

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

~~Maelson Fraud Abuse Cancer File~~

Maelson Fraud Abuse Cancer File

EXCESSIVE MEDICARE PAYMENTS
FOR PRESCRIPTION DRUGS



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EXECUTIVE SUMMARY

PURPOSE

To compare Medicare allowances for prescription drugs with drug acquisition prices currently available to the physician and supplier communities.

BACKGROUND

Medicare allowances for prescription drugs increased 25 percent from \$1.8 billion in 1995 to \$2.3 billion in 1996. However, the number of services allowed increased only 9 percent between the two years.

Medicare does not pay for over-the-counter or many prescription drugs that are self-administered. However, the program does pay for certain categories of drugs used by Medicare beneficiaries.

On January 1, 1998, Medicare Part B will begin to reimburse covered drugs at 95 percent of the average wholesale price. Currently, Medicare carriers may determine the amounts that Medicare will pay for these drugs based on either the lower of the Estimated Acquisition Cost (EAC) or the national Average Wholesale Price (AWP). The EAC is determined based on surveys of the actual invoice prices paid for the drug. The AWP is reported in *The Red Book* and other pricing publications and databases used by the pharmaceutical industry. Historically, it has been the AWP that carriers have used to develop Medicare reimbursement for prescription drugs.

To determine if average wholesale prices paid by Medicare truly represent wholesale prices available to physicians and prescription drug suppliers, we focused on 22 drug codes representing the largest dollar outlays to the program in 1995. We then compared the Medicare allowances for these drug codes with prices available to the physician and supplier communities.

FINDINGS

Medicare allowances for 22 drugs exceeded actual wholesale prices by \$447 million in 1996.

Medicare and its beneficiaries payments for the 22 drugs would have been reduced by an estimated 29 percent (\$447 million of \$1.5 billion) if actual wholesale prices rather than AWP's were the basis for Medicare reimbursement. Similar savings of \$445 million were also identified for 1995. If the savings percentage for just the 22 drugs was applied to Medicare's allowances for all drugs, the program and its beneficiaries would have saved an estimated \$667 million in 1996.

For more than one-third of the 22 drugs reviewed, Medicare allowed amounts were more than double the actual wholesale prices available to physicians and suppliers.

Medicare allowed between 2 and 10 times the actual average wholesale prices offered by drug wholesalers and group purchasing organizations for 8 of the 22 drugs reviewed. Medicare allowed at least 20 percent more than the actual average wholesale price for over 80 percent of the 22 drugs. For every one of the 22 drugs reviewed, Medicare allowed amounts were more than the actual average wholesale price in both 1995 and 1996. Not only did Medicare pay more than the actual average wholesale price, the program allowed more than the highest average wholesale price for every drug.

There is no consistency among carriers in establishing and updating Medicare drug reimbursement amounts.

Although Medicare's reimbursement methodology for prescription drugs does not provide for different payment rates based on geographical factors, the allowed amounts for individual drug codes varied among the carriers. Medicare guidelines allow carriers to update prescription drug reimbursement on a quarterly basis. However, not only did some carriers update yearly rather than quarterly but carrier allowed amounts for the same drug code differed within a single quarter.

RECOMMENDATIONS

The findings of this report provide evidence that Medicare and its beneficiaries are making excessive payments for prescription drugs. The published AWP's that are currently being used by Medicare-contracted carriers to determine reimbursement bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs.

We believe the information in this report provides further support for a previous recommendation made by the Office of Inspector General. We recommended that HCFA reexamine its Medicare drug reimbursement methodologies, with the goal of reducing payments as appropriate. Beginning in January 1998, Medicare reimbursement for prescription drugs will be 95 percent of average wholesale price. We believe that the 5 percent reduction is not a large enough decrease and that further options to reduce reimbursement should be considered.

We also believe that the variance of Medicare reimbursement for individual drug codes among carriers is inappropriate. The rate at which physicians and suppliers are paid for drugs should not depend on which carrier the providers bill. We, therefore, recommend that HCFA require all carriers to reimburse a uniform allowed amount for each HCFA Common Procedural Coding System (HCPCS) drug code. The HCFA could choose to supply all carriers with a list of average wholesale prices that it has determined represent each drug code. The carriers could then use the uniform prices to calculate payment. The HCFA could also designate one single entity to perform all

necessary calculations to determine reimbursement for each drug code on a quarterly basis. All carriers would then use this standard reimbursement amount.

AGENCY COMMENTS

The HCFA concurred with our recommendations. The HCFA's proposal in the President's 1998 budget that would have required physicians to bill Medicare the actual acquisition cost for drugs was not adopted by Congress. However, the agency states that it will continue to pursue this policy in other appropriate ways.

We support HCFA's continued pursuance of reducing drug payments where appropriate. We do not believe that the reimbursement methodology for prescription drugs recently adopted by Congress will curtail the excessive drug payments we've identified in the Medicare program. In this report we've identified Medicare allowances that were 11 to 900 percent greater than drug prices available to the physician and supplier communities.

To address the issue of uniformity among carriers, HCFA has convened a workgroup to develop an electronic file consisting of the average wholesale prices for drugs covered by Medicare. The agency reports it will distribute this file to Medicare contractors for their use in paying drug claims.

PRESIDENT CLINTON ADDS THREE NEW WEAPONS TO BUILD ON STRONG RECORD OF FIGHTING FRAUD AND ABUSE

(Released at SEIU speech)

Today President Clinton added three new weapons to the anti-fraud arsenal to combat fraud and abuse in the home health industry. The President announced: (1) an immediate moratorium on all new home health providers coming into the Medicare program to allow the Health Care Financing Administration to implement new regulations to prevent fly-by-night providers from entering Medicare; (2) a new renewal process for home health agencies currently in the program to ensure that all Medicare providers have to abide by these tough new regulations; and (3) a doubling of audits that will help weed out bad apple providers. These actions are consistent with recommendations to reduce fraud in home health by the Inspector General at the Department of Health and Human Services following a recent report on fraud in the home health care industry. These new initiatives build on the President's unprecedented record of fighting fraud and abuse in Medicare and Medicaid.

Took Strong Action to Fight Fraud and Abuse Right When He Took Office. The President's first budget closed loopholes in Medicare and Medicaid to crack down on fraud and abuse. In 1993, the Attorney General put fighting fraud and abuse at the top of the Justice Department's agenda. Through increased resources, focused investigative strategies and better coordination among law enforcement, the Justice Department increased the number of health care fraud convictions by 240 percent between FY1993 and FY1996 and we have saved taxpayers more than \$20 billion.

Launched Operation Restore Trust -- a Comprehensive Initiative to Fight Fraud and Abuse in Medicare and Medicaid. Two years ago the Department of Health and Human Services launched Operation Restore Trust, a comprehensive anti-fraud initiative in five key states. Since its inception, Operation Restore Trust has identified \$23 for every one dollar invested; identified more than \$187.5 million in fines, recoveries, settlements, audit disallowances, and civil monetary penalties owed to the Federal Government.

Obtained Additional Resources to Fight Fraud and Abuse When the President Signed Into Law Kassebaum-Kennedy Legislation. In 1996, the President signed the Health Insurance Portability and Protection Act (Kassebaum-Kennedy) into law which, for the first time, created a stable source of funding for fraud control. This legislation is enabling HHS to expand Operation Restore Trust to twelve states.

Passed New Initiatives to Combat Fraud and Waste Proposed by the President in the Balanced Budget Act of 1997. The Balanced Budget Act the President signed into law in August also included important new protections to fight fraud and abuse in Medicare and Medicaid. These new initiatives included:

- requiring providers to give proper identification before enrolling in Medicare;
- implementing new penalties for services offered by providers who have been excluded by Medicare or Medicaid;
- establishing guidelines for the frequency and duration of home health services;
- clarifying the definition of part-time or intermittent nursing care which will clarify the scope of the Medicare benefit and will make it easier to identify inappropriate services;
- establishing a prospective payment system (PPS) for home health services to be implemented in FY 1999, enabling HCFA to stem the excessive flow of home health care dollars;
- clearly defining skilled services so that home health agencies can no longer pad their bills with unnecessary services when a patient simply needs a simple service such as their blood drawn;
- and eliminating periodic interim payments that were made in advance to agencies and not justified until the end of the year.

INTRODUCTION

PURPOSE

To compare Medicare allowances for prescription drugs with drug acquisition prices currently available to the physician and supplier communities.

BACKGROUND

Medicare allowances for prescription drugs increased 25 percent from \$1.8 billion in 1995 to \$2.3 billion in 1996. However, the number of services allowed increased only 9 percent between the two years.

Medicare Coverage and Payment for Prescription Drugs

While Medicare does not pay for over-the-counter or many prescription drugs that are self-administered, it does pay for certain categories of drugs used by Medicare beneficiaries. Under certain circumstances, Medicare Part B covers drugs that are used with durable medical equipment or infusion equipment. Medicare will cover certain drugs used in association with dialysis or organ transplantation. Drugs used for chemotherapy and pain management in cancer treatments are also covered. The program also covers certain types of vaccines such as those for flu and hepatitis B.

Depending on the type of drug, both local carriers and four Durable Medical Equipment Regional Carriers (DMERCs) are responsible for processing claims for drugs covered under Part B of the Medicare program. The carriers are responsible for determining the allowance that Medicare will pay for these drugs.

Carriers base their current allowance rates on the regulations established in 42 Code of Federal Regulation 405.517. According to the regulations, Medicare computes an allowed amount for drugs based on either the lower of the Estimated Acquisition Cost (EAC) or the national Average Wholesale Price (AWP). The allowed amount is the price that Medicare and its beneficiaries pay a drug supplier. The EAC is determined based on surveys of the actual invoice prices paid for the drug. The AWP is determined through *The Red Book* or similar pricing publications and databases used by the pharmaceutical industry. The AWP's are mainly provided to these sources by pharmaceutical manufacturers. If a drug has multiple sources (more than one brand or generic version), the price is based on the lower of the EAC or the median of the national AWP for all generic sources. Historically, carriers have utilized AWP and not estimated acquisition cost to develop Medicare reimbursement for prescription drugs.

Drugs are billed to the Medicare program based on codes developed by the Health Care Financing Administration (HCFA). These codes are developed as part of the HCFA Common Procedure Coding System (HCPCS). The codes define the type of drug and, in most cases, a dosage amount. The codes do not indicate whether a brand

or generic version of the drug was administered; nor do the codes provide information on the manufacturer or distributor of the drug provided.

Change in Medicare Reimbursement for Prescription Drugs

In recent legislation, Congress established reimbursement for prescription drugs at 95 percent of a drug's average wholesale price. This change will be implemented on January 1, 1998.

A different proposal to change the Medicare reimbursement methodology for prescription drugs was included in the President's FY 1998 budget. The proposal provided for the amendment of 42 U.S.C. 1395u(o) to set payment for drugs not otherwise paid on a cost or prospective payment basis. The revision set payment at the lowest of: actual acquisition cost to the provider, AWP, median actual acquisition cost, or an amount otherwise determined under the Code. The actual acquisition cost was defined to include all discounts, rebates, or any other benefit in cash or in kind. This proposal was supported by HCFA but was not the version eventually adopted by Congress.

Related Work by the Office of Inspector General

This report is one of several Office of Inspector General reports concerning Medicare payments for prescription drugs. In 1996, we released a report entitled *Appropriateness of Medicare Prescription Drug Allowances* (OEI-03-96-00420) which compared Medicare drug reimbursement mechanisms with Medicaid payment mechanisms for 17 drugs and found that Medicare could achieve significant savings by adopting reimbursement strategies similar to those used by Medicaid. The OIG has also produced several reports focusing on inhalation drugs paid for by Medicare. In *Medicare Payments for Nebulizer Drugs* (OEI-03-94-00390), we found that Medicaid reimbursed albuterol sulfate and other nebulizer drugs at significantly lower prices than Medicare. In a companion report called *A Comparison of Albuterol Sulfate Prices* (OEI-03-94-00392), we found that many retail and mail-order pharmacies charge customers less for generic albuterol sulfate than Medicare's allowed price. *Suppliers' Acquisition Costs for Albuterol Sulfate* (OEI-03-94-00393) found that Medicare's allowances for albuterol sulfate substantially exceeded suppliers' acquisition costs.

The Office of Inspector General also recently issued a report on acquisition costs of brand name drugs by Medicaid pharmacies. In *Medicaid Pharmacy - Actual Acquisition Costs of Prescription Drug Products for Brand Name Drugs* (A-06-96-00030), the Office of Audit Services estimated that the actual acquisition cost for brand name drugs was 18 percent below AWP.

METHODOLOGY

To determine if average wholesale prices paid by Medicare truly represent wholesale prices available to physicians and prescription drug suppliers, we focused on drug

codes representing the largest dollar outlays to the program in 1995. We then compared the Medicare allowances for these drug codes with prices available to the physician and supplier communities.

We collected from three sources the data needed to compare Medicare allowed amounts to actual wholesale prices. For information on Medicare allowances for prescription drugs, we compiled statistics from HCFA's National Claims History (NCH) File. We then collected Medicare reimbursement rates for specific drugs from contracted carriers. Lastly, we analyzed wholesale prices from drug wholesalers and group purchasing organizations.

Medicare Allowance Data for Prescription Drugs

We decided to review the 30 drug codes with the highest Medicare allowances for 1995. We chose 1995 since the Medicare claims data was 98 percent complete at the commencement of the inspection. To determine the Medicare allowances for prescription drugs in 1995, we compiled a list of HCPCS codes that represent all of the drugs which Medicare reimburses. The drug code list primarily contained HCPCS codes beginning with a J (known as J codes) which represent mainly injectable drugs or drugs used in conjunction with durable medical equipment. Also included in our list of drugs were K codes which usually represent immunosuppressive drugs, Q codes which represent mainly drugs used for End Stage Renal Disease, several A codes that represent drugs used for diagnostic imaging, and immunization or vaccine codes that are represented by a five digit numeric code.

We then retrieved NCH allowance and utilization data using HCFA's Part B Extract and Summary System (BESS). We aggregated the allowances for each code to calculate Medicare's total prescription drug allowance for 1995. We then determined the 30 drug codes with the highest individual allowances for that year.

Using NCH data, we calculated the Medicare allowances for all drugs in 1996. We also determined the 1996 allowances for the 30 drug codes with the highest allowances in 1995. At the time of our inspection, the NCH data for 1996 was 95 percent complete.

Carrier Allowances for Prescription Drugs

We sent requests for carrier drug reimbursement rates to Medicare's 26 fraud information specialists. The fraud information specialists coordinate work among all HCFA contractors in the regions they represent. There are a total of 61 geographical regions that local carriers cover. We received drug allowances from 50 of the 61 areas. We also received responses from two of the four DMERCS.

We requested allowed amounts for prescription drug codes with the highest total allowances in 1995. The allowed amount reflects the dollar reimbursement that Medicare will allow for the specific dosage defined by the HCPCS drug code. We

asked the carriers to provide allowed amounts by quarter for calendar years 1995, 1996, and 1997. However, some carriers provided us with data on a yearly basis and others only for certain quarters.

Some carriers also furnished allowed amounts for both participating and non-participating physicians. Physicians participating in the Medicare program agree to accept Medicare allowed amounts as total reimbursement for their services. Participating physicians receive 5 percent more in Medicare reimbursement for services. In the instances where both participating and non-participating allowed amounts were provided, we used the participating physician allowed amounts. More than three-quarters of physicians across the nation now participate in the Medicare program.

Utilizing the data provided by carriers, we calculated an average Medicare allowed amount for each drug code by year. These allowed amounts were used to compare Medicare reimbursement with drug acquisition costs for physicians and suppliers.

Prescription Drug Costs for Physicians and Suppliers

In order to determine acquisition costs for the top drugs, we reviewed 1995 and 1996 prices offered by wholesale drug companies and group purchasing organizations (GPOs). We obtained pricing lists/catalogs for seven wholesale drug companies and seven group purchasing organizations. Group purchasing organizations provide members with lower cost products by negotiating prices for specific drugs from manufacturers. The member can then purchase drugs at the negotiated price either directly from the manufacturer or a drug wholesaler that agrees to accept the negotiated price. For the GPOs we reviewed, most of the major drug wholesalers accept the GPO contracted price.

The 14 pricing sources we used provided pharmaceutical products mainly to physician practices and specialized or closed pharmacies. Depending on individual State licensing practices, specialized or closed pharmacies normally do not provide retail prescription drug dispensing to walk-in customers. Instead, they often provide prescription drugs for home infusion or inhalation therapy.

After beginning our review of wholesale drug costs, we determined that 2 of the top 30 drugs codes we identified for 1995 could not be used for the inspection. Code J7699 represents not-otherwise-classified inhalation drugs and Code J7190 for Factor VIII (human anti-hemophilic factor) has a dosage requirement that is difficult to determine. Therefore, obtaining wholesale prices for these two codes would not be possible.

For the remaining 28 drug codes identified for our analysis, 17 were used for the treatment of cancer/leukemia, 5 were inhalation drugs, 2 were vaccines, and 2 were used for organ transplantation or valve replacement complications. There was also a drug used for immunodeficiencies and another for severe infections. The majority of

these drugs would most likely be purchased and administered by physicians or other health care practitioners. The inhalation drugs or drugs used for home infusion would most likely be provided by a specialized pharmacy or supplier.

For the 28 drug codes, we collected 1995 and 1996 prices from the 14 drug pricing lists/catalogs. We decided not to present prices for drugs where fewer than two different pricing sources could be identified per year. There were 6 codes that did not meet the two source minimum. These codes were: vaccine codes 90724 and 90732, inhalation codes J7645 and J7660, and codes K0121 and J1245 used for transplants/valve replacements. A list of the HCPCS codes' descriptions and dosages for the final 22 drugs used for our evaluation is provided in Appendix A.

The 22 drug codes represented 10 single-source, 9 multiple-source, and 3 multiple-brand drugs. A single-source drug has only one brand of drug available. A multiple-source drug has both brand and generic forms of the drug available. There were no drug products manufactured in the dosage defined by the HCPCS code for five drugs (J7620, Q0136, J2405, J9181, J9293). We selected all the drugs with higher dosages that met the drug description and applied a conversion factor to achieve prices for the HCPCS-specified dosage. For an additional code (J1561), we found that out of the multitude of prices we could find for the drug only three met the exact dosage requirement. Since the higher dosage products seemed to be the more prevalent way of purchasing this drug, we included them in our analysis.

We searched the 14 price lists for both brand and generic prices during 1995 and 1996. For nine drug codes, we obtained between 5 and 8 separate prices. Eight of the nine were single-source drugs. For another eight codes, we found between 12 and 29 separate prices. We found between 30 and 70 separate prices for the remaining five drug codes.

Calculation of Potential Medicare Savings for Prescription Drugs

To determine the potential savings to Medicare if acquisition costs rather than published AWP's were used for reimbursement, we compared Medicare's allowed amounts to the wholesale prices we collected. To do this, we compiled all the pricing information from the sources reviewed and calculated an average price by year for all 22 codes. We believe that the pricing information supplied by the drug wholesalers and group purchasing organizations provides factual evidence of acquisition costs available to physicians and suppliers.

The average price or average acquisition cost for each drug code was then compared to the average Medicare allowed amount that we calculated from the carrier data. For each drug code, the difference between the average price and the Medicare allowed amount was computed. We then applied this amount to the number of services paid by Medicare for each drug in 1995 and 1996. The resulting dollar amounts were aggregated to determine the total estimated savings to Medicare if acquisition costs rather than AWP had been used to determine reimbursement.

Appendix B provides the average Medicare allowed amounts and actual average wholesale prices computed for the 22 drug codes reviewed. Although we utilized the actual average wholesale price to report savings in the findings section of this report, the appendices also contains the potential savings to Medicare if the lowest and highest wholesale prices found were compared to the Medicare allowed amount.

FINDINGS

MEDICARE ALLOWANCES FOR 22 DRUGS EXCEEDED ACTUAL WHOLESALE PRICES BY \$447 MILLION IN 1996.

Medicare carriers now base prescription drug reimbursement on published average wholesales price of drugs. However, physicians and suppliers are often able to purchase drugs for prices that are much lower than the official AWP's provided by manufacturers.

After reviewing wholesale drug catalogs and group purchasing organizations' prices for the 22 drugs, we estimated that \$447 million would have been saved by Medicare and its beneficiaries if Medicare had based reimbursement on actual wholesale prices rather than published AWP's in 1996. These wholesale prices are available to physicians, specialized pharmacies, and other suppliers. These wholesale prices represent the actual acquisition costs to physicians and suppliers that bill Medicare for these drugs.

Total allowed charges for the 22 drugs would have been reduced by 29 percent (\$447 million of \$1.5 billion) if actual wholesale prices rather than AWP were the basis for Medicare reimbursement. The 22 drugs represented 67 percent of the \$2.3 billion in total Medicare drug allowances for 1996. If the savings percentage for just the 22 drugs was applied to Medicare's reimbursement for all drugs, the program and its beneficiaries would have saved an estimated \$667 million in 1996.

The savings for individual drugs ranged from 13 percent of allowances for three drugs (J9202, Q0136, J9185) to a high of 92 percent for leucovorin calcium (J0640). Almost half of the drugs (10 of 22) had estimated savings greater than 40 percent of allowances. A table provided in Appendix C lists the 1996 allowances and estimated savings for the 22 drugs. The table also lists the percentage of allowance saved for each individual drug if reimbursement had been based on the actual average wholesale prices available for the drug.

Similar savings of \$445 million were identified for 1995.

If Medicare had based reimbursement on actual wholesale costs in 1995, the program and its beneficiaries would have saved an estimated 35 percent in payments for the 22 drugs. This would have amounted to savings of \$445 million on \$1.3 billion in total 1995 program expenditures for these drugs. The \$1.3 billion in expenditures for the 22 drugs represented 70 percent of the \$1.8 billion in Medicare total drug allowances for 1995.

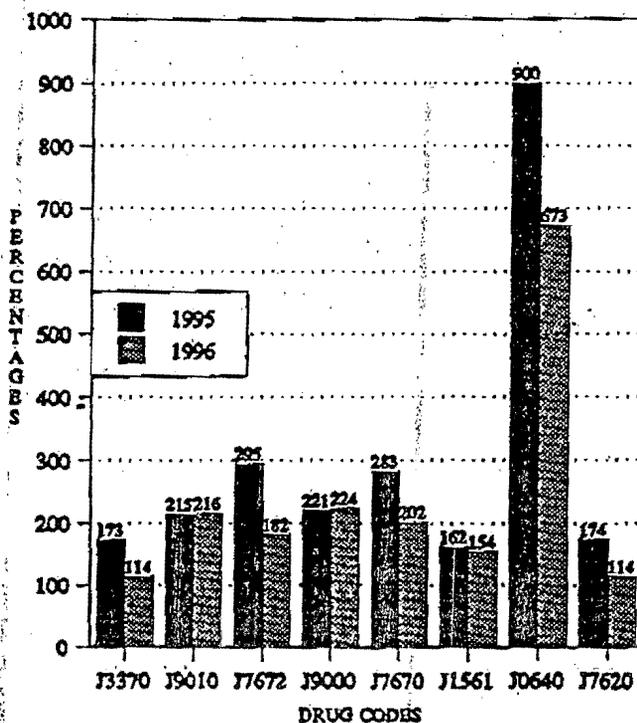
The percentage of allowance saved for individual drugs ranged from 15 percent for carboplatin (J9405) and fludarabine phosphate (J9185) to 95 percent for leucovorin calcium (J0640). Half of the drugs (11 of 22) had estimated savings greater than 40

percent of their 1995 allowances. Individual drug allowances and savings for 1995 are presented in Appendix C.

FOR MORE THAN ONE-THIRD OF THE 22 DRUGS REVIEWED, MEDICARE ALLOWED AMOUNTS WERE MORE THAN DOUBLE THE ACTUAL AVERAGE WHOLESALE PRICE AVAILABLE TO PHYSICIANS AND SUPPLIERS.

Medicare allowed between 2 and 10 times the actual average wholesale prices offered by drug wholesalers and group purchasing organizations for 8 of the 22 drugs reviewed. For one drug, Medicare allowed 900 percent more than the average price available for the drug in 1995 and 673 percent more in 1996. The chart below provides the percentage of the Medicare allowed amount that is greater than the actual average wholesale price for each of the eight drugs.

MEDICARE ALLOWED MORE THAN DOUBLE THE WHOLESALE PRICE FOR EIGHT DRUGS



Medicare allowances were also significantly higher than acquisition costs for the remaining 14 drugs reviewed. Medicare allowed 60 to 95 percent more than the actual average wholesale price for 3 drugs in 1995 and 2 drugs in 1996. Medicare allowed amounts were higher by 20 to 50 percent for 9 drugs in 1995 and 8 drugs in 1996. Reimbursement was between 11 and 18 percent more for the remaining 2 drugs in 1995 and 4 drugs in 1996.

Medicare and its beneficiaries paid at least 20 percent more than the actual average wholesale price for over 80 percent of the 22 drugs. For every one of the 22 drugs reviewed, Medicare allowed more than the average actual price in both 1995 and 1996. Not only did Medicare pay more than the average price, the program allowed more than even the highest wholesale price obtained for every drug. Appendix B provides information on the highest and lowest wholesale price available for each drug in 1995 and 1996.

Based on the differences found between Medicare allowed amounts and actual wholesale prices, it is apparent that the current Medicare reimbursement methodology is based on an significantly inflated AWP statistic which bears little resemblance to actual wholesale prices available in the marketplace.

THERE IS NO CONSISTENCY AMONG CARRIERS IN ESTABLISHING AND UPDATING MEDICARE DRUG REIMBURSEMENT AMOUNTS.

Although Medicare's reimbursement methodology for prescription drugs does not provide for different payment rates based on geographical factors, the allowed amounts for individual drug codes varied among the carriers. Medicare guidelines allow carriers to update prescription drug reimbursement on a quarterly basis. However, not only did some carriers update yearly rather than quarterly but carrier allowed amounts for the same drug code differed within a single quarter.

For some drug codes, the differences in allowed amounts were significant. Carriers' allowed amounts varied even for single-source drugs where the reimbursement rate is based on only one AWP. A carrier reimbursed code J9217 (leuprolide acetate, a single-source drug) at \$496.25 for all of 1995. Another carrier allowed \$412.29 for the first quarter of 1995, \$439.30 for the second and third quarters, and \$477.50 for the fourth. For the first quarter of 1995, providers in one State were receiving 20 percent more in reimbursement than providers billing the same drug code in another State. The second carrier eventually paid \$496.26 for this code in the first quarter of 1996. However, the first carrier increased reimbursement to \$515.63 in the same quarter.

Little uniformity was found among carriers when comparing changes in reimbursement from the first quarter of 1995 to the second quarter of 1997. One carrier's reimbursement for code J9000 (doxorubicin hcl, 10 mg.) increased 128 percent from \$20 to \$45.50. Another carrier's rate for the same code decreased 19 percent from \$48.20 to \$39.10.

Since Medicare does not allow geographical differences to effect drug reimbursement, variations would seem to be caused by carriers' decisions regarding when to update reimbursement, what sources to use for documenting AWP's, and in the case of multiple-source drugs which generic drugs to include in calculating the median statistic.

Date: Wednesday, July 16, 1997

FOR IMMEDIATE RELEASE

Contact: Judy Holtz (202) 619-0893, Ben St. John (202) 619-1343

Medicare Fraud Hotline Improved and Expanded

HHS Secretary Donna E. Shalala today announced that an expanded and improved Hotline for the public to report fraud and abuse in the Medicare and Medicaid programs will go into service nationwide tomorrow as part of a stepped-up campaign against health care fraud, waste and abuse.

"For the past four years, one of our key goals has been to run Medicare and other HHS programs in a more business-like and consumer-oriented way," Secretary Shalala said. "This is an important new step toward better service and better management."

With today's action, each caller to the toll-free Hotline during operating hours will be speaking directly with a Hotline representative, instead of relying on taped messages. "This will boost the potency of the Hotline as an effective weapon in our arsenal to combat fraud and abuse in Medicare, Medicaid, and other department programs," Shalala said.

The toll-free Hotline number is 1-800-HHS-TIPS (1-800-447-8477). The TTY number for the hearing impaired is 1-800-377-4950 and the fax number is 1-800-223-8164. The Hotline is located and staffed within the Office of Inspector General (OIG) and will operate from 8 a.m. to 5:30 p.m., eastern time, Monday through Friday, with both English- and Spanish-speaking representatives available to provide assistance.

"Medicare beneficiaries are the first line of defense in combating fraud and abuse in the health care programs," Inspector General June Gibbs Brown said. "The redesigned Hotline will make it easier and quicker for them to report suspected wrongdoing."

While HHS has had a Hotline since 1979, calls were processed electronically and callers were asked to leave a recorded message until two years ago. In 1995, as part of Operation Restore Trust, a two-year anti-fraud demonstration project undertaken in Florida, Texas, New York, California and Illinois, the Hotline was modified so callers in those states could directly reach a Hotline representative.

During the two-year project, the Hotline received more than 40,000 calls, of which 14,000 were complaints that warranted follow-up action. So far, about 3,200 have resulted in identifying more than \$6.2 million owed the Medicare Trust Fund, according to Inspector General Brown. More than \$4.2 million of that amount was a direct result of complaints from beneficiaries or their relatives. The success of the Hotline during Operation Restore Trust as an entry point for the public to report suspected fraud and abuse provided the basis for the decision by HHS to reformat the Hotline to make it more user friendly and accessible throughout the country.

"As we learned from Operation Restore Trust, our beneficiaries and honest health care providers can be some of our most important allies in fighting fraud," said Bruce Vladeck, administrator of the Health Care Financing Administration, which includes the Medicare and Medicaid program. "In addition, we are taking many other steps to combat fraud and abuse in Medicare and Medicaid, including the Medicare Integrity Program, a system of payment safeguards which identifies and investigates suspicious claims."

During its two-year demonstration phase, Operation Restore Trust identified almost \$188 million owed

to the federal government, a return of more than \$23 for every \$1 spent on the project. As a joint project of the Inspector General, HCFA and HHS' Administration on Aging, Operation Restore Trust used new techniques to target areas Medicare and Medicaid where higher levels of fraud and abuse exist.

Secretary Shalala announced earlier this year that Operation Restore Trust techniques are now being adopted throughout the Medicare system as part of the administration's broadening attack on fraud and abuse in health care. President Clinton announced a number of other new initiatives March 25. Total HHS spending for anti-fraud, waste and abuse efforts in Medicare and Medicaid is \$599 million in FY 1997, up from \$452 million five years earlier.

"The Hotline is a vital part of our efforts to fight waste, fraud and abuse, but more comprehensive efforts are also needed," Inspector General Brown said. "Last March, for example, President Clinton proposed legislation to strengthen the provider enrollment process, bar felons from the Medicare and Medicaid programs, add new sanctions for fraudulent activities, and close loopholes that can allow fraud and abuse to occur. If passed by Congress, these measures would greatly strengthen our ability to combat fraud."

Callers to the Hotline are not required to identify themselves, and if they do not want to speak to a Hotline representative, they can mail or fax their complaint to the Hotline. The mailing address is: Office of Inspector General, Department of Health and Human Services, HHS-TIPS Hot Line, P.O. Box 23489, Washington, D.C. 20026. The E-mail address is htips@os.dhhs.gov.

Note: HHS press releases are available on the World Wide Web at: <http://www.dhhs.gov>.

JUL 19 1997 12:17 PM FROM: DADE, J. P. 9/17

INTRODUCTION

respond to issues raised by the CFO audit &

Mr. Chairman and Members of the Subcommittee, I am very pleased to have this opportunity to discuss with you the findings of the recently completed Fiscal Year 1996 Chief Financial Officers (CFO) audit by the Department of Health and Human Services Office of the Inspector General (OIG), and our plan to improve our performance. HCFA's efforts to strengthen program integrity and contractor activities have had successes. For the past few years, the OIG has performed audits of selected accounts at the Health Care Financing Administration (HCFA). The 1996 audit was the first comprehensive audit of HCFA's financial statements and related systems alerts us to additional improvements that are needed. We are already working to address the concerns noted in the audit. We view this as an extremely valuable opportunity to take a fresh look at our financial management and payment safeguard strategies.

What is the CFO Audit?

has a long record of (list a few successes very briefly)

In order to understand the CFO audit findings it is necessary to describe briefly what the CFO audit is, why it was conducted, the separate components of the audit, and the audit findings.

The CFO Act of 1990 (Public Law 101-576) requires HCFA to prepare financial statements that fully disclose its financial position and the results of operation in a manner consistent with financial reporting standards that have long been employed in the private sector, but which differ significantly from prior Government practice. The objective of the Act was to improve systems of accounting, financial management, and internal controls throughout the Federal Government to help reduce waste and inefficiency, and to provide to Congress complete, reliable, timely, and consistent information on the financial status of the Federal Government. The Act required financial reporting to be on the *accrual* basis of accounting (expenses are recognized when incurred, revenues are recognized when earned) rather than on the *cash* basis of accounting (expenses are recognized when cash is paid and revenues when cash is received). Like other Government programs, Medicare and Medicaid have historically used a cash accounting basis for all budget and reporting purposes. We are currently in the process of making a transition to the accrual basis of accounting.

In 1994, the CFO Act was enhanced by the Government Management and Reform Act requiring Government-wide and Department-wide financial statements. This legislation required the Government Accounting Office (GAO) to audit and render an opinion on the financial statements. The OIG is required to conduct a full-scale audit of HCFA's financial statements, to determine whether the data are fairly represented; whether HCFA has an appropriate internal control structure to assure accurate record-keeping; and whether HCFA has complied with financially pertinent laws and regulations. Including both the Medicare and Medicaid programs, HCFA is among the four largest Federal agencies in terms of outlays, thus highly influencing the opinion on the Government-wide financial statements. This year's audit focuses only on Medicare.

Since this process is new to all of us, it may also be useful to spend a moment on the terminology auditors employ. In public accounting terms, the purpose of an audit is to permit the auditors to issue

determinations were only made through the "look-behind" review of medical documentation. Generally, the improper payments reported by the OIG were not obvious on the face of the claim, and required a thorough "look-behind" review to ascertain accuracy. For example, an incomplete medical history and/or diagnosis may cause the treatment prescribed to be viewed as unnecessary or improper, thus giving the appearance of error or fraud. Because of the significant expense involved in this type of review, the total amount of overpayments might not necessarily be recouped, after the cost of the review is considered.

The Substantive Claims Testing audit findings are extremely disturbing and require HCFA's immediate attention. We have carefully reviewed these deficiencies, and a corrective action plan has been initiated to improve our financial controls. We believe that these corrective actions will provide HCFA with an improved record in the FY 1999 CFO audit.

CURRENT PROGRAM INTEGRITY INITIATIVES

This Administration has already taken action & implemented a number of important initiatives to improve the medical program. Our current payment safeguards are already paying dividends in cost savings. These safeguards comprise a comprehensive system which attempts to identify improper claims before they are paid, to prevent the need to "pay and chase." HCFA's current strategy for program integrity focuses on prevention and early detection. Some of our payment safeguard activities include: Medicare Secondary Payer, medical review (MR), cost report audits, and anti-fraud activities.

The results of our current strategy have been substantial. In FY 1996, total administrative costs for all payment safeguard activities were \$441.1 million, with an associated savings of \$6.2 billion equally distributed between pre-payment and post-payment safeguard activities. This resulted in a cumulative ROI of \$14 dollars saved for every dollar spent on payment safeguard activities (ROI = 14:1).

•For Medicare Secondary Payer, our contractors spent an estimated \$109.3 million, producing associated savings of approximately \$3,308.6 million, resulting in an ROI of \$30 dollars saved for every dollar spent (ROI = 30:1).

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of important initiatives to improve the medical program.
The OIG has been empowered by the President & the Secretary to implement reforms that will help improve this program.

that we contract only with the existing intermediaries and carriers to perform MIP functions, the Government can seek to obtain the best value for its contracted services. Third, MIP permits HCFA to address potential conflict of interest situations. We will require our contractors to report situations which may constitute conflicts of interest, thus minimizing the number of instances where there is either an actual, or an apparent, conflict of interest.

We are currently developing regulations to implement MIP, and we are also working on a scope of work for competitive contracts. As we transition work from one of our contractors, Aetna (which is terminating its Medicare work), we are testing a new contracting relationship in several Western States that will separate out and consolidate payment integrity activities from claims processing. This will give us valuable experience as we prepare to implement MIP.

OUR CORRECTIVE ACTION PLAN *The Administration will take immediate action to respond to the concerns raised by the CFO audit.*

Our preliminary corrective action plan outlines changes and improvements to HCFA's payment safeguard program. We recognize that a level of tension will be created by a program that scrutinizes provider billing and requires the medical community to substantiate billing with medical documentation. At the same time, the National Performance Review is promoting government efficiency, less red tape, and less regulation. These two opposing constraints will be difficult to resolve. Many of the actions listed below will in fact be incorporated into the scope of work of our MIP contractors.

- **INCREASE THE AMOUNT OF PAYMENTS RECOUPED** - Our contractors have denied and are seeking overpayments for the improper claims identified in the audit. We will also instruct contractors to evaluate the providers identified in the report for more extensive review. For example, we will look more closely at the skilled nursing facility that was paid \$15,000 for respiratory and other services that could not be substantiated by medical documentation.

In Fiscal Year (FY) 1997, HCFA will continue working with the contractors to ensure compliance with accounting conventions for proper reconciliation of receivable and payables. These efforts will be supplemented by a review of internal controls in six contractors using the American Institute of Certified Public Accountants' Statement on Auditing Standard Number 70 (SAS-70), *Reports on the Processing of Transactions by Service Organizations*. Other contractors will be asked to review and certify the existence and operation of their internal controls, particularly in the area of financial reporting. Also, HCFA will hold a training session in 1997 to ensure that contractors understand the reconciliation process. We have begun an analysis of the Intermediary, Carrier, and DMERC shared systems as well as the Common Working File to determine how accounting and reporting processes can be incorporated into these systems. A longer-term corrective action planned for FY 1998 and FY 1999 will be to further implement a single integrated accounting system for the tracking and reporting of receivables as part of the broader process of developing the Medicare Transaction System (MTS).

I don't see why we should have this if it means we're not investing our money. There is a billion dollar problem in the for-profit program!

Is this consistent with where we are w/ regards to politics of MTS?

This section should be much broader about all of the efforts on fraud & abuse

● **CONTINUE COLLABORATION WITH PARTNERS**

The President has done

• **Operation Restore Trust:** HCFA will continue working with the OIG, Department of Justice, and State Survey agencies. Past collaborative projects have revealed problems in home health, skilled nursing, and hospice services. These collaborative projects stress review of medical records and have led to heightened provider awareness of the importance of documentation. In 1997, home health agencies and skilled nursing facilities remain a focus of ongoing reviews done in collaboration with HCFA's partners. Currently, we are developing projects for Fiscal Year 1998 that will focus on the areas identified in this audit.

See attached list. all should

The Operation Restore Trust (ORT) project was the first comprehensive effort at collaboration between HCFA and law enforcement agencies. This two-year demonstration project, which was launched by the President in May 1995 and concluded on March 31, 1997, was designed to demonstrate new partnerships and new approaches in finding and minimizing fraud in Medicare and Medicaid. As a demonstration project, ORT targeted four areas of high spending growth: home health agencies, nursing homes, DME suppliers, and hospices. Since more than a third of all Medicare and Medicaid beneficiaries are located in New York, Florida, Illinois, Texas, and California, ORT efforts were targeted at these five states.

*be included
↓
I will
oversee
one paper
in the
included*

Using monies made available through the Fraud and Abuse Control Account, established in HIPAA, we expanded our successful ORT efforts using the State survey agencies to be our "eyes and ears" in the field and to report back to the contractors whether providers are meeting Medicare billing as well as quality requirements. Eighteen States will participate in a total of 26 HIPAA-funded projects, allowing us to survey approximately 300 providers for both certification and reimbursement issues. This collaboration, which is being institutionalized through the Fraud and Abuse Control Program established in HIPAA, establishes a funding stream for health care fraud and abuse activities, and requires DoJ and HHS to establish priorities jointly.

nationwide

● **DEVELOP AND IMPLEMENT A SUBSTANTIVE TESTING PROGRAM:** The OIG will conduct the substantive testing activities and issue a report in FY 97 and FY 98. Pursuant to an agreement with the OIG, HCFA will have a substantive testing program fully operational by October 1, 1998. The program will establish performance measures, employ some level of random review, and include metrics to monitor outcomes. HCFA will replicate the OIG methodology used in the previous audits for the FY '99 audit. This will allow for consistency and comparison with previous audits.

This corrective action plan will re-engineer our medical review workload and strategy. We are in the process of understanding the required resources to implement this plan. As we work through this corrective action plan and implements its components, we will focus our efforts on the random prepayment review of claims and adherence to medical standards for documentation, which validate the medical necessity and reasonableness of the provided services. We will closely evaluate the successes gained through a reduced national error rate and the correct payment of claims, versus any short term impacts on our ROI. Most importantly, we will make every effort possible to ensure that paid claims are appropriately documented.

LRM ID: CBI31

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

Tuesday, July 15, 1997

URGENT

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below
FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT: Collin Brown III
PHONE: (202)395-7562 FAX: (202)395-6148
SUBJECT: HHS Testimony on Chief Financial Officers Audit of Medicare
DEADLINE: 10am Wednesday, July 16, 1997

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: If you have any comments on the attached HHS testimony on the FY 96 audit of Medicare, please let me know by the deadline above.

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- Bruce W. McConnell
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- Katherine Wallman
- Allison H. Eydt

Collin - Here are
comments
Additional
info on POTUS
~~con~~ fraud initiatives on
his way

Robert G. Damus
Christopher C. Jennings
Sarah A. Bianchi
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OMB-LA
James C. Murr
Janet R. Forsgren

LRM ID: CBI31 SUBJECT: HHS Testimony on Chief Financial Officers Audit of Medicare

RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:

- (1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
- (2) sending us a memo or letter

Please include the LRM number shown above, and the subject shown below.

TO: Collin Brown III Phone: 395-7562 Fax: 395-6148
 Office of Management and Budget
 Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ (Date)
 _____ (Name)
 _____ (Agency)
 _____ (Telephone)

The following is the response of our agency to your request for views on the above-captioned subject:

- _____ Concur
- _____ No Objection
- _____ No Comment
- _____ See proposed edits on pages _____
- _____ Other: _____
- _____ FAX RETURN of _____ pages, attached to this response sheet

STATEMENT OF

BRUCE C. VLADECK, PH.D.
ADMINISTRATOR

HEALTH CARE FINANCING ADMINISTRATION

ON

CHIEF FINANCIAL OFFICERS AUDIT, FY 1996

BEFORE

HOUSE COMMITTEE ON WAYS & MEANS
SUBCOMMITTEE ON HEALTH

JULY 17, 1997

an "opinion" on whether the amounts presented on the financial statements are reasonable. Four types of opinions are possible: 1) a "clean" opinion, which means without any deficiencies; 2) a "qualified" opinion, which indicates that there were comments or questions about some areas; 3) a "disclaimer," which gives reasons why an opinion cannot be given; and 4) an "adverse" opinion, which identifies an unacceptable number of deficiencies. In 1996, the OIG offered a disclaimer on HCFA's financial statements.

FINDINGS OF THE CFO AUDIT

In the CFO audit, the OIG raised concerns and issued disclaimers but did not issue an opinion on HCFA's financial statements and systems, which is not an uncommon occurrence for first-year audits. Briefly, the CFO audit findings identified five areas of concern: the actuarial methodology for estimating Medicare accounts payable; the lack of a review of the Supplemental Medical Insurance (SMI) premiums; the substantive testing error rate reflecting improper payments; the records for Medicare accounts receivable; and the retroactive settlement process was not reviewed by the OIG, which caused them to issue a disclaimer. I will discuss each area in the order of the OIG report and later I will outline our corrective action for each area.

For **MEDICARE PAYABLES**, \$36 billion was disclaimed. In other words, the OIG has expressed concern with the methodology used by HCFA's actuaries to estimate payables as well as the lack of a validation process. In FY 1997, OIG contracted with Ernst and Young (E&Y) who provided actuarial auditors to review the Office of the Actuary (OAct) methodology for estimating accounts payable. The E&Y auditors identified several areas where improvements could be made. The current HCFA estimating process is a byproduct of the overall process used by our actuaries to make Trust Fund projections. One of the chief concerns is that it is difficult for the auditors to validate, since the payables represent benefits incurred but not yet paid and some of these payments will be made as much as 2 years later. This creates a data set that is very volatile in the short term. However, it should be noted that the payable estimate is used *only* for financial statement purposes rather than for determining actual payments; our actuaries have traditionally made estimates for other purposes such as the Trustees' Report. HCFA will be working with Ernst & Young to develop a revised process that can be validated.

For **SUPPLEMENTAL MEDICAL INSURANCE or MEDICARE PART B PREMIUMS**, \$80.6 billion was disclaimed. The Social Security Administration (SSA) is responsible for withholding premiums from Social Security checks of Supplemental Medical Insurance (SMI) beneficiaries and transferring these funds to the Part B Trust Fund each month. Since the number is material to HCFA's financial statement, specific auditing of SSA must be done. Because the OIG was not able to audit the SSA process this year, the OIG disclaimed the \$18.9 billion in Part B premiums, as well as the \$61.7 billion Federal matching funds (representing about 75% of Part B costs). The OIG has assured us that the issue is resolved and that this Social Security function will be audited for Fiscal Year 1997.

For **SUBSTANTIVE CLAIMS TESTING**, the OIG found that the majority of our systems and

controls are effective. However, the Substantive Claim Testing audit demonstrated that contractor controls were not adequate to detecting the types of errors identified in the audit, especially in cases where medical necessity existed but the provider had not submitted the required documentation. These findings are not a criticism of HCFA's processes but an indication of the fact that providers are not fulfilling their responsibilities to provide adequate documentation. I will discuss this area in detail immediately following this section.

For **MEDICARE RECEIVABLES**, \$2.7 billion (net) was disclaimed. Much of Medicare's financial record-keeping is done by our contractors, under reporting and accounting rules that did not fully meet requirements of the CFO Act. Without an integrated general ledger and accounts receivable system maintained by the Medicare contractors, the OIG and their contract auditors had difficulty reconciling receivable data, as the contractors use many different systems for the tracking and reporting of receivables. The OIG has found that, contrary to HCFA instructions, many contractors do not reconcile the financial reports with their accounts receivable data reflected on the Provider Overpayment Report (POR), which reflects overpayments resulting from the cost settlement process, and the Physician Supplier Overpayment Report (PSOR), which is used to record most overpayments found by carriers except beneficiary debts and Medicare Secondary Payer debts. Difficulty following the "audit trail" is partly due to some contractors failing to save the documentation required to support the reports.

For the **COST REPORT SETTLEMENT PROCESS**, \$3 billion was disclaimed. The OIG was unable to determine an appropriate methodology to audit the cost settlement process, since this activity involves a fiscal intermediary (FI) audit of cost reports submitted by providers. The FIs conduct desk reviews of all cost reports, and also audit some providers' cost reports, using either a full or limited scope approach. HCFA's position has been to focus the limited scope audits on those providers that have a greater potential for overpayment in order to recover misspent Medicare funds and to provide a sentinel effect on all providers. The OIG has not challenged the quality of the current process and, in fact, has recognized its high cost-savings ratio.

Government audit standards would allow the OIG to rely on HCFA's provider audit process if it were based upon a methodology that would select a representative sample of cost reports to be audited. Presently, it is not possible for the OIG to review a sub-sample of the HCFA audits and develop a statistically valid national error rate, or to ensure that the number reported on the financial statement is "fairly represented" as an accurate reflection of HCFA's liability. HCFA plans to work with the OIG to determine how to make the process auditable, and to implement that process.

FINDINGS OF THE SUBSTANTIVE CLAIMS TESTING AUDIT

Appropriately enough, most of the attention surrounding the CFO audit has focused on Substantive Claims Testing. First of all, the Substantive Claims Testing audit demonstrated that contractor controls were adequate to: 1) ensure beneficiary and provider Medicare eligibility, through actions such as confirmation of the Provider Identification Number; 2) ensure that payment for claims was appropriate based on information submitted; and 3) ensure that services billed were allowable under

Medicare rules and regulations. However, these controls were not effective in detecting the types of errors identified in the audit which originated at the provider level. Medicare, like other insurers, makes payment based on standard claim forms and validates the information submitted only in limited circumstances.

Numerous allegations of high rates of fraud and abuse in health care programs prompted the OIG to review in detail the supporting medical documentation accompanying a sample of claims. We want to note that this is the first time that this type of audit has been done. To the best of our knowledge, no other audit either in the private or public sector has included such a comprehensive review as was done by the OIG in this audit. Since these reviews must be performed by medical personnel from the contractor or PRO, it is costly and time-consuming.

The OIG report on the CFO audit also included an assessment of HCFA's compliance with laws and regulations. The good news is that the CFO audit findings tell us that most of our systems and controls are working. The audit demonstrated that based on the information provided on the claim, payment was correct. However, in a number of cases sufficient medical documentation did not exist to support payment of the service. In fact, 99% of improper payments were detected as a result of the look-behind review and were not the failure of our system or controls.

Of the 5,314 claims audited, roughly 30 percent were found to be incorrect. From this limited sample, the actual dollars in error were approximately \$440 thousand. When these audit findings were extrapolated to the set of all existing claims, the total dollars paid in error were projected to be \$23.2 billion, which is approximately 14 percent of the \$168.6 billion in adjudicated fee-for-service payments reported by HCFA. Eighty-eight percent of incorrect payments, or approximately \$20 billion of the projected dollars in error, occurred in six provider types of services roughly in proportion to total Medicare payments by provider type. The six types of service are: Inpatient Hospital, Physician, Home Health Agency, Outpatient, Skilled Nursing Facility, and Laboratory.

Almost half the errors identified resulted from insufficient or lack of documentation from providers, and one third of the documentation errors were associated with providers who failed to respond to repeated requests from the OIG to submit documentation. This lack of response from the medical community raises some important questions, for which we must find the answers:

- ▶ Why don't providers document the reasons for health care services? And why did one third of them ignore repeated requests for medical documentation?
- ▶ Was the care in fact reasonable, but poorly documented, in which case it would still not be reimbursable by Medicare? Or, did we pay when we should not have? The results of this audit should also be a wake-up call to the medical community, to document as they were trained or be prepared to face the consequences of delayed or denied claims, or other actions.

This is new information for HCFA, and will be key to our future program integrity strategy. It is important to note that the errors were not evident on the face of the claim, meaning that the error

Given these high rates of return, and the fact that we have known for many years that our payment integrity activities were under-funded, we began four years ago to seek additional resources. Thanks to the leadership of this Committee and others in Congress, last year's Health Insurance Portability and Accountability Act contained provisions establishing a stable funding base for the Medicare Integrity Program (MIP). This legislation will help provide us the tools to address the concerns raised in the CFO audit. This audit, however, covers a period prior to the implementation of those new provisions.

In Fiscal Year 1997, which is the first year of Medicare Integrity Program (MIP) funding under HIPAA, the total allocations for program safeguard activities are \$440 million, with projected savings of \$5.3 billion. The 1997 funding amount is not an increase from Fiscal Year 1996 allocations.

HCFA'S CURRENT MEDICAL REVIEW STRATEGY

Because of historically limited resources, our payment safeguard strategy has focussed on areas where we receive the biggest return on investment (ROI). We have streamlined our medical review strategies to increase our ROI. The specific components of HCFA's current Medical Review strategy are:

- **Medical Review of Claims:** Since 1989, administrative funding for medical review and the percentage of claims reviewed has decreased. In 1990, 16% of claims were reviewed with an ROI of 7 to 1. In 1996, the percentage of claims reviewed decreased to 9%, yet the ROI increased to 14 to 1. This performance stems from increased efficiency in the use of resources that we have available to target and correct outstanding problems.
- Currently, about 9% of all 800 million claims, representing about \$70 million, are reviewed each year on either a pre-payment or post-payment basis. Ninety-seven percent of current MR savings come from pre-payment reviews. Whenever possible, review is automated to avoid the costs associated with manual documentation review. Many errors, however, cannot be discovered without documentation or some other form of manual review external to the claims. Documentation is not routinely received with the Medicare claims, but instead is submitted on request.
- **Education:** HCFA's contractors "educate" the provider billing community, including hospitals, physicians, home health agencies, and laboratories. This education covers current payment policy, documentation requirements and coding changes through quarterly bulletins, fraud alerts, seminars, and, more importantly, via local medical review policy. These efforts offer providers information and guidance that enable them to bill correctly.
- **Use of Data and Innovative Technology -** Analysis that leads to the efficient use of resources is critical to our strategy. HCFA and its contractors continue to pursue ways to make available data usable by invoking innovative technology in a number of ways:

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- ▶ HCFA's willingness to fund new technology has driven private industry to develop and market software that our contractors use to profile providers, compare utilization trends and patterns and identify claims review priorities. Some of this software utilizes sophisticated methods such as neural network or fuzzy logic to mine the data for what may not be obvious, thereby enhancing surveillance of fraudulent and abusive practices. HCFA has chosen not to endorse any specific software, but has funded contractors to purchase software so that competition continues and the best state-of-the-art software is produced.
 - ▶ We are also utilizing a dedicated statistical analysis contractor to support DME Regional Carriers, who are responsible for payment safeguards in the area of DME, prosthetics, orthotics and supplies. The statistical analysis contractor works closely with the four DME Regional Carriers and produces ongoing analysis of utilization trends, impact of carrier policy and pre-payment review strategy, and unusual payment patterns at the national and regional levels. As a result of this comprehensive examination of utilization, duplicate billing and other aberrant billing practices have been quickly identified and addressed. The continued success of this concept will shape future contracting strategy.
 - ▶ At the National level, HCFA is developing and continuing to support the HCFA Customer Information System (HCIS), which provides rapid access to national, provider and beneficiary level data.
 - ▶ To prepare for the future, HCFA is also pursuing research and development of long range strategies for data analysis with the Los Alamos National Laboratories that will employ mathematical, computer-based methods to efficiently identify potentially fraudulent or abusive providers and claims on a pre-payment basis.
 - ▶ HCFA has been working with the Lewin Associates to develop a methodology for determining a provider compliance rate that will complement the CFO Audit. This rate will indicate the percentage of providers that comply with Medicare rules and regulations and will include review of the documentation supporting the claim. For Fiscal Year 1998, we will continue to develop this methodology and pilot this prepayment initiative.
- **Current Efforts for Collaboration and Cooperation with Partners - The Operation Restore Trust (ORT) initiatives** required HCFA and its contractors to work closely with the Office of the Inspector General, the Federal Bureau of Investigation, State Medicaid and State Survey Agencies to seek out and stop fraud, waste and abuse. ORT focused on many provider types which were also identified in the CFO audit, for example skilled nursing facilities and home health agencies. The ORT initiative continues and is being expanded to 12 additional States.
- **Medicare Integrity Program (MIP)** - The Medicare Integrity Program was enacted to strengthen the Secretary's ability to deter fraud and abuse in the Medicare program in a number of ways. First, it created a separate and stable long-term funding mechanism for program integrity activities. Second, by permitting the Secretary to use full and open competition rather than requiring

● **INCREASE THE LEVEL OF CLAIMS REVIEW** - If we could look at every claim and the associated documentation, we could achieve the ideal error rate of zero. However, the reality is that the processing of 800 million claims a year makes an 100% review unfeasible, and cost-prohibitive. However, we will work to establish a control system that provides ^{to the extent possible} reasonable but perhaps not absolute assurance that payments are made properly. At a minimum, the cost of reviewing 100% of claims would be a tenfold increase in medical review cost. Increasing the level of review and requiring documentation with initial claim submissions may have a negative impact on our ability to process claims in a timely manner. While the audit findings clearly argue for increased and intensified review levels, determining how to attack this problem is an issue which HCFA must, and will, resolve. Some level of review — between the current 9% and the unattainable 100% --- will most effectively resolve this problem. Finding the right number is our challenge.

The most commonly billed physician services are the evaluation and management codes. In 1992, in conjunction with physician payment reform, the AMA issued new CPT codes for evaluation and management services. The interpretation and use of these new codes were questioned by the medical community and the carriers, resulting in HCFA instructing the carriers to cease review until documentation could be developed. In 1994, the AMA and HCFA jointly released documentation guidelines and embarked on an educational program. With the completion of the first round of provider education seminars, carriers were given discretion to conduct medical review of evaluation and management codes beginning in September 1995.

In Fiscal Year 1998, our Medicare contractors will be instructed to conduct a random prepayment review of evaluation and management claims. A detailed implementation plan, including instructions to our contractors, will be developed in the fourth quarter of Fiscal Year 1997, for implementation in October of 1998. Our plan will include monitoring the effectiveness of the review process and further action will depend on the findings of this random review. We will instruct the contractors to make changes accordingly. Based on analysis of the CFO audit report and analysis of the data, HCFA will expand the scope of services subject to prepayment review of medical documentation.

● **CONTINUE INITIATIVE REQUIRING DOCUMENTATION** - ~~Despite controversy and protest,~~ We will maintain and continue to reinforce the position that those providers who bill the Medicare program are accountable for the documentation to support the payment of a claim. Our position has been, and will continue to be, that the documentation of services is not a burden imposed by the government. We are requiring that providers follow standard medical practice, which requires careful documentation of health services. This requirement includes entities that bill for services that are ordered, referred or otherwise certified by physicians (e.g., clinical labs, skilled nursing facilities). Critical to this initiative is our ability to require diagnostic information on the claim.

● **INCREASE THE NUMBER OF CONTRACTOR MEDICAL DIRECTORS** - Contractor Medical Directors (CMD) are a critical component of all medical review and educational activities. To expand payment safeguard activities in Fiscal Year 1997, we required CMDs at all carriers and regional home health intermediaries. Given the budget for Fiscal Year 1998, we will increase the number of Medical Director Full Time Equivalents (FTEs) by 15 percent for the Fiscal Intermediaries.

*no comments
on 2/3/94*

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Secrets to be implemented

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reforms that will help

improve this program

Given these high rates of return, and the fact that we have known for many years that our payment integrity activities were under-funded, we began four years ago to seek additional resources. Thanks to the leadership of this Committee and others in Congress, last year's Health Insurance Portability and Accountability Act contained provisions establishing a stable funding base for the Medicare Integrity Program (MIP). This legislation will help provide us the tools to address the concerns raised in the CFO audit. This audit, however, covers a period prior to the implementation of those new provisions.

In Fiscal Year 1997, which is the first year of Medicare Integrity Program (MIP) funding under HIPAA, the total allocations for program safeguard activities are \$440 million, with projected savings of \$5.3 billion. The 1997 funding amount is not an increase from Fiscal Year 1996 allocations.

HCFA'S CURRENT MEDICAL REVIEW STRATEGY

Because of historically limited resources, our payment safeguard strategy has focussed on areas where we receive the biggest return on investment (ROI). We have streamlined our medical review strategies to increase our ROI. The specific components of HCFA's current Medical Review strategy are:

- **Medical Review of Claims:** Since 1989, administrative funding for medical review and the percentage of claims reviewed has decreased. In 1990, 16% of claims were reviewed with an ROI of 7 to 1. In 1996, the percentage of claims reviewed decreased to 9%, yet the ROI increased to 14 to 1. This performance stems from increased efficiency in the use of resources that we have available to target and correct outstanding problems.

- ▶ Currently, about 9% of all 800 million claims, representing about \$70 million, are reviewed each year on either a pre-payment or post-payment basis. Ninety-seven percent of current MR savings come from pre-payment reviews. Whenever possible, review is automated to avoid the costs associated with manual documentation review. Many errors, however, cannot be discovered without documentation or some other form of manual review external to the claims. Documentation is not routinely received with the Medicare claims, but instead is submitted on request.

- **Education:** HCFA's contractors "educate" the provider billing community, including hospitals, physicians, home health agencies, and laboratories. This education covers current payment policy, documentation requirements and coding changes through quarterly bulletins, fraud alerts, seminars, and, more importantly, via local medical review policy. These efforts offer providers information and guidance that enable them to bill correctly.

- **Use of Data and Innovative Technology -** Analysis that leads to the efficient use of resources is critical to our strategy. HCFA and its contractors continue to pursue ways to make available data usable by invoking innovative technology in a number of ways:

- ▶ HCFA's willingness to fund new technology has driven private industry to develop and market software that our contractors use to profile providers, compare utilization trends and patterns and identify claims review priorities. Some of this software utilizes sophisticated methods such as neural network or fuzzy logic to mine the data for what may not be obvious, thereby enhancing surveillance of fraudulent and abusive practices. HCFA has chosen not to endorse any specific software, but has funded contractors to purchase software so that competition continues and the best state-of-the-art software is produced.
 - ▶ We are also utilizing a dedicated statistical analysis contractor to support DME Regional Carriers, who are responsible for payment safeguards in the area of DME, prosthetics, orthotics and supplies. The statistical analysis contractor works closely with the four DME Regional Carriers and produces ongoing analysis of utilization trends, impact of carrier policy and pre-payment review strategy, and unusual payment patterns at the national and regional levels. As a result of this comprehensive examination of utilization, duplicate billing and other aberrant billing practices have been quickly identified and addressed. The continued success of this concept will shape future contracting strategy.
 - ▶ At the National level, HCFA is developing and continuing to support the HCFA Customer Information System (HCIS), which provides rapid access to national, provider and beneficiary level data.
 - ▶ To prepare for the future, HCFA is also pursuing research and development of long range strategies for data analysis with the Los Alamos National Laboratories that will employ mathematical, computer-based methods to efficiently identify potentially fraudulent or abusive providers and claims on a pre-payment basis.
 - ▶ HCFA has been working with the Lewin Associates to develop a methodology for determining a provider compliance rate that will complement the CFO Audit. This rate will indicate the percentage of providers that comply with Medicare rules and regulations and will include review of the documentation supporting the claim. For Fiscal Year 1998, we will continue to develop this methodology and pilot this prepayment initiative.
- **Current Efforts for Collaboration and Cooperation with Partners** - The Operation Restore Trust (ORT) initiatives required HCFA and its contractors to work closely with the Office of the Inspector General, the Federal Bureau of Investigation, State Medicaid and State Survey Agencies to seek out and stop fraud, waste and abuse. ORT focused on many provider types which were also identified in the CFO audit, for example skilled nursing facilities and home health agencies. The ORT initiative continues and is being expanded to 12 additional States.
 - **Medicare Integrity Program (MIP)** - The Medicare Integrity Program was enacted to strengthen the Secretary's ability to deter fraud and abuse in the Medicare program in a number of ways. First, it created a separate and stable long-term funding mechanism for program integrity activities. Second, by permitting the Secretary to use full and open competition rather than requiring

that we contract only with the existing intermediaries and carriers to perform MIP functions, the Government can seek to obtain the best value for its contracted services. Third, MIP permits HCFA to address potential conflict of interest situations. We will require our contractors to report situations which may constitute conflicts of interest, thus minimizing the number of instances where there is either an actual, or an apparent, conflict of interest.

We are currently developing regulations to implement MIP, and we are also working on a scope of work for competitive contracts. As we transition work from one of our contractors, Aetna (which is terminating its Medicare work), we are testing a new contracting relationship in several Western States that will separate out and consolidate payment integrity activities from claims processing. This will give us valuable experience as we prepare to implement MIP.

OUR CORRECTIVE ACTION PLAN *The Administration will take immediate action to respond to the concerns raised by the CFO audit.*

Our preliminary corrective action plan outlines changes and improvements to HCFA's payment safeguard program. We recognize that a level of tension will be created by a program that scrutinizes provider billing and requires the medical community to substantiate billing with medical documentation. At the same time, the National Performance Review is promoting government efficiency, less red tape, and less regulation. These two opposing constraints will be difficult to resolve. Many of the actions listed below will in fact be incorporated into the scope of work of our MIP contractors.

- **INCREASE THE AMOUNT OF PAYMENTS RECOUPED** - Our contractors have denied and are seeking overpayments for the improper claims identified in the audit. We will also instruct contractors to evaluate the providers identified in the report for more extensive review. For example, we will look more closely at the skilled nursing facility that was paid \$15,000 for respiratory and other services that could not be substantiated by medical documentation.

In Fiscal Year (FY) 1997, HCFA will continue working with the contractors to ensure compliance with accounting conventions for proper reconciliation of receivable and payables. These efforts will be supplemented by a review of internal controls in six contractors using the American Institute of Certified Public Accountants' Statement on Auditing Standard Number 70 (SAS-70), *Reports on the Processing of Transactions by Service Organizations*. Other contractors will be asked to review and certify the existence and operation of their internal controls, particularly in the area of financial reporting. Also, HCFA will hold a training session in 1997 to ensure that contractors understand the reconciliation process. We have begun an analysis of the Intermediary, Carrier, and DMERC shared systems as well as the Common Working File to determine how accounting and reporting processes can be incorporated into these systems. A longer-term corrective action planned for FY 1998 and FY 1999 will be to further implement a single integrated accounting system for the tracking and reporting of receivables as part of the broader process of developing the Medicare Transaction System (MTS).

I don't think we should invest in more sophisticated auditing. The billions in the payment program.

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● **INCREASE THE LEVEL OF CLAIMS REVIEW** - If we could look at every claim and the associated documentation, we could achieve the ideal error rate of zero. However, the reality is that the processing of 800 million claims a year makes an 100% review unfeasible, and cost-prohibitive. However, we will work to establish a control system that provides ^{to the extent possible} reasonable but perhaps not absolute assurance that payments are made properly. At a minimum, the cost of reviewing 100% of claims would be a tenfold increase in medical review cost. Increasing the level of review and requiring documentation with initial claim submissions may have a negative impact on our ability to process claims in a timely manner. While the audit findings clearly argue for increased and intensified review levels, determining how to attack this problem is an issue which HCFA must, and will, resolve. Some level of review — between the current 9% and the unattainable 100% --- will most effectively resolve this problem. Finding the right number is our challenge.

The most commonly billed physician services are the evaluation and management codes. In 1992, in conjunction with physician payment reform, the AMA issued new CPT codes for evaluation and management services. The interpretation and use of these new codes were questioned by the medical community and the carriers, resulting in HCFA instructing the carriers to cease review until documentation could be developed. In 1994, the AMA and HCFA jointly released documentation guidelines and embarked on an educational program. With the completion of the first round of provider education seminars, carriers were given discretion to conduct medical review of evaluation and management codes beginning in September 1995.

In Fiscal Year 1998, our Medicare contractors will be instructed to conduct a random prepayment review of evaluation and management claims. A detailed implementation plan, including instructions to our contractors, will be developed in the fourth quarter of Fiscal Year 1997, for implementation in October of 1998. Our plan will include monitoring the effectiveness of the review process and further action will depend on the findings of this random review. We will instruct the contractors to make changes accordingly. Based on analysis of the CFO audit report and analysis of the data, HCFA will expand the scope of services subject to prepayment review of medical documentation.

● **CONTINUE INITIATIVE REQUIRING DOCUMENTATION** - ~~Despite controversy and protest,~~ We will maintain and continue to reinforce the position that those providers who bill the Medicare program are accountable for the documentation to support the payment of a claim. Our position has been, and will continue to be, that the documentation of services is not a burden imposed by the government. We are requiring that providers follow standard medical practice, which requires careful documentation of health services. This requirement includes entities that bill for services that are ordered, referred or otherwise certified by physicians (e.g., clinical labs, skilled nursing facilities). Critical to this initiative is our ability to require diagnostic information on the claim.

● **INCREASE THE NUMBER OF CONTRACTOR MEDICAL DIRECTORS** - Contractor Medical Directors (CMD) are a critical component of all medical review and educational activities. To expand payment safeguard activities in Fiscal Year 1997, we required CMDs at all carriers and regional home health intermediaries. Given the budget for Fiscal Year 1998, we will increase the number of Medical Director Full Time Equivalents (FTEs) by 15 percent for the Fiscal Intermediaries.

● **USE SAMPLING TO PROJECT AND COLLECT OVERPAYMENT** - We are working on detailed methodology to develop and enhance cost-effective, yet fair, ways to estimate and collect overpayments to providers. This method involves post-payment review of a statistically valid sample of a provider's claims where results are extrapolated to the entire spectrum of claims. While our carriers have been active in using this approach, the fiscal intermediaries will begin this process when instructions are released later this summer. This methodology is a new tool for fiscal intermediaries that creates stronger deterrents to reduce improper payments.

● **REVIEW INPATIENT HOSPITAL CLAIMS** - Although peer review organizations (PROs) are not conducting random review of individual cases, PROs continue to perform mandatory review of a limited number of cases which include: assistants used in cataract surgery, beneficiary complaints, higher-weighted DRG adjustments, beneficiary requests for immediate review of continued stay notices of noncoverage, concerns identified during project data collection, dumping violations, and referrals from HCFA, OIG, and intermediaries. Work has begun on a system to scan Medicare billings for evidence of unnecessary admissions, which will be supplemented by a narrowly targeted review process to follow up on any leads generated. PROs will use these and other appropriate data to perform surveillance analyses to monitor patterns, trends, and variations in health status and care among Medicare beneficiaries, to identify sentinel events or clusters of events that may indicate less-than-optimal care and to identify, prioritize, and act upon opportunities for improvement. The implementation of the Health Care Quality Improvement Program in 1993 shifted the focus of the PRO program from its emphasis on identifying individual (and often isolated) clinical errors to helping providers and practitioners improve the mainstream of medical care. However, PROs continue to perform mandatory review of a limited number of cases.

● **ENGAGE THE PROVIDER COMMUNITY** - HCFA cannot do this alone. We will continue to seek the help of national organizations and the provider community to take more responsibility for identifying and eliminating widespread fraud and abuse. Although providers have been understandably reluctant to welcome the additional work associated with maintaining and submitting documentation, HCFA is working to facilitate provider documentation, via increased education programs that promote correct coding and documentation. In addition, we have scheduled meetings with professional provider organizations who will be invited to participate in an educational briefing to explain the audit findings and enlist their assistance in addressing the audit's identified problems.

● **CORRECT CODING INITIATIVE** - In 1994, HCFA began the Correct Coding Initiative by awarding a contract to AdminaStar Federal for the development of correct coding policy for all physician CPT codes. This contract resulted in more than eighty thousand automated mandated carrier claims processing edits that bundle services prior to payment. Implemented in 1996, this enhanced pre-payment control and associated software update resulted in savings of about \$217 million in its first year.

In FY 1998, HCFA will continue to develop coding policy and edits with a focus on new CPT codes with the potential for high utilization. This project includes ongoing evaluation of the utilization and associated pairing of CPT codes to ensure that all significant CPT codes are included in this initiative.

● **STRENGTHEN PROVIDER ENROLLMENT SAFEGUARDS** - Due to the often covert nature of illegal acts, a review of documentation provides no assurance that illegality will be detected. HCFA will impose stricter standards, requirements and post application investigation to prevent those illegitimate providers, bent on fraud and abuse, from admission into the Medicare program in the first place. In Fiscal Year 1998, proposed legislation will support this ongoing activity by requiring providers to disclose Employer Identification Numbers (EINs), their Social Security Number (SSN) and prohibiting entry into the Medicare or Medicaid Program to individuals or entities convicted of felonies. We are developing a Notice of Proposed Rule Making (NPRM) that would establish much stricter standards for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Among other things, this NPRM will establish a requirement that each DMEPOS supplier obtain a surety bond as a prerequisite for participation in the Medicare program.

Implementation of the National Provider Identifier (NPI) is also well underway. This initiative will prevent providers from obtaining multiple billing numbers and distributing billing across contractors. One provider identifier will allow HCFA to track and monitor the complete picture of a provider's billing practice. As these NPI numbers gain universal use and acceptance, we will be better able to identify and, more importantly, track abusive providers who have had numerous billing numbers in the past. A Notice of Proposed Rulemaking (NPRM) will be issued shortly on the NPI.

● **IMPROVE USE OF TECHNOLOGY AND DATA** - In FY 1998, HCFA will continue developing and refining the HCFA Customer Information System, which provides rapid access to national provider and beneficiary level data. Proposed additions for FY 1998 designed to enhance identification of abuse include expanded cost data, beneficiary profiles, and detailed HCPCS (HCFA Common Procedure Coding System) and Revenue Center code level analysis.

• In Fiscal Year 1998, HCFA is planning a contract for a **National Statistical Analysis Contractor**. This initiative is modeled after the success of a similar contractor for the Durable Medical Equipment Regional Carriers, which improved contractor identification of abusive and fraudulent providers. The proposed statistical analysis contractor will also have a new capability to combine Part A and Part B claims data to develop comprehensive beneficiary profiles.

• **Los Alamos National Laboratories (LANL)** - As mentioned earlier, LANL is currently investigating new sophisticated statistical methods for HCFA that combine both provider and beneficiary profiles for development of algorithms based on patterns of care that could potentially identify providers at risk for submitting fraudulent and abusive claims. LANL has developed sophisticated computer pattern-recognition programs that quickly spot new types of fraud and abuse, before the claims are paid. LANL methodology will "look at unusual data clusters" and refer suspect claims for our analysis. We expect this research to translate into methods that can be incorporated into our claims processing systems to enhance the efficiency of claims review and proactively identify providers for review.

This section should be much broader about all of the efforts on fraud & abuse

● **CONTINUE COLLABORATION WITH PARTNERS**

The President has done

• **Operation Restore Trust:** HCFA will continue working with the OIG, Department of Justice, and State Survey agencies. Past collaborative projects have revealed problems in home health, skilled nursing, and hospice services. These collaborative projects stress review of medical records and have led to heightened provider awareness of the importance of documentation. In 1997, home health agencies and skilled nursing facilities remain a focus of ongoing reviews done in collaboration with HCFA's partners. Currently, we are developing projects for Fiscal Year 1998 that will focus on the areas identified in this audit.

See after list. all should

The Operation Restore Trust (ORT) project was the first comprehensive effort at collaboration between HCFA and law enforcement agencies. This two-year demonstration project, which was launched by the President in May 1995 and concluded on March 31, 1997, was designed to demonstrate new partnerships and new approaches in finding and minimizing fraud in Medicare and Medicaid. As a demonstration project, ORT targeted four areas of high spending growth: home health agencies, nursing homes, DME suppliers, and hospices. Since more than a third of all Medicare and Medicaid beneficiaries are located in New York, Florida, Illinois, Texas, and California, ORT efforts were targeted at these five states.

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Using monies made available through the Fraud and Abuse Control Account, established in HIPAA, we expanded our successful ORT efforts using the State survey agencies to be our "eyes and ears" in the field and to report back to the contractors whether providers are meeting Medicare billing as well as quality requirements. Eighteen States will participate in a total of 26 HIPAA-funded projects, allowing us to survey approximately 300 providers for both certification and reimbursement issues. This collaboration, which is being institutionalized through the Fraud and Abuse Control Program established in HIPAA, establishes a funding stream for health care fraud and abuse activities, and requires DoJ and HHS to establish priorities jointly.

- **DEVELOP AND IMPLEMENT A SUBSTANTIVE TESTING PROGRAM:** The OIG will conduct the substantive testing activities and issue a report in FY 97 and FY 98. Pursuant to an agreement with the OIG, HCFA will have a substantive testing program fully operational by October 1, 1998. The program will establish performance measures, employ some level of random review, and include metrics to monitor outcomes. HCFA will replicate the OIG methodology used in the previous audits for the FY '99 audit. This will allow for consistency and comparison with previous audits.

This corrective action plan will re-engineer our medical review workload and strategy. We are in the process of understanding the required resources to implement this plan. As we work through this corrective action plan and implements its components, we will focus our efforts on the random prepayment review of claims and adherence to medical standards for documentation, which validate the medical necessity and reasonableness of the provided services. We will closely evaluate the successes gained through a reduced national error rate and the correct payment of claims, versus any short term impacts on our ROI. Most importantly, we will make every effort possible to ensure that paid claims are appropriately documented.

CONCLUSION

The initiatives and corrective actions described in this testimony are designed to improve HCFA's record in the future CFO audits, and, in accordance with GPRA, strengthen our ability to monitor and track Program Integrity efforts. However, the degree to which these efforts will influence the error rate is unclear at this time. As we gain experience, these actions will be monitored, evaluated and adjusted in future years to ensure effectiveness.

The work of this Committee and other Members of Congress has been vital to increasing our ability to protect the integrity of the Medicare program, and to safeguard the interests of our beneficiaries. Most importantly, the lessons and experience gained from our efforts in the past few years will guide us as we put our new legislative and administrative tools to use. By effectively utilizing the solid partnerships between State and Federal agencies, the public, and private health care organizations, we will preserve Medicare and Medicaid for future generations.

Wed, March 26, 1997

Clinton hails Florida crackdown; sends Medicare fraud bill to Congress By Carol Rosenberg Knight-Ridder Newspapers (KRT)

WASHINGTON Hailing South Florida's crackdown on fraud as a model, President Clinton sent Congress a bill Tuesday that makes it tougher for health care providers to plunder from Medicare and Medicaid.

Gov. Lawton Chiles appeared with Clinton and Health and Human Services Secretary Donna Shalala for a briefing on the bill and touted the Sunshine State's success story in punishing doctors and other providers who try to bilk the federal reimbursement system.

"Medicare fraud costs billions of dollars every year," Clinton said. "It amounts to a fraud tax that falls on all of our taxpayers, but most heavily upon our senior citizens."

In a poignant counterpoint, Clinton hobbled into the White House's Roosevelt Room with the help of elbow-high metal crutches as support while he recovers from knee surgery.

"Good morning, everybody," he said as some in the audience looked stunned, but leaped to their feet.

Chiles was there to push the joint Florida-federal effort called "Operation Restore Trust," which the governor said will save nearly \$200 million this year and next through a systematic effort "to weed out fraudulent providers and prevent future abuses."

One special Florida anti-fraud program, for example, studied suspicious billing practices and triggered inspections of some 19 laboratories, Chiles said. It uncovered \$4 million in overpayments to facilities that did not even have the equipment to carry out the procedures for which the government repaid them.

"Florida's success in fighting health care fraud can and should be copied by other states," said Chiles, a longtime Clinton ally. "Mr. President, thank you for your leadership in this war on fraud and abuse."

Clinton said the legislation sent to Congress on Tuesday should send

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a special signal to America's elderly about the nation's commitment to senior citizens.

"Medicare and Medicaid are more than just programs. They are the way we do honor to our parents, the way we strengthen our families, the way we care for our poorest and most vulnerable children," he said. "We cannot tolerate fraud that robs taxpayers even as it harms those of us to whom we owe a great duty."

He also referred to his recent knee injury which occurred while staying at the South Florida home of golfer Greg Norman as proof of his intimate knowledge of America's health care system.

"As all of you know, and as I have given further evidence of here today, I was recently reminded the hard way that our doctors and medical care are the best in the world," Clinton said. "I can vouch for all of the doctors and nurses in the hospital in Florida that cared for me when I was recently injured."

Medicare provides health care coverage to 38 million senior citizens and people living with disabilities. Medicaid is the state-administered program for the poor.

Shalala said her administration's two-year focus on cracking down on Medicare fraud had resulted so far in 69 convictions of people who collected repayments that they were not entitled to and the disqualification of 177 health care providers from Medicare and Medicaid reimbursement "because of their fraudulent actions."

One key aspect of the legislation, she added, would require health care providers to register their Social Security numbers with the federal government, to make it harder for scam artists to go from state to state setting up bogus facilities and collecting government funds.

It would also:

Punish doctors, either criminally or through administrative penalties, who accept kickbacks when they recommend a Medicare and Medicaid patient to a specialist.

Make it more difficult for providers who are rejected from participating in Medicare or Medicaid to reapply for participation later on.

Create new civil monetary penalties for physicians, hospitals and other providers who falsely certify somebody for Medicaid or Medicare who is not eligible.

Close a loophole that has allowed providers to file for bankruptcy as a mechanism for avoiding fraud-related penalties.

Broaden the HHS secretary's portfolio to deny participation in Medicare and Medicaid for any person who has been convicted of a felony.

In one instance cited by Clinton, federal investigators in Florida found a medical equipment supplier previously convicted of securities fraud who was "bilking the Medicare program." He was ordered to pay \$32 million in restitution and is now in jail serving a nine-year sentence.

"People like this should not be allowed to join Medicare in the first place," he said. "With this legislation, it's less likely that they'll be able to do that."

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Stephen Crowley/The New York Times

A Plan to Fight Health Care Fraud

President Clinton yesterday sent Congress a bill with stricter punishment for Medicare and Medicaid fraud. In announcing the plan, Mr. Clinton, recovering from a knee injury, used metal crutches.

The New York Times

WEDNESDAY, MARCH 26, 1997 |

Wed
March 26, 1997

**Feds to Widen Program to Ferret Out Medicare
Fraud (Nashville) By Robert A. Rosenblatt
(c) 1997, Los Angeles Times**

NASHVILLE, Tenn. The federal government plans to more than double the number of states where it is aggressively combating fraud in Medicare and Medicaid, officials said, warning that some criminals active in the drug trade are targeting the health care system.

Operation Restore Trust, which has been running anti-fraud campaigns in five states, will be expanded this year to Ohio, Connecticut, Iowa, Oklahoma, Tennessee and South Carolina, health care officials announced at the annual convention of the American Society on Aging here Monday.

USA Today
Wed, Mar 26, 1997

WASHINGTON

Clinton takes on health-care fraud

President Clinton unveiled legislation Tuesday aimed at preventing unscrupulous doctors, labs and other health-care providers from bilking government programs that aid the elderly and the poor.

Clinton this week is focusing on health initiatives. Today he is to name some of the 32 members of an advisory commission to study the quality of care provided in managed-care organizations. Thursday, he is expected to endorse recommendations on when women in their 40s should seek mammograms.

The legislative proposals Tuesday include stiffer penalties for Medicare and Medicaid fraud by health-care providers, a requirement that providers register their social security numbers with regulators to track offenders and a provision to allow officials to bar convicted felons from participating in Medicare or Medicaid.

Health and Human Services Secretary Donna Shalala estimated the new provisions would save taxpayers \$1 billion over five years.

Clinton, on crutches, said his knee surgery to repair a torn tendon reminded him "the hard way that our doctors and medical care are the best in the world."

Wed
March 26, 1997

To Curb Medicare Fraud

By a WALL STREET JOURNAL Staff Reporter

WASHINGTON — President Clinton proposed cracking down on dishonest health-care providers as part of an initiative to reduce fraud and abuse in the Medicare and Medicaid programs.

Announcing a package of legislative proposals he plans to send Congress next month, the president said, "The best way to prevent fraud is to keep dishonest doctors and other scam artists out of the Medicare system in the first place."

To that end, the bill would allow the program's administrators to bar health-care providers convicted of a felony from participating in the program. In addition, it would require providers to furnish Medicare officials with their Social Security numbers in an effort, said the president, to make it easier "to track and stop fraudsters who try to repeat their crimes by setting up shop under phony names with dummy corporations or in new states."

The legislation also would toughen penalties against those who violate the law and close loopholes that let Medicare and Medicaid providers pocket overpayments from the government by declaring bankruptcy, Mr. Clinton said.

President Announces Steps To Reduce Medicare Fraud

Impact Will Be Minimal, Republicans Say

The Washington Post

WEDNESDAY, MARCH 26, 1997

By Judith Havemann
Washington Post Staff Writer

President Clinton announced efforts yesterday to reduce the amount of fraud in the government's Medicare program, saying efforts to bilk the federal health care system force senior citizens to pay billions of dollars a year in higher premiums.

"The best way to prevent fraud is to keep dishonest doctors and other scam artists out of the Medicare system in the first place," Clinton said at a White House ceremony.

The president said he would send Congress legislation to bar doctors and other health care providers who have been convicted of felonies from participating in the Medicare and Medicaid programs. The bill would make health care business owners supply their Social Security numbers to the government so rip-off artists could be prevented from jumping from state to state. Providers also would be prevented from pocketing overpayments simply by declaring bankruptcy.

"These steps," Clinton said, "will save the American people a great deal of money. They will also buy something that money cannot alone buy—a greater sense of security and peace of mind for our parents, our most vulnerable families, and children."

Republicans applauded the president's efforts, but said the changes amount to only small adjustments in a law passed by Congress last year. They suggested the effort was largely a public relations tactic.

"There is a significant amount of abuse in the program and I'm pleased that the administration is responding to last year's congressional initiative to find it, fight it and fix it," said Rep. Bill Thomas (R-Calif.), chairman of the House Ways and Means subcommittee on health.

Sen. Charles E. Grassley (R-Iowa) said that "while every step in the fight against fraud and waste is important, this proposal will have a minimal impact on maintaining the financial security of Medicare and Medicaid."

Republicans, whom Clinton attacked mercilessly in the last election campaign over their plans to restructure Medicare, are daring Clinton to go first this year in making a proposal to assure the long-term solvency of the program.

Yesterday's announcement, they said, was far from sufficient to deal

with the projected \$60 billion deficit in the Medicare trust fund expected by the year 2002. "The projected shortfall . . . is almost 60 times what this bill hopes to save," Grassley said.

The Kassebaum-Kennedy health care bill approved in 1996 gave Congress authority to expand a five-state anti-fraud initiative nationwide, and increased funds for the Health and Human Services Department to conduct health care investigations. Last month, the department announced plans to increase the number of inspectors and auditors by 20 percent this year and to double the number by the year 2002.

Florida Gov. Lawton Chiles (D), who attended the White House ceremony with Clinton, expects to save \$192.5 million from anti-fraud efforts in his state over the next two years. Florida has had much of its success through "site visits" to health care providers and by making owners of firms that provide home health care, transportation services and equipment such as wheelchairs and post-\$50,000 bonds before they open for business.

Clinton did not mention either proposal in his announcement, but HHS Secretary Donna E. Shalala said "site visits" are included in the president's initiative and the government had the authority under current law to require health care entrepreneurs to post bonds.

HHS spokeswoman Melissa Skotfield disputed Republicans' remarks that the president's proposals were largely public relations. "These are real, measurable proposals that will build on what we have already done to fight waste, fraud and abuse in Medicare and Medicaid," she said.

Clinton's announcement yesterday was the first of several health care events this week. The president today will name most of the members of his Cabinet-level commission on health care quality, sources said, and on Thursday will endorse expected recommendations from a cancer advisory board that women in their forties should get annual mammograms.

FOR MORE INFORMATION

To read a consumer's guide to Medicare, including eligibility requirements, statistics and the full text of Medicare and Medicaid legislation, click on the above symbol on the front page of The Post's Web site at www.washingtonpost.com

File

American Medical Association

Physicians dedicated to the health of America



1101 Vermont Avenue, NW
Washington, DC 20005

*Medicare
fraud? Abuse/
Advise on
opinions*

Date: 7/24/96

From: Rich Deem

To: Nancy Ann-Min

Division of Federal Affairs

Marilyn Yager
Chris Jennings

Phone number: _____

Message: This is being mailed out today.

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Total Pages including cover sheet:

FAX TRANSMISSION SHEET

July 24, 1996

The President of the United States
The White House
Washington, DC 20500

Dear Mr. President:

As health insurance reform legislation moves toward final passage in Congress, the American Medical Association (AMA) and the American Hospital Association (AHA) are writing to alert you to an issue of great importance to physicians and hospitals. The pending legislation devotes an entire title to eliminating fraud and abuse in our health care marketplace. Both the AMA and the AHA support efforts to rid our health care system of these abhorrent practices that drain limited health care resources and threaten quality health care for all Americans.

We firmly believe, however, that physicians and hospitals deserve to be governed by fraud and abuse laws that are clear and provide useful guidance as to what conduct is prohibited. Key provisions such as intent standards and advisory opinions are essential to protect honest physicians and hospitals from what has become an exceedingly complex and vast web of fraud and abuse laws and regulations.

The antikickback laws, for example, are full of overly broad and inexact language. As HHS Inspector General, June Gibbs Brown, recognized in a March 22, 1994 letter to Representative Pete Stark, "the [antikickback] statute is broad and encompasses many arrangements between health care providers, many of which may not be abusive." As a result, a number of physicians and hospitals avoid activities that in many cases would benefit patients, precisely because they fear these activities might be in violation of the antikickback statute.

The variety and complexity of financial relationships in today's health care market make it impossible for physicians and hospitals to depend solely upon statutes and regulations of general applicability. In addition, the regulatory process simply cannot keep pace with developing new and innovative, integrated delivery systems. Without advisory opinions to guide physicians and hospitals, many beneficial arrangements that would provide high quality health care more efficiently will never see the light of day.

Contrary to what many have argued, the advisory opinion process contemplated in the House version of the health insurance reform bill, would not require the Office of the Inspector General (OIG) to make a finding of a provider's intent. Rather, the opinion would be based solely on the factual circumstances presented. A physician or hospital would be required to make an accurate presentation to the OIG of all relevant facts. The opinion would not be valid if significant facts were omitted or changed.

Moreover, an advisory opinion would not shield a physician or provider acting in bad faith. Thus, despite the issuance of an advisory opinion, the OIG would be free to prosecute physicians or hospitals that exhibited an intent to commit fraudulent acts.

Providing physicians and hospitals with guidance on what factual arrangements violate the fraud and abuse laws would not overwhelm the OIG with frivolous requests. More than 11 federal agencies successfully provide similar guidance.

We hope that we have alleviated some of the concerns surrounding the issue of advisory opinions, and we thank you for your consideration of our arguments. If the health care field is to be subjected to new federal criminal and civil penalties, physicians and hospitals must be assured they will be assisted, rather than hampered, in their number one goal of treating patients.

Sincerely,



P. John Seward, MD
Executive Vice President
American Medical Association



Richard J. Davidson
President
American Hospital Association

cc: Leon E. Panetta, Chief of Staff to the President
Donna E. Shalala, Secretary of Health and Human Services
Janet Reno, Attorney General
June Gibbs Brown, HHS Inspector General