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TO: Chris Jennings

ATTN:

FACSIMILE NUMBER: 6-5557

TELEPHONE NUMBER:

FROM: Bill Marshall at (202) 456-6611

COMMENTS:

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U.S. Department of Justice

Associate Deputy Attorney General

Washington, D.C. 20530

Fax Transmission Cover Sheet

To: Bill Marshall, White House Counsel's Office (202) 456-6279

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Date: April 19, 2000

Number of Pages (including Cover Sheet): 4

Message:

Per our conversation.

Note: The information contained in this facsimile should be considered confidential.



State of New York

**OFFICE OF THE ATTORNEY GENERAL
MEDICAID FRAUD CONTROL UNIT**

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PATRICK E. LUPINETTI
Director, Special Projects Division

February 16, 2000

Pharmacy Director
Division of Health Care Financing
6101 Yellowstone Road
Room 259B
Cheyenne, WY 82002

Dear Medicaid Pharmacy Director:

As you may be aware, a current national investigation by State and federal agencies has revealed a pattern of misrepresentations by some drug manufacturers of the average wholesale prices and wholesale acquisition costs of certain of their products. As a result of these misrepresentations, Medicaid and Medicare have substantially overpaid for these drugs and will continue to do so until corrective measures are implemented. To that end, First DataBank, Inc. ("FDB") has been cooperating with representatives of the State Medicaid Fraud Control Units in the development of procedures that will improve the accuracy and validity of the information provided to the States.

We believe we have reached an agreement that will effect immediate and significant reform of the process, as the initial phase of an overall effort to ensure that Medicaid drug prices are based on true information. Indeed, the substance of this proposal has already been outlined to State Pharmacy Directors, particularly at your July 1999 national conference, in a presentation in which Assistant United States Attorney Reed Stephens, HHS-OIG Associate Counsel Mary Riordan, Maryland MFCU Director Carolyn McElroy and most State Pharmacy Directors participated. We consequently write to inform you of the substance of the procedures FDB will adopt and the effect you may anticipate from it, as well as to solicit your comments or suggestions, which should be submitted to the us at the above address by March 6, 2000.

Stated briefly, under the impending change to current procedures, FDB will base the average wholesale prices it reports on market prices, rather than the prices identified by

manufacturers. Additionally, FDB will no longer report a price for a product unless its manufacturer has certified the completeness and accuracy of the pricing information submitted. We are enclosing for your review a copy of the market price survey that will be used initially and a draft letter from FDB enunciating the specific terms of the revised pricing procedure. This revised procedure does not change the existing terms of the company's contract with your state, but merely provides an improved means for FDB to provide more accurate information to the States. More importantly, in view of the Medicaid program's legal obligation to reimburse true provider acquisition costs, such an effort by the States to ensure that payment is based on actual prices is mandatory. Consequently, no current legal commitment or program regulations are being altered. On the contrary, it is the goal of the revised reporting process to ensure compliance with existing laws and contracts. FDB is implementing these changes on a voluntary basis and without any additional charges to the States or their agents during the existing terms of the applicable contracts.

It is also important to note that the drug price misrepresentations that have occurred, and that will be corrected through FDB, relate to only a limited number of medications, generally infusion, inhalation and injectable products. Thus, while total Medicaid expenditures for the drugs in question are quite substantial, the price of most drugs will be unaffected by the revised procedure.

Nonetheless, we anticipate that the more accurate price information will result in a significant reduction in reimbursement for the affected drugs, and you will in all likelihood receive initial complaints or objections about lowered Medicaid payments. Accordingly, we wish to emphasize the following facts:

- 1) The revised First Data reporting process does not involve any changes in statutes, regulations, program rules or contractual terms. Any resulting reduction in prices will be the result of First Data more effectively performing the task it is already required to perform.
- 2) As a result, there is no basis for a contention that any individual state is answerable for diminished Medicaid payments - no provider can rationally criticize a single state agency for a change in pricing when the SSA has taken no action to cause it.
- 3) Since no reduction in payment will occur unless real world pricing justifies it, the revised procedure is not only fair to providers, but an altogether appropriate shift from reliance on false to true information.
- 4) If providers concede that reimbursements exceed acquisition costs but maintain that the surplus is necessary to cover ancillary costs of the drug's administration, e.g., nursing or incidental supply expenses, their argument runs expressly counter to law. Under Medicaid Program requirements, reimbursement is dependent on the acquisition cost of the drugs, not the overhead costs involved in dispensing them.
- 5) Finally, it cannot be overemphasized that in view of the clear evidence we possess that certain current AWP and WAC data is grossly inaccurate for certain drugs, a

modification of existing practices is mandatory. No entity charged with implementation or enforcement of Medicaid program rules can responsibly countenance a reimbursement system that violates the statutory obligation to reimburse provider acquisition costs.

We encourage you to communicate this information to your fiscal intermediaries, so that they will also be prepared for the anticipated changes. Ultimately, it is our intention that continuation of our inquiry will result in fundamental changes regarding the reporting of pharmaceutical prices and a consequent reduction in the cost of drugs to government health care programs. One such change we envision as a necessary component to any negotiated resolution with a manufacturer is the obligation to certify that the prices it reports to First Data reflect true wholesale prices.

Thank you for your attention to this matter, and we look forward to your response. The State Medicaid Fraud Control Units have already made numerous contacts with their corresponding State Pharmacy Directors, and we will undoubtedly continue to solicit information and input from you as our investigation develops

Very truly yours,



Patrick E. Lupinetti

For the NAMFCU Drug Pricing Team:

L. Timothy Terry, Director Nevada MFCU,
President NAMFCU

Kerry O'Brien, Director Maine MFCU

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Attorney General, New York MFCU

cc: State MFCU Directors

6/12/97

Estimate of Improper Medicare Costs Soars

By GEORGE ANDERS

Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON—The federal Medicare program made an estimated \$23 billion in improper payments to medical providers in fiscal 1996, according to a financial audit being prepared by government reviewers.

The new calculation by the inspector general's office of the Department of Health and Human Services represents a

Senate Medicare Plan

The Senate GOP plan to overhaul Medicare would raise the eligibility age to 67 from 65 and would seek slightly deeper cuts in payments to hospitals than the House plan. Article on page A4.

claims filed with the Medicare system. Auditors reportedly found problems with 30% of the claims.

The main recipient of the audit will be the Health Care Financing Administration, which oversees Medicare. A HCFA spokesman said he believes the audit "will be a useful roadmap to protect the Medicare program," and could help reduce flaws in the system. The spokesman said that in recent years, "we've made pretty good progress in improving Medicare integrity on all fronts."

The inspector general's office declined to comment on the audit, noting that the report is still being completed. HCFA is due to get an official draft of the report next month, with an opportunity to attach its own comments before formal publication of the audit later this year.

The audit found billing problems were common throughout Medicare, according to people knowledgeable about the study. Irregularities were especially pervasive in home-health services and skilled nursing facilities, but there weren't any areas that were deemed spotless.

The report is likely to be welcome news for federal fraud investigators, who recently have gained extra funds to pursue health-care cases. The audit may be less-welcome news for medical providers. They are likely to raise questions about whether the study's relatively small size — \$5 million in claims — is enough to justify its extrapolation to the entire Medicare program.

Fraud or Lapses?

Doctors and other providers also are likely to question whether apparent evidence of improper payments is fully justified. At this stage, people involved in drafting the report aren't saying how many of the suspected problem cases reflect underlying fraud and abuse, compared with those that simply may reflect innocent lapses in record-keeping.

The audit is being carried out under the Government Management Reform Act, which calls for rigorous review of government agencies' bookkeeping under generally accepted accounting principles. Under

that act, government auditors have taken new steps to review individual case records, rather than relying on summary data.

Historically, Medicare has delegated much of its claims-processing to private insurance companies, which pay bills for specific parts of the country. These insurers, known as "fiscal intermediaries," have their own fraud-investigation units, as well as statistical screens that look for aberrant billing patterns.

But critics, including Malcolm Sparrow, a fraud expert at Harvard University, have contended that the fiscal-intermediary system focuses mainly on making sure that claims are submitted in a standard fashion, rather than checking whether Medicare is paying for appropriate care.

big jump from traditional estimates of medical-spending irregularities. Policy analysts generally have pegged fraud and abuse at 3% to 10% of overall health spending. The inspector general's report, which hasn't yet been made public, would suggest that improper payments last year amounted to 12% of Medicare's \$194 billion budget.

The audit "verifies what a lot of people at the grass roots have been saying," remarked Charles Grassley, chairman of the Senate Special Committee on Aging. "There's a great deal of suspicion among taxpayers, particularly senior citizens, with regard to overbillings in Medicare," the Iowa Republican added.

Bill-by-Bill Review

People familiar with the audit say it is based on a detailed, bill-by-bill review of about 5,000 Medicare claims filed last year. Investigators visited doctors, hospitals, laboratories and other providers to check whether medical records corroborated

CORRECTIONS & AMPLIFICATIONS

AN ARTICLE in the Florida Journal edition last Wednesday incorrectly stated that Orlando tourism officials' data on out-of-state visitors would indicate demand for 52.4 million room-nights in 1996. A room-night is generally defined in the lodging industry as a room sold no matter how many individuals are in it. The article failed to report that an average of 2.46 individuals stay in a typical room and should have stated the number of room-nights as 21.3 million.

WFA
Let's see...
Consistent
Robertson
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THE WALL STREET JOURNAL
WEDNESDAY, JUNE 11, 1997

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Prescription

Drugs / Justice Dept Investigation File

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EXECUTIVE SUMMARY
ISSUES IN PHARMACY BENEFIT MANAGEMENT
KICKBACKS, FRAUD, AND PATIENT HARM

BACKGROUND: Pharmacy Benefit Management firms (PBMs) provide their customers (health plans, employers, and government agencies) with five basic services with significant benefits to customers and opportunities for expansion of drug benefits for beneficiaries:

- 1) real-time claims processing, reducing administrative costs per transaction
- 2) access to large networks of retail pharmacies, at reduced prices
- 3) control of use of expensive drugs (prior approval, exclusion)
- 4) data about usage, trends, growth areas
- 5) formulary management-maintaining lists of covered drugs

Over time, PBMs have expanded from these services to five other service areas, each with potential to reduce costs and improve benefits:

- 1) drug utilization review, minimizing harmful interactions for patients
- 2) brand to generic substitution, reducing therapy costs
- 3) mail order pharmacies, reducing prices per prescription
- 4) disease management programs, improving patient compliance and outcomes
- 5) solicitation of payments and rebates from manufacturers, some of which are returned to their customers.

PBMs compete with each other on the following bases:

- 1) Price (usually expressed as discount off AWP ("average wholesale price")).
Typical PBM price to customers: AWP-12% plus \$3 dispensing fee, less for mail order.
- 2) payments from manufacturers passed through to customers
- 3) Network retail pharmacy access-convenience for members
- 4) on-time delivery of mail order prescriptions
- 5) brand to generic drug ratios

PBMs make their profits from five primary sources:

- 1) the spread between their price to customers and the price paid to pharmacies.
- 2) the spread between their costs and mail order payments.

- 3) fees from add-on services (utilization review, disease management)
- 4) sales of data about patient, physician utilization to drug information wholesalers
- 5) payments from drug manufacturers

Of these profit areas, by far the most important are payments from drug manufacturers and data sales. (the other profit areas are minimally above break-even). Both manufacturer payments and data sales depend primarily on the number of "covered lives" controlled by the PBM, so that the PBM will "loss lead" on claim processing to get access to covered lives. According to information we have received, some PBMs allegedly also engage in illegal acts to increase their payments from drug manufacturers, and to avoid passing on discounts and rebates to customers or beneficiaries.

WHAT DO SOME PBMS DO THAT IS WRONG?

1. They solicit, accept, and retain payments from manufacturers to influence their discretion about providing the right drug, at the right price, to the right patient, and to influence their advice to health plans..
 - "we can kill your drug"
 - "we control x doctors, and x patients"
 - we agree to use best efforts to cause each health plan "to add all Pfizer Products to the Plan's formulary" and to "cause each Plan to treat each Pfizer product in a favorable manner" (Pfizer vs. PCS).

2. They solicit, accept and retain payments from manufacturers to influence their discretion as an agent for customers and beneficiaries, and do not disclose the payments received.
 - counterdetailing fees
 - information collection fees
 - market share movement payments
 - disease management fees
 - intervention cost participation

3. They make false statements to manufacturers and customers in order to obtain rebates and retain them. (lie-up, lie-down)
 - secret rebate agreements
 - customers and manufacturers not permitted to directly review records of payments, or rebate agreements (must use selected auditors who sign confidentiality agreements)
 - aggregate reports to manufacturers which double-count sales, fail to exclude Medicare/Medicaid.

4. PBMs use professional pharmacists to contact physician offices seeking changes in prescriptions.

These pharmacists do not exercise independent professional judgment in providing their best recommendation to the physician office based upon appropriate professional review of the

patient; rather, they are either paid by the PBM to influence their recommendation, or (if employees) they are given scripts and quotas to "move" market share in the desired direction. Often, they are forbidden from deviating from the scripts, and forbidden from contacting the patient to determine if a switch involves risks or problems for the patient. The scripts often mislead the physician about the coverage for the drugs, and the likelihood of adverse outcomes.

5. The PBM payments to influence pharmacist recommendations, and the quotas for successful switches, result in false statements and false records by pharmacists of physician approval for drug switches.

6. The calls from pharmacists to physician offices results in delivery of products to beneficiaries by mail other than what they ordered, paid for, expected, and need to take to continue their treatment.

7. The "therapeutic interventions" (industry term) by pharmacists to change prescriptions put many patients at risk for adverse outcomes resulting from the change, a risk that PBMs are either aware of and ignore, or fail to follow.

- most "drug switches" involve drugs taken for chronic conditions, by patients taking multiple drugs for multiple medical problems-blood pressure, gastric reflux disease, high cholesterol
- failure to counsel with patients, or even advise them of switch efforts, increases risk of harm
- some patients fail to continue drug regimen after switch because of side effects
- bad reactions to switched drugs
- failure of new drug to control condition
- failure of PBM or doctor to monitor results of change.

8. The "therapeutic interventions" in some cases, result in higher costs to customers or beneficiaries:

- higher priced drugs are the switched-to drugs
- switch is made from product going off patent to newer, patented version
- added costs of monitoring, lab work, dosage adjustment

9. PBMs make payments to other fiduciaries of rebate funds to obtain and retain their patient base:

- "advance rebates"
- asset purchases (e.g., buildings)
- aggregated rebate checks-not passed on to ultimate customer.
- "disease management payments"

POTENTIAL VIOLATIONS

- Anti-Kickback Act, 41 U.S.C. 51
- Mail, Wire and Health Care Fraud 18 U.S.C. 1341, 1345, 1346
- False Claims Act 31 U.S.C. 3729

- Travel Act(interstate travel to commit commercial bribery)
- False Statements 18 U.S.C. 1001
- breach of duty as ERISA fiduciary under 29 U.S.C. 1104

THIS DOCUMENT CONTAINS AN ANALYSIS OF ALLEGATIONS PRESENTED BY VARIOUS PERSONS CONCERNING VARIOUS PBMs. IT DOES NOT DISCLOSE ALLEGATIONS OR CONCLUSIONS RELATING TO ANY PARTICULAR INVESTIGATION OR ANY PARTICULAR PBM.

Managed Care Operations

Table Definitions

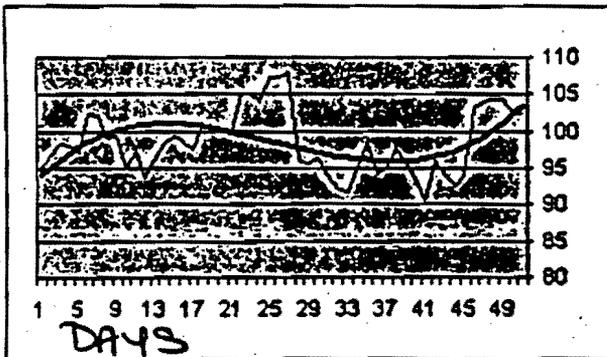
Chart Calculations

Week Ending 08/28/99

Overall Performance Report

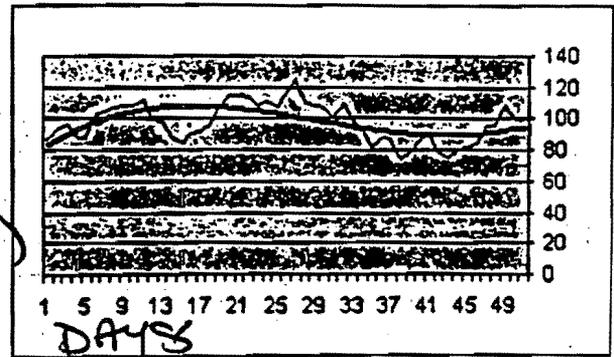
Action	Overall Rate	Personal Plan	Actual % of Plan Rate
Switches:	48%	48%	100%
Contacts:	92%	90%	102%

Contact Rate



06/14/1999 thru 08/28/1999, Days

Switch Rate



06/14/1999 thru 08/28/1999, Days

Percent of Plan
(90%)

Intervention Results by Drug

CLASS FROM NO CALLS

Folost

Service	Drug	Handler	Scrout	Callible	Contact	Contact Rate	Switches	Switch Rate	Plan Switch Rate
MATL	ACCOLATE	2	1	2	1	50	1	50	50
MATL	ALTACE	1	1	1	1	100	1	100	52
MATL	AVAPRO	2	1	2	2	100	1	100	65
MATL	CAPOTEN	1	1	1	1	100	1	100	42
MATL	LESQOL	1	1	1	1	100	1	100	50
MATL	LIPITOR	21	6	15	13	86%	3	72	22
MATL	MEVACOR	1	1	1	1	100	1	100	62
MATL	MONORIL	1	1	1	1	100	1	100	55
MATL	BRAYACHOL	4	1	3	3	100	1	100	45
MATL	ZESTORETC	1	1	1	1	100	1	100	79
MATL	ZESTRIL	2	2	2	2	100	2	100	78
MATL	ADALAT	1	1	1	1	100	1	100	66
MATL	AEROBIO	2	2	2	2	100	2	100	53
MATL	BECONASE	1	1	1	1	100	1	100	73
MATL	CARDENE SR	2	2	2	2	100	1	100	25
MATL	ESTROGENS	1	1	1	1	100	1	100	67
MATL	INSULIN SYRINGE	3	1	2	2	100	2	100	67
MATL	NASAL STEROIDS	1	1	1	1	100	1	100	75
MATL	ORAL CONTRACEPT	3	1	3	3	100	2	66	60
MATL	OTHER TIER 2	10	1	10	9	90	5	55	63
MATL	BRAYACHOL	1	1	1	1	100	1	100	100
MATL	PROCARDIA XL	7	1	6	6	100	1	100	84
MATL	SULAR	1	1	1	1	100	1	100	40
MATL	KLONOPIN	2	1	2	1	50	1	50	58
MATL	OTHER TIER 3	5	1	5	4	80	3	75	73
RETATL	ARTHRONEX	25	8	19	19	100	10	57	48
RETATL	AVAPRO	1	1	1	1	100	1	100	66
RETATL	LIPITOR	2	2	2	2	100	1	100	22
RETATL	PREVACID	1	1	1	1	100	1	100	58
RETATL	VANCENASE	1	1	1	1	100	1	100	70
TOTALS		107	37	90	83	82%	40	48%	

30 August 1999 Managed Care Operations

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Service	Drug	Handled	Smart	Call Mar	Compass	Smart	Smart	Smart	Smart
MAIL	1 ACCOLATE	1	1	1	1	1	1	1	52
MAIL	1 ALFACE	3	3	3	3	100	1	1	52
MAIL	1 AVAPRO	2	2	2	2	100	1	1	55
MAIL	1 LIBTOR	12	3	2	3	53	2	5	22
MAIL	1 OTHER TIER 1	1	1	1	1	1	1	1	50
MAIL	1 PRAVACHOL	7	1	6	6	100	1	16	45
MAIL	2 AEROBID	4	1	3	3	100	1	1	53
MAIL	2 BECONASE	2	2	2	2	100	2	1	73
MAIL	2 CARDENE SR	1	1	1	1	100	1	1	25
MAIL	2 OTHER TIER 2	20	1	19	16	84	7	43	63
MAIL	2 PREVACID	3	3	3	3	66	3	50	60
MAIL	2 PROCARDIA XL	6	6	6	6	60	3	33	34
MAIL	2 SULAR	2	2	2	2	100	1	5	40
MAIL	2 TIAZAG	3	3	3	3	100	2	3	53
MAIL	2 VANCENASE	1	1	1	1	100	1	1	70
MAIL	3 CORGARD	1	1	1	1	100	1	1	60
MAIL	3 IMURAN	1	1	1	1	100	1	1	64
MAIL	3 LOZOL	1	1	1	1	100	1	1	62
MAIL	3 OTHER TIER 3	3	3	3	3	100	2	66	78
MAIL	3 TENORMIN	2	2	2	2	100	1	1	65
RETAIL	2 VANCENASE	1	1	1	1	1	1	1	70
	1 TOTALS	77	3	69	60	2565	25	416	

23 August 1999 Managed Care Operations

These materials are the confidential property of [redacted] and are intended for the internal use of authorized employees only. These materials may not be duplicated or distributed without authorization.

A Recent Example: 12 Weeks of Performance Drug Program Opportunities by State

	#Stores w/ Opportunities	Completed Interventions
AK	23	10%
AL	692	14%
AR	252	15%
AZ	359	19%
CA	2196	32%
CO	432	16%
CT	433	22%
DC	80	8%
DE	113	16%
FL	1648	22%
GA	1233	18%
HI	5	33%
IA	360	18%
ID	113	14%
IL	1118	19%
IN	764	15%
KS	313	19%
KY	534	25%

	#Stores w/ Opportunities	Completed Interventions
LA	489	25%
MA	584	15%
MD	764	18%
ME	168	11%
MI	1167	26%
MN	432	26%
MO	580	28%
MS	438	8%
MT	75	19%
NC	1223	11%
ND	36	20%
NE	136	14%
NH	190	27%
NJ	1061	18%
NM	121	19%
NV	187	19%
NY	1827	17%

	#Stores w/ Opportunities	Completed Interventions
OH	1465	23%
OK	457	18%
OR	294	21%
PA	1631	21%
RI	81	25%
SC	617	12%
SD	90	13%
TN	680	21%
TX	2018	23%
UT	227	22%
VA	908	15%
VT	53	26%
WA	484	31%
WI	383	28%
WV	318	17%
WY	50	17%
Totals:	29842	19%



FAX COVER SHEET
OFFICE OF LEGISLATION

*fraud & abuse
papers for 11/18.*

Number of Pages: 6

Date: _____

To: Chris Jennings / Divorah Adler	From: Bonnie Washington / Marcy Oppenheimer
Fax: _____	Fax: <u>202-690-8168 or 205-5157</u>
Phone: _____	Phone: _____

REMARKS: _____

HEALTH CARE FINANCING ADMINISTRATION
200 Independence Ave., SW
Room 341-H, Humphrey Building
Washington, DC 20201

Medicare Fraud File

use of authority
Exhibits kept but to print paper
Good for some notes

November 16, 1998

HEALTH CARE FINANCING ADMINISTRATION
Descriptions of FY 2000 Fraud and Abuse Legislative Proposals

PROPOSALS ALREADY SUBMITTED TO OMB

o Authorize a Demonstration of Independent Home Health Case Management (HCFA 2000/05)

Cost or save?
Can measure

As authorized by the Balanced Budget Act of 1997 (BBA), HCFA is currently developing a home health prospective payment system (PPS) that will include adjustments based upon the beneficiary's health status and ability to perform activities of daily living. Under current rules, the home health provider would be responsible for performing this assessment of the beneficiary, leaving room for providers to overstate the needs of beneficiaries in order to inflate payments. We propose to request general demonstration authority to charge an independent home health case manager (HHCM) with the task of performing home health eligibility determinations, initial assessments, and reassessments of beneficiaries who may qualify for home health services. The HHCM would also be responsible for plan of care follow-up, assuring ongoing quality care. Only home health agencies in the designated demonstration areas would be required to participate in the demonstration. HCFA would require the care managers to be registered nurses. The HHCM would be prohibited from having any financial relationship with any Medicare provider and would be paid on a fee schedule.

o Allow Home Health Agencies to Secure Only One Bond for Both Medicare and Medicaid (HCFA 2000/06)

Fee, but no sure cost?



BBA requires home health agencies to obtain a surety bond of at least \$50,000, and requires that agencies participating in both Medicare and Medicaid obtain a bond for each program. This proposal would allow agencies to obtain a single bond, naming both HCFA and the Medicaid state agency as dual obligees. This proposal would keep the cost of surety bonding to a minimum while preserving the benefits of the bonding requirement. HCFA has already issued program instructions that allow home health agencies with combined Medicare/Medicaid reimbursements of \$334,000 or less to purchase a single bond for both programs, in response to concerns that small agencies were having difficulty obtaining two bonds. This proposal would provide a specific statutory basis for this rule and expand it to include all home health agencies.

o Provide 75% Federal Financial Participation for State Agency Administrative Costs Related to Fraud and Abuse (HCFA 2000/08)

Currently, states receive rates of federal financial participation (FFP) that vary depending on the activity -- for example, states receive 75% FFP for their Medicaid Fraud Control Units (MFCUs) and for automated claims processing systems (MMIS), but 50% for most administrative activities.

Cost or Service?
 ZERO
 Costs +
 ✓
 2

Many of the new programs and services that states use to identify fraud and waste are outside the definition of MMIS, and are used prior to referral to a MFCU, and therefore do not now qualify for 75% FFP. This proposal would raise the FFP for these programs and services, encouraging states to bolster their anti-fraud activities.

o Terminate Medicare Benefits of Incarcerated Felons (HCFA 2000/32)

Push
 Cost shift
 X

Currently, incarcerated felons are entitled to Medicare benefits, though they lose entitlement to Social Security benefits. Prisoners are entitled to Medicare benefits when the prison health care system imposes cost sharing on the prisoner. This proposal would require the state or federal prison system to bear the cost of health care for incarcerated felons. It would also prevent felons from selling their Medicare numbers, thereby serving to avert both fraud and cost-shifting.

1999 PROPOSALS SOON TO BE RE-SUBMITTED TO OMB

MEDICARE

o Reduce Misuse of Partial Hospitalization Services by CMHCs (HCFA 99/46)*, **

These two proposals would prohibit providers from furnishing partial hospitalization services in a beneficiary's home or in an inpatient or residential setting. They would also authorize the Secretary to set additional standards or requirements for services furnished by community mental health centers (CMHCs). Partial hospitalization is a very narrow benefit intended only for persons in acute psychiatric distress who, but for these intensive services, would likely be hospitalized. However, the benefit has been frequently abused. These proposals would reduce the abuse of the partial hospitalization benefit and improve the Medicare program's ability to screen out unqualified CMHC providers.

§ 133 mhc or 5 yr

o Create Civil Monetary Penalties for False Certification of the Need for Care (HCFA 99/31) *, **

This proposal would create new civil monetary penalties for false certification of the need for partial hospitalization and hospice services when the certifying physician knows that the beneficiary does not meet eligibility criteria for such services.

o Require Private Insurance Companies to Provide Medicare Secondary Payer Information (HCFA 99/36)*, **

Currently, there is no requirement that group health plans let Medicare know about those beneficiaries for whom they provide primary coverage. Medicare faces numerous hurdles in recovering mistaken payments for beneficiaries who have private health insurance. This proposal would require all group health plans to provide information that will enable Medicare to identify

beneficiaries who have other coverage. As a result, HCFA would know immediately whether Medicare was responsible for making the primary payments for health care services. > \$300 million

o Require Insurance Companies to Report Liability and No Fault Insurance Payments for Medicare Beneficiaries (HCFA 99/34)*

Currently, no fault and liability insurance companies are not required to notify Medicare when a beneficiary has been involved in an accident and a no fault or liability insurance settlement is paid. As a result, Medicare is often billed for services and makes a conditional payment in cases where another party should have assumed primary payment. Providers and suppliers of services rarely notify Medicare of situations in which it is the secondary payer. If medical expenses for an accident are mistakenly paid by Medicare, the program must be reimbursed by the insurance settlement. This proposal would require insurance companies to notify Medicare of any liability and no fault insurance payments made to Medicare beneficiaries or health care providers for health care services.

o Impose Double Damages When a Third-Party Payer Fails to Acknowledge its Status as Primary Payer (HCFA 99/37)*

Currently, the government can collect damages in recovering mistaken Medicare primary payments from third-party payers that have failed to comply with Medicare secondary payer provisions. Unfortunately, some private insurers, who by law are obligated to pay a medical claim before Medicare, purposely fail to pay the claim for which they are responsible knowing that Medicare will inadvertently pay the bill. This proposal would allow Medicare to recoup double the amount owed by the insurer in these cases.

o Permit Medicare and Medicaid to Recover Overpayments and Penalties from Providers that Declare Bankruptcy (HCFA 99/42)*, **

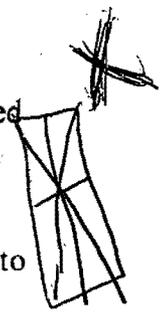
Currently, providers who owe fines or who must return overpayments to the Medicare and Medicaid programs can effectively block recovery by declaring bankruptcy. This proposal would give Medicare and Medicaid the right of first recovery when a provider files for bankruptcy.

o Provide Additional Remedies to End Illegal "Kickback" Schemes*, **

A serious area of fraud is "kickback" schemes, where health care providers unnecessarily send patients for tests or to facilities and receive inappropriate financial rewards. While we have established criminal penalties for these schemes, additional tools are needed to stop this practice. This proposal would allow prosecutors to get a court order to put an immediate halt to such schemes and levy civil as well as criminal remedies. This proposal was developed by DOJ.

o **Extend Subpoena and Injunction Authority (HCFA 99/39)**

Currently, the Secretary has authority to issue civil monetary penalties in cases of fraud. Included in that authority are the powers of subpoena and injunction. However, these powers are not included in the Secretary's authority for other administrative sanctions such as exclusion. The Secretary needs more powerful tools in order to aggressively investigate fraud, kickbacks and other prohibited activities. This proposal gives the Secretary the authority to require witnesses to appear and produce testimony related to cases involving fraudulent claims, excluded providers who continue to provide services, and other sanctioned activities.



o **Expand Sanctions for Steering or Failure to Provide Services to Plans' Contractors (HCFA 99/27)**

Currently, HCFA can penalize contracting organizations for failing to provide covered services or for screening potential enrollees for health problems. This proposal would expand current protections by allowing the imposition of separate penalties against a health plan's providers, contractors, or agents. These new penalties may be in lieu of, or in addition to, any penalties assessed against the plan directly.



o **Allow Civil Money Penalties for Services Ordered or Prescribed by Excluded Providers (HCFA 99/43)**

Currently, CMPs can be levied against excluded individuals who are furnishing a service, but not against individuals providing a service ordered by an excluded provider. This proposal authorizes CMPs when the individual providing a service knew that the orderer was excluded.



o **Clarify Applicability of Civil Money Penalties (HCFA 99/32)**

Current law contains contradictory language regarding HCFA's ability to impose CMPs in a number of areas involving non-compliance with Medicare rules and regulations. This proposal clarifies HCFA's authority to impose CMPs.

o **Re-establish a "Knowing" Standard for Kickback Penalties (HCFA 99/40)**

A 1995 Ninth Circuit decision interpreted the anti-kickback statute to require "knowing and wilful" action. This proposal would remove the requirement that the government prove "wilfulness," making the burden of proof more similar to that of other criminal statutes.

o **Reinstate Reasonable Diligence Standard For Imposition of CMPs (HCFA 99/44)**

CMPs can be imposed in cases of false claims for Medicare reimbursement. HIPAA altered the legal burden of proof for the government, making providers liable only if they acted with "deliberate ignorance" or "reckless disregard" of the truth. This proposal would return to the previous standard of "reasonable diligence" for imposing CMPs for false Medicare claims.

o **Impose CMPs for Failure to Submit Diagnosis Information as Required By BBA (HCFA 99/29)**

BBA requires practitioners to provide certain medical information when ordering certain items or services. There is no penalty for failure to comply with this provision. This proposal would authorize CMPs for failure to comply.

MEDICAID

o **Prohibit Affiliations with Individuals Debarred by Federal Agencies (HCFA 99/12)**

Current law prohibits debarred individuals from participating in Medicaid as providers, but does not prohibit them from affiliating with providers. This proposal would require Medicaid providers to assure that they do not have debarred individuals as employees, consultants, or in other affiliations.

o **Impose a Surety Bond Requirement Upon Providers of Non-Emergency Transportation (HCFA 99/13)**

Non-emergency transportation has grown from \$100 million to a \$1 billion industry in the past five years. States have requested this authority. States would be allowed to except volunteers who are paid only mileage for their efforts in cases where access might be a problem.

o **Impose a Surety Bond Requirement Upon Non-Physician Clinic Operators (HCFA 99/14)**

States have requested this authority.

o **Impose a Surety Bond Requirement Upon Pharmacies (HCFA 99/15)**

This would be an option for the states. States could also set a threshold, for example requiring bonds only of pharmacies that receive more than \$200,000 annually from Medicare.

o **Permit States to Exclude Beneficiaries for State Convictions (HCFA 99/17)**

Currently, states can exclude beneficiaries from Medicaid if the individual is convicted of specific Federal crimes involving the defrauding of Medicaid. This proposal would allow states to prosecute recipients in state court and to use a state court conviction as a basis for exclusion.

- * Part of President Clinton's January, 1998 Radio Address
- ** Part of HCFA's 1998 Fraud Bill
- *** Part of 1999 Budget Bill

8:00

9:00

- Mgmt + 9:00

9:30

9:45

8:13

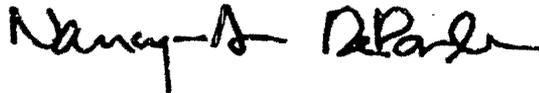
9:15

- ADA - John Callahan
- Wisconsin - Medicaid users, ADP eligibility class
Reintroduction

MEDICARE FRAUD AND ABUSE

- **Proposed Medicare Contracting Reform.** Since 1994, HCFA has developed several legislative proposals targeting Medicare contracting reform. The legislation is intended to improve the Secretary's flexibility in negotiating with Medicare claims processing contractors by removing some of the statutory restrictions on HHS' contracting authority. Under current law, the Secretary can only terminate a Medicare fiscal intermediary agreement after the contractor is given notice and provided with an opportunity for a public hearing. The part of the contracting reform legislation that is relevant to Medicare fraud and abuse is the provision that eliminates the special provisions for termination of contracts with fiscal intermediaries and carriers. This would bring Medicare contractors under the same legal framework as other government contractors and allow HCFA to terminate contractors who did not live up to program standards in any area, including fraud and abuse standards.
- **HCFA Response to OIG Report.** OIG recently found that HCFA's fraud units do not proactively identify instances of fraud and abuse or program vulnerability and made recommendations as to how to address the problem. HCFA's written response to the OIG recommendations is attached. The recommendations center around improving the contractor performance evaluation system, requiring contractor performance evaluations to list HCFA's national and regional objectives, standardizing data collection procedures and definitions of key terms, and providing an opportunity for fraud units to exchange best practices. HCFA concurred with the recommendations and mentioned the fact that they are using their Customer Information System as a fraud detection tool and will require contractors to attend OIG regional training session to educate them about the proper development of cases to refer to law enforcement agencies.
- **HCFA Implementation of Medicare Integrity Program.** Kassenbaum/Kennedy gave HCFA new authority to contract with private sector entities to promote the integrity of the Medicare trust fund. Prior to this legislation, commercial activities carriers were contracting with the providers whose claims they process, reducing their incentive to detect fraudulent claims and putting other providers at a competitive disadvantage. HCFA's new authority allows it to contract with private entities that are not insurance companies who have the potential to carry out fraud and abuse activities as well as or better than existing contractors. HCFA has put an RFP out and hopes to contract with three companies to conduct fraud and abuse audits by the end of 1999.

DEPARTMENT OF HEALTH & HUMAN SERVICES

The Administrator
Washington, D.C. 20201**DATE:** OCT 27 1998**TO:** June Gibbs Brown
Inspector General**FROM:** Nancy-Ann Min DeParle
Administrator**SUBJECT:** Office of Inspector General (OIG) Draft Report: "Fiscal Intermediary Fraud Units," (OEI-03-97-00350)

We welcome the suggestions in the above-referenced report that provides national information on the performance of fiscal intermediary fraud units. We appreciate OIG's efforts to help us strengthen the monitoring and oversight of fraud unit efforts.

The data collected for the report covered fiscal year (FY) 1996. Beginning in 1997, the Health Care Financing Administration (HCFA) mandated that fiscal intermediaries (FIs) use the HCFA Customer Information System as a fraud detection tool. The tool will enable the FIs to proactively identify fraud. In addition, during FY 1999, HCFA contractors will attend OIG regional training sessions that will further educate them about the proper development of cases to be referred to law enforcement agencies.

We concur with the report's recommendations. Our specific comments follow:

OIG Recommendation #1

HCFA should improve the contractor performance evaluation system so that it not only encourages continuous improvement, but also holds contractors accountable for meeting specific objectives.

HCFA Response

We concur and plan to develop specific national objectives to be evaluated during FY 1999. In September 1998, we visited 13 contractor fraud units to gather information that will help us develop ambitious, but practical, objectives. In addition, HCFA through its contractor has just completed gathering the requirements to be used in the design of a new program integrity management information system. The process required that the data metrics needed to evaluate Medicare contractor medical review and benefit integrity effectiveness be identified before building the new system. A contract has been let to build the new system.

Page 2 - June Gibbs Brown

OIG Recommendation #2

HCFA should require that all contractor performance evaluations list HCFA's national and regional objectives and address whether or not the fraud unit is meeting those objectives.

HCFA Response

We concur with the intent. The fraud unit contractor performance evaluation standards are being re-examined and will reference national objectives. Our regional offices have the authority to negotiate individual performance objectives with each contractor, so the creation of regional standards may not be necessary.

OIG Recommendation #3

HCFA should establish a standard set of data that can be used to measure fraud units' performance in meeting established objectives. Require that all contractor performance evaluation reports contain this data.

HCFA Response

We concur. In March 1998, HCFA identified and distributed a list of the most significant data metrics for regional office use in the FY 1998 contractor evaluation process. The development of national objectives will include the data metrics to be used in determining if objectives have been met.

OIG Recommendation #4

HCFA should establish clear definitions of key words and terms (e.g., complaint, case, program vulnerability, and overpayment). Disseminate definitions and require that HCFA program integrity staff and fraud unit staff use the same definitions. In a future update of the Medicare Intermediary Manual, revise sections so that these words are consistently used to mean the same thing.

HCFA Response

We concur. We will review the definitions of key words in our current Medicare Intermediary Manual. To the extent that we find inconsistencies, we will make appropriate revisions.

OIG Recommendation #5

HCFA should provide opportunities for fraud units to exchange ideas, compare methods, and highlight best practices relating to fraud and abuse detection.

Date: Wednesday, June 3, 1998

FACT SHEET

Contact: HHS Press Office (202) 690-6343

THE CLINTON ADMINISTRATION'S COMPREHENSIVE STRATEGY TO FIGHT HEALTH CARE FRAUD, WASTE AND ABUSE

Overview: *Since 1993, the Clinton Administration has focused unprecedented attention on the fight against fraud, abuse and waste in the Medicare and Medicaid programs. Today, the result is a series of investigations, indictments and convictions, as well as new management tools to identify wasteful mispayments to health care providers.*

The heightened focus on fraud and abuse since 1993 by the HHS Inspector General, the FBI and Department of Justice, HHS' Health Care Financing Administration (HCFA) and others throughout government is yielding a new, more detailed picture of fraudulent activities aimed at the Medicare and Medicaid systems. New surveys and audits have helped investigators pinpoint areas of vulnerability and ongoing patterns of abuse, which in turn are leading to changes in law enforcement and administrative actions.

At HHS, Secretary Shalala launched Operation Restore Trust, a ground-breaking project aimed at coordinating federal, state, local and private resources and targeting them on areas most plagued by abuse. During its two-year demonstration phase, the project identified \$23 in overpayments for every \$1 of project costs. In addition, the Secretary led the way toward steady, guaranteed funding for anti-fraud efforts by the HHS Inspector General, included in the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

On January 26, 1998, President Clinton sent to Congress the first annual report of the Health Care Fraud and Abuse Control Program -- created by HIPAA -- which shows remarkable progress in rooting out health care fraud and abuse. In FY 1997 alone -- the first full year of anti-fraud and abuse funding under HIPAA -- nearly \$1 billion was returned to the Medicare Trust Fund, the largest amount ever. HHS also excluded more than 2,700 individuals and entities from doing business with Medicare, Medicaid, and other federal and state health care programs in FY 1997 for engaging in fraud or other professional misconduct -- a near doubling (a 93 percent increase) over 1996. In addition, HHS increased convictions for health care fraud-related crimes by nearly 20 percent, and pursued 4,010 civil health care fraud cases -- an increase of 61 percent over 1996. Since 1993, actions affecting HHS programs alone have saved taxpayers more than \$20 billion and increased health care fraud convictions by more than 240 percent.

The Administration will continue to expand its efforts to identify wrongdoers and to obtain convictions. The budget bill signed by President Clinton in August 1997 includes many new fraud fighting tools sought by the Administration. In addition, President Clinton proposed an anti-fraud and abuse legislative package as part of his FY 1999 budget that would save Medicare some \$2 billion over 5 years.

CLINTON ADMINISTRATION EFFORTS TO FIGHT FRAUD, WASTE, AND ABUSE

Operation Restore Trust. In May 1995, President Clinton launched Operation Restore Trust (ORT), a comprehensive anti-fraud initiative in five key states designed to test the success of several innovations in fighting fraud and abuse in the Medicare and Medicaid programs. HCFA, the HHS Inspector General, and the HHS Administration on Aging are working in partnership to carry out ORT. During the two year demonstration, ORT identified \$23 in overpayments for every \$1 spent looking at the fastest-growing areas of Medicare, including home health care, skilled nursing facilities, and providers of durable medical equipment. In May 1997, Secretary Shalala announced a new, nationwide expansion of ORT to look at additional areas of fraud and abuse this year.

- **Fraud and Abuse Hotline.** HHS has expanded the 1-800-HHS-TIPS hotline started in 1995 to report fraud and abuse in Medicare and Medicaid programs. Over 38,000 complaints that warranted follow-up action have been received since it began service. The hotline is staffed Monday through Friday, 8:30 a.m. to 6:00 p.m. Eastern Time, and assistance is available in both English and Spanish. Medicare beneficiaries across the nation are now receiving the toll-free number on their monthly Medicare statements, making it easier for them to help Medicare crack down on fraud and abuse.
- **Administration on Aging Ombudsman Program.** As a partner in Operation Restore Trust, the Administration on Aging has trained thousands of paid and volunteer long term care ombudsman and other aging services providers to recognize and report fraud and abuse in nursing homes and other long term care settings.

Guaranteed and Expanded Funding. In August 1996, President Clinton signed the Health Insurance Portability and Accountability Act (HIPAA) legislation into law, which for the first time created a stable source of funding for fraud control. This law established the Health Care Fraud and Abuse Control Account, a key proposal of the Clinton Administration, to which money is deposited annually from the Medicare Part A Trust Fund to help finance expanded fraud and abuse control activities. The additional funding, \$104 million in FY 1997 and up to almost \$120 million in FY 1998, is divided between HHS and the Department of Justice to coordinate federal, state and local health care law enforcement programs; conduct investigations, audits, evaluations and inspections relating to the delivery and payment of health care; help facilitate enforcement of civil, criminal and administrative statutes on health care fraud and abuse; provide guidance to the health care industry on fraudulent health care practices; and establish a national data bank to receive and report final adverse actions against health care providers.

- **New Anti-Fraud Grants.** On August 21, 1997, HHS awarded more than \$2.25 million in grants funded by HIPAA for new programs to aid in the fight against health care fraud and abuse. Of this amount, more than \$1.5 million in "Health Care Fraud and Abuse Control Grants" will be administered by HCFA, the HHS Inspector General, and the Department of Justice. The HHS Administration on Aging also announced a total of \$900,000 in grants to be administered through state offices on aging, which will help expand the Department's highly successful Operation Restore Trust program. In June 1997, the Administration on Aging also awarded funds to 12 local agencies to recruit and train retired professionals to teach older persons and their families what to look for when reviewing their billing statements and how to report potential waste, fraud, and abuse.
- **Expanded Office of the Inspector General (OIG).** In FY 1997, the Office of the Inspector General received approximately \$70 million from the Health Care Fraud and Abuse Control Account. The

funding enabled the OIG to open six new field offices to facilitate enforcement actions, increasing from 26 to 31 the number of states in which the OIG is present. Provisions under HIPAA will also establish a fraud and abuse database to identify health care providers who have been the subject of adverse actions as the result of illegal or abusive practices and award grants to partner agencies engaged in investigations, prosecutions and audits of health care fraud and abuse.

- **Increased Efforts by the Department of Justice (DOJ).** The Department of Justice was allocated approximately \$24 million of the money appropriated from the Health Care Fraud and Abuse Control Act to step-up their efforts to investigate fraud and abuse and enforce criminal and civil statutes applicable to health care fraud and abuse. In the last four years the Department of Justice has increased resources, focused investigative strategies, and improved coordination among law enforcement to fight health care fraud. Due to DOJ's comprehensive efforts, the number of health care fraud convictions increased by more than 240 percent since FY 1992.
- **Incentive Program for Fraud and Abuse Information.** On June 3, 1998, HHS announced a new regulation to implement the Incentive Program for Fraud and Abuse Information, created in the Health Insurance Portability and Accountability Act. Under this program, which starts in January 1999, rewards will be paid to Medicare beneficiaries and others who report fraud and abuse in the Medicare program if their information leads directly to the recovery of Medicare money for fraudulent activity not already under investigation by law enforcement agencies, the HHS Inspector General, state agencies or Medicare's contractors. Rewards will be for 10 percent of the recovered overpayment or a \$1,000 maximum, and will be financed from the collected overpayments, after all other fines and penalties have been recovered.

Tightening Standards for Home Health Care Providers. HHS declared a moratorium on enrollment of new home health providers in the Medicare program while implementing new regulations to prevent fraud in home health care. The new regulations include provisions to: (1) require home health agencies to post surety bonds of at least \$50,000 before they can enroll or re-enroll in Medicare; (2) require a minimum number of patients to establish an agency's experience in the industry prior to seeking Medicare enrollment; and (3) require agencies to submit detailed information about all businesses they own to prevent the use of shady financial transactions to exploit Medicare. This action is consistent with strong evidence that the best way to stop fraud and abuse in our Medicare program is to prevent unscrupulous providers from ever entering the program. The moratorium was lifted on January 14, 1998. HHS is also developing a new renewal process for home health agencies currently in the program, and is doubling audits and increasing claims reviews to help weed out bad apple providers. In addition, the Clinton Administration in March 1997 proposed a new regulation that would revise the federal standards (Condition of Participation) that home health agencies must meet in order to participate in the Medicare program. The new rules require home health agencies to be more accountable for the care they provide and to conduct criminal background checks on the aides they hire.

At the Clinton Administration's urging, several measures to fight fraud in home health care were included in the Balanced Budget Act of 1997, including:

- Establishing a prospective payment system for home health services, to be implemented by Oct. 1, 1999. Moving to a PPS system will be a tremendous tool to stem the flow of home health care dollars. HCFA will set, in advance, what it will pay for a unit of service, how many visits will be included in that unit and what mix of services will be provided.
- Paying home health services based upon the location where the service is provided-the patient's home-as opposed to where the service is billed. This will stop agencies from getting higher urban

reimbursement when, in fact, the service occurred in a lower-cost rural setting.

- Eliminating periodic interim payments to home health agencies. These payments were previously used to encourage Medicare participation and now are no longer necessary.
- Tightening eligibility for home health services so that providers can no longer game the system by certifying patient eligible for home health services simply because they need blood drawn on a regular basis. There is a separate benefit for blood drawing services only.

New Requirements for Durable Medical Equipment Suppliers. On January 20, 1998, HHS published a regulation to help prevent fraud and abuse in the supply of durable medical equipment (DME) for Medicare beneficiaries. DME has been identified as a prime area for potential fraud against Medicare, and it is one of the special focuses of HHS' anti-fraud initiative, Operation Restore Trust. Under the regulation, suppliers of DME, including wheelchairs, canes, and other medical supplies, would be required to obtain surety bonds of at least \$50,000. The requirement applies to payment for any DME furnished on or after January 1, 1998. In addition, the proposed regulation would ban DME supplier telemarketing; require suppliers to have a physical office and a listed phone number; codify a requirement that suppliers reenroll in Medicare every three years; prohibit suppliers from reassigning a supplier number; and apply criminal and civil sanctions for misrepresentations on billing number applications. On January 24, 1998, the President announced that, to ensure that medical equipment suppliers are providing the medical devices they claim, the Department of Health and Human Services will conduct nationwide on-site inspections of medical equipment suppliers.

The Medical Integrity Program (MIP) and Payment Safeguards. This system of payment safeguards, also authorized by HIPAA, identifies and investigates suspicious claims throughout Medicare, and ensures that Medicare does not pay claims other insurers should pay. MIP also ensures that Medicare only pays for covered services that are reasonable and medically necessary. HCFA's 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 the payment safeguard activities include: the Medicare Secondary Payer Program, medical review, cost report audits and anti-fraud activities. The payment safeguard activities returned \$14 for every \$1 spent, and saved an estimated \$7.5 billion for FY 1997. The Secondary Payment Program alone, which is identifying whether insurers should pay claims that in the past have inappropriately been paid by Medicare, saved more than \$1.1 billion in 1997.

Improving Health Care Industry Compliance. The HHS Office of the Inspector General has issued compliance program guidance for hospitals to assist in developing measures to combat fraud and abuse in the hospital industry. In addition, the OIG released guidelines identifying steps the clinical laboratory industry should undertake to improve adherence to Medicare and Medicaid statutes, regulations, and program directives. The guidelines are part of the Inspector General's continuing efforts to work with health care providers to promote voluntary compliance with the applicable statutes, regulations, and program requirements pertaining to federal and other health care programs. In addition, the OIG has issued fraud alerts, advisory opinions and other guidance as part of an ongoing effort to promote the highest level of ethical and lawful conduct by the health care industry.

Correct Coding Initiative. In 1994, HCFA began the Correct Coding Initiative by awarding a contract for the development of correct coding policy for all physician billing codes referred to as current procedural terminology (CPT) codes. Implemented in 1996, this enhanced pre-payment, control and associated software update resulted in a projected \$260 million in savings in FY 1997. 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.

Substantive Claims Testing. HCFA is now working to develop a substantive testing process to help determine not only whether claims are paid properly, but also whether services are actually rendered and medically necessary.

Education Efforts. HCFA's contractors educate the provider billing community, including hospitals, physicians, home health agencies and laboratories about Medicare payment rules and fraudulent activity. This education covers current payment policy, documentation, requirements and coding changes through quarterly bulletins, fraud alerts, seminars and, more importantly, through local medical review policy.

Los Alamos National Laboratory. The lab is developing sophisticated pattern detection methods for application to Medicare's vast data banks. These methods will help identify and target suspect claims which need additional review. This effort could start directing investigators to new cases of fraud and abuse.

Tough New Requirements for Medicare and Medicaid Participants. President Clinton's FY 1998 budget proposal included several additional anti-fraud provisions. In addition, President Clinton introduced new legislation in March 1997, the "Medicare/Medicaid Anti-Waste, Fraud and Abuse Act of 1997," that established tough new requirements for individuals and companies that wish to participate in Medicare and Medicaid. Most of the Clinton Administration's recommendations were included in the budget bill signed by the President on August 5, 1997, including:

- Penalties for services billed by a provider who has been excluded by Medicare and Medicaid.
- Penalties for hospitals who contract with providers who have been excluded by Medicare and Medicaid.
- Civil monetary penalties levied on providers that violated the anti-kickback statute, under which the physician received some kind of incentive for referring patients.
- Requiring health care providers applying to participate in Medicare or Medicaid to provide their Social Security numbers and their employer identification numbers so HCFA can check an applicant's history for past fraudulent activity.
- Barring convicted felons from participating in Medicare and Medicaid.

➔ **10-Step Anti-Fraud and Abuse Legislative Package.** To build on the Administration's unprecedented success in fighting health care fraud, waste, and abuse, President Clinton's FY 1999 budget proposal includes an anti-fraud and abuse legislative package that saves Medicare some \$2 billion over five years. The package includes measures that would:

- Eliminate excessive payments for certain drugs, for which the Inspector General has reported Medicare currently overpays;
- Ensure Medicare does not pay for claims that ought to be paid by private insurers, such as taking steps to ensure that Medicare is aware of liability settlements and of other coverage obligations of private insurers;

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- Ask providers to pay for their audits, which will allow Medicare to double the number of audits; and
- Ensure that filing for bankruptcy cannot shield providers from their obligations to Medicare.

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**PRESIDENT UNVEILS TEN LEGISLATIVE PROPOSALS AS PART OF HIS
ONGOING ANTI-FRAUD, WASTE, AND ABUSE COMMITMENT**

January 23, 1998

- (1) **Eliminating Wasteful Excessive Medicare Reimbursement for Drugs.** A recent report by the HHS Inspector General found that Medicare currently pays hundreds of millions of dollars more for 22 of the most common and costly drugs than would be paid if market prices were used. For more than one-third of these drugs, Medicare paid more than double the actual average wholesale prices, and in one case pays as high as ten times the amount. This proposal would ensure that Medicare payments be reduced to the actual amount that the drugs cost. O/D
- (2) **Eliminating Overpayments for Epogen.** In a 1997 report, the HHS Office of Inspector General (OIG) found that reducing the Medicare reimbursement for Epogen (a drug used for kidney dialysis patients) to reflect current market prices would result in more than \$100 million in savings to the Medicare program and beneficiaries.
- (3) **Doubling the Number of Audits to Ensure That Medicare Only Reimburses for Appropriate Provider Costs.** Right now, not all cost-based providers (e.g., hospitals, home health, non-PPS, skilled nursing facilities) are audited. This proposal would assess a fee to cover all audits and cost settlement activities for health care providers. These steps help ensure that Medicare only makes payments for appropriate provider costs.
- (4) **Lowering Medicare's Payments for Equipment Through A Nationwide Competitive Pricing Program.** Competitive Pricing would let Medicare do what most private and other government health care purchasers do to control cost -- lower costs by injecting competition into the pricing for equipment and non-physician services. O/D
- (5) **Eliminating Abuse of Medicare's Outpatient Mental Health Benefits.** The HHS Inspector General has found abuses in Medicare's outpatient mental health benefit -- in particular that Medicare is sometimes billed for services in inpatient hospitals or homes. This proposal would eliminate this abuse by requiring that these services are only provided in the appropriate treatment setting.
- (6) **Creating Civil Monetary Penalties For False Certification of The Need For Care.** Recent HHS Inspector General reports identified providers who inappropriately certified that beneficiaries needed out-patient mental health benefits and hospice services. This proposal would impose penalties on physicians who falsely certify their patients' need for these two benefits. O/D

- 11/07/00 THE 10:00 FAX 202 500 0070 DBBS/ASFA 0009
- (7) **Preventing Providers From Taking Advantage of Medicare By Declaring Bankruptcy.** Providers who have defrauded and abused Medicare often file for bankruptcy in order to avoid paying fines or returning overpayments, leaving Medicare strapped with the bills. This proposal would give Medicare priority over others when a provider files bankruptcy.
- (8) **Taking Action To End Illegal Provider "Kickback" Schemes.** A serious area of fraud is "kickback" schemes, where health care providers unnecessarily send patients for tests or to facilities where the provider is financially rewarded. While we have established criminal penalties for these schemes, additional tools are needed to stamp out this practice: specifically, allowing prosecutors to get a court order put an immediate halt to such schemes, and to allow civil as well as criminal remedies.
- (9) **Ensuring Medicare Does Not Pay For Claims Owed By Private Insurers.** Too often, Medicare pays claims that are owed by private insurers because Medicare has no way of knowing the private insurer is the primary payer. These proposals would take steps to address these problems including: requiring insurers to report any Medicare beneficiaries they cover; allowing Medicare to recoup double the amount owed by insurers who purposely let Medicare pay claims the group plan should have made; and imposing fines for not reporting no-fault or liability settlements for which Medicare should have been reimbursed.
- (10) **Enable Medicare to Capitate Payments for Certain Routine Surgical Procedures Through a Competitive Pricing Process With Providers.** This will expand HCFA's current "Centers of Excellence" demonstration to enable Medicare to receive volume discounts on these surgical procedures and, in return, enable hospitals to increase their market share and gain clinical expertise.
- O/R
- Some P/O



U.S. Department of Justice

Office of the Deputy Attorney General

Medicare Fraud, Abuse File

Washington, D.C. 20530

April 8, 1998

To: Chris Jennings
Deputy Assistant to the President

From: John T. Bentivoglio *JTB*
Special Counsel for Health Care Fraud

Subj: Correspondence between DOJ and the American Hospital
Association

I thought you might be interested in the attached. The DOJ letter is only an initial response, pending further discussions with the AHA. While the AHA is unlikely to be completely satisfied, we believe we are taking appropriate steps to address legitimate concerns from various quarters about the procedures we are using in national projects. Some of those steps are outlined in the DOJ response. However, we have emphatically rejected a number of AHA recommendations, including a moratorium on False Claims Act enforcement activity and imposition of a \$100,000 threshold on FCA cases. *rejected moratorium*

If you have any questions, please feel free to contact me at (202) 514-2707.



U.S. Department of Justice

Executive Office for United States Attorneys

Attorney General's Advisory Committee
of United States Attorneys

Room 1619
10th & Constitution Avenue, N.W.
Washington, D.C. 20530

April 6, 1998

Joseph P. diGenova
diGenova & Toensing
901 15th Street, N.W.
Suite 430
Washington, D.C. 20005

Dear Mr. diGenova:

I write to provide an initial response to your March 27, 1998, letter to the Deputy Attorney General about the concerns of the American Hospital Association regarding the Justice Department's law enforcement efforts under the civil False Claims Act (FCA). I also want to thank you for meeting with other Department representatives and me on March 31, 1998. Since we had just received your letter, we were not in a position to respond fully to your concerns at the meeting, but we soon will supplement this response in order to do that.

We appreciate your support for our efforts to protect the Medicare Trust Fund from fraud and abuse. It may be helpful to clarify what conduct does -- and does not -- constitute a violation of the FCA. The statute and case law make clear that honest billing mistakes that are the result of simple negligence do not violate the FCA, and it is not the policy of the Department of Justice to use the FCA to address such honest or inadvertent mistakes. On the other hand, health care providers who submit claims to Medicare (or other federal health benefit programs) with actual knowledge that the claim is false or in reckless disregard or deliberate indifference to the truth or falsity of the claim may be held accountable under the FCA. The reckless disregard and deliberate indifference provisions include provider actions that ignore or fail to inquire about readily discoverable facts which would alert them that false claims are being submitted.

submit
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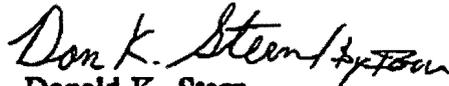
The only way to determine whether a matter is cognizable under the FCA is to consider carefully the pertinent facts and our actions under the FCA (like those under any other federal statute) should be based upon the particular facts and circumstances of each individual matter. In connection with national enforcement projects in the health care area, we have established mechanisms within the Department to provide national-level coordination and to encourage the use of best practices by offices participating in those projects. For example, in the national project investigating laboratory test unbundling, we are encouraging United States Attorneys' offices to use initial, pre-litigation contact letters that invite

providers to confer with us about their potential FCA liability. While we will continue in appropriate circumstances to use other legitimate means to pursue an investigation, we hope these and other steps we have taken will avoid future misunderstandings about the Department's goals for enforcing the FCA.

We cannot agree to your request for a moratorium on our law enforcement responsibilities under the FCA. To do so would be inconsistent with our professional obligations and our policy of resolving each potential FCA action on its own merits. We have made substantial efforts to implement the statute in a fair and responsible manner. For example, while we have sent demand letters to providers in the unbundling project, we also have agreed to provide reasonable extensions of time upon requests from the providers. In most instances, United States Attorneys' offices have requested and providers have agreed to tolling agreements so potential false claims are not forfeited under the statute of limitations while discussions continue between the United States Attorneys' offices and the providers. These actions represent a reasonable and professional accommodation to potential litigants, which we hope will facilitate just resolutions of the claims. Of course, we encourage hospitals, through their counsel, to communicate directly with the relevant Assistant United States Attorneys and, if necessary, the United States Attorney, concerning these matters. In the unlikely event that those communications do not resolve issues that arise in the next thirty days relating to an extension of time for discussions, prior to the commencement of litigation, counsel should contact Michael Hertz, Director, Commercial Litigation Branch of the Department's Civil Division.

I hope this information is helpful. We welcome a continuing dialogue with the provider community and encourage you to contact us directly if you have additional concerns.

Sincerely,



Donald K. Stern
 United States Attorney
 District of Massachusetts
 Chairman
 Attorney General's Advisory
 Committee



diGENOVA & TOENSING
ATTORNEYS-AT-LAW

March 27, 1998

VIA COURIER

The Honorable Eric H. Holder, Jr.
Deputy Attorney General
Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530

RE: American Hospital Association Proposal for National
Enforcement Guidelines for Hospitals

Dear Mr. Holder:

Thank you for meeting with us Wednesday, February 25, 1998 to discuss the use of the False Claims Act (FCA) against hospitals. We appreciate your civility and willingness to listen to our concerns about the current Department of Justice (DOJ) policy on this issue.

As you know, we represent the American Hospital Association (AHA). The AHA, in turn, represents over 5,000 hospitals, health systems and other providers of care throughout the country. The AHA's members have become the subjects of a disturbing trend in the enforcement of the FCA. This enforcement effort appears to us not the result of a coordinated and well articulated national policy, but instead the result of a piecemeal and inconsistent policy adapted from an individual U.S. Attorney's initiative against healthcare providers, often in conjunction with the Office of the Inspector General, Department of Health and Human Services (OIG). This ad hoc development of policy has continued as U.S. Attorneys have pursued FCA settlements in their own jurisdictions without clear guidance from the DOJ.

As we discussed in our meeting, below is our outline of our concerns and suggestions for a solution. Ultimately, what the AHA desires is a return to the traditional process whereby billing disputes are initially analyzed and negotiated with dispatch by the Health Care Financing Administration (HCFA) and, absent evidence indicating some wrongdoing, the DOJ will not insert itself and make demands for the payment of monies under the threat of a FCA suit. If a true violation of the FCA is discovered by HCFA or its agents, then a referral to DOJ would occur in the same fashion as occurs in all other

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areas of regulatory activity. Unlike now, such a referral would occur only after an appropriate evidentiary predicate had been established. In short, the AHA seeks to restore objective and reasoned prosecutorial judgment and discretion to a significant area of enforcement where, in our opinion, they are currently lacking.

THE NATION'S HOSPITALS HAVE WASTED VALUABLE LIMITED FUNDS AND PERSONNEL TO REACT TO THE GOVERNMENT'S MISUSE OF THE FCA

Hospitals are being forced to reallocate staff and funds in order to defend their innocence against a potentially endless series of broad and frequently uncoordinated recovery projects and investigations. Several investigation initiatives have already been started: DRG 3-Day Window Rule; pneumonia upcoding; Project "Bad Bundle" concerning laboratory unbundling, and the PATH Audit investigations. The lack of centralized management over these initiatives has created fundamental problems in the use of the FCA against hospitals. These problems, explained below, include misuse of Executive Order 12778, use of inadequate evidentiary predicates, and disparate treatment of hospitals. The fiscal health and reputation of this nation's hospitals and lack of a clear legal foundation for enforcement under the FCA require that these problems be addressed as soon as possible, whether it be through the national enforcement guidelines we advocate in this letter, corrective legislation, or, if necessary, litigation.

Misuse of Executive Order 12778

Executive Order 12778 on Civil Justice Reform (October 23, 1991) requires that DOJ attorneys notify possible defendants in a FCA suit in order to attempt to resolve the matter without litigation. As the DOJ has stated in its own talking points on the FCA, the idea behind this Executive Order is that early discussion with possible defendants would lead to just and efficient resolution of the government's claims through informal discussion, negotiations, and settlements.

Unfortunately, under the FCA, Executive Order 12778 is being used against innocent hospitals in a manner contrary to the spirit and intent of the order. Demand letters are being sent to hospitals without any specific evidence of fraud or wrongdoing. A valid government claim was envisioned when Executive Order 12778 was drafted. However, the enormous potential penalties of the FCA and small windows of time within which targeted hospitals must commit to settle (often less than two weeks) are being used to force hospitals to settle and pay large fines despite the lack of evidence of fraud. The potential costs of losing in court, including the fiscal death sentence of exclusion from the Medicare program, are simply too great. As a result, the settlements brought about by these demand letters do not reflect the uncovering of fraud, rather they reflect what we

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believe to be an improper interpretation and use of Executive Order 12778 to extort settlements out of innocent hospitals by way of the FCA. In short, the government secures "victory" not on the merits, but because hospitals have to calculate the cost-benefit of engaging in costly and potentially ruinous litigation or "settling" to end the matter.

Use of Inadequate Evidentiary Predicates

U.S. Attorney's offices, in most cases, have sent out these demand letters to hospitals without any evidentiary predicates. The result has been the targeting of innocent hospitals and settlements through the threat of draconian penalties under the FCA. Consequently, these settlements, some of which are tied to subsequent audits of hospital records, have turned up astonishingly low error rates in the hospitals' billing of Medicare.

This has notably been the case for Project "Bad Bundle." For example, the U.S. Attorney's Offices for the Eastern District of Virginia, South Carolina, and Oregon, without any apparent prior factual inquiry in most cases, sent letters to hospitals threatening FCA action if the hospitals did not agree to perform a self-audit. It turns out that one of the Virginia hospitals had Medicare and Medicaid overpayment liability of a mere \$1,410; several other hospitals' overpayment liability was less than \$10,000. (To its credit, the Virginia office abandoned initial demands for expensive self-audits, and proposed its own calculations of "damages" for settlement.) In addition, in Missouri, the U.S. Attorney's Office for the Eastern District not only sent similar demand letters, but also commenced a criminal investigation without any prior inquiry.

Under a PATH audit investigation, Mary Hitchcock Hospital in New Hampshire was forced to incur more than \$1 million in internal staff time and external fees for attorneys, consultants, and accounting assistance to perform a self-audit on Medicare billing. The audit turned up zero violations.

Similarly, in Connecticut, 34 hospitals in the state were sent demand letters on the DRG 3-Day Window Rule. The investigation covered the years 1990 to 1995. During that time, Connecticut hospitals handled more than 10 million Medicare claims. Of that total, fewer than 3,000 claims were cited by the government as in error. That translates into an error rate of less than three one-hundredths of one percent (.03%) of all Medicare claims filed. These errors totaled less than \$1 million worth of payment errors out of a total of \$6 billion in total Medicare payments. That amount is less than \$29,500 per hospital over a multi-year period -- hardly indicative of parallel schemes to defraud.

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In Maine, 24 Hospitals settled in response to government demand letters on the DRG 3-Day Window Rule. Again, the investigation covered the years 1990 to 1995. During that time, these hospitals handled more than 2.9 million Medicare claims. Of that total, fewer than 1,000 claims were cited by the government as in error. That translates into an error rate of thirty four hundredths of one percent (.034%) of all Medicare claims filed. These errors totaled only \$139,000 (\$5,800 per hospital) out of a total of \$2.6 billion in total Medicare payments, or a .005% error rate.

In other cases, the U.S. Attorneys acting on their own discretion have elected not to employ the draconian approach pushed on them by the Inspector General and several local U.S. Attorneys. For example, Iowa U.S. Attorneys initiated a dialogue with the hospitals in the district and assured them that it would not be following the "Bad Bundle" approach. The U.S. Attorney in the Eastern District of Virginia, after initially adopting the "Bad Bundle" approach, opened up a constructive dialogue with counsel as more facts became evident. Even in that case, however, a reasonable approach was adopted by the U.S. Attorney only after hospitals had already received and reacted to the "Bad Bundle" threat and had already incurred substantial legal and consulting costs.

These are just a few examples of government overreaching in its FCA initiatives. As these investigations continue and new initiatives are developed the government's enforcement methods ensure that more examples will follow.

Disparate Treatment of Hospitals

The lack of centralized management over these investigations has resulted in the disparate treatment of hospitals depending on which U.S. Attorney's office is initiating the action. For instance, as noted previously, the U.S. Attorney in the Eastern District of Missouri has commenced criminal investigations under Project "Bad Bundle" against multiple hospitals apparently to force the hospitals into civil settlement. In South Carolina, in complete disregard of the dictates of Executive Order 12778, the U.S. Attorney's office refused to meet with the counsel of a hospital being investigated unless and until the hospital had signed a tolling agreement and agreed to participate in the self-audit program. Indeed, in one of the South Carolina cases, the U.S. Attorney's office refused to meet with the hospital's counsel for four months and repeatedly stated that there was no purpose in meeting unless the hospital first acceded to all the government's demands. There have also been inconsistent settlement demands and self-audit requirements throughout the country due to the varying language of demand letters and different settlement policies within the various U.S. Attorneys offices.

In the context of Project Bad Bundle, the U.S. Attorneys have adopted inconsistent approaches to the audits being conducted. Some have treated the audits as

hospital self-audits, whereas other U.S. Attorneys treat them as government-directed audits being conducted by the hospitals. Those U.S. Attorneys taking the latter view are demanding that hospitals first agree to turn over all their work papers relating to the Project "Bad Bundle" self-audit as a condition for approving audit work plans. This condition forces hospitals to waive, in advance, the attorney-client privilege over these documents in order to meet the government's demands.

Selective Enforcement of Conflicting and Ever-Changing Medicare Rules

The U.S. Attorneys appear unwittingly to have been put in a position of enforcing Medicare "rules" that until recently were not considered to impose substantive legal obligations upon hospitals by the government agencies that created and applied them.⁶ These "rules" were created to set Medicare payment standards, not to regulate substantive hospital conduct; and they were understood as such by HCFA, the OIG and Medicare's fiscal intermediaries and carriers.

Again, the best example of this is perhaps Project Bad Bundle. It is important to understand that, for the most part, the practices which are the focus of Bad Bundle are not what was found at several recently prosecuted commercial independent laboratory companies that had developed marketing practices that in some cases clearly crossed the line. Over the years, numerous fiscal intermediaries and carriers advised hospitals that failure to bundle blood chemistry lab tests would not constitute a basis for nonpayment; the fiscal intermediaries and carriers announced that they would perform any necessary bundling in the course of processing the claims, and, in those instances, hospitals would be reimbursed at the bundled rate. Consider the following examples:

- An Illinois Medicare carrier memo from 1990 provides that "the above tests will be combined and coded with the appropriate multi-channel test code when two or more are billed"
- A Florida fiscal intermediary memo from 1992 states that "[i]f providers do not code these tests in the multi-channel [i.e., bundled] format, the system will automatically roll them up and reimburse the tests at the multi-channel rate."
- A South Carolina fiscal intermediary memo from 1994 states that "[c]laims containing these codes [i.e., blood chemistry tests subject to bundling] will not be suspended and developed to determine if a payment is duplicated. The following examples illustrate how multi-channel tests will be rolled together." The memo proceeds to give examples as to how the fiscal intermediary will itself perform the bundling.

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If the fiscal intermediaries and carriers believed – and advised hospitals – that the separate billing of lab tests (i.e., the failure to bundle) did not preclude Medicare reimbursement, it is impossible to understand how this conduct could be considered fraud. Ironically, the U.S. Attorneys are investigating the hospitals for violating a non-existent rule, not the fiscal intermediaries for failing to follow HCFA's guidance to them concerning how to calculate and pay Medicare claims.

Consistent with the fiscal intermediaries' memoranda, the OIG repeatedly declared that hospitals were not required to submit lab claims in bundled fashion. For instance, in both the 1995 and 1996 editions of its "Red Book," the OIG stated that "[t]here is no requirement that the tests ordered as a panel by the physician be billed only as a panel." However, in contradiction to that position, the OIG announced to Congress in its 1998 Work Plan that unbundling lab tests is "illegal" and can subject hospitals to FCA liability.

Moreover, the rules on payment for lab tests have been constantly changing. HCFA announced in March, 1997 that hospitals had their choice of whether to bundle blood chemistry tests. Then, HCFA announced that effective April 1998, hospitals were not to bundle blood chemistry tests (unless the tests happened to coincide with certain organ and disease panels). All these changes occurred against the backdrop of the U.S. Attorneys sending out letters accusing hospitals of fraudulently failing to bundle lab tests.

In sum, the regulatory history in this and other areas of Medicare reimbursement and agency interpretation of the requirements is ever-changing. Medicare reimbursement requirements generally are set forth in a variety of informal guidance documents interpreted in different ways by different government agencies at different times. These rules typically are not the product of formal notice and comment rulemaking in which affected parties have the opportunity to point out conflicting and confusing aspects. The legal authority is clear that HCFA can rely on its informal rules in making its payment determinations; however, in the absence of a misrepresentation of the services provided, the mere violation of an informal Medicare payment policy does not rise to the level of a legal violation of the FCA.

Again, the example of lab reimbursement is instructive. If one were to examine a hospital's claim for "unbundled" lab tests, one would find nothing "false" about it. The services listed on the claim correspond exactly to the services provided. There is nothing untruthful about such a claim. As noted above, fiscal intermediaries did not even consider unbundling to preclude Medicare reimbursement, and, until recently, the OIG itself believed that hospitals were not required to bundle.

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The regulatory foundation for Project Bad Bundle -- and other allegations of Medicare fraud -- is simply too shaky to support the Department of Justice's use of the mighty False Claims Act. Lab unbundling (practices yesterday the OIG considered legal and what HCFA now says are required) has been reclassified as "fraud." Medicare payment regulations and methodologies are complex and U.S. Attorneys are reasonably relying upon what other agencies have declared to be "illegal." We respectfully suggest, however, that the U.S. Attorneys have not been provided by the OIG, and have not researched for themselves the full regulatory history before they have enforced alleged Medicare overpayments as fraud.

**THE NATION'S HOSPITALS SHARE THE GOVERNMENT'S
CONCERNS ABOUT COMPLIANCE WITH MEDICARE
REGULATIONS**

Long ago the AHA sought a partnership with government on the development of improved guidance on how its members can better comply with the myriad and complex rules governing Medicare. The AHA submitted comments and worked diligently in good faith with the HHS and the OIG to develop a model compliance program. However, in a testament to the complexity and enormity of the task, it was not until February 11 of this year that the OIG published guidance for the development of an effective compliance program for hospitals. Inspector General June Gibbs Brown had the wisdom to collaborate with hospitals and health systems during the development of this guidance and should be commended for completing such a Herculean task. Interestingly, the OIG's guidance "recognizes that HCFA regulations and contractor guidelines already include procedures for returning overpayments to the Government as they are discovered," even as it urges hospitals to report wrongdoing to law enforcement.

In response to the publication of the OIG's guidance, AHA's members have been working diligently to adopt conforming compliance programs or adapt their existing compliance programs to meet the new government guidelines. This cooperative attitude on the part of hospitals is not a new phenomenon. The AHA's members have always been serious about compliance with Medicare regulations and, even before the government produced guidance, the AHA's Board passed a resolution urging its members to develop voluntary compliance programs. Last fall, the AHA, in conjunction with the consulting firm Coopers & Lybrand, published a guide to designing a compliance manual and created an interactive Internet compliance site for hospitals. The AHA/Coopers & Lybrand guide and Internet site are constantly updated to help the AHA's members adjust and fine tune their individual compliance programs.

However, the AHA's members remain concerned that despite all the best intentions and constant vigilance to comply with the Medicare regulations, these efforts

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will do nothing to quell the current and future investigations threatened by individual U.S. Attorney offices. The AHA's members fear that they will be forced by economics to admit to wrongdoing, pay enormous fines and face public ignominy, due to simple, inevitable mistakes and despite provable innocence. Guidelines for these investigations must be developed so that innocent hospitals are not caught in the dragnet.

THE AHA PROPOSES THE DEVELOPMENT OF NATIONAL ENFORCEMENT GUIDELINES FOR HOSPITALS

Excluding the rare, headline-grabbing exception, hospitals are active, responsible participants in the communities where they are located. They are not the fly-by-night fraudsters who constitute the overwhelming majority of true FCA violators in the health care area. The AHA and its members strongly support a crackdown on such criminals and against hospitals and individuals who commit fraud. However, conflicting, complex government regulations covering Medicare will inevitably generate inadvertent billing errors. Mistakes are not fraud and will occur when a hospital is trying to comply with and navigate a payment system covered by 1,756 pages of law, 1,257 pages of regulations interpreting the law, and thousands of additional pages of instructions.

Until recently, the government and hospitals acted as partners, to make sure both sides were treated fairly. Sometimes hospitals were underpaid, sometimes overpaid. Either way, they and the government would "settle up" at the end of the year. The government has abandoned this partnership and now insists on punishing as a fraud what was once correctly viewed as a simple mistake. Without any filter to identify truly criminal conduct, community hospitals have been targeted simply because they represent easy marks and big numbers for U.S. Attorneys. The AHA strongly opposes these actions and advocates, instead, a return to a partnership with the government to find a solution to these regulatory problems.

Attorney General Reno stated in her speech on February 2, 1998 to the AHA that "[i]t is not the policy of the Department of Justice to punish honest mistakes, nor do we prosecute doctors or hospitals for mere negligence." If that is indeed the policy of the DOJ, then the only way to ensure it is followed in the U.S. Attorney offices throughout the country in a consistent manner is to develop a comprehensive national program of guidelines. The AHA recommends the following:

1. Coordinate FCA investigations against individual hospitals through the DOJ as a national program subject to DOJ approval and oversight. This assumes that only true FCA cases will be referred to the DOJ. The other instances of misbilling would be handled by the traditional, but expedited, HCFA-HHS

and fiscal intermediary annual review to determine underpayments and overpayments.

2. Develop and publish national enforcement guidelines concerning investigations of hospitals, whether under the FCA or any other federal law, which would do the following:
 - develop a materiality threshold for overpayments that refers all overpayments under \$100,000 back to HCFA for administrative resolution. Actual overpayments amount to an extremely small proportion of the overall billing, and absent specific evidence of fraudulent conduct, should not be a part of a DOJ investigation. Rather, in such instances, hospitals should refund the overpayment.
 - state that no threats of criminal prosecution may be used to force hospitals to accept civil settlements.
 - require DOJ civil attorneys be available to meet with representatives of any targeted hospitals and consider the local needs and circumstances of these hospitals.
 - develop clear and objective standards that differentiate between a regulatory overpayment and a civil/criminal fraud and publish these standards in the U.S. Attorney's Manual so that the AHA may advise its members on the standards. The DOJ needs to speak clearly and precisely to retain its enforcement credibility which is now at risk as it attempts to stretch its enforcement resources with collection efforts of this sort.
 - develop a self disclosure program for regulatory overpayments that encourages compliance and not fear of unreasonable claims of penalties and damages.
 - ◊ establish standard that the self disclosure program would not require payment of penalties beyond standard interest penalties absent specific evidence of fraud or reckless disregard of overbilling.

- cease applying overpayment recoveries, derived from DOJ initiatives against hospitals, to the Health Care Fraud and Abuse Control Account (established under the Health Insurance Portability and Accountability Act (HIPPA)) to avoid the appearance that the initiatives are motivated by the government's desire to fund future fraud investigations.
- along with the HHS OIG, develop "safe harbor" treatment for hospital overpayments that occur as a result of inaccurate or incomplete fiscal intermediary/carrier instructions
- recognize and give credit for hospitals that have effective compliance programs, the effectiveness of which is determined by an objective set of criteria.

The AHA recognizes that along with DOJ, other agencies, namely HHS, HHS OIG, and HCFA, also have jurisdiction over these issues. Indeed, there have been problems in the past getting answers to important regulatory and policy questions due to finger-pointing amongst these various agencies. Therefore, in the interests of reaching an acceptable settlement with all parties, the AHA recommends the formation of a working group with representatives from the DOJ, HHS, HHS OIG, HCFA and the AHA to develop a solution that addresses the above proposal.

This type of a solution is not unprecedented. During the mid-1980's, the defense industry worked with the DOJ and the Department of Defense to design a policy for fraud investigations of the defense industry and developed the Defense Industry Initiatives. More recently, in the early 1990's, the AHA worked closely with the DOJ and the Federal Trade Commission to resolve problems of antitrust enforcement in the health care area and developed the Antitrust Enforcement Policy. Both these efforts were very successful and well received.

* * *

As noted above, many hospitals have been forced by economics to settle in response to demand letters. As these enforcement actions proliferate, the AHA must consider pursuing other solutions:

1. corrective legislation to amend the FCA so that innocent hospitals are protected from overzealous prosecutions;

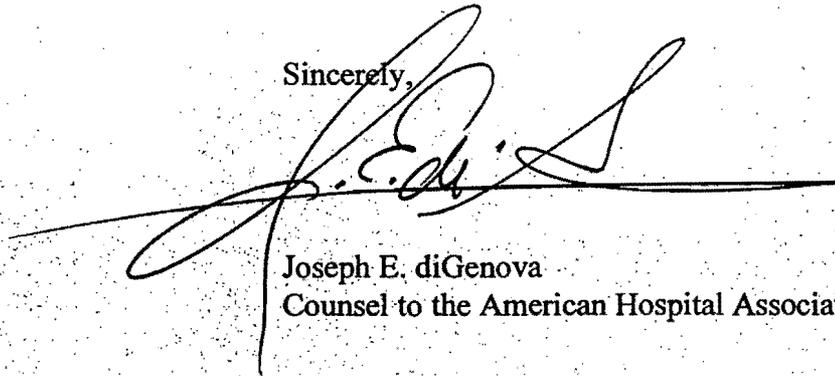
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2. litigation on behalf of select hospitals in response to these demand letters (the current factual and legal predicates supporting the demand letters will not withstand the scrutiny of litigation); and
3. litigation to challenge the validity of selected Medicare rules serving as the basis for penalties beyond the non-payment of a claim under the Administrative Procedure Act and the Social Security Act.

Of course, the AHA proposal is our strong preference as it would help foster a long-term, productive partnership with the government concerning the enforcement of Medicare regulations and it would likely obviate the need to pursue the other solutions. We propose a moratorium on the issuance of demand letters and a suspension of all non-criminal FCA enforcement action until a solution is reached. We also propose a deadline of August 1, 1998 within which to reach this solution.

Representatives from the AHA and I would appreciate another opportunity to meet with you to discuss this proposal in detail. As we stated in our meeting, a global approach to this enforcement problem is needed. Thank you again for agreeing to listen to our concerns and our suggestions. We look forward to working on this proposal with you and HHS. We believe it presents an opportunity to develop a responsible public policy approach to this complex issue of billing errors.

Sincerely,



Joseph E. diGenova
Counsel to the American Hospital Association

cc: The Honorable Donna Shalala
Secretary, U.S. Department of Health and Human Services

Nancy-Ann Min DeParle
Administrator, Health Care Financing Administration

June Gibbs Brown
Inspector General, U.S. Department of Health and Human Services



U.S. Department of Justice

Office of the Deputy Attorney General

Medicaid Fraud & Abuse File

Washington, D.C. 20530

FAX TRANSMISSION SHEET

TO: *Chris Lennings*

Phone: _____ **Fax:** *456-5557*

FROM: **John T. Bentivoglio**
Special Counsel for Health Care Fraud

Phone: (202) 514-2707 **Fax:** (202) 616-1239

DATE: *3/25/98*

NUMBER OF PAGES (including this cover sheet): _____

MESSAGE: *Per your request.*

Note: The information in this facsimile should be considered confidential.

The False Claims Act

The False Claims Act, 31 U.S.C. § 3729, et seq., provides that liability may be imposed on “[a]ny person who . . . knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval . . .”

As amended in 1986, the FCA defines “knowingly” to mean that a person (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or, (3) acts in reckless disregard of the truth or falsity of the information. Mere negligence, mistakes, or inadvertence are not actionable under the FCA.

Congress clearly intended the FCA to deal with those who, like ostriches with their heads in the sand, ignore or fail to inquire about readily discoverable facts which would alert them that fraudulent claims are being submitted. *See 132 Cong. Rec. 20535-36 (August 11, 1986)(statement of Sen. Grassley); H.R. Rep. No. 660, 99th Congress, 2d Sess., p. 20-21 (1986).*

A person who submits such a false claim to the United States may be liable for a civil penalty of between \$5,000 and \$10,000, plus up to three times the amount of damages sustained by the Government.

Since the statute was first enacted in 1863, the False Claims Act (FCA) has been applied to a variety of areas, including defense procurement fraud, food stamp fraud, fraud in HUD programs, and health care fraud.

Applying the FCA to health care fraud is not a novel use of the statute. When Congress amended the FCA in 1986, both the Senate and the House clearly indicated their intent to apply it specifically to false claims for reimbursement from the Medicare and Medicaid programs. *See S. Rep. No. 345, 99th Congress, 2d Sess., pp. 21-22 (1986); H. Rep. No. 660, 99th Congress, 2d Sess., p. 21 (1986).*

The FCA discourages health care providers from committing fraud that depletes the Medicare Trust Fund. Absent this enforcement tool, providers knowingly submitting false claims to Medicare may not face any sanction beyond repayment of the wrongfully obtained funds. The FCA’s provision for penalties serves as an important incentive for providers to take appropriate responsibility for ensuring that their claims for payment from the Medicare Trust Fund are accurate. Through the use of this and other enforcement tools, in Fiscal Year 1997, \$968 million was returned to the Medicare Trust Fund to pay for health care for millions of Americans.

In accordance with Executive Order 12778 on Civil Justice Reform (October 23, 1991), Department of Justice attorneys routinely notify possible defendants in a False Claim Act suit about the nature of the dispute and attempt to resolve the matter without litigation. It is hoped that early discussions with possible defendants will lead to the just and efficient resolution of the Government's claims through informal discussions, negotiations, and settlements. This provides a formal mechanism for potential defendants to discuss the specific facts and circumstances of their cases with U.S. Attorneys' offices prior to the initiation of civil litigation. Each case is evaluated on its own merits.

Laboratory Unbundling Cases

The application of the False Claims Act (FCA) to Medicare billing practices is a well established use of the statute. In fact, when Congress amended the FCA in 1986, both the Senate and the House clearly indicated their intent to apply it specifically to false claims for reimbursement from the Medicare and Medicaid programs. Examples of the Department's successful prosecutions of laboratories for health care fraud under the FCA include the 1992 settlement with National Health Laboratories for \$100 million; and the 1997 settlement with SmithKline Beecham Clinical Laboratories for \$325 million.

- Since at least 1988 and 1989, providers have received clear instruction (including the American Medical Association's CPT-4 Codebook) from a number of agency and fiscal intermediary representatives about how to properly bill certain automated laboratory tests in a bundled fashion.
- Despite receiving notice regarding the proper billing of certain automated blood chemistry and hematology laboratory tests, many hospitals repeatedly "unbundled" these tests, and submitted false bills seeking payment by Medicare and other government health insurance programs.
- Generally, after conducting a review of the AMA CPT-4 Codebook, fiscal intermediary and agency billing guidance, and provider claims data, the Department of Justice works with representatives of the Department of Health and Human Services, Office of Inspector General (HHS-OIG), other investigative agencies, and/or fiscal intermediaries to determine the overall scope of the problem in a particular district.
- After reviewing the billing practices of the provider and the guidance provided by the agency and fiscal intermediary, the government evaluates on a case-by-case basis whether the conduct may constitute a violation of the FCA.
- If the conduct appears to constitute a violation of the FCA, the Justice Department notifies the health care provider that certain conduct is under investigation. The provider is given an opportunity, prior to formal litigation, to review the allegations and present any defenses and/or other mitigating circumstances for consideration by the Department of Justice. Keeping in mind statute of limitation concerns, reasonable extensions of time may be granted.
- Upon the request of a hospital, negotiations are held in an attempt to resolve the matter informally. If a health care provider claims financial distress, the provider's financial statements and other information bearing on its financial standing will be reviewed, and the provider's ability to pay will be considered in appropriate circumstances.
- Claims for payment are reviewed and negotiations with hospitals are conducted on an individual, case-by-case basis.

In laboratory unbundling cases, like all health care fraud cases brought under the FCA, actual damages paid in civil judgments and settlements are sent directly to the Health Care Financing Administration or any other affected agency, where they are restored to Medicare or any other affected health benefits program. Pursuant to the Health Insurance Portability and Accountability Act (HIPAA), an amount equal to penalties and damages exceeding actual damages (excluding relators' awards), is deposited in the Federal Hospital Insurance Trust Fund (the Trust Fund).

HIPAA appropriates monies from the Trust fund to a newly created expenditure account, the Health Care Fraud and Abuse Control Account (HCFAC), in amounts that the Secretary of HHS and Attorney General jointly certify are necessary to finance anti-fraud activities. The maximum amounts available for expenditure are specified in HIPAA.

There is no connection between amounts recovered in health care fraud cases, and the appropriation to the HCFAC. Appropriations to the HCFAC are mandatory, in that they were prospectively provided by statute (HIPAA), and would be made even in the unlikely event that no deposits were made to the Trust Fund. All deposits to the Trust Fund, as required by HIPAA, are available for the operation of the Medicare program.

72 Hour / DRG Window Project

Under 42 C.F.R. § 412.2, non-physician outpatient services (such as tests conducted before surgery) rendered in connection with subsequent hospital admissions (and within three days before such admissions) may not be billed separately to Medicare. Instead, such services are covered by the set fee paid to the hospital for the admission/procedure itself. These regulations were first adopted in 1984 and have been in continuous use since then (the regulation was renumbered in 1985 with no substantive change). Over time, the length of the "window" has increased from one to three days.

In 1988, 1990, and 1992, the Department of Health and Human Services, Office of Inspector General (HHS-OIG), conducted three formal audits of hospitals, identifying gross overpayments ranging from approximately \$28 million to \$40 million. On each of three separate occasions, the government allowed hospitals to treat these wrongful billings merely as overpayments, with the hospitals only returning the amount they were overpaid, without any additional penalties.

In 1994, despite repeated notice of proper Medicare billing regulations and the previous experience with overpayments, a fourth audit found that a number of hospitals continued to falsely bill Medicare in the same fashion. As a result, HHS-OIG referred these matters to the United States Attorney's Office (USAO), Middle District of Pennsylvania for enforcement under the False Claims Act.

HHS-OIG initially referred approximately 4700 hospitals to the USAO. These hospitals were chosen as a result of having been identified, through three prior audits, as having filed duplicate claims in violation of the "window" rule, resulting in prior repayments of money for these violations.

In addition to their knowledge of recoupments, hospitals had received several specific mailings from HCFA and its fiscal contractors, highlighting the duplicate billing problem.

To date, \$53 million has been recovered nationwide. These recoveries include duplicate payments through 1996.

Medicare Fraud Act

Potential Proposals for Health Care Fraud
Legislative Agenda

Administrations proposals not included in HIPAA

- o Amend Rule 6(e) of the Federal Rules of Criminal Procedure to allow criminal and civil government attorneys to share information in health care fraud cases. Under current law, information obtained by criminal prosecutors via the grand jury cannot be shared with attorneys responsible for pursuing civil health care fraud matters.
- o Expand the anti-kickback provisions in the Health Insurance Portability and Accountability Act (P.L. 104-191, Aug. 21, 1996) to the private health care industry. This will, in effect, establish tough new penalties for paying bribes or other kickbacks for patient referrals in private health care programs. (The illegal remuneration provisions in current law apply only to health plans receiving federal funds).
- o Expand the use of authorized investigative demands in support of the full range of civil and criminal health care fraud matters. This will provide powerful new investigative tools to ferret out illegal kickback and other health care fraud schemes. Under existing law, such investigative demands are limited to certain criminal health fraud offenses listed in 18 USC 24.
- o Authorize the use of injunctive relief in kickback cases. This will allow prosecutors to get a court order to put an immediate halt to kickback schemes. As with authorized investigative demands, criminal kickback violations are not included in the current list of predicate offenses under 18 USC 24.
- o Provide a civil remedy for illegal kickback schemes. This will ensure the full range of administrative, civil and criminal remedies are available for kickback schemes. This avoids the problem of forcing prosecutors from choosing between taking no action or pursuing criminal charges where the conduct warrants some action but does not rise to the level of justifying criminal charges.
- o Make certain Medicare obligations non-dischargeable in bankruptcy. > CIVIL

DRG window
 4700 hospital
 3 smartKOTG Auditor - Rural w/ no penalties
 \$53 million

February 6, 1998

ARRP

- Proc. Budget

John O'Connor Act

OIG 1998 LEGISLATIVE PROPOSALS

Improvements to OIG Sanction Authorities

1. Bankruptcy - Exempting exclusions from the automatic stay imposed in bankruptcy and making Medicare/Medicaid overpayment and CMP debts nondischargeable in bankruptcy.
2. Carrier Payment to Excluded Providers - Holding Medicare contractors and State Medicaid agencies liable for erroneous payment of claims for items or services furnished by excluded providers, as of 30 days after notice of the exclusion is provided to them.
3. CMPs for Excluded Parties' Orders - Authorizing the imposition of civil monetary penalties (CMPs) on excluded parties who order or prescribe items or services during their period of exclusion.
4. Overturing Hanlester Case - Deleting the "willfully" standard from the Medicare/Medicaid anti-kickback statute.
5. Dumping by Physicians at Specialty Hospitals - Amending the Patient Dumping Statute to provide that physicians at hospitals with specialized capabilities or facilities are obligated to accept and provide treatment to patients who are appropriately transferred by other facilities, and authorizing CMPs for violations by such physicians.
6. HIPDB Identifiers - Amending the authority for the Health Integrity Protection Data Bank (HIPDB) to require the submission of a social security number and, if applicable, taxpayer identification number when reporting a final adverse action taken against an individual or entity.
7. Safe Harbors for CMP for Incentives to Beneficiaries - Amending the CMP statute to provide OIG flexibility to exempt certain payment practices from the CMP prohibiting inducements to beneficiaries.

Fraud & Abuse Rtg.

January 22, 1998

To: Chris Jennings
From: John Bentivoglio *JB*
Subj: Examples of health care fraud recoveries

Attached are examples in FY 1997 where we have recovered large amounts of money in civil health care fraud cases. The best examples of large dollar recoveries are in civil cases because the settlements require upfront payment of the settlement amounts. In criminal cases, we frequently seek to recover lost funds through forfeiture, restitution, and the like, but this can take time and we frequently don't recover our losses dollar for dollar.

I'm still looking for one or two good criminal cases in the relevant time period (FY 1997, since that's the period of the report). If you don't need criminal examples, please let me know.

FY 1997: Significant Civil Health Care Fraud Recoveries

Independent Clinical Labs

In one of the two largest False Claims Act settlements ever reached, SmithKline Beecham Clinical Laboratories, headquartered in Philadelphia, paid \$325 million to resolve federal and state fraud claims alleging overcharges to the Medicare, Medicaid, Federal Employees Health Benefits, Railroad Retirement, and the Department of Defense Tricare (formerly known as CHAMPUS) health care programs. A wide range of different types of fraud schemes were alleged in the settlement arising out of SmithKline's performance of laboratory tests, including billing for laboratory tests not provided, not requested by the referring physician, or not medically necessary; and paying various forms of kickbacks to referring physicians. SmithKline was also alleged to have obtained payment from Medicare by inserting false "diagnosis" codes on claims, and to have double billed for tests for kidney dialysis patients. The settlement resolved three qui tam actions filed against SmithKline while Operation LABSCAM was under way.

Also arising out of the Department's LABSCAM investigation was an \$83.7 million civil settlement with Damon Clinical Laboratories, Inc., formerly headquartered in Needham, Massachusetts, for fraud on the same federal and state-funded health care programs. In response to Medicare fee reductions, Damon bundled together certain groups of tests which it marketed as a package to physicians. The laboratory made it difficult for physicians to order the tests separately, and did not inform physicians that if they ordered the package Damon would bill Medicare and other federal health care programs separately for each test. As a result, physicians ordered, and government programs paid for, millions of medically unnecessary tests. Two qui tam plaintiffs who filed lawsuits against Damon during the government's investigation received a total of approximately \$10.5 million of the settlement amount.

In a third major LABSCAM settlement reached this year, Laboratory Corporation of America (LabCorp) agreed to pay \$182 million to resolve allegations of fraudulent billings to federal and state health insurance programs by Allied Clinical Laboratories, Inc., Roche Biomedical Laboratories, Inc., and

National Health Laboratories, Inc. (NHL). These three entities merged to form LabCorp in 1995. Allied, Roche and NHL also marketed tests to physicians in a bundled fashion -- making it difficult for physicians to order separate tests -- without disclosing that when a physician ordered "bundled" tests the laboratories would bill government programs a separate charge for each test. In 1992, NHL had entered a criminal guilty plea and paid a \$100 million civil settlement arising out of this conduct, which nonetheless continued after the settlement date. The Labcorp settlement also resolved allegations that NHL overbilled the government for mileage charges for phlebotomists who drew blood from nursing home patients. Five qui tam lawsuits filed during the government's investigation resulted in total payments to the qui tam plaintiffs of approximately \$12 million.

Home Health

In the home health area, the nation's largest home health provider, First American Health Care of Georgia, Inc., and its purchaser, Integrated Health Services, Inc., agreed to reimburse the federal government about \$252 million for overbilled and/or fraudulent Medicare claims submitted by the company. First American, which operated 425 facilities in more than 30 states, billed Medicare for personal expenses of First American's senior management, and for marketing and lobbying expenses. First American filed for bankruptcy protection last year in Georgia and its purchaser in bankruptcy agreed to pay the government on First American's behalf.

Carrier Fraud

Blue Shield of California, one of the government's Medicare carriers, paid \$12 million to resolve allegations that it had obstructed efforts by the Health Care Financing Administration to review Blue Shield's performance under its Medicare contract by altering or destroying documents that showed claims processing errors. Blue Shield substituted backdated and altered documents for those containing errors, and manipulated random samples of files pulled by HCFA to create the impression that the company's performance was better than it was. A qui tam plaintiff received \$2.1 million in connection with this settlement.

Violations of Anti-kickback Statute

Other significant recoveries in Fiscal Year 1997 were the Department's settlements with Baptist Medical Center (\$17 million), Apria Healthcare Group, Inc. (\$1.65 million), and OrNda Healthcorp (\$12.6 million) for submitting claims to Medicare for goods and services provided pursuant to prohibited kickback arrangements.

Baptist Medical Center, a hospital located in Kansas City, Missouri, agreed in September 1997 to pay the United States \$17.5 million to settle allegations that it paid more than \$1 million in kickbacks to a local medical group in return for the group's referral of Medicare-eligible patients. The agreement resolves claims that Baptist submitted false cost reports and fraudulent Medicare claims for patients whose referrals it received through various kickback schemes. The United States claimed that Baptist entered into sham consulting contracts with Robert C. LaHue, D.O.; Ronald H. LaHue, D.O.; and Robert C. LaHue, D.O., Chartered d/b/a the Blue Valley Medical Group (collectively referred to as "Blue Valley"). The agreement also settles claims that Baptist violated the Stark I statute, by submitting clinical laboratory claims for Medicare patients referred by Blue Valley, with which the hospital had a financial relationship.

Apria Healthcare Group Inc., one of the nation's largest suppliers of durable medical equipment, agreed to pay the United States \$1.65 million to settle allegations it submitted false claims for oxygen supplied to patients referred pursuant to kickback arrangements between Apria and providers in Georgia and Florida. Georgia Lung Associates, a group of four physicians practicing in Austell, Georgia, is paying the United States almost \$350,000 to settle allegations that patient referrals for oxygen supplies were provided to Apria in return for kickbacks, and two other providers are paying additional sums to settle similar allegations. We alleged that Apria entered into sham consulting contracts with GLA and other physicians in Florida in order to induce referrals.

OrNda Healthcorp, recently acquired by Tenet Healthcare Corporation, will pay the United States \$12.6 million to resolve claims that OrNda hospitals paid physicians for referrals of Medicare patients and that the hospitals received referrals from

physicians with whom they had prohibited financial relationships under applicable law. The United States claimed that the hospitals, which OrNda acquired as a result of a merger with Summit Healthcare Ltd. in 1994, entered into sham directorship contracts with numerous physicians and provided other inducements, such as reduced lease payments and loans which were later forgiven, so the doctors would refer Medicare patients to the hospitals. The agreement settles a dispute originally brought as a *qui tam* case, United States ex rel. Montagano v. Midway Hospital Medical Center, Inc., OrNda Healthcorp and Summit Health Ltd. (C.D. CA). As part of the settlement, relator James Montagano, M.D. will receive \$2,339,814 of the recovery.

Quality of Care

The Department achieved a significant legal victory, as well as a noteworthy civil settlement, in U.S. ex rel. Aranda v. Community Psychiatric Centers of Oklahoma, Inc., Civ-94-608-A (W.D. Okla.), a case involving allegations of patient abuse and seriously inadequate care at psychiatric centers for youth that were financed by the Medicaid Program. In response to a motion to dismiss filed by the Defendant, the Court rejected the Defendant's arguments that a False Claims Act action can not be based on allegations of inadequate care, and ruled that nothing bars the Government from basing a False Claims Act case on such a theory. 945 F. Supp. 1485 (W.D. Okla. October 1, 1996.) The United States then reached a \$750,000 settlement with the Defendant in February 1997.

MANDATORY HEALTH BUDGET OPTIONS

(Dollars in billions, fiscal years)

	1999	2000	2001	2002	2003	5 Years
MEDICARE						
Anti-Fraud *	-0.2	-0.4	-0.5	-0.5	-0.6	-2.2
Reduce payment for EPO	-0.045	-0.065	-0.065	-0.07	-0.075	-0.3
Payment for drugs	-0.07	-0.13	-0.15	-0.16	-0.18	-0.7
Partial hospitalization	-0.015	-0.015	-0.02	-0.03	-0.04	-0.1
MSP	-0.01	-0.14	-0.16	-0.18	-0.2	-0.7
Centers of Excellence	-0.06	-0.07	-0.08	-0.1	-0.11	-0.42
Pre-65	0.095	0.359	0.33	0.299	0.282	1.4
Displaced workers	0.006	0.028	0.034	0.044	0.056	0.2
Clinical Cancer	0.2	0.25	0.3	0	0	0.8
NET MEDICARE	0.1	0.2	0.2	-0.2	-0.3	0.0

CHRIS- I'M A LITTLE CONCERNED
 THAT IF WE PUT CANCER TRIALS
 IN FUNCTION 570, WE TIP THE
 SCALE IN THE early years.

[These are rough-based on pieced-
 together information]

550

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