panels/profiles." Since the CPT manual used "profile" and the Carriers Manual used "panel," we chose to define our terminology consistently with the Carriers Manual. Accordingly, we defined our use of these terms in the Background section of this report.

With regard to HCFA's second technical comment, the OIG did not exclude claims from physician office laboratories from its recommendations, and consider our recommendations to apply to physician office laboratory claims. Such claims were excluded from the sample population based on discussions with HCFA officials at the entrance conference, held on September 14, 1993. At that conference, we agreed with HCFA officials that our review should include a review of hospital and independent laboratories sampled by geographic location since HCFA guidelines define panel tests as those available in a carrier's service area and commonly performed on automated equipment (see page 5 of this report for Carriers Manual citation). The contention was that it would be sufficient to conclude that the testing capability was available in a geographic area if it were available at hospital and independent laboratories. Therefore, we agreed with HCFA officials that a review of testing equipment at physician office laboratories was not necessary.

OTHER MATTERS

ADDITIONAL AUTOMATED TESTS

In many of the 8 States, tests other than the 10 cited above were commonly performed on automated laboratory equipment and available in their respective service areas. Even though we did not recommend adding the tests to the national panel test list, HCFA may consider these tests to be panel tests. Our questionnaire included an open-ended question requesting providers to list all chemistry tests performed on automated laboratory equipment. In response to this question, many providers listed automated tests which were not panel tests in the CPT manual and were not included in this review. Details of the information obtained regarding other tests are contained in Attachment III of this report.

RELATED REPORTS AND HCFA'S ACTIONS

This is the fourth in a recent series of reports concerning unbundled chemistry and hematology tests. Two of the prior reports involve compliance issues while the other relates to HCFA policy. The prior reports are summarized below:

-- One of the compliance reports (A-01-93-00520) was issued on April 26, 1994. The review concerned payments by intermediaries to hospitals for unbundled and duplicate charges for chemistry and hematology tests performed as an outpatient service. Officials from HCFA issued comments to our draft report on January 31, 1994. Their comments were incorporated into the final report.

-- The other compliance review (A-01-94-00513) was issued on May 3, 1994. This report contained findings similar to the first report but involved payments by carriers to independent laboratories and physicians. The HCFA agreed to implement our recommendations in their comments issued June 30, 1994.

-- The third report, (A-01-94-00512), was issued on June 17, 1994. It concerns Medicare payment guidelines for laboratory services. This review disclosed that the Medicare program is paying more than necessary for claims containing fewer than three chemistry panel tests and unbundled hematology tests. On September 26, 1994, HCFA issued comments concurring with our recommendations.

ATTACHMENTS

SAMPLE METHODOLOGY

From HCFA's Five Percent Beneficiary Sample Standard Analytic File, clinical laboratory claims for services performed during CY 1992 were extracted. Using computer applications, all claims containing at least 1 of 18 test or 2 organ panel CPT codes were identified. (See Attachment II.)

This extract yielded a total of 254,771 Part B claims paid to hospital laboratories and 563,063 Part B claims paid to independent laboratories after all claims that could not be identified to a hospital or independent laboratory were removed.

Eight States were randomly selected and, through computer applications, the claims that related to providers residing in those eight States were extracted. This extract was conducted by using the two-digit State code which is part of the provider number. This extract resulted in sample populations for each State as follows:

STATE	STATE CODE	HOSPITAL LABORATORY CLAIMS	INDEPENDENT LABORATORY CLAIMS
CONNECTICUT	07	4,167	7,574
FLORIDA	10	12,108	81,062
HAWAII	12	431	617
MINNESOTA	24	4,470	1,699
MISSISSIPPI	25	1,895	8,793
NEW HAMPSHIRE	30	1,184	2,392
PENNSYLVANIA	39	24,781	40,891
TEXAS	45 & 67	11,221	38,171

Eighty claims were randomly selected for each State, 40 hospital and 40 independent laboratory claims. For each of the 640 claims, supporting documentation was obtained from intermediaries and carriers consisting of copies of paper claims or paid claims detail for claims submitted electronically, remittance advices, explanation of Medicare benefits and any other documentation submitted by the provider to support the claim.

We utilized a two-stage ratio estimate to quantify savings for automated chemistry tests which should be paneled as shown in the schedules below.

SAVINGS FROM HOSPITAL LABORATORIES					
STATE	NUMBER OF CLAIMS	NUMBER SAMPLED	EXAMINED VALUE	NO. OF CLAIMS W/ SAVINGS	VALUE OF SAVINGS
CONNECTICUT	4,167	40	$1,169	29	$487
FLORIDA	12,108	40	1,247	30	548
HAWAII	431	40	1,179	37	551
MINNESOTA	4,470	40	1,075	25	432
MISSISSIPPI	1,895	40	1,031	21	219
NEW HAMPSHIRE	1,184	40	1,109	26	390
PENNSYLVANIA	24,781	40	1,147	29	557
TEXAS	11,221	40	1,380	24	486
TOTAL	60,257	320	$9,337	221	$3,670

SAVINGS FROM INDEPENDENT LABORATORIES					
STATE	NUMBER OF CLAIMS	NUMBER SAMPLED	EXAMINED VALUE	NO. OF CLAIMS W/ SAVINGS	VALUE OF SAVINGS
CONNECTICUT	7,574	40	$1,821	32	$1,088
FLORIDA	81,062	40	1,145	34	525
HAWAII	617	40	1,132	17	235
MINNESOTA	1,699	40	1,068	33	441
MISSISSIPPI	8,793	40	1,444	35	687
NEW HAMPSHIRE	2,392	40	1,177	20	253
PENNSYLVANIA	40,891	40	1,135	23	392
TEXAS	38,171	40	1,261	29	597
TOTAL	181,199	320	$10,183	223	$4,218

For hospital laboratories, the results of our statistical sample of Part B payments disclosed that 221 of the 320 claims represented savings for automated chemistry tests that were performed using automated laboratory equipment and, in our opinion, could be included as panel tests. Projecting the results of the statistical sample over the population using standard statistical methods, the Medicare Part B program would have saved an estimated $65 million in payments to hospital laboratories. At the 90 percent confidence level, the precision of this estimate is plus or minus 13.0 percent. Since the claims for this review were extracted from HCFA's five percent sample file, the results were multiplied by 20 to reflect savings nationwide.

For independent laboratories, the results of our statistical sample of Part B payments disclosed that 223 of the 320 claims represented savings for automated chemistry tests that were performed using automated laboratory equipment and, in our opinion, could be included as panel tests. Projecting the results of the statistical sample over the population using standard statistical methods, the Medicare Part B program would have saved an estimated $151 million in payments to independent laboratories. At the 90 percent confidence level, the precision of this estimate is plus or minus 27.4 percent. The results were multiplied by 20 to reflect savings nationwide.

The table below shows that in 272 of the 640 claims sampled, the number of tests billed exceeded the current panel limitation of 19 tests. Therefore, HCFA should consider whether reimbursement for the number of tests in a panel should be expanded above the current level.

SAMPLE CLAIMS WITH MORE THAN 19 TESTS

NUMBER OF TESTS	NUMBER OF HOSPITAL LABORATORY CLAIMS	NUMBER OF INDEPENDENT LABORATORY CLAIMS
20 tests	37	84
21 tests	20	45
22 tests	16	27
23 tests	3	12
24 tests	9	5
25 tests	5	4
26 tests	2	1
29 tests	1	0
35 tests	1	0
Total	94	178

Although significant savings could be realized by adding the 10 chemistry tests to HCFA's list of chemistry tests that should be paid as a panel, the amount of savings will depend on the method used to set panel pricing and the maximum number of tests that can be paid as a panel. Currently, fee schedules only define a separate payment for a panel of 19 or more tests and the 1993 CPT manual lists only 19 panel tests. However, our results indicate that the list of panel tests could be expanded to as many as 29 tests. Based on whether the claim contained 1 of the 10 tests identified and also contained at least 2 other panel tests or at least 1 panel, we quantified the savings that would occur for each of the 444 claims. To calculate the savings on each claim, the payment that would have been made if the tests had been bundled was subtracted from the amount paid by Medicare at single test payment rates. The payment that would have been made if the tests had been bundled was obtained from the fee schedule for the particular intermediary or carrier which processed the claim. For those claims with more than 19 panel tests, the savings calculated were reduced by $.52 per test for each test over 19. In this manner, a savings amount was calculated for each of the 444 claims and used to project the results of the sample to the population.

To recognize in the savings projection that the billing codes may need to be expanded, we allowed an additional payment of $.52 per test for each test over 19. This additional payment of $.52 was derived from the 1992 national limitation fee schedule. This amount represents the average incremental payment for each additional test between a panel of 2 tests and a panel of 19 tests. The fee amount for a panel of 2 tests was $7.96 and for 19 tests was $16.87. To calculate the average incremental price of $.52, we divided the difference in the 2 panel fee amounts, $8.91 ($16.87 - $7.96), by the difference in the number of tests included in the panels, 17 (19 - 2).

To ensure the reasonableness of our estimates, the following assumptions were used:

-- On claims where the carrier's fee schedule allowed a payment for one of the organ panels higher than the national limit, effective in 1993, we used the national limit to calculate the savings. In this manner, any savings that resulted to the Medicare program due to the implementation of a national limit on organ panels were excluded from the savings that would result based on this review.

-- On claims where there were unbundled tests with regard to the 19 panel tests already in the CPT manual, we bundled the tests before calculating the savings. In this manner, the savings realizable to the Medicare program that would result from installation of proper system edits were excluded from our savings.

-- On claims where the billed charges were less than the fee schedule allowed, we used the billed amount (the actual amount paid) to calculate the savings.

-- On claims where tests were denied for payment, such tests were excluded in calculating the savings for this review.

Of the 640 claims reviewed, 196 did not result in savings due to 1 of the following conditions:

(1) Claims with fewer than three panel tests were excluded since current HCFA guidelines state that when three or more tests are performed for a patient on the same day, payment should be based on an automated panel.
(2) Claims with more than one date of service were excluded since we could not determine which tests were performed on the same date.
(3) Claims that did not contain at least 1 of the 10 commonly performed tests were excluded. These claims contained at least 1 of the 18 tests initially included in this review, but did not include any of the 10 commonly performed tests.
(4) Claims for which the intermediary or carrier could not provide sufficient documentation to conclude that the claims were actually paid were excluded.
(5) Claims from providers which resided in a State other than the eight selected were excluded. We identified providers by the provider number on the claim and removed claims submitted by physicians or by independent laboratories that could not be identified. Due to varying carrier methods of assigning provider numbers to independent laboratories and physicians, we did not achieve 100 percent identification of the laboratories during our initial extract.
(6) Claims from providers which were denied for payment under the Medicare program by the intermediary or carrier were excluded.

SAMPLE CLAIMS THAT DID NOT RESULT IN SAVINGS

REASON WHY CLAIMS EXCLUDED FROM SAVINGS	NUMBER OF HOSPITAL LABORATORY CLAIMS	NUMBER OF INDEPENDENT LABORATORY CLAIMS
FEWER THAN 3 PANEL TESTS	61	49
MULTIPLE DATES OF SERVICE	25	0
DID NOT HAVE 1 OF 10 TESTS	11	1
COULD NOT LOCATE DOCUMENTATION	2	3
PROVIDER NOT IN SAMPLED STATE	0	37
CLAIM DENIED FOR PAYMENT	0	7
TOTAL	99	97

TESTS NOW SUBJECT TO PANELING AND ADDITIONAL TESTS AND PANELS IN OIG'S REVIEW

Individual Chemistry Tests Subject to Paneling (1)

1.	Albumin	82040
2.	Bilirubin Total or Direct	82250
3.	Bilirubin Total and Direct	82251
4.	Calcium	82310, 82315, 82320, 82325
5.	Carbon Dioxide	82374
6.	Chlorides	82435
7.	Cholesterol	82465
8.	Creatinine	82565
9.	Glucose	82947
10.	Lactic Dehydrogenase (LDH)	83615, 83610, 83620, 83624
11.	Alkaline Phosphatase	84075, 84078
12.	Phosphorus	84100
13.	Potassium	84132
14.	Total Protein	84155, 84160
15.	Sodium	84295
16.	Transaminase (SGOT)	84450, 84455
17.	Transaminase (SGPT)	84460, 84465
18.	Blood Urea Nitrogen (BUN)	84520
19.	Uric Acid	84550

Additional Tests and Organ Panels Included in OIG Review (2)

1.	Amylase (AMY)	82150
2.	Creatinine phosphokinase (CPK)	82550, 82555
3.	Triglycerides	84478
4.	Magnesium	83735, 83740, 83750
5.	Glutamyltransferase, gamma (GGT)	82977
6.	High Density Lipoprotein (HDL)	83718
7.	Thyroxine (T4)	84435, 84436
8.	Iron	83540, 83545
9.	Triiodothyronine (T3 uptake)	84479
10.	Iron Binding Capacity (IBC)	83550, 83555
11.	Ammonia	82140
12.	Lipase	83690
13.	Acid Phosphatase	84060
14.	Lactate	83605

Additional Tests and Organ Panels Included in OIG's Review (cont.)

15.	Cholinesterase	82480
16.	Glucose-6-PD	82955
17.	Apolipoprotein	82172
18.	Bile Acids	82240
1.	Lipid Panel (cholesterol, HDL, triglycerides)	80061
2.	Thyroid Panel (thyroxine, T3 uptake)	80070

Notes:

(1) These 19 chemistry tests identified by the 29 procedure codes represent chemistry tests currently recognized as panel tests.

(2) These 18 tests and 2 organ panels were identified as automated chemistry tests not currently subject to paneling and were reviewed during this audit to determine whether tests should be added to the panel test list.

ADDITIONAL AUTOMATED TESTS

In addition to expanding the national list of panel tests to include the 10 commonly performed tests recommended for addition to the panel test list, HCFA may also consider other tests when updating the panel test list.

In many of the 8 States, tests other than the 10 cited above were commonly performed on automated equipment and available in the carriers service area. Four such tests are: ammonia (NH3), lipase (LIP), acid phosphatase (ACP), and lactate (LAC). The HCFA may consider these tests in determining additions to the panel test list even though they were not recommended for addition to the panel test list based on our review. (See tables below.)

For example, the ammonia test (NH3) was only performed in-house by 69 percent of responding providers for all eight States and, hence, was not determined by OIG to be a panel test. However, as shown in Table A, the ammonia test is performed in-house by 85 percent of responding providers in Pennsylvania, and, as shown in Table B, of those in Pennsylvania which perform the test in-house, 94 percent use automated laboratory equipment.

TABLE A

ANALYSIS BY STATE FOR CHEMISTRY TESTS PERFORMED IN-HOUSE BY PROVIDERS

	NH3	LIP	ACP	LAC
CONNECTICUT	73%	81%	69%	62%
FLORIDA	64%	70%	62%	46%
HAWAII	57%	64%	36%	36%
MINNESOTA	52%	44%	33%	33%
MISSISSIPPI	77%	57%	57%	50%
NEW HAMPSHIRE	53%	21%	26%	16%
PENNSYLVANIA	85%	83%	66%	71%
TEXAS	73%	73%	57%	33%

TABLE B

ANALYSIS BY STATE FOR CHEMISTRY TESTS PERFORMED IN-HOUSE ON AUTOMATED EQUIPMENT

	NH3	LIP	ACP	LAC
CONNECTICUT	100%	95%	78%	100%
FLORIDA	100%	100%	97%	100%
HAWAII	100%	100%	80%	100%
MINNESOTA	100%	100%	100%	100%
MISSISSIPPI	91%	100%	100%	100%
NEW HAMPSHIRE	100%	100%	100%	100%
PENNSYLVANIA	94%	94%	96%	97%
TEXAS	100%	100%	97%	100%

Responses shown in Table A are the percentage of providers performing the test in their own laboratories as compared to the total number of providers which responded to the questionnaire. Those providers which do not perform the test in-house, send the test to a reference laboratory.

Responses shown in Table B are the percentage of providers performing the test on automated laboratory equipment as compared to the total number of providers which responded that they perform the test in their own laboratories. Those providers which do not perform the test on automated equipment use a manual testing method.

Based on this data, for providers in Pennsylvania, ammonia would be a panel test based on our criteria as established in this report. Upon further review, HCFA may determine that, based on their own criteria, ammonia should be added to the national panel test list. This methodology applies to the other three tests in Tables A and B as well.

In addition to the four tests noted above, other tests were identified during this review as automated by many providers and could be considered for addition to the panel test list. The questionnaire included an open-ended question to the providers asking them to list all chemistry tests that they perform on automated laboratory equipment; 204 providers chose to respond to the open-ended question. Of those which responded, many included automated tests in addition to the 19 panel tests in the CPT manual and 18 tests in this review. These tests were not specifically addressed in the questionnaires and claims for these tests were not extracted for inclusion in this review. As such, these tests were not considered in calculating the savings. For a listing of the specific tests and the number of providers reporting each test, see Table C.

TABLE C

NUMBER OF PROVIDERS WHO LISTED ADDITIONAL AUTOMATED TESTS

TEST	1993 CPT CODE	NUMBER OF PROVIDERS*
TSH	84443	140
FERRITIN	82728	103
HCG	84702	95
PSA	84153	69
CEA	82378	58
FSH	83001	56
PROLACTIN	84146	55
CORTISOL	82533	55
LH	83002	49
B12	82607	45
TOTAL T3	84480	43
FREE T4	84436	39
FOLATE	82746	32

* out of 204 responding providers

It should be noted that two chemistry tests which were reported by many providers as automated tests were thyroid stimulating hormone (TSH) and ferritin. Both of these tests could be considered by HCFA for updates to the list of panel tests, since 140 providers stated that TSH is an automated test and 103 stated that ferritin is an automated test. The TSH test is of particular interest since it is a component of thyroid organ panel II (1993 CPT code 80092). The other component tests of this organ panel, thyroxine and T3 uptake, were determined to be panel tests based on the results of this review. If TSH were also a panel test, the organ panel made up of these three tests would be eliminated for billing purposes, resulting in additional savings to the Medicare program.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Memorandum

Date DEC 2 1994

From Bruce C. Vladeck
Administrator

Subject Office of Inspector General (OIG) Draft Report: "Review of Chemistry Tests Performed on Automated Laboratory Equipment" (A-01-93-00521)

To June Gibbs Brown
Inspector General

We reviewed the above-referenced draft report which identifies chemistry tests which should be paid as a panel, but are not currently required to be paneled by the Health Care Financing Administration.

We generally concur with the two recommendations in the report. Our detailed comments are attached for your review.

Thank you for the opportunity to review and comment on this draft report. Please advise us at your earliest convenience if you would like to discuss our position on the recommendations.

Attachment

Health Care Financing Administration (HCFA) Comments on Office of Inspector General (OIG) Draft Report: Review of Chemistry Tests Performed on Automated Laboratory Equipment (A-01-93-00521)

Recommendation 1

HCFA should update its guidelines by expanding the national list of chemistry panel tests to include the 10 automated chemistry tests identified by our audit.

Response

We concur in general. HCFA recognizes the need to initiate changes in payment policy for automated profile tests, and we are in the process of making such changes. One change will be the addition of tests to our listing of automated profile tests. Any additional tests will be developed in conjunction with the laboratory industry and the Medicare Carrier Medical Directors (CMDs). The discretionary authority of Medicare carriers to add tests to the listing will be removed. There will also be a single listing of automated profile tests to which all Medicare carriers must adhere.

However, we do not concur with 2 of the 10 additional tests which OIG proposed. Based on preliminary discussions with representatives of the laboratory industry and the CMDs, we have a potential additional listing of 20 automated profile tests. The tests proposed by OIG were included among those considered by HCFA, and 2 were rejected. It is our belief that high density lipoprotein and iron binding capacity tests should be excluded from consideration as prospective automated profile tests because both are 2-step process tests. These two tests get preprocessed and are not done along with other panel tests.

Of the other 8 tests cited in tables I and II (tests 11-18), 6 of the tests are included in our additional listing of 20 tests. Lactate and bile acids do not meet our criteria for inclusion as additional automated profile tests. In 1994, the American Medical Association added evocative/suppression testing panels, which include Current Procedural Terminology (CPT) codes 80400 through 80440. These panels also indicate which tests must be performed in order to use these codes.

Recommendation 2

HCFA should establish a process whereby advances in technology and laboratory practices are periodically reviewed to further update the national list.

Response

We agree. On a periodic cycle, a listing of test analytes and the approved equipment for such analytes will be reviewed. Using established criteria, HCFA will recommend new analytes for inclusion in the listing and will submit the recommendations to the CMDs for review and comment.

Technical Comments

Certain terminology used in the report is technically incorrect: the word "panel" has been used for the word "profile" and vice versa. As stated on page 493 of the Physicians' CPT, Fourth Edition (CPT-4), profiles are those tests that can be and are done as groups and combinations on automated multichannel equipment. CPT-4 codes 80002 through 80019 denote the automated profile tests. Organ or disease oriented panels are denoted by CPT-4 codes 80050 through 80092. The tests listed with each panel identify the defined components of the panel. Therefore, the term "panel" should be changed to "profile" wherever it appears in this report, except for references to organ disease panels.

We are concerned that physician office laboratory claims were excluded from the sample population to identify chemistry tests which should be paid as a profile. We understand that certain criteria were used to select the tests to add to the list. However, we want to be sure that any edits on claims also apply to physician office laboratories as well as clinical laboratories. For the week ending September 30, the total number of claims processed for Medicare payment for clinical laboratories was 1,497,880, and the total number of claims processed for physician office laboratories was 1,303,564.